

9**STANDING COMMITTEE ON
CHEMICALS & FERTILIZERS
(2014-15)****MINISTRY OF CHEMICALS AND FERTILIZERS
(DEPARTMENT OF PHARMACEUTICALS)****DEMANDS FOR GRANTS
(2014-2015)**

[Action Taken by the Government on the Observations/Recommendations contained in the Second Report of the Standing Committee on Chemicals and Fertilizers (Sixteenth Lok Sabha) on Demands for Grants (2014-2015) of the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals)]

**NINTH REPORT****LOK SABHA SECRETARIAT
NEW DELHI***22 July, 2015 / 31 Ashadha 1935, (Saka)*

REPORT**STANDING COMMITTEE ON
CHEMICALS AND FERTILIZERS
(2014-15)****SIXTEENTH LOK SABHA****MINISTRY OF CHEMICALS AND FERTILIZERS
(DEPARTMENT OF PHARMACEUTICALS)****DEMANDS FOR GRANTS
(2014-2015)**

[Action Taken by the Government on the Observations/Recommendations contained in the Second Report of the Standing Committee on Chemicals and Fertilizers (Sixteenth Lok Sabha) on Demands for Grants (2014-2015) of the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals)]

Presented to Lok Sabha on 22.07.2015

Laid in Rajya Sabha on 22.07.2015



**LOK SABHA SECRETARIAT
NEW DELHI**

22 July, 2015 / 31 Ashadha 1935, (Saka)

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(ii)

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

Shri Anandrao Adsul - Chairperson	
MEMBERS	
LOK SABHA	
2.	Shri Idris Ali
3.	Smt. Anju Bala
4.	Shri B.N Chandrappa
5.	ShriSankar Prasad Datta
6.	Smt. Veena Devi
7.	Shri R. Dhruvanarayana
8.	Shri Satish Kumar Gautam
9.	Shri K Ashok Kumar
10.	Shri Kamalbhan Singh Marabi
11.	ShriChhediPaswan
12.	Smt. Kamala Devi Patle
13.	Shri Rajendran S
14.	Shri ChanduLal Sahu
15.	Dr. Kulamani Samal
16.	Dr. Uma Saren
17.	Dr. Krishan Pratap Singh
18.	Shri Taslimuddin
19.	Smt. Rekha Arun Verma
20.*	Shri Innocent
21.*	ShriKotha Prabhakar Reddy
RAJYA SABHA	
22.	Shri Biswajit Daimary
23.	Dr. MS Gill
24.	Shri Sanjay Dattatraya Kakade
25.	Shri Narayan LalPanchariya
26.	Shri K Parasaran
27.	Shri Garikapati Mohan Rao
28.	Dr. Sanjay Sinh
29.*	Shri Palvai Govardhan Reddy
30.%	Shri Mansukh L. Mandaviya
31.\$	Vacant

SECRETARIAT

- | | | | |
|----|----------------------------|---|---------------------|
| 1. | Smt Rashmi Jain | - | Joint Secretary |
| 2. | Shri U.B.S. Negi | - | Director |
| 3. | Shri Anil Kumar Srivastava | - | Additional Director |
| 4. | Shri Nishant Mehra | - | Under Secretary |

 Changed the nomination of ShriMurliDeora, Member of RajyaSabha from the Committee on Chemicals and Fertilizers to the Committee on External Affairs w.e.f. 25-09-2014.

* ShriPalvaiGovardhan Reddy, Member of RajyaSabha nominated w.e.f. 08-10-2014

Shri Mohanbhai KalyanjibhaiKundariya Nominated as Minister of State w.e.f. 09.11.2014

The term of ShriBrijlalKhabri, MP (RS) has expire w.e.f. 25.11.2014

Changed the nomination of Adv. Joice George, Member of LokSabha from the Committee on Chemicals and Fertilizers to the Personnel, Public Grievances, Law and Justice w.e.f. 24-12-2014.

*Shri Innocent, and ShriKothaPrabhakar Reddy, Member of LokSabhanominated w.e.f. 22-12-2014

% ShriMansukh L. Mandaviya, Member of RajyaSabha nominated w.e.f. 31-12-2014

% Dr. Chandrapal Singh Yadav, Member of RajyaSabha nominated w.e.f. 29.01.2015

\$Changed the nomination of Dr. Chandrapal Singh Yadav, Member of Rajya Sabha from the Committee on Chemicals and Fertilizers to the Committee on Industry w.e.f. 07.05.2015

INTRODUCTION

I, the Chairperson Standing Committee on Chemicals and Fertilizers (2014-15) having been authorised by the Committee to present the Report on their behalf, present this Ninth Report (Sixteenth Lok Sabha) on Action Taken by the Government on the observations/recommendations contained in the Second Report (Sixteenth Lok Sabha) of the Standing Committee on Chemicals and Fertilizers (2014-2015) on Demands for Grants (2014-2015) of the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals).

2. The Second Report (Sixteenth Lok Sabha) of the Standing Committee on Chemicals and Fertilizers was presented to Lok Sabha on 10.12.2014 . The Action Taken replies of Government to all observations/recommendations contained in the Report were received on 30.4.2015 . The Standing Committee on Chemicals and Fertilizers(2014-2015) considered and adopted this Report at their sitting held on 16.6.2015.

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

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

New Delhi;

14 January, 2014

23 ASHADHA,1937 (Saka)

ANANDRAO ADSUL
Chairperson,
Standing Committee on
Chemicals and Fertilizers

REPORT

CHAPTER I

This Report of the Standing Committee on Chemicals and Fertilizers deals with the action taken by the Government on the Observations/Recommendations contained in the Second Report (Sixteenth Lok Sabha) of the Committee on Demands for Grants (2014-15) of the Ministry of Chemicals & Fertilizers (Department of Pharmaceuticals) which was presented to Lok Sabha on 10.12.2014. In all, the Committee made 7 Observations / Recommendations in the Report.

2. Ministry of Chemicals & Fertilizers (Department of Pharmaceuticals) were requested to furnish replies to the Observations / Recommendations contained in the Second Report within three months from the date of presentation of the Report, i.e., by 10.3.2015. The Action Taken Replies of the Government in respect of all the 7 Observations / Recommendations contained in the Report have been received from the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals) vide their O.M. No.23003/2/2014-Fin.II dated 30.4.2015. These Replies have been categorized as follows:-

- | | | |
|-------|---|------------------------------|
| (i) | Observations/Recommendations that have been accepted by the Government :-
Sl.Nos. 1,2, 3, 4, 5 and 6 | (Total =6)
Chapter II |
| (ii) | Observations/Recommendations which the Committee do not desire to pursue in view of the Government's reply :-
Sl.No.Nil | (Total =Nil)
Chapter III |
| (iii) | Recommendations / Observations in respect of which replies of the Government have not been accepted by the Committee :-
Sl.No. Nil | (Total = Nil)
Chapter IV |
| (iv) | Observations/Recommendations in respect of which final replies of the Government are of interim nature :-
Sl.Nos. 7 | (Total =1)
Chapter V |

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 V for which final replies are still awaited should be furnished 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 to allocate funds commensurate to the outlays proposed by the Department.

Recommendation No.1

5. While stressing that the allocations made by the Planning Commission should commensurate to the outlays proposed by the Department, the Committee had recommended as under:-

“The Committee note that the Planning Commission had approved an outlay of Rs. 2968 crore for the 12th Plan period. However, the actual budget allocation by the Planning Commission during the first three years was only 583 crore (Rs. 188 crore, Rs. 188 crore and Rs. 207 crore respectively) and the balance outlay of Rs.2386 crore (Rs.1193 + Rs.1193) has been redistributed for the remaining two years of the 12th Five Year Plan period. For Annual Plan 2010-11, against a BE of Rs.165 crore (RE was restricted to Rs. 119 crore), actual expenditure incurred amounted to Rs.69.66 crore. Further, against a BE of Rs.175 crore for Annual Plan 2011-12 (RE was Rs.77.78 crore), actual expenditure incurred was Rs.40.33 crore only. For Annual Plan 2012-13, Department of Pharmaceuticals proposed an outlay of Rs.1127.45 crore against which outlay approved by Planning Commission was Rs. 188 crore, RE was Rs.85 crore and actual expenditure incurred was Rs.51.78 crore which is 60.92% of RE outlay. For Annual Plan 2013-14, the Department proposed an outlay of Rs. 567.60 crore. However, Planning Commission allocated only Rs. 188.00 crore, RE was Rs.75 crore and actual expenditure incurred was Rs.74.07 crore which is 98.76 % of the RE. For the year 2014-15, the Department proposed an outlay of Rs. 871.81 crore to Planning Commission against which Planning Commission approved only Rs. 207 crore, which works out to just 10 percent more than last year’s allocation of Rs. 188 crore. According to the Department, actual expenditure incurred in previous years would have been one of the criteria for allocation of funds in subsequent years. As a result of lesser allocations than the proposed outlays, the Department was compelled to spread thinner allocations amongst its various schemes during the year 2014-15. As for illustration, a provision of Rs. 20 crore for NIPER, Mohali has been made against proposed amount of Rs.88.40 crore. Similarly, a provision of Rs.88 crore has been made for New NIPERs as against the proposed amount of Rs. 193 crore. Rs. 6 crore was allocated for upgradation of MEs to WHO-GMP Standards etc. as against proposed amount of Rs.200.50 crore. For New Scheme, only Rs.15 crore was allocated against proposed amount of Rs.60 crore. The Committee therefore, strongly feel that the allocations made by the Planning Commission should commensurate to the outlays proposed by the Department. However, the Committee are anguished to note that the Department even failed to utilize fully, the outlay provided at RE stage during the year 2012-13 and 2013-14. Since various schemes of the Department are of paramount importance, any reduction in the allocation will have an adverse impact on the implementation of the schemes undertaken by the Department. It is therefore imperative for the Department to take proactive role in this regard and ensure optimum utilisation of

its resources to avoid substantial reduction of outlay at RE stage. The Committee recommend that the Planning Commission should provided adequate budgetary allocation to the Department at RE stage under various Head for effective implementation of its various schemes. The Committee would like to be apprised of the initiatives under taken by the Department in this regard”.

Reply of the Government

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

“The details of the recommendation have been brought to the notice of Industries Division, Planning Commission with reference to allocation of Plan funds for the remaining years of Twelfth Five Year Plan.

Regarding requesting Planning Commission to allocate adequate funds for the remaining period of Twelfth five Year Plan, this Department has raised this aspect with the Planning Commission during the Mid-Year Review Meeting. The reason for higher requirement of funds under different schemes was also submitted to Planning Commission. Regarding improving the utilization of funds by the Administrative Divisions regular Meeting are convened at the level of Secretary (Pharma) for monitoring Plan expenditure and identifying bottlenecks in timely utilization of Plan funds”.

Comments of the Committee

7. **The Committee had noted that an allocation of Rs. 2968 crore was approved by the Planning Commission for the 12th Plan period. However, the actual budget allocation by the Planning Commission during the first three years was only Rs.583 crore (Rs. 188 crore for 2012-13, Rs. 188 crore for 2013-14 and Rs. 207 crore for 2014-15). For the year 2014-15, the Department proposed an outlay of Rs. 871.81 crore to Planning Commission against which only Rs. 207 crore was approved by them, which works out to just 10 percent more than last year’s allocation of Rs. 188 crore. As a result of lesser allocations than the proposed outlays, the Department was compelled to spread thinner allocations amongst its various schemes during the year 2014-15. The Committee strongly felt that the allocations made by the Planning Commission should commensurate to the outlays proposed by the Department. The Committee had, therefore, recommended that the Planning Commission should provide adequate budgetary allocation to the Department at RE stage under various Heads for effective implementation of its various schemes. However, the Committee were also distress to note that the outlay provided at RE stage during the year 2012-13 and 2013-14 was not even fully utilized by the Department. The Committee had, therefore, recommended that the Department should take proactive role in this regard and ensure optimum utilisation of its resources to avoid substantial reduction in outlay at RE stage. In its Action Taken Reply, the Department has stated that the details of recommendations of the Committee have been brought to the notice of Planning Commission with reference to**

allocation of Plan funds for the remaining years of Twelfth Five Year Plan. The reasons for higher requirement of funds under different schemes was also submitted to Planning Commission. Regarding improving the utilization of funds by the Administrative Divisions, regular meetings are convened at the level of Secretary (Pharma) for monitoring Plan expenditure and identifying bottlenecks in timely utilization of Plan funds. In view of the foregoing, the Committee hope and trust that Planning Commission (Now National Institution for Transforming India (NITI) Aayog) /Ministry of Finance will allocate adequate funds to the Department for effective implementation of its various schemes. However, it is now for the Department to take proactive action to utilize the plan funds judiciously, optimally and timely. For this purpose, it would be imperative for the Department that all the bottlenecks which impede the effective implementation of its various scheme and timely utilization of plan funds are identified and removed. The Committee, therefore, recommend that the Department should spell out its action plan and remove all bottlenecks in order to implement all its scheme effectively and efficiently. The Committee would like to be apprised of the action plan formulated by the Department for optimum and timely utilization of funds allocated to them.

B. Need to expedite the establishment of New NIPERs in their own campuses.

Recommendation No.3

8. While expressing concern over the slow progress in construction of new NIPER campuses, the Committee had recommended as under:-

“The Committee note that National Institute of Pharmaceutical Education Research (NIPER) was declared as an “Institute of National Importance” under the Act of Parliament on 26th June 1998. One of the main purpose for starting these institutes is to establish the linkage with industry as well as academics. In addition to NIPER, SAS Nagar, Mohali, the Government has set up six new NIPERs at Hajipur (Bihar) , Hyderabad (Andhra Pradesh) , Gandhinagar (Gujarat) , Rae Bareli (Uttar Pradesh), Guwahati(Assam) and Kolkata (West Bengal). These new NIPERs will cater to the growing demand of the pharmaceutical industry for highly trained man power for continuous growth of the pharmaceutical sector with increased focus on R&D, particularly after the amendment of Indian Patent Act. At present, these six new NIPERs are functioning with the assistance of Mentor Institutes. While the process for construction of new campus for NIPER, Guwahati and NIPER, Gandhinagar has already started, the land for NIPER, Hyderabad and NIPER, Rae Bareli has been allotted by the respective State Governments and the process of selection of Project Management Consultants (PMC) has been initiated. NIPER, Hajipur and NIPER, Kolkata are yet to be allocated land for which the matter has been taken up with the respective State Governments. The Committee are extremely unhappy with the slow pace of progress in the acquisition of land and construction of new campus for new NIPERs. As a result , new NIPERs are still continuing to function with the assistance of their mentor Institutes In the absence of requisite infrastructure facilities, the Committee feel that it would be difficult for NIPERs to achieve its optimum level of efficiency imparting education and to focus on R&D.

The Committee, therefore, recommend that the Department should make concerted and coordinated efforts to expedite the establishment of new NIPERs in their own campuses in a time bound manner so that they could achieve their avowed objectives to establish its links with pharmaceutical industry and nurture and promote quality and excellence in pharmaceutical education and research. They should pursue with respective State Governments at the highest level. Further, the process of selection of PMC for NIPER, Hyderabad and NIPER, Rae-Bareilly for which land has already been acquired should also be expedited and be completed within a fixed time frame. The Committee would like to be apprised of the initiatives taken by the Department in this regard”.

Reply of the Government

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

“The Department has since awarded the work of construction of NIPER campus from concept to completion at Guwahati to Engineering Project India Ltd. (EPIL) and Gandhinagar to Hindustan Steelworks Constructions Ltd. (HSCL). Memorandum of Understanding (MoU) to be signed by NIPER, Hyderabad with the National Project Construction Corporation (NPCC) Ltd. After signing the MoU, funds would be released to NIPER for making available to the concerned PSU so as to enable them to commence work relating to construction of NIPER campus at Gandhinagar and Hyderabad.

Construction activity to start at:

1. NIPER, Guwahati MoU Signed with EPIL.
2. NIPER, Ahmedabad MoU signed with HSCL.
3. NIPER, Hyderabad MoU is likely to be signed.

However, construction could not be taken up as sufficient fund has not been provided. Land with respect to NIPERs of 1. Hajipur 2. Kolkata 3. Rae Bareilly are yet to be resolved.

The construction of NIPERs Guwahati, Ahmedabad and Hyderabad will start during the current year. Department is planning for supplementary demands/budget proposal for additional funds to undertake construction properly.

Latest developments w.r.t. NIPER, Kolkata and Hajipur are given below:-

Status of land allocation at NIPER, Kolkata (West Bengal)

A). National Institute of Pharmaceutical Education & Research (NIPER), Kolkata was set up to nurture and promote quality and excellence in Pharmaceutical education and research at Masters and Ph. D level after the State Government committed to provide 100 acre of land free of cost. Subsequently, State Government allotted 35 acres land free of cost at Baruipur. However, out of 35 acres, NIPER was required to spare 10 acres for common facilities, which leaves a very small piece of land for setting up of an Institute of national importance. In addition, State Government wanted Government of India to pay for the External Development Charges (EDC). Since, Union Cabinet approved setting up of NIPERs in other parts of country, including Kolkata, on the premise that 100 acres of land would be provided free of cost by the State Governments. Therefore, it is not possible to pay for EDC. Accordingly, earlier also the State Government was requested to confirm the following:

- (i) Possession of 100 Acres of land near Kolkata free of cost free from all encumbrances.

B). The matter has been followed up vigorously with the State Government. However, response from the State Government is yet to be received.

(c) A letter has also been written on 29.12.2014 by Hon'ble Minister (C&F) to the Chief Minister of West Bengal.

Status of land allocation at NIPER, Hajipur (Bihar)

I. Based on the firm assurances given in writing by the State Government of Bihar for allotment of 100 acre land free of cost, vide letter No. dated 29/5/2006 and 28/8/2006 by the Industrial Development Commissioner Govt. of Bihar this Department set up NIPER at Hajipur in 2007 under the mentorship of Rajendra Memorial Research Institute of Medical Sciences (RMRIMS), Patna. Since, 2007, NIPER is functioning in the EPIP Campus, BIADA Industrial Area, Hajipur. State Govt. has, however, not yet allotted the land for setting up full-fledged NIPER Campus at Hajipur, in spite of the matter being followed up with the State Govt. at Chief Minister and Chief Secretary level.

II. The matter has been brought to the notice that in the 10th State level coordination Committee meeting held at Hajipur on 21.3.2013. The Principal Secretary, Industries, Bihar has advised that 50 acres of land was not readily available for allotment to NIPER, the institution may proceed with vertical construction worked on the 12.43 acres of land already in possession of NIPER Hajipur, along with 3 buildings. At the same time the institute has been advised to pursue with the District Magistrate Vaishali for alternative land for acquisition for the NIPER.

In the Eastern Zonal Council meeting held on 16.01.2015 chaired by Union Home Minister, the matter was taken up and State Government reiterated their view that 50 acre of land around Patna is not available and that the NIPER campus at the present site may be constructed vertically.

III. Matter has not been settled as yet. Recently, the matter has been taken up at the level of Secretary and Minister. However, the quantum and location of land is yet to be settled satisfactorily.

IV. Establishment of NIPER may be a great addition to the educational infrastructure of any State. However, since 2007 NIPER, Kolkata and Hajipur are functioning from the premises of their mentor institutes, and facing acute shortage of accommodation and they are unable to plan construction of full-fledged campus for providing inter-alia all essential infrastructure facilities essential for quality education at Post Graduate level and Ph.D in Pharmaceutical Sciences.

V. A letter has also been written on 30.12.2014 by Hon'ble Minister (C&F) to the Chief Minister of Bihar.

NIPER, Raebareli

As regards NIPER, Raebareli, the Steering Committee constituted for all the NIPERs in its 20th meeting held on 18.11.2014 observed that the issues related to adequacy and clear title of the land be assured and the related issues should be resolved before proceeding further in the matter of the appointment of the PMC for NIPER, Rae Bareli. Accordingly, the issue is being taken up with State Government to sort out the impediments so that PMC could be selected."

Comments of the Committee

10. Expressing its deep concern over delay in construction of NIPER Campuses, the Committee had noted that six new NIPERs are functioning with the assistance of Mentor Institutes. The Committee had, therefore, recommended that the Department should make concerted and coordinated efforts to expedite the establishment of new NIPERs in their

own campuses in a time bound manner so that they could achieve their avowed objectives to establish its links with pharmaceutical industry and nurture and promote quality and excellence in pharmaceutical education and research. However, the Committee regret to note from the Action Taken Reply of the Department that in the absence of sufficient funds, the construction of NIPERs of Guwahati, Ahmedabad and Hyderabad could not be taken up. However, the Department has assured that the construction of these NIPERs will start during the current financial year and the Department is planning for supplementary demands/budget proposal for additional funds to undertake construction properly. The Committee also note that the issues relating to allocation of land in respect of NIPERs Kolkata, Hajipur and Raebareli is yet to be resolved. In the context of NIPER, Kolkata, the Department has stated that the matter has been followed up vigorously with the State Government of West Bengal but the response from them is yet to be received. A letter has also been written on 29.12.2014 by Hon'ble Minister (C&F) to the Chief Minister of West Bengal. Similarly, the State Government of Bihar has not yet allotted the land for setting up full-fledged NIPER Campus at Hajipur in spite of matter being followed up with the State Government at Chief Minister and Chief Secretary level. As regards NIPER, Raebareli, the issues related to adequacy and clear title of the land are yet to be assured and resolved before proceeding further in the matter of the appointment of the PMC for NIPER, Rae Bareli. The issue is being taken up with State Government to sort out the impediments so that PMC could be selected. In view of the foregoing, the Committee are extremely distress to note that the construction of NIPERs of Guwahati, Ahmedabad and Hyderabad could not be taken up simply for the reason that adequate funds are not available. However, the Department has planned for supplementary demands/budget proposal for additional funds to NIPERs, The Committee, therefore, hope and trust that the Department would pursue the matter vigorously with the Ministry of Finance/Planning Commission (Now National Institution for Transforming India (NITI) Aayog) and urge them to provide adequate funds so that the construction of NIPERs at Guwahati, Ahmedabad and Hyderabad could be taken up with out further delay. As regards the construction of NIPERs Kolkata, Hajipur and Raebareli is concerned, the Committee expect the Department to pursue the matter rigorously and consistently with the respective State Governments impressing upon them to allocate the requisite land for the purpose. The Committee, therefore, reiterate its recommendation that the Department should make concerted and coordinated efforts to expedite the establishment of new NIPERs in their own campuses in a time bound manner. The Committee would like to be apprised of the initiatives taken by the Department in this regard.

C. Price Control of all Essential Drugs by National Pharmaceutical Pricing Authority (NPPA)

Recommendation No.4

11. While observing that Government/NPPA to urgently bring down the prices of all essential drugs, the Committee had recommended as under:-

“The Committee note that the functions of National Pharmaceutical Pricing Authority (NPPA) inter-alia include fixation and revision of prices of scheduled drugs under the Drug (Price Control) Order, 1995 (DPCO’95)/DPCO, 2013, as well as monitoring and enforcement of prices. NPPA also provides inputs to Government for policy formulation and on other specific issues concerning affordable medicines to the consumers. The Government has notified New DPCO, 2013 on 15th May, 2013 in supersession of DPCO, 1995. Out of the 628 NLEM medicines specified in the Schedule-I of DPCO, 2013, NPPA has fixed / notified the ceiling prices in respect of 489 medicines upto 15th September, 2014 under provisions of the said order. In order to fix the ceiling prices in respect of the remaining NLEM medicines, NPPA has made sincere efforts to obtain / collect the data from all available sources like IMS-Health, PharmaTrac, Pharma Industry Associations, Marketing Companies etc. In addition, NPPA took up the matter with Department of Health, Drugs Controller General (India), State Health Secretaries and State Drugs Controllers for providing the information / data so as to enable NPPA to fix prices of remaining NLEM medicines under provisions of DPCO, 2013. The DPCO, 2013 also provides for monitoring of the production and availability of scheduled formulations and the active pharmaceutical ingredients contained in the scheduled formulations. In this regard, the manufacturers/ importers/ marketing companies of the scheduled formulations and Active Pharmaceutical Ingredients are required to furnish information as stated in Form- III of the said order quarterly. NPPA regularly monitors the availability of essential medicines in the country through Drugs Control Administration of State Governments. Whenever shortage is reported by the State Drug Controllers or comes to its notice otherwise, NPPA takes remedial steps for ensuring availability of drugs by impressing upon manufacturers to rush the stocks to the places of shortage. In this regard, the Committee were informed that recently the scarcity of certain essential medicines, namely, Anti-Snake Venom, Rabies vaccine, Rabies Immunoglobulin, Albumin Injection and Anti-malarial combination of Sulfadoxine + Pyrimethamine Tablets was reported to the NPPA. According to the Department, the concerned manufacturers of these drugs were not maintaining normal supply of the medicines in domestic market and / or Institutions. So, NPPA vide its notification S.O. No. 2292 (E) dated 09.09.2014 directed all the concerned manufacturers / importers to comply with the requirements contained in para 21(1) and furnish the month-wise production and sale figures for the last 12 months. In view of the foregoing, the Committee of the strong view that the prices of all essential drugs need to be regulated. In this regard, the role of the Government in procuring drugs and providing it at affordable price to the public can not be undermined. It is imperative for the Government/NPPA to urgently bring down the prices of all essential drugs so that the same are available to the common man, poor or the needy at affordable price. To keep this end in view, the Committee strongly feel that the scope of price control needs to be enlarged taking into consideration cost effectiveness, safety and efficacy and more and more therapeutic segments should be brought under price control. At the same time, NPPA/Government should be vigilant enough to ensure that all essential drugs are accessible to the public and a stock-out situation like the one as referred above should never arise. NPPA should also expedite the process of notifying the ceiling price of the remaining NLEM medicines i.e. 139 out of 628 NLEM medicines. The Committee would like the Department to act accordingly

and be apprised of the initiatives taken by Department to fix/notify the prices of remaining NLEM medicines”.

Reply of the Government

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

“Out of the 628 NLEM medicines specified in the Schedule- I of DPCO,2013, NPPA has fixed/ notified the ceiling price in respect of 509 medicines upto 05th February, 2015 under provisions of the said order. In order to fix the ceiling prices in respect of the remaining NLEM medicines, NPPA has made sincere efforts to obtain/ collect the price data from all available sources like IMS- Health, Pharma Trac, Pharma Industry Associations, Marketing Companies etc. In addition, NPPA took up the matter with Ministry of Health & Family Welfare, Drugs Controller General (India), State Health Secretaries and State Drugs Controllers for providing the information/ data so as to enable NPPA to fix prices of remaining NLEM medicines under provisions of DPCO, 2013. An office memorandum was also placed on NPPA’s website on 27.01.2015 requesting all companies / pharma associations to provide data in respect of pending 102 formulations.

There are 680 medicines specified in the first schedule of DPCO, 2013 covering 27 therapeutic groups as defined in the NLEM, 2011 that are currently under price control regime. Out of 680 medicines, 52 medicines are commonly appearing at more than one therapeutic group, therefore, there are 628 scheduled formulations.

As on 10.2.2015, the ceiling price of 509 medicines has been notified and the same are available in the public domain at the official website of NPPA at www.nppaindia.nic.in.

The status in respect of all 680 cases of price fixation of scheduled formulations is as follows:

Pricing Status as on 10.02.2015

Sl. No.	Particulars			
1	Total number of NLEM medicines (after separating tablets and capsules)			680
	Common medicines under different sections of DPCO, 2013			52
	Net medicines for which prices are to be fixed			628
2	Break up of number of items dealt under different category			
	A	Notification issued upto 18 th meeting of the Authority under DPCO, 2013	509	
	B	Common items under DPCO, 1995 and DPCO, 2013 for which price notifications are to be issued in 2014, but are pending for want of information/data from IMS-Health	15	
	C	Common items under DPCO, 1995 and DPCO, 2013 for which price notifications will be issued in 2015 onwards	17	
	d (a to c)	Total Cases Processed / To be processed	541	
	E	Total cases Pending for non-availability of data Referred to SDC’s/uploaded on NPPA’s websites. Industry, Trade and State Governments have been requested to provide available data, if any.	87	
	Sub total (d + e)			628

3	Number of items under examination for data collection/pricing (1 - 2)		Nil
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Out of the remaining 119 formulations, 17 formulations are not yet due for price revision. The price of remaining 102 formulations could not be fixed mainly due to non-availability of price data in respect of these formulations. All possible efforts are being made to collect the same including writing to industry associations, trade associations, State Drug Controllers, State Health Secretaries, and Chief Secretaries. Hon'ble Minister, Chemicals and Fertilizers has also written to the Health Minister. But progress is minimal.

Impact of Price Fixation

The details of reduction in prices scheduled formulations effected under DPCO, 2013 as compared to the highest price prevailed prior to the announcement of DPCO, 2013 are given as under:

% reduction with respect to Maximum Price	No. of drugs
0<= 5%	52
5<=10%	45
10<=15%	56
15<=20%	44
20<=25%	66
25<=30%	55
30<=35%	30
35<=40%	34
Above 40%	127
	509

Regarding shortage of drugs, it is stated that the availability of essential medicines is regularly monitored by the NPPA mainly through Drugs Control Administration of State Governments. Whenever shortage is reported by the State Drug Controllers or comes to its notice otherwise, NPPA takes remedial steps for ensuring availability of drugs by impressing upon manufacturers to rush the stocks to the places of shortage.

In the recent past, short supply of certain essential medicines namely, Anti-Snake Venom, Rabies Vaccine, Rabies Immunoglobulin, Albumin Injection and Anti-malarial combination in Sulfadoxine + Pyrimethamine Tablets was reported to NPPA. In order to maintain normal supply of these medicines in the domestic market and / or institutions, NPPA issued notification S.O. No. 2292 (E) dated 09.09.2014 wherein all the concerned manufacturer / importers were directed to ensure a smooth supply and to furnish compliance report in this regard. In connection with recent shortages of Human Albumin Injection reported by major hospitals throughout the country, NPPA has held a meeting with the major manufacturers/importers of Albumin Injection. During the course of discussion, it was observed that the shortage of Human Plasma is one of the main constraints in expanding the production capacity of Human Albumin in the Country. In this regard, Chairman, NPPA has written a D.O. letter on 04.02.2015 to the Additional Secretary, Department of Health regarding supply of Human Plasma to manufacturer of Human Albumin by NACO. There has been a reference from the Drugs Controller General (India) regarding non-availability of Injection Anti-Diphtheria Serum in Post Graduate Institute of Medical Education & Research, Chandigarh. In order to make the drug available, in and around Chandigarh, all the concerned manufacturers have been advised for necessary action in the matter. In this regard, M/s Haffkine Bio-Pharmaceuticals Corporation Limited,

a Govt. of Maharashtra undertaking has offered a quotation for supply of the said drug to Govt. Medical College and Hospital, Chandigarh while another manufacturer namely M/s Serum Institute of India Ltd., has informed that there is a shortage of plasma, however, they would expedite the process of getting the plasma in order to make the Diphtheria Antitoxin available.

Regarding enlarging the span of price control, it is informed that NPPA in its 20th Authority meeting held on 05.02.2015 approved recommendations for enlarging NLEM-2011 based on a comprehensive study conducted by NPPA for the consideration of the Department of Pharmaceuticals and onward recommendation to the Core Committee on Revision of NLEM set up by the M/o Health & Family Welfare. The study was conducted in pursuance with directions received from the Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers vide their letter no. 31026/24/2010-PI.I dated 07.08.2014. Summary of recommendation sent to Department of Pharmaceuticals for further necessary action, are as follows:

- (i) Correction / modifications in respect of anomalies / discrepancies in specification / descriptions in the NLEM.
- (ii) Recommendation for addition of 43 medicines / drugs with specified dosage / strength in the NLEM.
- (iii) Two separate studies in respect of anti-cancer drugs and medical devices for making recommendations for inclusion in the NLEM / Schedule-I of DPCO, 2013.
- (iv) Final report by NPPA on the study done by the NHSRC on current pricing practice followed with regard to cardiac stents and reasonable pricing of Bare Metal Stents and Drug Eluting Stent.
- (v) Differential pricing of NLEM drugs based on product distinctiveness i.e. source of origin, process differentiation, drug delivery system, site specific delivery, therapeutic benefit in terms of increased efficiency of the drug etc.
- (vi) Price fixation of injectable dosage form specified in the NLEM as per standard dosage unit.
- (vii) Ministry of Health and Family Welfare may be requested to work on the list of Life Saving Drugs”.

Comments of the Committee

13. The Committee had noted that the functions of National Pharmaceutical Pricing Authority (NPPA) inter-alia include fixation and revision of prices of scheduled drugs under the Drug (Price Control) Order, 1995 (DPCO'95)/DPCO, 2013, as well as monitoring and enforcement of prices. NPPA also provides inputs to Government for policy formulation and on other specific issues concerning affordable medicines to the consumers. Whenever a shortage is reported by the State Drug Controllers or comes to its notice otherwise, NPPA takes remedial steps for ensuring availability of drugs by impressing upon manufacturers to rush the stocks to the places of shortage. The Committee were of the strong view that the prices of all essential drugs need to be regulated and strongly felt that the scope of price control be enlarged taking in to consideration cost effectiveness, safety and efficacy and that more and more therapeutic segments be brought under price control. NPPA should also expedite the process of notifying the ceiling price of the remaining NLEM medicines. In its Action Taken Reply, the Department has stated that out of the remaining 119

formulations, the price of 102 formulations have not yet been fixed due to non-availability of price data in respect of these formulations. In spite of all possible efforts being made to collect the same but the progress in this respect is minimal. The Committee are extremely distressed to note the slow pace of progress in the fixation of prices of the remaining formulations. The Committee reiterate its view that prices of all essential drugs are brought down so that the same are available to the poor and common man at affordable prices and therefore, the Committee strongly recommend that the concerted and coordinated efforts be made by the Department to collect the requisite data in respect of aforesaid 102 formulations so that their prices could be fixed with out further delay. As regards shortage of essential drugs, the Department has stated that NPPA takes remedial steps for ensuring availability of drugs by impressing upon manufacturers to rush the stocks to the places of shortages. The Committee hope and trust that NPPA would be vigilant enough and take proactive action to ensure that there is no shortage of essential drugs especially in far flung, remote and hilly areas of the country. Regarding enlarging the scope of price control, the Committee have been informed that NPPA in its meeting held on 05.02.2015 approved recommendations for enlarging NLEM-2011 based on a comprehensive study conducted by NPPA for the consideration of the Department of Pharmaceuticals and onward recommendation to the Core Committee on Revision of NLEM set up by the M/o Health & Family Welfare. In view of this, the Committee expect the Department to expedite the follow up action on the recommendations approved by NPPA in a time bound manner. The Committee would like to be apprised of the initiatives undertaken by them in this regard.

D. Cluster Development Programme for Pharma Sector.

Recommendation No.7

14. With the objective to create/upgrade the common facilities in the area where there is cluster of Pharma manufacturers, the Committee had recommended as under:-

“The Committee note that the Department has come up with a scheme, Cluster Development Programme for Pharma Sector with the objective to create/upgrade the common facilities in the area where there is a cluster of Pharma Manufacturers. The total outlay of the scheme is Rs.125 crore for 12th Plan period. Through this scheme, the cluster of small and medium enterprises can avail financial assistance for common facilities like Common Testing Facilities, Training Centres, Effluent Treatment Plant, Common Logistics Centres. The Committee also note that the Department has already created a large number of Pharma clusters in the country at places like Hyderabad, Chennai, Maharashtra and Gujarat, Uttarakhand and Himachal Pradesh and many Pharma clusters will come up over a period of time. These Pharma clusters lack certain common facilities, like quality testing facility, library facility, training facility, effluent treatment plant etc. An initial allotment of Rs.6 crore would be used to start the process and from next year onwards for the next two years, the Department will spend substantial amount of money and create common

facilities in these Pharma clusters. The Committee expect the Department to implement the programme expeditiously in a systematic, professional and transparent manner. The Committee are of the view that these Pharma Cluster may also be associated with regional centres of NIPER and universities/colleges for their technical support and testing facilities. As a result thereof, the Committee hope that good quality medicines at affordable prices would be available to the common people. The Committee would like to be apprised of the progress made in the matter”.

Reply of the Government

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

“The Scheme with an overall allocation of Rs.125 Crores has now been approved by the Competent Authority. Department has invited bids from eligible companies for selection of the Project Management Consultant for implementing the scheme. The technical bids were evaluated by a Committee which found that only 1 bidder out of 3 bidders had qualified. The file was submitted to IFD who had opined that since qualification of only 1 bidder out of the 3 tendering firm at the stage of technical evaluation would not render sufficient comparison nor enable the Department to ascertain L1. They advised the Department to call for tenders afresh.

After the failure of EOI which was called for selection of Project Management Consultant (PMC), the Department has decided in principle to appoint Project and Development India Ltd(PDIL), a Government of India undertaking for taking over the role of PMC on a nomination basis as per Rule 176 of the GFR.”

Comments of the Committee

16. **The Committee had noted that the Department has come up with a scheme, Cluster Development Programme for Pharma Sector with the objective to create/upgrade the common facilities in the area where there is a cluster of Pharma Manufacturers. The total outlay of the scheme is Rs.125 crore for 12th Plan period. The Committee had also noted that the Department has already created a large number of Pharma clusters in the country at places like Hyderabad, Chennai, Maharashtra and Gujarat, Uttarakhand and Himachal Pradesh and many Pharma clusters will come up over a period of time. However, these Pharma clusters lack certain common facilities, like quality testing facility, library facility, training facility, effluent treatment plant etc. The Committee had, therefore, expected the Department to implement the programme expeditiously in a systematic, professional and transparent manner. The Committee were also of the view that these Pharma Cluster may also be associated with regional centres of NIPER and universities/colleges for their technical support and testing facilities. In its Action Taken Reply, the Department has stated that the Scheme with an overall allocation of Rs.125 Crores has now been approved by the Competent Authority. The Committee also note that in the technical bids only 1 bidder out of 3 bidder was found to be qualified and IFD had opined that qualification of 1**

bidder out of the 3 tendering firm at the stage of technical evaluation would not render sufficient comparison nor enable the Department to ascertain L1. Therefore, the Department has been advised to call tenders afresh. However, after the failure of EOI (Expression of Interest) which was called for selection of Project Management Consultant (PMC), the Department has decided in principle to appoint Project and Development India Ltd (PDIL), a Government of India undertaking for taking over the role of PMC on a nomination basis as per Rule 176 of the GFR. In view of the foregoing, the Committee expect the Department to urge PMC to expedite the implementation of the Cluster Development Programme so that the objectives of scheme could be achieved with in the remaining period of 12th plan. The Committee would like to be apprised of the initiatives undertaken and the road map formed by the Department for speedy progress in the implementation of the Cluster Development Programme.

CHAPTER – II**OBSERVATIONS / RECOMMENDATIONS WHICH HAVE BEEN ACCEPTED BY THE GOVERNMENT****Recommendation No.1**

The Committee note that the Planning Commission had approved an outlay of Rs. 2968 crore for the 12th Plan period. However, the actual budget allocation by the Planning Commission during the first three years was only 583 crore (Rs. 188 crore, Rs. 188 crore and Rs. 207 crore respectively) and the balance outlay of Rs.2386 crore (Rs.1193 + Rs.1193) has been redistributed for the remaining two years of the 12th Five Year Plan period. For Annual Plan 2010-11, against a BE of Rs.165 crore (RE was restricted to Rs. 119 core), actual expenditure incurred amounted to Rs.69.66 crore. Further, against a BE of Rs.175 crore for Annual Plan 2011-12 (RE was Rs.77.78 crore), actual expenditure incurred was Rs.40.33 crore only For Annual Plan 2012-13, Department of Pharmaceuticals proposed an outlay of Rs.1127.45 crore against which outlay approved by Planning Commission was Rs. 188 crore, RE was Rs.85 crore and actual expenditure incurred was Rs.51.78 crore which is 60.92% of RE outlay. For Annual Plan 2013-14, the Department proposed an outlay of Rs. 567.60 crore. However, Planning Commission allocated only Rs. 188.00 crore, RE was Rs.75 crore and actual expenditure incurred was Rs.74.07 crore which is 98.76 % of the RE. For the year 2014-15, the Department proposed an outlay of Rs. 871.81 crore to Planning Commission against which Planning Commission approved only Rs. 207 crore, which works out to just 10 percent more than last year's allocation of Rs. 188 crore. According to the Department, actual expenditure incurred in previous years would have been one of the criteria for allocation of funds in subsequent years. As a result of lesser allocations than the proposed outlays, the Department was compelled to spread thinner allocations amongst its various schemes during the year 2014-15. As for illustration, a provision of Rs. 20 crore for NIPER, Mohali has been made against proposed amount of Rs.88.40 crore. Similarly, a provision of Rs.88 crore has been made for New NIPERs as against the proposed amount of Rs. 193 crore. Rs. 6 core was allocated for upgradation of MEs to WHO-GMP Standards etc. as against proposed amount of Rs.200.50 crore. For New Scheme, only Rs.15 crore was allocated against proposed amount of Rs.60 crore. The Committee therefore, strongly feel that the allocations made by the Planning Commission should commensurate to the outlays proposed by the Department. However, the Committee are anguished to note that the Department even failed to utilize fully, the outlay provided at RE stage during the year 2012-13 and 2013-14. Since various schemes of the Department are of paramount importance, any reduction in the allocation will have an adverse impact on the implementation of the schemes undertaken by the Department. It is therefore imperative for the Department to take proactive role in this regard and ensure optimum utilisation of its resources to avoid substantial

reduction of outlay at RE stage. The Committee recommend that the Planning Commission should provided adequate budgetary allocation to the Department at RE stage under various Head for effective implementation of its various schemes. The Committee would like to be apprised of the initiatives under taken by the Department in this regard”.

Reply of the Government

The details of the recommendation have been brought to the notice of Industries Division, Planning Commission with reference to allocation of Plan funds for the remaining years of Twelfth Five Year Plan.

Regarding requesting Planning Commission to allocate adequate funds for the remaining period of Twelfth five Year Plan, this Department has raised this aspect with the Planning Commission during the Mid-Year Review Meeting. The reason for higher requirement of funds under different schemes was also submitted to Planning Commission. Regarding improving the utilization of funds by the Administrative Divisions regular Meeting are convened at the level of Secretary(Pharma) for monitoring Plan expenditure and identifying bottlenecks in timely utilization of Plan funds”

Comments of the Committee

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

Recommendation No.2

The Committee note that under the Head Plan Capital Loan for Phama Industries, BE allocation for the year 2014-15 under the scheme Support for PSUs is Rs.16.79 crore for HAL, for BCPL the allocation is Rs. 7 crore, for IDPL it is Rs.5 crore and for RDPL the allocation is Rs.1.21 crore. Further, under Critical Assistance Scheme (Grant for WHO-GMP compliance). for BE 2014-15 an amount of Rs.6.84 crore has been allocated to RDPL and Rs.3.16 crore (Rs.2 crore + Rs.1.16 crore) has been allocated to IDPL under the Head New Scheme for Pharma. The Committee are distressed to note from the status of release of funds that no proposal has been received from RDPL in respect of loans to PSUs. Similarly RDPL has not requested for release of second installment in respect of Grant for WHO GMP Compliance as the funds received for the project had been utilized for some other purpose. A Committee has been set up to reassess the project and its report is being processed. The Committee ,therefore, would like to to know the reasons for non-receipt of any proposal from RDPL for their Project Based Support (Loans to PSUs) as well as for Grant for WHO GMP Compliance. The Committee also stress that funds allocated to the Department for the year 2014-15 should be fully and prudently utilized to enable them to take the

load of allocation of funds of last two years of 12th Five Year Plan. The Committee, would like to be apprised of the action taken in this regard.

Reply of the Government

An amount of Rs. 1.21 crores was kept for the project 'Capacity Enhancement' in RDPL. However, properly framed proposal was not received in the requisite EFC format. As such, the proposal received from RDPL was examined and RDPL was advised to submit the proposal in proper format and in light of observations of the DoP. In the meantime, drastic cut in the budget was imposed by Ministry of Finance in RE stage. Hence, in the re-allocation of meager funds to various schemes, this scheme allocation was reduced to nil. Hence, no expenditure was incurred.

As regards, release of Rs. 6.84 crores to RDPL under Critical Assistance Scheme for WHO(GMP) Compliance project, funds were not released because there was not much physical progress of the scheme due to majority of funds having being diverted by the then MD, RDPL (since deceased) for paying salaries and re-payment of loan to Banks). A Committee was formed to reassess the project and also find out the actual requirement of the funds for this project. The Committee assessed the total requirement of the funds for the project at Rs. 7.58 crores which included certain non-urgent items also. It recommended release of Rs. 6.84 crores to RDPL with adequate safeguards to prevent future diversion. The Committee was of the view that if funds are not sanctioned the earlier expenditure incurred in phase I of the project would go waste. In addition to this, the Chief Vigilance Officer, RDPL was asked to investigate the matter. The CVO in his report has stated that since MD, RDPL who authorized diversion has died, no action can be taken in the matter. CVO also advised that MD, RDPL should not be allowed to incur expenditure on his own. One of the Directors on the Board of RDPL should also authorize release of funds jointly with MD, RDPL. The entire amount of Rs. 6.84 crore released on 31st March, 2015. MD, RDPL has been issued necessary instructions. The Department has also requested the Internal Audit Department to conduct concurrent audit of the project. A Preliminary Audit Report has already been conducted. The Committee would be pleased to note that out of Rs. 30.00 crores for the scheme 'Support to PSUs' Rs. 26.49 crores that was made available in RE has been fully released. As regards the Critical Assistance Scheme Rs. 6.84 crores available at RE stage has been released fully.

Recommendation No.3

The Committee note that National Institute of Pharmaceutical Education Research (NIPER) was declared as an "Institute of National Importance" under the Act of Parliament on 26th June 1998. One of the main purpose for starting these institutes is to establish the linkage with industry

as well as academics. In addition to NIPER, SAS Nagar, Mohali, the Government has set up six new NIPERs at Hajipur (Bihar) , Hyderabad (Andhra Pradesh) , Gandhinagar (Gujarat) , Rae Bareli (Uttar Pradesh), Guwahati(Assam) and Kolkata (West Bengal). These new NIPERs will cater to the growing demand of the pharmaceutical industry for highly trained man power for continuous growth of the pharmaceutical sector with increased focus on R&D, particularly after the amendment of Indian Patent Act. At present, these six new NIPERs are functioning with the assistance of Mentor Institutes. While the process for construction of new campus for NIPER, Guwahati and NIPER, Gandhinagar has already started, the land for NIPER, Hyderabad and NIPER, Rae Bareli has been allotted by the respective State Governments and the process of selection of Project Management Consultants (PMC) has been initiated. NIPER, Hajipur and NIPER, Kolkata are yet to be allocated land for which the matter has been taken up with the respective State Governments. The Committee are extremely unhappy with the slow pace of progress in the acquisition of land and construction of new campus for new NIPERs. As a result , new NIPERs are still continuing to function with the assistance of their mentor Institutes In the absence of requisite infrastructure facilities, the Committee feel that it would be difficult for NIPERs to achieve its optimum level of efficiency imparting education and to focus on R&D. The Committee, therefore, recommend that the Department should make concerted and coordinated efforts to expedite the establishment of new NIPERs in their own campuses in a time bound manner so that they could achieve their avowed objectives to establish its links with pharmaceutical industry and nurture and promote quality and excellence in pharmaceutical education and research. They should pursue with respective State Governments at the highest level. Further, the process of selection of PMC for NIPER, Hyderabad and NIPER, Rae-Bareli for which land has already been acquired should also be expedited and be completed with in a fixed time frame. The Committee would like to be apprised of the initiatives taken by the Department in this regard.

Reply of the Government

The Department has since awarded the work of construction of NIPER campus from concept to completion at Guwahati to Engineering Project India Ltd. (EPIL) and Gandhinagar to Hindustan Steelworks Constructions Ltd. (HSCL). Memorandum of Understanding (MoU) to be signed by NIPER, Hyderabad with the National Project Construction Corporation (NPCC) Ltd. After signing the MoU, funds would be released to NIPER for making available to the concerned PSU so as to enable them to commence work relating to construction of NIPER campus at Gandhinagar and Hyderabad.

Construction activity to start at:

- 1.NIPER, Guwahati MoU Signed with EPIL
- 2..NIPER, Ahmedabad MoU signed with HSCL.
3. NIPER, Hyderabad MoU is likely to be signed.

However, construction could not be taken up as sufficient fund has not been provided. Land with respect to NIPERs of 1. Hajipur 2. Kolkata 3. Rae Bareli are yet to be resolved.

The construction of NIPERs Guwahati, Ahmedabad and Hyderabad will start during the current year. Department is planning for supplementary demands/budget proposal for additional funds to undertake construction properly.

Latest developments w.r.t. NIPER, Kolkata and Hajipur are given below:-

Status of land allocation at NIPER, Kolkata (West Bangal)

A). National Institute of Pharmaceutical Education & Research (NIPER), Kolkata was set up to nurture and promote quality and excellence in Pharmaceutical education and research at Masters and Ph. D level after the State Government committed to provide 100 acre of land free of cost. Subsequently, State Government allotted 35 acres land free of cost at Baruipur. However, out of 35 acres, NIPER was required to spare 10 acres for common facilities, which leaves a very small piece of land for setting up of an Institute of national importance. In addition, State Government wanted Government of India to pay for the External Development Charges (EDC). Since, Union Cabinet approved setting up of NIPERs in other parts of country, including Kolkata, on the premise that 100 acres of land would be provided free of cost by the State Governments. Therefore, it is not possible to pay for EDC. Accordingly, earlier also the State Government was requested to confirm the following:

(i) Possession of 100 Acres of land near Kolkata free of cost free from all encumbrances.

B). The matter has been followed up vigorously with the State Government. However, response from the State Government is yet to be received.

(c) A letter has also been written on 29.12.2014 by Hon'ble Minister (C&F) to the Chief Minister of West Bengal.

Status of land allocation at NIPER, Hajipur (Bihar)

I. Based on the firm assurances given in writing by the State Government of Bihar for allotment of 100 acre land free of cost, vide letter No. dated 29/5/2006 and 28/8/2006 by the Industrial Development Commissioner Govt. of Bihar this Department set up NIPER at Hajipur in 2007 under the mentorship of Rajendra Memorial Research Institute of Medical Sciences (RMRIMS), Patna. Since, 2007, NIPER is functioning in the EPIP Campus, BIADA

Industrial Area, Hajipur. State Govt. has, however, not yet allotted the land for setting up full-fledged NIPER Campus at Hajipur, in spite of the matter being followed up with the State Govt. at Chief Minister and Chief Secretary level.

II. The matter has been brought to the notice that in the 10th State level coordination Committee meeting held at Hajipur on 21.3.2013. The Principal Secretary, Industries, Bihar has advised that 50 acres of land was not readily available for allotment to NIPER, the institution may proceed with vertical construction worked on the 12.43 acres of land already in possession of NIPER Hajipur, along with 3 buildings. At the same time the institute has been advised to pursue with the District Magistrate Vaishali for alternative land for acquisition for the NIPER.

In the Eastern Zonal Council meeting held on 16.01.2015 chaired by Union Home Minister, the matter was taken up and State Government reiterated their view that 50 acre of land around Patna is not available and that the NIPER campus at the present site may be constructed vertically.

III. Matter has not been settled as yet. Recently, the matter has been taken up at the level of Secretary and Minister. However, the quantum and location of land is yet to be settled satisfactorily.

IV. Establishment of NIPER may be a great addition to the educational infrastructure of any State. However, since 2007 NIPER, Kolkata and Hajipur are functioning from the premises of their mentor institutes, and facing acute shortage of accommodation and they are unable to plan construction of full-fledged campus for providing inter-alia all essential infrastructure facilities essential for quality education at Post Graduate level and Ph.D in Pharmaceutical Sciences.

V. A letter has also been written on 30.12.2014 by Hon'ble Minister (C&F) to the Chief Minister of Bihar.

NIPER, Raebareli

As regards NIPER, Raebareli, the Steering Committee constituted for all the NIPERs in its 20th meeting held on 18.11.2014 observed that the issues related to adequacy and clear title of the land be assured and the related issues should be resolved before proceeding further in the matter of the appointment of the PMC for NIPER, Rae Bareli. Accordingly, the

issue is being taken up with State Government to sort out the impediments so that PMC could be selected.

Comments of the Committee

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

Recommendation No.4

The Committee note that the functions of National Pharmaceutical Pricing Authority (NPPA) inter-alia include fixation and revision of prices of scheduled drugs under the Drug (Price Control) Order, 1995 (DPCO'95)/DPCO, 2013, as well as monitoring and enforcement of prices. NPPA also provides inputs to Government for policy formulation and on other specific issues concerning affordable medicines to the consumers. The Government has notified New DPCO, 2013 on 15th May, 2013 in supersession of DPCO, 1995. Out of the 628 NLEM medicines specified in the Schedule-I of DPCO, 2013, NPPA has fixed / notified the ceiling prices in respect of 489 medicines upto 15th September, 2014 under provisions of the said order. In order to fix the ceiling prices in respect of the remaining NLEM medicines, NPPA has made sincere efforts to obtain / collect the data from all available sources like IMS-Health, PharmaTrac, Pharma Industry Associations, Marketing Companies etc. In addition, NPPA took up the matter with Department of Health, Drugs Controller General (India), State Health Secretaries and State Drugs Controllers for providing the information / data so as to enable NPPA to fix prices of remaining NLEM medicines under provisions of DPCO, 2013. The DPCO, 2013 also provides for monitoring of the production and availability of scheduled formulations and the active pharmaceutical ingredients contained in the scheduled formulations. In this regard, the manufacturers/ importers/ marketing companies of the scheduled formulations and Active Pharmaceutical Ingredients are required to furnish information as stated in Form- III of the said order quarterly. NPPA regularly monitors the availability of essential medicines in the country through Drugs Control Administration of State Governments. Whenever shortage is reported by the State Drug Controllers or comes to its notice otherwise, NPPA takes remedial steps for ensuring availability of drugs by impressing upon manufacturers to rush the stocks to the places of shortage. In this regard, the Committee were informed that recently the scarcity of certain essential medicines, namely, Anti-Snake Venom, Rabies vaccine, Rabies Immunoglobulin, Albumin Injection and Anti-malarial combination of Sulfadoxine + Pyrimethamine Tablets was reported to the NPPA. According to the Department, the concerned manufacturers of these drugs were not maintaining normal supply of the medicines in domestic market and / or Institutions. So, NPPA vide its notification S.O. No. 2292 (E) dated 09.09.2014 directed all the concerned manufacturers / importers to comply with the

requirements contained in para 21(1) and furnish the month-wise production and sale figures for the last 12 months. In view of the foregoing, the Committee of the strong view that the prices of all essential drugs need to be regulated. In this regard, the role of the Government in procuring drugs and providing it at affordable price to the public can not be undermined. It is imperative for the Government/NPPA to urgently bring down the prices of all essential drugs so that the same are available to the common man, poor or the needy at affordable price. To keep this end in view, the Committee strongly feel that the scope of price control needs to be enlarged taking into consideration cost effectiveness, safety and efficacy and more and more therapeutic segments should be brought under price control. At the same time, NPPA/Government should be vigilant enough to ensure that all essential drugs are accessible to the public and a stock-out situation like the one as referred above should never arise. NPPA should also expedite the process of notifying the ceiling price of the remaining NLEM medicines i.e. 139 out of 628 NLEM medicines. The Committee would like the Department to act accordingly and be apprised of the initiatives taken by Department to fix/notify the prices of remaining NLEM medicines.

Reply of the Government

Out of the 628 NLEM medicines specified in the Schedule- I of DPCO,2013, NPPA has fixed/ notified the ceiling price in respect of 509 medicines upto 05th February, 2015 under provisions of the said order. In order to fix the ceiling prices in respect of the remaining NLEM medicines, NPPA has made sincere efforts to obtain/ collect the price data from all available sources like IMS-Health, Pharma Trac, Pharma Industry Associations, Marketing Companies etc. In addition, NPPA took up the matter with Ministry of Health & Family Welfare, Drugs Controller General (India), State Health Secretaries and State Drugs Controllers for providing the information/ data so as to enable NPPA to fix prices of remaining NLEM medicines under provisions of DPCO, 2013. An office memorandum was also placed on NPPA's website on 27.01.2015 requesting all companies / pharma associations to provide data in respect of pending 102 formulations.

There are 680 medicines specified in the first schedule of DPCO, 2013 covering 27 therapeutic groups as defined in the NLEM, 2011 that are currently under price control regime. Out of 680 medicines, 52 medicines are commonly appearing at more than one therapeutic group, therefore, there are 628 scheduled formulations.

As on 10.2.2015, the ceiling price of 509 medicines has been notified and the same are available in the public domain at the official website of NPPA at www.nppaindia.nic.in.

The status in respect of all 680 cases of price fixation of scheduled formulations is as follows:

Pricing Status as on 10.02.2015

Sl. No.	Particulars			
1	Total number of NLEM medicines (after separating tablets and capsules)			680
	Common medicines under different sections of DPCO, 2013			52
	Net medicines for which prices are to be fixed			628
2	Break up of number of items dealt under different category			
	A	Notification issued upto 18 th meeting of the Authority under DPCO, 2013	509	
	B	Common items under DPCO, 1995 and DPCO, 2013 for which price notifications are to be issued in 2014, but are pending for want of information/data from IMS-Health	15	
	C	Common items under DPCO, 1995 and DPCO, 2013 for which price notifications will be issued in 2015 onwards	17	
	d (a to c)	Total Cases Processed / To be processed	541	
	E	Total cases Pending for non-availability of data Referred to SDC's/uploaded on NPPA's websites. Industry, Trade and State Governments have been requested to provide available data, if any.	87	
	Sub total (d + e)			628
3	Number of items under examination for data collection/pricing (1 - 2)			Nil

Out of the remaining 119 formulations, 17 formulations are not yet due for price revision. The price of remaining 102 formulations could not be fixed mainly due to non-availability of price data in respect of these formulations. All possible efforts are being made to collect the same including writing to industry associations, trade associations, State Drug Controllers, State Health Secretaries, and Chief Secretaries. Hon'ble Minister, Chemicals and Fertilizers has also written to the Health Minister. But progress is minimal.

Impact of Price Fixation

The details of reduction in prices scheduled formulations effected under DPCO, 2013 as compared to the highest price prevailed prior to the announcement of DPCO, 2013 are given as under:

% reduction with respect to Maximum Price	No. of drugs
0<= 5%	52
5<=10%	45
10<=15%	56
15<=20%	44
20<=25%	66
25<=30%	55

30<=35%	30
35<=40%	34
Above 40%	127
	509

Regarding shortage of drugs, it is stated that the availability of essential medicines is regularly monitored by the NPPA mainly through Drugs Control Administration of State Governments. Whenever shortage is reported by the State Drug Controllers or comes to its notice otherwise, NPPA takes remedial steps for ensuring availability of drugs by impressing upon manufacturers to rush the stocks to the places of shortage.

In the recent past, short supply of certain essential medicines namely, Anti-Snake Venom, Rabies Vaccine, Rabies Immunoglobulin, Albumin Injection and Anti-malarial combination in Sulfadoxine + Pyrimethamine Tablets was reported to NPPA. In order to maintain normal supply of these medicines in the domestic market and / or institutions, NPPA issued notification S.O. No. 2292 (E) dated 09.09.2014 wherein all the concerned manufacturer / importers were directed to ensure a smooth supply and to furnish compliance report in this regard. In connection with recent shortages of Human Albumin Injection reported by major hospitals throughout the country, NPPA has held a meeting with the major manufacturers/importers of Albumin Injection. During the course of discussion, it was observed that the shortage of Human Plasma is one of the main constraints in expanding the production capacity of Human Albumin in the Country. In this regard, Chairman, NPPA has written a D.O. letter on 04.02.2015 to the Additional Secretary, Department of Health regarding supply of Human Plasma to manufacturer of Human Albumin by NACO. There has been a reference from the Drugs Controller General (India) regarding non-availability of Injection Anti-Diphtheria Serum in Post Graduate Institute of Medical Education & Research, Chandigarh. In order to make the drug available, in and around Chandigarh, all the concerned manufacturers have been advised for necessary action in the matter. In this regard, M/s Haffkine Bio-Pharmaceuticals Corporation Limited, a Govt. of Maharashtra undertaking has offered a quotation for supply of the said drug to Govt. Medical College and Hospital, Chandigarh while another manufacturer namely M/s Serum Institute of India Ltd., has informed that there is a shortage of plasma, however, they would expedite the process of getting the plasma in order to make the Diphtheria Antitoxin available.

Regarding enlarging the span of price control, it is informed that NPPA in its 20th Authority meeting held on 05.02.2015 approved recommendations for enlarging NLEM-2011 based on a comprehensive study conducted by NPPA for the consideration of the Department of

Pharmaceuticals and onward recommendation to the Core Committee on Revision of NLEM set up by the M/o Health & Family Welfare. The study was conducted in pursuance with directions received from the Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers vide their letter no. 31026/24/2010-PI.I dated 07.08.2014. Summary of recommendation sent to Department of Pharmaceuticals for further necessary action, are as follows:

- (i) Correction / modifications in respect of anomalies / discrepancies in specification / descriptions in the NLEM.
- (ii) Recommendation for addition of 43 medicines / drugs with specified dosage / strength in the NLEM.
- (iii) Two separate studies in respect of anti-cancer drugs and medical devices for making recommendations for inclusion in the NLEM / Schedule-I of DPCO, 2013.
- (iv) Final report by NPPA on the study done by the NHSRC on current pricing practice followed with regard to cardiac stents and reasonable pricing of Bare Metal Stents and Drug Eluting Stent.
- (v) Differential pricing of NLEM drugs based on product distinctiveness i.e. source of origin, process differentiation, drug delivery system, site specific delivery, therapeutic benefit in terms of increased efficiency of the drug etc.
- (vi) Price fixation of injectable dosage form specified in the NLEM as per standard dosage unit.
- (vii) Ministry of Health and Family Welfare may be requested to work on the list of Life Saving Drugs”.

Comments of the Committee

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

Recommendation No.5

The Committee note that the Department has 5 running PSUs under its administrative control viz. Karnataka Antibiotics & Pharmaceuticals Limited (KAPL), Rajasthan Drugs & Pharmaceuticals Limited (RDPL), Bengal Chemicals & Pharmaceuticals Limited (BCPL), Hindustan Antibiotics Limited (HAL) and Indian Drugs & Pharmaceuticals Limited (IDPL). Out of these KAPL and RDPL are profit making and BCPL, HAL & IDPL are BIFR referred Companies. However, RDPL during the year 2013-14, has registered losses for the first time though it is not a very sick unit in that way.

As the HAL is still incurring losses, a Modified Draft Rehabilitation Scheme (MDRS) based on the report submitted by IFCI limited, a professional Consultant, involving the cash infusion of Rs.497.45 crores was submitted by IDBI, the Monitoring Agency to BIFR on 17 February 2014. MDRS was subsequently revised by HAL with the assumption that the entire fund requirement for the revival of HAL would be made available by the Government of India from budgetary support.

The Statutory Auditors are in the process of completing the audit of the statutory dues and other current liabilities of the company and the same will be submitted to IDBI by the company shortly. IDBI will then circulate the revised proposal to the Banks and Government/ Statutory Departments seeking their views/opinions on the same and then a joint meeting of the stake holders of the company will be convened by IDBI for finalizing MDRS before submitting to BIFR.

In the context of IDPL, the Committee were informed that the process of revival of IDPL as per the Laws, Rules & Procedures laid down by the Government of India is underway. No time frame can be indicated because other agencies of the Government are also involved. However, the process is at an advanced stage and all efforts are being made to bring the process to conclusion at the earliest. At present, the MDRS is being modified by IDBI, as per the cut off date approved by the BIFR in its last hearing held in September, 2014. During the course of evidence, the Committee were also informed that the rehabilitation programme of IDPL is under active consideration and very shortly the matter will go to the Cabinet for a decision. In this context, the Committee were also informed that 80% of the bulk drugs are coming from outside India and that has resulted in closing down of drug units in India. Therefore, the Department intends to create capacity for bulk drugs in India itself for which a policy will be brought out very shortly in a month's time or so. Once that policy is brought out, the Department hopes to revive IDPL and HAL to produce bulk drugs in a very big way which will help the country to attain self-reliance in bulk drugs.

As regards the BCPL, the Committee were informed that acute shortage of working capital and expiry of Purchase Procurement Policy in the year 2011 were the main reasons for gradual decrease in the production and sales turnover of the company. The said policy has since been renewed for another 5 years from December 2013. They are producing a lot of good quality drugs and have improved their performance to a great extent. Earlier they were producing quality drugs for Rs.10 crore which has since increased to Rs.30 to 40 crore.

In view of the foregoing, the Committee are extremely unhappy to note that no significant progress has been made over the years to revive the loss making/sick units particularly IDPL and HAL. During the course of evidence, the Secretary of the Department pointed out that a lot of time is lost in the Government decision making process as many agencies are involved therein. The Committee are, however, not satisfied with the explanation given by the Department as it is their responsibility to speed up its functioning/working and to act effectively and efficiently. The Committee are also of the view that over-dependence on outside countries for bulk drugs/critical raw material is very risky as any deterioration in relationship with them can potentially result in severe shortages in the supply of essential drugs to the country. There will also be a risk of increase in prices of the drugs where there is virtual monopoly. It is, therefore, essential that a well thought policy may be brought out with out further delay to create capacity of bulk drugs in

the country itself and to attain self-reliance in bulk drugs for which revival of sick units would be extremely essential. The Committee, therefore, recommend that the Department should make vigorous efforts in coordination with all concerned to revive these sick units within a fixed time line. The Committee are of the strong view that the revival of these units is absolutely essential for the country to ensure availability and adequate quantity of drugs at an affordable price to the public. The Committee would like to be apprised of the action plan of the Department in this regard.

Reply of the Government

The Modified Draft Rehabilitation Scheme for Hindustan Antibiotics Ltd. has been submitted by IDBI in February 2015, after taking into account the various observations of BIFR on the earlier DRS. The IDBI has advised that the approval of Board of Directors of HAL, BRPSE, Govt. of India may be obtained with approval of the Cabinet to the MDRS as well as permission for sale of land to fund the MDRS. Thereafter, the matter may be taken up to BIFR for final approval of the Second Rehabilitation Scheme. The Board of Directors, HAL has approved the MDRS. The BRPSE has been requested to agree to the MDRS. A Cabinet Note is being prepared for circulation among concerned Ministries after approval of Minister (C&F).

As regards, revival of IDPL, the MDRS has been submitted by IDBI in February, 2015. Action is being taken by IDPL to convey the approval of Board of Directors of IDPL to the MDRS. Approval of BRPSE would be sought. Thereafter, Cabinet Note would be prepared as in the case of HAL.

Recommendation No.6

The Committee note that access to quality medicines at affordable prices is a key challenge for the Government. The prices of branded medicines are generally higher than generic medicines due to various reasons including limited regulation through Drug Prices Control Order, 1995 etc. For fulfilling this goal, 'Jan Aushadhi Campaign' has been launched. The purpose of this campaign is to make available medicines at affordable prices for all, especially the poor and the disadvantaged. Under this campaign, less priced quality generic medicines will be made available through Jan Aushadhi Stores (JAS) which are of same quality, efficacy and safety as compared to branded generic medicines. The Bureau of Pharma Public Sector Undertakings of India (BPPI) was set up on 1st December 2008 with the major objective to have a focused and empowered structure to implement the Jan Audhadhi Campaign initiated by the Department. BPPI monitors the functioning of Jan Aushadhi Stores and is also involved in promotion of the unbranded generic drugs. The first Jan Aushadhi Generic Drug Store was opened in Civil Hospital, Amritsar on 25

November 2008. So far, 199 Jan Aushadhi Generic Drug Stores in various States have been opened and out of that only 99 are running as in many place these stores have been closed as the free drugs are being supplied to all the patients in hospitals by the State Governments.

The Committee also note that on the recommendation of this Committee in its 32nd Report (Recommendation No.9) regarding opening of more JAS on a mission mode, a revised Business Plan has been worked out by the Department which aims to open more than 3000 stores during 12th Plan period. However, the Committee regret to note that JAS is not being accepted either by the public or the drugs under the scheme are not being prescribed by the doctors to the patients. Even after six years, no efforts have been made by the Government to educate the peoples and to reach out the doctors' community in this regard. The Committee, therefore, recommend that a vigorous campaign should be launched by the Department to create awareness among the people about the generic drugs and Jan Aushadhi Stores and its quality, efficacy and safety comparable with branded medicines and to reach out to the doctors' community by way of conferences to impress upon them to prescribe generic drugs to the patients. The Committee desire that special emphasis be given by the Department for improving the functioning of the Jan Aushadhi Stores. The Committee also note that almost double amount has been earmarked for Jan Aushadhi Scheme in BE 2014-15 i.e Rs.30 crore as compared to Rs.15.20 crore in RE 2013-14. The Committee, therefore recommend that the increased amount should be utilized judiciously for opening more Jan Aushadhi stores in the remote areas where Jan Aushadhi stores are not in existence and for vigorous publicity campaign to create awareness amongst the people about generic drugs. The Committee would like to be apprised of the initiatives taken by the Department in this regard.

Reply of the Government

- a. Details of campaign made by BPPI to create awareness among the people about the generic drugs and Jan Aushadhi stores and its quality, efficacy and safety comparable with branded medicines.

Availability and timely supply of medicines to Jan Aushadhi Stores is a pre-requisite before any publicity on awareness is launched, a concrete action plan is under finalization. The availability of medicines and supply position substantially improved after BPPI took complete control over procurement and supply chain management by creating its own Central Warehouse for storage of medicines as per the new business plan approved in August, 2013. With the improvement in situation towards the middle of 2014-15, the

following publicity campaign has been carried out in some of the states where the Jan Aushadhi Scheme is working well:

- (i) Disease specific Publicity was given through print media in the states of Punjab, Chandigarh, Himachal Pradesh and Odisha in the month of November, 2014 making public aware about the availability of quality generic medicines at affordable prices at Jan Aushadhi stores by giving illustrative price difference between average market branded prices and Jan Aushadhi medicines. Copies of this advertisement are enclosed.
- (ii) Publicity was carried out in different districts of Odisha in the months of December-January, 2015 by participating in exhibitions during Dhanushyatra, Lok Mahotsav, Beach festivals and making public aware about the Jan Aushadhi generic medicines and their advantages.
- (iii) Awareness campaign was also carried out by participating in the Arogya Mela organized by the Ministry of Ayush at Bhubaneswar in February, 2015.
- (iv) In addition to above, advertisement for Expression of Interest for opening of Jan Aushadhi stores highlighting the price difference between branded medicines and generic Jan Aushadhi medicines were issued.

An amount of about Rs. 20 lakh has been spent on these awareness campaigns.

For the year 2015-16, an action plan consisting of multi-media for creating awareness about Jan Aushadhi and its efficiency etc. is being prepared. According to the plan, the first phase of the publicity campaign consisting of display and distribution of pamphlets, posters and hoarding at Medical College Hospitals and prominent places in different places is proposed. There will also be radio & sms campaign.

- b. Steps taken by BPPI to reach out to the doctor's community. Whether any conference has been held.

To encourage doctors to prescribe generic medicines, a brochure containing list of medicines is proposed to be printed. Workshops/seminars with doctors to disseminate and sensitize them on promotion of low priced generic medicines are proposed to be organized during 2015. Engagement with Indian Medical Association has been undertaken for promoting generic drugs prescription.

- c. What special emphasis has been given for improving the functioning of the Jan Aushadhi stores?

- i. The management team of BPPI has been strengthened.
- ii. To improve the functioning of Jan Aushadhi Stores by making them financial viable, the basket of medicines is being augmented . It is planned to increase the basket from the existing 361 at present to 504. In addition, certain surgical items are also

proposed to be supplied from Jan Aushadhi stores. This would improve the viability of Jan Aushadhi Stores and stoppage of undispensed prescriptions.

- iii. The supply chain management is being improved.
 - iv. In respect of Jan Aushadhi stores located in Govt. Hospitals with the help of State Government, a onetime assistance of Rs. 2.50 lakh as establishment cost and start-up cost is given to the operating agency
 - v. Jan Aushadhi stores opened by NGO/Society/Pharmacist etc., financial assistance as incentive linked to sale of medicines @ of 10% of the monthly sales amount subject to a ceiling of Rs. 10,000/- per month for a period of first 12 months is provided. In case of stores opened in North Eastern states and other difficult areas, the rate of incentive is 15% of monthly sale amount subject to a ceiling of Rs. 15,000/- per month.
- d. Rs. 30 crore was earmarked in BE 2014-15 but BPPI could not utilize same. The reason thereof may be furnished.

Due to lack of progress in opening of New Jan Aushadhi Stores, resulting in poor utilization of funds provided to BPPI in 2013-14, the budget of Rs. 30.00 crores could not be released to BPPI.

CHAPTER - III

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

-NIL-

CHAPTER - IV

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

-NIL-

CHAPTER – V**OBSERVATIONS/ RECOMMENDATIONS IN RESPECT OF WHICH REPLIES OF THE GOVERNMENT ARE OF INTERIM NATURE****Recommendation No.7**

The Committee note that the Department has come up with a scheme, Cluster Development Programme for Pharma Sector with the objective to create/upgrade the common facilities in the area where there is a cluster of Pharma Manufacturers. The total outlay of the scheme is Rs.125 crore for 12th Plan period. Through this scheme, the cluster of small and medium enterprises can avail financial assistance for common facilities like Common Testing Facilities, Training Centres, Effluent Treatment Plant, Common Logistics Centres. The Committee also note that the Department has already created a large number of Pharma clusters in the country at places like Hyderabad, Chennai, Maharashtra and Gujarat, Uttarakhand and Himachal Pradesh and many Pharma clusters will come up over a period of time. These Pharma clusters lack certain common facilities, like quality testing facility, library facility, training facility, effluent treatment plant etc. An initial allotment of Rs.6 crore would be used to start the process and from next year onwards for the next two years, the Department will spend substantial amount of money and create common facilities in these Pharma clusters. The Committee expect the Department to implement the programme expeditiously in a systematic, professional and transparent manner. The Committee are of the view that these Pharma Cluster may also be associated with regional centres of NIPER and universities/colleges for their technical support and testing facilities. As a result thereof, the Committee hope that good quality medicines at affordable prices would be available to the common people. The Committee would like to be apprised of the progress made in the matter.

Reply of the Government

The Scheme with an overall allocation of Rs.125 Crores has now been approved by the Competent Authority. Department has invited bids from eligible companies for selection of the Project Management Consultant for implementing the scheme. The technical bids were evaluated by a Committee which found that only 1 bidder out of 3 bidders had qualified. The file was submitted to IFD who had opined that since qualification of only 1 bidder out of the 3 tendering firm at the stage of technical evaluation would not render sufficient comparison nor enable the Department to ascertain L1. They advised the Department to call for tenders afresh.

After the failure of EOI which was called for selection of Project Management Consultant (PMC), the Department has decided in principle to appoint Project and Development India

Ltd(PDIL), a Government of India undertaking for taking over the role of PMC on a nomination basis as per Rule 176 of the GFR.

Comments of the Committee

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

**NEW DELHI;
14 JULY, 2015
23 Ashadha, 1937 (Saka)**

**ANANDRAO ADSUL
Chairperson
Standing Committee on
Chemicals and Fertilizers**

Appendix - I**MINUTES****MINUTES OF THE SEVENTEENTH SITTING OF THE
STANDING COMMITTEE ON CHEMICALS & FERTILIZERS
(2014-15)**

The Committee sat on Tuesday, the 16 June, 2015 from 1500 hrs. to 1600 hrs. in Room No. 139, Parliament House Annexe, New Delhi.

Shri Anandrao Adsul - Chairperson***Members*
Lok Sabha**

2. Shri Idris Ali
3. Smt. Anju Bala
4. Shri B.N. Chandrappa
5. Shri Shankar Prasad Datta
6. Smt. Veena Devi
7. Shri R. Dhruvanarayana
8. Shri Satish Kumar Gautam
9. Shri Chhedi Paswan
10. Shri Chandu Lal Sahu
11. Dr. Krishan Pratap Singh
12. Smt. Rekha Arim Verma
13. Shri Innocent

Rajya Sabha

14. Shri Narayan Lal Panchariya
15. Shri Palvai Govardhan Reddy

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 Hon'ble Chairperson welcomed the members of the Committee.
3. The Committee thereafter took up for consideration the following draft Reports:

a) ***** ***** ***** *****

b) ***** ***** ***** *****

- c) Action Taken Reports on Demands for Grants (2014-15) of the Ministry of Chemicals and Fertilizers (Department of Pharmaceutical)

4. The draft Reports relating to the Department of Fertilizers, Department of Pharmaceuticals and Department of Chemicals and Petrochemicals were adopted by the Committee without any amendment.

5. The Committee authorised the Chairman to make consequential changes, if any, arising out of the factual verification of the Reports by the Department of Fertilizers, Department of Chemicals and Petrochemicals and Department of Pharmaceuticals of the Ministry of Chemicals and Fertilizers and present the same to both the Houses of Parliament.

6. The Committee then decided to hold its next meeting on 25th June, 2015 for briefing on the subject " Functioning of National Institute of Pharmaceutical Education and Research (NIPER)" by the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals).

The Committee then adjourned.

***** *Matters not related to this Report.*

Appendix - II**(Vide Para 3 of the Introduction)****ANALYSIS OF ACTION TAKEN BY THE GOVERNMENT ON THE RECOMMENDATIONS CONTAINED IN THE SECOND REPORT (SIXTEENTH LOK SABHA) OF THE STANDING COMMITTEE ON CHEMICALS AND FERTILIZERS (2014-15) ON 'DEMANDS FOR GRANTS (2014-15)' OF THE MINISTRY OF CHEMICALS AND FERTILIZERS (DEPARTMENT OF PHARMACEUTICALS)**

I	Total No. of Recommendations	7
II	Observations / Recommendations which have been accepted by the Government: (Vide Recommendation Nos. 1,2,3,4 , 5 and 6)	6
Percentage of Total		85.72
III	Observations / Recommendations which the Committee do not desire to pursue in view of the Government's reply:- NIL	00
Percentage of Total		00
IV	Observations / Recommendations in respect of which reply of the Government have not been accepted by the Committee and which require reiteration:- NIL	00
Percentage of Total		00
V	Observations / Recommendations in respect of which final replies of the Government are still awaited: (Vide Recommendation No. 7)	1
Percentage of Total		14.28