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STANDING COMMITTEE ON CHEMICALS & FERTILIZERS (2012-13)

FIFTEENTH LOK SABHA

MINISTRY OF CHEMICALS AND FERTILIZERS (DEPARTMENT OF PHRMACEUTICALS)

DEMANDS FOR GRANTS (2012-2013)

[Action Taken by the Government on the Observations/Recommendations contained in the Twenty-Seventh Report of the Standing Committee on Chemicals and Fertilizers (Fifteenth Lok Sabha) on Demands for Grants (2012-13) of the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals)]

सत्यमेव जयते

REPORT

LOK SABHA SECRETARIAT
NEW DELHI

December, 2012/ Agrahayana 1934, (Saka)

CC&F No. 32

REPORT

STANDING COMMITTEE ON CHEMICALS AND FERTILIZERS (2012-13)

FIFTEENTH LOK SABHA

MINISTRY OF CHEMICALS AND FERTILIZERS (DEPARTMENT OF PHARMACEUTICALS)

DEMANDS FOR GRANTS (2012-2013)

[Action Taken by the Government on the Observations/Recommendations contained in the Twenty-Seventh Report of the Standing Committee on Chemicals and Fertilizers (Fifteenth Lok Sabha) on Demands for Grants (2012-13) of the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals)]

Presented to Lok Sabha on 17.12.2012

Laid in Rajya Sabha on 17.12.2012

LOK SABHA SECRETARIAT
NEW DELHI

December, 2012/Agrahayana, 1934 (Saka)

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3.	Shri Gajanan D. Babar
4.	Shri P.P. Chauhan
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SECRETARIAT

1.	Smt Rashmi Jain	-	Joint Secretary
2.	Shri Anil Kumar Srivastava	-	Additional Director
3.	Smt. Emma C. Barwa	-	Under Secretary
4.	Shri Ajit Kumar Sahu	-	Committee Officer

Shri P. Balaram Naik appointed as a minister of state

INTRODUCTION

I, the Chairman, Standing Committee on Chemicals and Fertilizers (2012-13) having been authorised by the Committee to present the Report on their behalf, present this Thirty Second Report (Fifteenth Lok Sabha) on Action Taken by the Government on the observations / recommendations contained in the Twenty-Seventh Report (Fifteenth Lok Sabha) of the Standing Committee on Chemicals and Fertilizers (2011-12) on 'Demands for Grants (2012-13)' of the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals).

2. The Twenty-Seventh Report (Fifteenth Lok Sabha) of the Standing Committee on Chemicals and Fertilizers was presented to Lok Sabha on 2 May, 2012. The Action Taken replies of Government to all observations / recommendations contained in the Report were received on 20 July, 2012. The Standing Committee on Chemicals and Fertilizers (2012-13) considered and adopted this Report at their sitting held on 10 December, 2012.

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

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

New Delhi;

17 December, 2012
26 Agrahayana, 1934 (Saka)

GOPINATH MUNDE
Chairman,
Standing Committee on
Chemicals and Fertilizers

REPORT

CHAPTER – I

This Report of the Standing Committee on Chemicals and Fertilizers deals with the action taken by the Government on the Observations/Recommendations contained in the Twenty-Seventh Report (Fifteenth Lok Sabha) of the Committee on Demands for Grants (2012-13) of the Ministry of Chemicals & Fertilizers (Department of Pharmaceuticals) which was presented to Lok Sabha on 2.05.2012. The Report contained 10 Observations / Recommendations.

2. The Ministry of Chemicals & Fertilizers (Department of Pharmaceuticals) were requested to furnish replies to the Observations / Recommendations contained in the Twenty-Seventh Report within three months from the date of presentation of the Report, i.e., by 2.08 2012. The Action Taken Replies of the Government in respect of all the 10 Observations / Recommendations contained in the Report have been received from the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals) vide their O.M. No.16(3)/2012-Fin.II, dated 20.07.2012. These have been categorized as follows:-

(i) Recommendations / Observations that have been accepted by the Government :-
Sl.Nos. 2,3,4 and 6 (Total =4)
These may be included in Chapter II of the Draft Report.

(ii) Recommendation / Observation which the Committee do not desire to pursue in view of the Government's reply :-
Sl.No.Nil (Total =Nil)
This may be included in Chapter III of the Draft Report.

(iii) Recommendations / Observations in respect of which replies of the Government have not been accepted by the Committee :-
Sl.Nos. 1 and 9 (Total =2)
These may be included in Chapter IV of the Draft Report.

(iv) Recommendations / Observations in respect of which final replies of the Government are of interim nature :-
Sl.Nos.5,7, 8 and 10 (Total =4)
These may be included in Chapter V of the Draft Report.

3. The Committee desire that the Action Taken Notes on the Observations / Recommendations contained in Chapter-I of this Report and the final replies in respect of the Observation / Recommendation contained in Chapter V for which only interim replies have been furnished by the Ministry 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. FIVE YEAR PLANS

RECOMMENDATION NO.1

5. Taking a critical view regarding significantly less allocation of fund in comparison to the initial outlay during the Eleventh Five Year Plan period (2007-12), the Committee had observed/recommended as under:-

> "The Committee note that out of an outlay of Rs.1396.17 crore for the Eleventh Five Year Plan (2007-12) for the Department of Pharmaceuticals, the budget allocation for the period is only Rs.741.76 crore, which is only about 53% of the total outlay for the Eleventh Five Year Plan. Hence, during the entire five years of the Eleventh Five Year Plan, the allocation sanctioned to the Department of Pharmaceuticals is much below than that approved by Planning Commission. The Committee fail to understand this mis-match between the overall outlay for the Plan period and the funds actually provided to the Department and want an explanation from the Department of Pharmaceuticals. The Committee is also of the view that the Planning Commission while approving the allocation, should also be realistic so that there may not be much difference between approved allocation and the allocation actually disbursed to the Department.
>
> The Committee also observe that there is underutilization of funds by the Department which may be one of the reasons for getting lesser allocation. The Committee, therefore, recommend that the Department should improve its physical performance in order to have a semblance between financial allocation and physical performance. This would also help the Department in obtaining more funds as per the stipulations of Planning Commission.
>
> The Committee also note that in its Mid-term Appraisal Report, the Planning Commission has recommended that the Pharmaceutical Research and Development Programme (PRDP), which has been pursued by Department of Science and Technology (DST), would be transferred to Department of Pharmaceuticals at the end of Eleventh Five Year Plan. However, the Committee note with regret that no allocation has been made for the PRDP in the Detailed Demands for Grants for the year 2012-13. As PRDP is a vital programme in the area of pharmaceutical research and development, the Committee recommend that the Department should make concerted efforts towards getting allocation for the scheme from the next financial year and implement the same to achieve the desired goals."

REPLY OF THE GOVERNMENT

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

> "The matter relating to transfer of PRDP is being examined in consultation with Department of Science and Technology."

COMMENTS OF THE COMMITTEE

7. In their recommendation the Committee had observed that the budget allocation for the Department of Pharmaceuticals during the Eleventh Five Year Plan period was only 53 % of the initial outlay which was much below than that approved by the Planning Commission. The Committee, therefore, recommended that during the Twelfth Five Year Plan, the Planning Commission while approving

the allocation, should be realistic so that there may not be much difference between approved allocation and the allocation actually disbursed to the Department. Further, while observing that under-utilization of funds by the Department of Pharmaceuticals might be one of the reasons for getting lesser allocation, the Committee recommended that the Department of Pharmaceuticals should improve its physical performance in order to have a semblance between financial allocation and physical performance.

In addition to above, the Committee also recommended that the Department of Pharmaceuticals should make concerted effort towards getting allocation for the Pharmaceutical Research and Development Programme (PRDP) from the next financial year and implement the same to achieve the desired goals. The Department's reply regarding transfer of the PRDP to the Department of Pharmaceuticals and allocation of funds for the same is also regrettable as the Department has only briefly replied that matter relating to transfer of PRDP is being examined in consultation with Department of Science and Technology. In view of the incomplete reply furnished by the Department, the Committee reiterate that the Department of Pharmaceuticals should hasten its efforts regarding transfer of the Programme.

The Committee are unhappy to point out that Department of Pharmaceuticals has not informed in their action taken reply specifically about the action taken or planned to be taken to make realistic allocation and disbursal of funds by the Planning Commission which would be utilized fully by the Department of Pharmaceuticals. The Committee therefore, strongly recommend that Department of Pharmaceuticals should take pro-active steps for fully utilizing the funds allocated by the Planning Commission during the Twelfth Five Year Plan and also Planning Commission should make realistic allocation so that there may not be much difference between approved allocation and the allocation actually disbursed to the Department.

B. NATIONAL INSTITUTE OF PHARMACEUTICAL EDUCATION AND RESEARCH (NIPER)

RECOMMENDATION NO.3

8. While expressing concern over delay in construction of new NIPER campuses, the Committee had made following recommendation:-

> "The Committee note that establishment of NIPERs is a significant effort towards development of quality human resource for the growth of pharmaceutical sector in India. However, the Committee is concerned that work relating to construction of new NIPER campuses could not be initiated in 2011-12 and hence, the funds allocated for the purpose could not be utilized. The Committee note that availability of land has been a serious impediment in establishment of new

NIPERs. Further, the Committee is dismayed to note that despite of availability of land at Guwahati and Ahmedabad, the construction of campus has not been started in 2011-12. This shows lack of proper planning and effort on the part of the Department. The Committee desire that the construction work at Guwahati and Ahmedabad should start immediately and the Department of Pharmaceuticals should make all necessary efforts towards acquisition of lands at other four places namely, Hyderabad, Hajipur, Kolkata and Rae Bareli. The Committee desire to be apprised about the Department's effort towards acquisition of land for New NIPERs at the above four places and also progress in the construction of campuses for new NIPERs."

REPLY OF THE GOVERNMENT

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

"In 2007, Cabinet granted in-principle approval to the setting up of six new NIPERs and commencement of classes with the help of mentor Institutes. On 30.09.2011, Cabinet finally approved establishment of six new NIPERs. At present, land is available at Guwahati & Gandhinagar. As such, the issue of construction of NIPER campus at Guwahati & Gandhinagar is under the consideration of Steering Committee for new NIPERs. Minister (C&F) has since requested Chief Ministers of Bihar and Andhra Pradesh vide letters dated 10.4.2012 and Chief Minister of Uttar Pradesh vide letter dated 24.4.2011 to allot requisite land for construction of NIPER campus. West Bengal Government has allotted 35 acres land at Baruipur. It is being developed by the State Government agency viz. Kolkata Metropolitan Development Authority (KMDA). However, issues relating to payment of development charges, extent of availability of land exclusively for NIPER are being sorted out. The matter has since been taken up at the level of Minister (C&F) with the Chief Minister, West Bengal vide letter dated 10/4/2012. Reply from the state Government is awaited."

COMMENTS OF THE COMMITTEE

10. Expressing serious concern over delay in development of infrastructure for new NIPERs, the Committee had earlier recommended that the Department of Pharmaceuticals should start construction of campuses at Guwahati and Ahmedabad where land was already available and make all necessary efforts towards acquisition of land at four places i.e. Hyderabad, Hajipur, Kolkata and Rae Bareli. In this regard, the Committee have been apprised by the Department that the issue of construction of NIPER campuses at Guwahati and Gandhinagar is under the consideration of Steering Committee for new NIPERs. Further, the Department has also stated that the Chief Ministers of Bihar, Andhra Pradesh and Uttar Pradesh have been requested to allot land for construction of NIPER Campuses. Also, the West Bengal Government has allotted 35 acres of land and it is being developed by the State Government Agency viz. Kolkata Metropolitan Development Authority (KMDA). However, issues relating to payment of development charges and extent of availability of land exclusively for NIPER are being sorted out with the Government of West Bengal.

In view of the Action Taken Reply, the Committee feel that no substantial information has been provided by the Department regarding progress in construction of campuses at Guwahati and Gandhinagar except stating that the issue is under consideration of Steering Committee for new NIPERs. The Committee strongly disapprove such replies and are inclined to presume that under the guise of Steering Committee for new NIPERs, the reasons for delay in construction of campuses at these two places have not been reported to the Committee. Hence, the Committee deprecate such practice and desire to be apprised about progress in construction of campuses for new NIPERs at these two places. Further, the Committee take note of efforts made by the Department regarding acquisition of land in Bihar, Andhra Pradesh, Uttar Pradesh and West Bengal and hope that the land acquisition and related issues will be vigorously pursued further with the respective State Governments. The Committee also desire to know the progress made in this regard within three months of presentation of the report.

C. FINALISATION OF PHARMACEUTICAL POLICY

RECOMMENDATION NO.5

11. Citing many past instances when the Committee strongly recommended finalization of the National Pharmaceutical Policy at the earliest, the Committee had stated as under:-

> "The Committee note that at present the Drugs (Price Control) Order(DPCO), 1995 allows control of prices of 74 scheduled bulk drugs and formulations containing any of the scheduled drugs defined in First Schedule of DPCO. They are disturbed to note that initially the Government announced Pharmaceutical Policy 2002. Then, a draft National Pharmaceutical Policy was prepared which has not been finalized till date in spite of the repeated recommendations# of the Committee to finalise the same. Further, new Group of Ministers (GoM) is yet to give its recommendation on draft National Pharmaceutical Policy 2006. As apprised to the Committee, the Department of Pharmaceuticals has now prepared a new Draft National Pharmaceutical Pricing Policy 2011 (NPPP 2011) based on the criteria of essentiality and requirements as stipulated by Ministry of Health and Family Welfare. The Committee also note that the draft National Pharmaceutical Pricing Policy (NPPP)-2011 proposes to bring 348 essential drugs and medicines under National List of Essential Medicines (NLEM)-2011 and associated medicines under price control. The Committee were informed that the draft Policy NPPP-2011 will now be examined by the Group Of Ministers (GoM) on 25.04.2012 and the recommendations of the GoM will go to the Cabinet and the Cabinet in their wisdom will approve the policy. The Committee hope that now the Department of Pharmaceuticals will not resort to dilly dallying tactics in finalizing the NPPP-2011 as done in the case of National Pharmaceutical Policy, which has been under consideration since 2002, so that common man can get the medicines at affordable prices."

Twentieth Report on Action Taken by the Government on the recommendations contained in the Seventh Report of the Committee (2005-06), Twenty-Fifth Report on Demands for Grants (2008-09) and First Report on Demands for Grants (2009-10).

REPLY OF THE GOVERNMENT

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

> "The Group of Ministers (GoM) met on 25.04.2012 and further two more meetings have been held by the GoM."

COMMENTS OF THE COMMITTEE

13. While noting the long delay in finalization of the National Pharmaceutical Policy, the Committee had earlier hoped that the Department of Pharmaceuticals would not resort to further delays in finalizing the draft National Pharmaceutical Pricing Policy 2011 (NPPP-2011). In this regard, in their Action Taken Reply, the Department of Pharmaceuticals has informed the Committee that the Group of Ministers (GoM) met on 25.4.2012 and further two more meetings have been held by the GoM to consider the NPPP-2011. From the above reply, the Committee are inclined to infer that the GoM has yet not been able to finalize its recommendations on the draft NPPP-2011. The Committee strongly feel that early finalization of such a policy will have a huge positive impact on common man. Hence, the Committee express unhappiness over further delay in the finalization of the NPPP-2011 and reiterate that the Department of Pharmaceutical should make all out effort to expedite the finalization and implementation of NPPP-2011 at the earliest. The steps taken in this regard may be informed to the Committee within three months of presentation of this report.

D. AVAILABILITY AND AFFORDABILITY OF MEDICINES

RECOMMENDATION NO.6

14. Expressing apprehension over possibility of malpractices like projecting higher production cost by some companies, the Committee had recommended that :-

> "The Committee also feel that there should not be much difference between the production price and sale prices of a medicine. For this purpose the Committee recommend that Department of Pharmaceuticals should have a tab on the production prices of medicines by different companies and ensure that its sale price do not exceed much beyond a reasonable rate. In such case, the Committee have their apprehension that some companies may resort to malpractices like projecting higher production cost. The Committee, therefore recommend Department of Pharmaceuticals to be cautious in this regard so as to curb the malpractice of gold plating by some of the companies."

REPLY OF THE GOVERNMENT

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

"National Pharmaceutical Pricing Authority (NPPA) fixes/revises prices of 74 bulk drugs included in the First Schedule of the Drugs (Prices Control) Order, 1995 (DPCO, 1995) and formulations containing any of these drugs with an objective to make these drugs affordable. No one can sell any scheduled drug/formulation at a price higher than the price fixed by NPPA. NPPA may, from time to time, by notification in the official gazette under Para 8, 9 and 11 of the DPCO, 1995 fix the price of a scheduled formulation in accordance with the formula laid down in Para 7 of DPCO,95 keeping in view the cost or efficiency or both of major manufacturers of such formulation and such price shall operate as the ceiling sale price for all such packs including those sold under generic name and for every manufacturer of such formulations. A manufacturer, distributor or wholesaler shall sell a formulation to a retailer, unless otherwise permitted under the provisions of this order or any order made there under, at a price equal to the retail price, as specified by an order or notified by the Government (excluding excise duty, if any), minus sixteen per cent, thereof in the case of scheduled drugs. The NPPA may either on its own motion or on application made to it in this behalf by manufacturer in Form-III or Form-IV, as the case may be, after calling for such information as it may consider necessary, by notification in the Official Gazette, to fix a revised ceiling price for a scheduled formulation."

COMMENTS OF THE COMMITTEE

16. The Committee in its earlier recommendation had stated that the Department of Pharmaceuticals should keep a tab on the production prices of medicines by different companies and ensure that the sale prices of medicines do not exceed beyond a reasonable rate. In this regard, the Committee have been informed by the Department of Pharmaceuticals in its Action Taken Reply that NPPA from time to time by notification in the Official Gazette fix the price of Scheduled formulations in accordance with the formula laid down in para 7 of DPCO, 95 keeping in view the cost or efficiency or both of major manufacturers of such formulations and such price operate as the ceiling sale price for all such packs including those sold under generic name and for every manufacture of such formulations.

However, the Committee are disappointed to note that though the prices of scheduled drugs/formulations are fixed by the Government/NPPA, there is possibility of huge difference between production prices and sales prices of non-scheduled drugs in which case only annual increase in prices is monitored by the NPPA. Hence, the Committee recommend that the NPPA/Government should also monitor the initial price fixation of all drugs by the companies so that there will not be huge difference between the actual production cost of medicines and its retail price by various manufacturers. The Committee also recommend that NPPA should devise norms regarding such initial price fixation by pharma companies so that the practice of gold plating can be curbed.

E. REVIVAL OF INDIAN DRUGS AND PHARMACEUTICALS LIMITED (IDPL)

RECOMMENDATION NO.7

17. Noting the long delay in revival of the Indian Drugs and Pharmaceuticals Limited (IDPL), the Committee had recommended as under :-

> "Indian Drugs and Pharmaceuticals Limited (IDPL), the largest Pharma Public Sector Undertaking, was formally declared sick in 1992. Regarding the revival process in respect of IDPL, the Committee note that though the draft Cabinet Note for revival of IDPL was already prepared, the Department requested Ernst & Young (E&Y) to re-assess the liabilities etc. of IDPL and now the Department is examining the report of E&Y to finalize the Cabinet Note. The same report of E&Y is also being examined by IDBI (Operating Agency) and the same may be considered simultaneously by Board for Industrial and Financial Reconstruction (BIFR) and the Ministry for taking early view in the matter. In view of this, the Committee strongly feel that the revival process in respect of IDPL is bogged down in the labyrinth of bureaucratic processes as two decades have passed since IDPL was formally declared sick. This shows nothing but the lackadaisical approach of the Department and other involved organizations towards this issue. In view of the sorry state of affairs regarding revival of IDPL, the Committee recommend that a time frame should be fixed, possibly in consultation with BIFR and other stake holders, so that responsibility can be fixed if the time frame is violated. The Committee desire to be apprised about further progress in this regard."

REPLY OF THE GOVERNMENT

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

> "Draft Note for the Cabinet has been prepared. However E&Y was requested to re-assess the liabilities etc. of IDPL. A re-assessment report of E&Y has since been received and being examined in the Department to finalize a Cabinet Note. In the mean while BIFR meeting was held on 10.01.2012 and 21.03.2012(case No. 503/1992), the Board directed that the copy of E&Y report be submitted to BIFR as well as IDBI (Operating agency) and IDBI to examine the report, prepare Draft Rehabilitation Scheme (DRS) and submit to BIFR by July, 2012."

COMMENTS OF THE COMMITTEE

19. The Committee, considering the inordinate delay in the revival of IDPL, had earlier recommended that a time-frame should be fixed for revival of the company, possibly in consultation with BIFR and other stake holders so that responsibility can be fixed if the timeframe is violated. In response to this, the Department of Pharmaceuticals in its Action Taken Reply has stated that Draft Note for the Cabinet has been prepared and a re-assessment report of E&Y has since been received and the same is being examined in the Department to finalize a Cabinet note. Meanwhile, BIFR meeting was held on 10.01.2012 and 21.3.2012, the Board directed that the copy of E&Y report be submitted to BIFR as well as to IDBI

(Operating Agency). IDBI was supposed to examine the report and prepare the Draft Rehabilitation Scheme (DRS) and submit to BIFR by July, 2012. The Committee in this regard hope that IDBI might have submitted the DRS to BIFR by now. The Committee would therefore like to be apprised in this regard and hope that Cabinet would soon consider the issue. The Committee here feel that sufficient and substantial work is yet to be done for speedy revival of IDPL. Therefore, the Committee strongly reiterate that a time-frame should be fixed for the revival of IDPL and responsibility should be fixed if the time-frame is violated.

F. JAN AUSHADHI SCHEME

RECOMMENDATION NO. 9

20. Noting that wide geographic and therauptic coverage is indispensable for success of the Jan Aushadhi Scheme, the Committee had recommended that:-

> "The Committee note that for success of the Jan Aushadhi Scheme, wide geographic and therauptic coverage is indispensable. Regarding the geographic coverage, so far, only 117 Jan Aushadhi Stores (JAS) are opened and the Business Plan of the Department proposes to open 612 Jan Ausadhi Stores(JAS) in the first phase. In the second phase, the proposal is to open at least 5 JAS in each of the 630 Districts of the country. The Committee feel that the plan of geographical expansion of JAS is rather slow and inadequate and hence, recommend that the Department should open JAS in a mission mode, in coordination with State governments. The Committee recommend that the Department should explore options like opening up of JAS through public private partnership and also individual entrepreneurs should also be encouraged to open JAS. Regarding therauptic coverage, the Committee is unhappy to note that at present, only the medicines manufactured by the Central Pharma Public Sector Undertakings (CPSUs) are being sold at the existing JAS and as such, the range of medicines available at th JAS are limited. The Committee feel that this is one of the major weaknesses of the Jan Aushadhi Scheme. Hence, the Committee recommend that urgent steps should be taken by the Department to rope in State PSUs and private manufactures to increase the coverage of generic drugs at JAS."

REPLY OF THE GOVERNMENT

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

> "As of now, there are 121 Jan Aushadhi Stores (JASs) in 11 States including UTs of Chandigarh in the country. To take this campaign forward, based on the request received from the Government of West Bengal, the matter is in the process of sending funds to them for opening of 20 new JASs in the State in addition to the three already existing there. Request have also been received from the Government of Uttar Pradesh to open JASs in the State, for which meeting with the State Government officers will be held shortly to finalize the modalities in this regard. Simultaneously, the matter is also actively being pursued with other States to open Jan Aushadhi Stores. Although, request has been sent to such States earlier also, fresh reminders are being issued now, which will be followed by personal meetings with the concerned officers to impress upon them to open

Jan Aushadhi Stores in their respective States. Recently, meeting was held with the Secretary, Cooperation, Food & Consumer Affairs and Secretary, Health & Family Welfare, Government of Tamil Nadu with regard to their proposal to sell generic unbranded medicines through 191 pharmacies run by Triplicane Urban Cooperative Society Kamadhenu, a society recognized by the Ministry of Cooperation, Food & Consumer Affairs. The final details in this connection are

being worked out with regard to this proposal and it is expected that this is likely to be finalized in the next couple of months,

The Department has engaged Public Health Foundation of India (PHFI) to conduct a Third Party Evaluation of the on-going Jan Aushadhi Campaign and submit its report/recommendation to the Department at the earliest so as to enable this Department to implement the Jan Aushadhi Campaign in a more effective manner."

COMMENTS OF THE COMMITTEE

22. The Committee in its report had earlier recommended that to increase the geographical coverage of the Jan Aushadhi Scheme, the Department of Pharmaceuticals should explore options like opening up of Jan Aushadhi Stores (JAS) through Public Private Partnerships (PPP) and also through encouragement to individual entrepreneurs. In this regard, the Committee have been informed that requests have been received from Governments of West Bengal and Uttar Pradesh to open JAS in their States. The Committee also note the Department's effort towards sale of generic unbranded medicines through 191 pharmacies run by Triplicane Urban Cooperative Society, Kamadhenu. While appreciating the efforts of the Department, the Committee recommend that all options for opening of JAS viz. PPP, individual entrepreneurship and cooperatives etc. should be explored in all the States and Union Territories.

Further, with regard to increasing the therapeutic coverage of generic medicines, the Committee had earlier recommended that urgent steps should be taken by the Department to include the state PSUs and private manufacturers to increase the coverage of generic drugs available at JAS. The Committee are unhappy to note that the Department of Pharmaceuticals has not given any information regarding action taken on this recommendation of the Committee. As the range of generic medicines that are available through the JAS now is limited, it is a huge drawback of the Scheme, the Committee therefore, strongly reiterate its recommendation that the Department of Pharmaceuticals should involve the state PSUs and private manufacturers to increase the coverage of generic drugs available at JAS.

CHAPTER – II

OBSERVATIONS / RECOMMENDATIONS WHICH HAVE BEEN ACCEPTED BY THE GOVERNMENT

RECOMMENDATION NO.2

The Committee note that the budgetary allocation of the Department of Pharmaceuticals for the year 2011-12 was Rs. 213 crore, and the same was drastically reduced to Rs. 116.08 crore at the RE stage. Even this amount could not be utilized fully as the actually utilization during the year 2011-12 is Rs. 77.89 crore. The Committee also note that the Department has attributed this reduction in funds in the year 2011-12 to under-utilization of the funds to the extent of Rs. 81.94 crore in respect of construction of new NIPER campuses (including that in Guwahati). Also, new schemes could not be introduced to the extent of Rs. 12.04 crore. In view of this, the Committee conclude that there is lack of planning and implementation deficit on the part of the Department and hence, Committee reiterate# that the implementation machinery of the needs to be geared up so that sanctioned funds are properly and timely used to achieve the avowed objectives of the Department.

19th Report on Demands for Grants for the year 2011-12

REPLY OF THE GOVERNMENT

The matter relating to allotment of land for NIPERs by State Governments is being pursued at the highest level with the Chief Minister / Chief Secretary of the respective States. Simultaneously, action is being initiated for construction of NIPER Campus at places, where adequate land has been allotted by State Governments i.e. in Gandhinagar and Guwahati.

[Department of Pharmaceuticals O.M.No. 16(3)/2012-Fin.II dated 20.7.2012]

RECOMMENDATION NO. 3

The committee note that establishment of NIPERs is a significant effort towards development of quality human resource for the growth of pharmaceutical sector in India. However, the Committee is concerned that work relating to construction of new NIPER campuses could not be initiated in 2011-12 and hence, the funds allocated for the purpose could not be utilized. The Committee note that availability of land has been a serious impediment in establishment of new NIPERs. Further, the Committee is dismayed to note that despite of availability of land at Guwahati and Ahmedabad, the construction of campus has not been started in 2011-12. This shows lack of proper planning and effort on the part of the Department. The Committee desire that the construction work at Guwahati and Ahmedabad should start immediately and the Department of Pharmaceutical should make all necessary efforts towards acquisition of lands at other four places namely, Hyderabad, Hajipur, Kolkata and Rae Bareli. The Committee desire to be apprised about the Department's effort towards acquisition of land for New NIPERs at the above four places and also progress in the construction of campuses for new NIPERs**.**

REPLY OF THE GOVERNMENT

In 2007, Cabinet granted in-principle approval to the setting up of six new NIPERs and commencement of classes with the help of mentor Institutes. On 30.09.2011, Cabinet finally approved establishment of six new NIPERs.

2. At present, land is available at Guwahati & Gandhinagar. As such, the issue of construction of NIPER campus at Guwahati & Gandhinagar is under the consideration of Steering Committee for new NIPERs.

3. Minister (C&F) has since requested Chief Ministers of Bihar and Andhra Pradesh vide letters dated 10.4.2012 and Chief Minister of Uttar Pradesh vide letter dated 24.4.2011 to allot requisite land for construction of NIPER campus.

4. West Bengal Government has allotted 35 acres land at Baruipur. It is being developed by the State Government agency viz. Kolkata Metropolitan Development Authority (KMDA). However, issues relating to payment of development charges, extent of availability of land exclusively for NIPER are being sorted out. The matter has since been taken up at the level of Minister (C&F) with the Chief Minister, West Bengal vide letter dated 10/4/2012. Reply from the state Government is awaited.

[Department of Pharmaceuticals O.M.No. 16(3)/2012-Fin.II dated 20.7.2012]

COMMENTS OF THE COMMITTEE

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

RECOMMENDATION NO.4

The Committee note that the National Pharmaceuticals Pricing Authority (NPPA) plays vital role in fixation/revision of price of 74 scheduled bulk drugs and formulation containing any of the scheduled drugs under the Drugs (Price Control) Order, 1995 as well as monitoring and enforcement of prices. NPPA also provides inputs to the Government for policy formulation. During the Eleventh Five Year Plan period (2007-2012), NPPA had proposed five new schemes amounting to Rs.49.95 crore. These schemes are (i) Building Robust and Responsive Statistical System for NPPA; (ii) Creation of NPPA Cells in States; (iii) Scheme for Interaction with States; (iv) Proposal for Consumer Awareness and Publicity through Print, Electronic and other medium; and (v) Proposal for strengthening the existing Monitoring and Enforcement work. The Committee note that out of these five schemes, Building Robust and Responsive Statistical System for NPPA was already approved by the Planning Commission and implemented during the Eleventh Plan period and in principle approval in respect of the scheme, Proposal for Consumer Awareness and Publicity through Print, Electronic and other medium was given in February, 2011 and in the budget allocation for the year 2012-13, funds are allocated only for these two schemes. However, the Committee are unhappy to note that other three schemes of the NPPA, namely, Creation of NPPA Cells in States; Scheme for Interaction with States and Proposal for strengthening the existing Monitoring and Enforcement work, are yet to get in-principle approval of the Planning Commission. Hence, the Committee can not but reiterate its earlier recommendations @ that the Department should take up the issue with Planning Commission and make all out effort towards getting in-principle approval for these three schemes. The Committee also desire to be apprised about the outcomes achieved in case of two schemes,

namely, Building Robust and Responsive Statistical System for NPPA and Proposal for Consumer Awareness and Publicity through Print, Electronic and other medium.

@ 19th Report on Demands for Grants 2011-12

REPLY OF THE GOVERNMENT

Out of five components of the scheme for strengthening of NPPA, Planning Commission has accorded in principle approval for two components concerning 'Building Robust & Responsive Statistical System for NPPA" and proposal for "Consumer awareness and publicity through Print, Electronic and other medium" in March, 2008 and 15th March, 2011 respectively. For the remaining components, Planning Commission vide letter dated 15.3.2011 had intimated that the proposal may be considered to be integrated in 12th Plan schemes of NPPA subject to its relevance and establishment of need.

2. Consequent upon decision of Planning Commission communicated vide their letter dated 15.3.2011, Department of Pharmaceuticals requested Planning Commission vide D.O. letter dated 24.3.2011 from Secretary(Pharma) to reconsider its decision in respect of the remaining 2 components viz. (i) Scheme for Interaction with States and (ii) Strengthening the existing Monitoring and Enforcement work for 11th Five Year Plan so that Plan funds allocated for the year 2011-12 do not lapse and are utilized for strengthening NPPA.

3. In response, Planning Commission vide its letter dated 20.5.2011 intimated that the proposal of according 'in-principle' approval in respect of two components i.e. (a) Interaction with States and (b) Strengthening of Existing Monitoring and Enforcement Work has been re-examined in consultation with their Health Division. Further, Planning Commission suggested that under the circumstances the aforesaid schemes can be discussed in the Twelfth Five Year Plan Working Group on Drugs & Pharmaceuticals. The said Working Group on Drug & Pharmaceuticals for Twelfth Five Year Plan (2012-2017), as constituted vide order No. I&M 2(25)/20011 dated 10.05.2011 by the Planning Commission under the Chairmanship of Secretary (Pharma), in its Report to Planning Commission, has proposed/recommended schemes for strengthening of NPPA, for such functions as - (a) Strengthening of Monitoring and Enforcement work, (b) Building Consumer Awareness about pricing and availability, (c) Creation of NPPA Cells in States and (d) Interaction with States - for the 12th Five Year Plan Period.

The work done and likely to be accomplished under the following two schemes:

1. Building Robust & responsive statistical system for NPPA

The First Pharmaceutical Census of India (FPCI) was commenced in April 2008. Initially, a "Directory of Pharmaceuticals Manufacturing Units in India 2007" was prepared which served as the Universe Frame for the above census. It contains data such as addresses and contact details on 10563 allopathic pharmaceuticals manufacturing units.

The Ministry of Micro, Small and Medium Enterprises (MSME) was entrusted to collect data from the manufacturing units concurrently with their 4th" All India Census of Micro, Small and Medium Enterprises. The schedules were not filled up for all the manufacturing units.

M/s ICRA Management Consulting Services Limited have been awarded contract in the month of August and November 2010 in respect of following two studies:

1. First Pharmaceutical Census of India;

2. Collection of annual turnover data from the Bulk Drug manufacturing units.

In respect of 1st study i.e. First Pharmaceutical Census of India, the services of M/s ICRA Management were commissioned for:-

(i) Processing of data collected by MSME for 6262 schedules to generate about 16 tables, generate PMI and submission of report.
(ii) Collection of data from the left over Units (i.e. 10563-6262)=4301
(iii) Amalgamation of both sets of data i.e. collected by MSME and M/s ICRA and
(iv) Writing a final report based on processing of this data.

In the "first phase, M/s ICRA was required to generate Pharmaceutical Map of India and generate about 16 tables from the canvassed Schedules of MSME. M/s ICRA has submitted an interim report giving the Pharmaceutical Map of India and also 13 tables generated from data collected by MSME.

In respect of 2nd study, M/s ICRA Management Consulting Services Limited has been entrusted to carry out a detailed nationwide survey to collect data on Annual turnover of Bulk Drugs manufactured in India. M/s ICRA Management has submitted a preliminary report bringing out the methodology of survey and problems being faced by them in getting the data for the study.

M/s ICRA Management is yet to submit its report in respect of both these studies. These studies are likely to be completed during next financial year 2012-13.

2**. Consumer Awareness and Publicity through Print, Electronic and other Medium**

'In Principle' approval for the scheme was accorded by the Planning Commission vide O.M. dated 29th October, 2010. The Scheme is to be implemented on cost sharing basis with the Department of Consumer Affairs. The modalities of implementation of the Scheme has been finalized and the Media Plan for the Scheme has been prepared by Department of Consumer Affairs for the NPPA. As the finalization of modalities and preparation of Media Plan for NPPA by the Department of Consumer Affairs has taken time, it could not be possible to take up the work under the scheme during the year 2011-12. For the year 2012-13 an amount of Rs. 3.42 crore is provided under the scheme. NPPA is ready with two ads for print media and has written to Department of Consumer Affairs for providing matching funds for the scheme. On receipt of their response, Rs. 52 lakh will be released to DAVP under intimation to Department of Consumer Affairs to release two print ads for publication in National and Regional newspapers along with their share of money to the DAVP. A meeting with the agencies approved by DAVP has also been held in the NPPA for preparation of ad films for publicity through electronic media. Nine agencies have submitted the scripts which are being scrutinized in the NPPA.

[Department of Pharmaceuticals O.M.No. 16(3)/2012-Fin.II dated 20.7.2012]

RECOMMENDATION NO.6

The committee also feel that there should not be much difference between the production price and sale prices of a medicine. For this purpose the Committee recommend that Department of Pharmaceuticals should have a tab on the production prices of medicines by different companies and ensure that its sale price do not exceed much beyond a reasonable rate. In such case, the Committee have their apprehension that some companies may resort to malpractices like projecting higher production cost.

The Committee, therefore, recommend Department of Pharmaceuticals to be cautious in this regard so as to curb the malpractices of gold plating by some of the companies.

REPLY OF THE GOVERNMENT

National Pharmaceutical Pricing Authority (NPPA) fixes/revises prices of 74 bulk drugs included in the First Schedule of the Drugs (Prices Control) Order, 1995 (DPCO, 1995) and formulations containing any of these drugs with an objective to make these drugs affordable. No one can sell nay scheduled drug/formulation at a price higher than the price fixed by NPPA.

NPPA may, from time to time, by notification in the official gazette under Para 8, 9 and 11 of the DPCO, 1995 fix the price of a scheduled formulation in accordance with the formula laid down in Para 7 of DPCO,95 keeping in view the cost or efficiency or both of major manufacturers of such formulation and such price shall operate as the ceiling sale price for all such packs including those sold under generic name and for every manufacturer of such formulations. A manufacturer, distributor or wholesaler shall sell a formulation to a retailer , unless otherwise permitted under the provisions of this order or any order made there under, at a price equal to the retail price, as specified by an order or notified by the Government (excluding excise duty, if any), minus sixteen per cent, thereof in the case of scheduled drugs.

The NPPA may either on its own motion or on application made to it in this behalf by manufacturer in Form-III or Form-IV, as the case may be, after calling for such information as it may consider necessary, by notification in the Official Gazette, to fix a revised ceiling price for a scheduled formulation.

[Department of Pharmaceuticals O.M.No. 16(3)/2012-Fin.II dated 20.7.2012]

COMMENTS OF THE COMMITTEE

(Please see Para No. 12 of Chapter- I of the Report)

CHAPTER – III

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

NIL

CHAPTER – IV

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

RECOMMENDATION NO.1

The Committee note that out of an outlay of Rs.1396.17 crore for the Eleventh Five Year Plan(2007-12) for the Department of Pharmaceuticals, the budget allocation for the period is only Rs. 741.76 crore, which is only about 53% of the total outlay for the Eleventh Five Year Plan. Hence, during the entire five years of the Eleventh Five Year Plan, the allocation sanctioned to the Department of Pharmaceuticals is much below than that approved by Planning Commission. The Committee fail to understand this mis-match between the overall outlay for the Plan period and the funds actually provided to the Department and want an explanation from the Department of Pharmaceuticals. The Committee is also of the view that the Planning Commission while approving the allocation, should also be realistic so that there may not be much difference between approved allocation and the allocation actually disbursed to the Department.

The Committee also observe that there is underutilization of funds by the Department which may be one of the reasons for getting lesser allocation. The Committee, therefore, recommend that the Department should improve its physical performance in order to have a semblance between financial allocation and physical performance. This would also help the Department in obtaining more funds as per the stipulations of Planning Commission.

The Committee also note that in its Mid-term Appraisal Report, the Planning Commission has recommended that the Pharmaceutical Research and Development Programme (PRDP), which has been pursued by Department of Science and Techno logy(DST), would be transferred to Department of Pharmaceuticals at the end of Eleventh Five Year Plan. However, the Committee note with regret that no allocation has been made for the PRDP in the Detailed Demands for Grants for the year 2012-13. As PRDP is a vital programme in the area of pharmaceutical research and development, the Committee recommend that the Department should make concerted efforts towards getting allocation for the next financial year and implement the same to achieve the desired goals.

REPLY OF THE GOVERNMENT

The matter relating to transfer of PRDP is being examined in consultation with Department of Science and Technology.

[Department of Pharmaceuticals O.M.No. 16(3)/2012-Fin.II dated 20.7.2012]

COMMENTS OF THE COMMITTEE

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

RECOMMENDATION NO.9

The Committee note that for success of the Jan Aushadhi Scheme, wide geographic and therapeutic coverage is indispensable. Regarding the geographic coverage, sofar, only 117 Jan Aushadhi Stores (JAS) are opened and the Business Plan of the Department proposes to open 612 Jan Aushadhi Stores (JAS) in the first phase. In the second phase, the proposal is to open at least 5 JAS in each of the 630 Districts of

the country. The Committee feel that the plan of geographical expansion of JAS is rather slow and inadequate and hence, recommend that the Department should open JAS in a mission mode, in coordination with State Governments. The Committee recommend that the Department should explore options like opening up of JAS through public private partnership and also individual entrepreneurs should also be encouraged to open JAS.

Regarding therapeutic coverage, the Committee is unhappy to note that at present, only the medicines manufactured by the Central Pharma Public Sector Undertaking (CPSUs) are being sold at the existing JAS and as such, the range of medicines available at the JAS are limited. The Committee feel that this is one of the major weakness of the Jan Aushadhi Scheme. Hence, the Committee recommend that urgent steps should be taken by the Department to rope in State PSUs and private manufacturers to increase the coverage of generic drugs at JAS.

REPLY OF THE GOVERNMENT

As of now, there are 121 Jan Aushadhi Stores (JASs) in 11 States including UTs of Chandigarh in the country. To take this campaign forward, based on the request received from the Government of West Bengal, the matter is in the process of sending funds to them for opening of 20 new JASs in the State in addition to the three already existing there. Request have also been received from the Government of Uttar Pradesh to open JASs in the State, for which meeting with the State Government officers will be held shortly to finalize the modalities in this regard. Simultaneously, the matter is also actively being pursued with other States to open Jan Aushadhi Stores. Although, request has been sent to such States earlier also, fresh reminders are being issued now, which will be followed by personal meetings with the concerned officers to impress upon them to open Jan Aushadhi Stores in their respective States. Recently, meeting was held with the Secretary, Cooperation, Food & Consumer Affairs and Secretary, Health & Family Welfare, Government of Tamil Nadu with regard to their proposal to sell generic unbranded medicines through 191 pharmacies run by Triplicane Urban Cooperative Society Kamadhenu, a society recognized by the Ministry of Cooperation, Food & Consumer Affairs. The final details in this connection are being worked out with regard to this proposal and it is expected that this is likely to be finalized in the next couple of months.

The Department has engaged Public Health Foundation of India (PHFI) to conduct a Third Party Evaluation of the on-going Jan Aushadhi Campaign and submit its report/recommendation to the Department at the earliest so as to enable this Department to implement the Jan Aushadhi Campaign in a more effective manner.

[Department of Pharmaceuticals O.M.No. 16(3)/2012-Fin.II dated 20.7.2012]

COMMENTS OF THE COMMITTEE

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

CHAPTER – V

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

RECOMMENDATION NO.5

The Committee note that at present the Drugs(Price Control) Order(DPCO), 1995 allows control of prices of 74 scheduled bulk drugs and formulations containing any of the scheduled drugs defined in first Schedule of DPCO. They are disturbed to note that initially the Government announced Pharmaceutical Poly 2002. Then, a draft National Pharmaceutical Policy was prepared which has not been finalized till date in spite of the repeated recommendations# of the Committee to finalize the same. Further, new Group of Ministers (GoM) is yet to give its recommendation on draft National Pharmaceutical Policy 2006. As apprised to the Committee, the Department of Pharmaceuticals has now prepared a new Draft National Pharmaceutical Pricing Policy 2011 (NPPP 2011) based on the criteria of essentiality and requirements as stipulated by Ministry of Health and Family Welfare. The Committee also note that the draft National Pharmaceutical Pricing Policy (NPPP -2011) proposes to bring 348 essential drugs and medicines under price control. The Committee were informed that the draft Policy NPPP-2011 will now be examined by the Group of Ministers (GoM) on 25.04.2012 and the recommendations of the GoM will go to the Cabinet and the Cabinet in their wisdom will approve the policy.

The Committee hope that now the Department of Pharmaceuticals will not resort to dilly dallying tactics in finalizing the NPPP-2011 as done in the case of National Pharmaceutical Policy, which has been under consideration since 2002, so that common man can get the medicines at affordable prices.

Twentieth Report on Action Taken by the Government on the recommendations contained in the Seventh Report of the Committee (2005-06), Twenty-Fifth Report on Demands for Grants (2008-09) and First Report on Demands for Grants (2009-10).

REPLY OF THE GOVERNMENT

The Group of Ministers (GoM) met on 25.04.2012 and further two more meetings have been held by the GoM.

[Department of Pharmaceuticals O.M.No. 16(3)/2012-Fin.II dated 20.7.2012]

COMMENTS OF THE COMMITTEE

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

RECOMMENDATION NO.7

Indian Drugs and Pharmaceuticals limited (IDPL), the largest Pharma Public Sector Undertaking, was formally declared sick in 1992. Regarding the revival process in respect of IDPL, the Committee note that though the draft Cabinet Note for revival of IDPL was already prepared, the Department requested Ernst & Young (E&Y) to re-assess the liabilities etc. of IDPL and now the Department is examining the report of E&Y to finalize the Cabinet Note. The same report of E&Y is also being examined by IDBI (operating Agency) and the same may be considered simultaneously by Board for Industrial and Financial Reconstruction (BIFR) and the Ministry for taking early view of this, the Committee strongly feel that the revival process in respect of IDPL is bogged down in the labyrinth of bureaucratic processes as two decades have passed since IDPL

was formally declared sick. This shows nothing but the lackadaisical approach of the Department and other involved organizations towards this issue. In view of the sorry state of affairs regarding revival of IDPL, the Committee recommends that a time frame should be fixed, possibly in consultation with BIFR and other stake holders, so that responsibility can be fixed if the time frame is violated. The Committee desire to be apprised about further progress in this regard.

REPLY OF THE GOVERNMENT

Draft Note for the Cabinet has been prepared. However E&Y was requested to re-assess the liabilities etc. of IDPL. A re-assessment report of E&Y has since been received and being examined in the Department to finalize a Cabinet Note.

In the mean while BIFR meeting was held on 10.01.2012 and 21.03.2012(case No. 503/1992), the Board directed that the copy of E&Y report be submitted to BIFR as well as IDBI (Operating agency) and IDBI to examine the report, prepare Draft Rehabilitation Scheme (DRS) and submit to BIFR by July, 2012.

[Department of Pharmaceuticals O.M.No. 16(3)/2012-Fin.II dated 20.7.2012]

COMMENTS OF THE COMMITTEE

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

RECOMMENDATION NO.8

The Committee note that since April, 2004 to December, 2011, there has been 141 instances of Foreign Direct Investments (FDI) in various Indian Drug Manufacturing Companies. The Committee also note that after take over of many big domestic Pharma companies like Ranbaxy etc. by Foreign Multi-National Companies (MNCs), there are apprehensions in some quarters that these take over will not only have adverse impact on availability of medicines for common man at affordable prices but also affect the overall health care scenario in India. On the other hand, the Committee also notes that there is an urgent need for attracting foreign investments in the pharmaceutical sector, particularly in areas like new chemical entities reserve, bio-pharmaceuticals, inspection and certification infrastructure etc. In this context, the Department of Industrial Policy and Promotion (DIPP) Press Note No.3(2011 series) dated 8.11.2011 which allows FDI up to 100% for brown field investment in pharmaceutical sectors, under government approval route is a temporary measure, as this would be reviewed after a period of six months. Committee feels that though there is need for attracting FDI in the Indian pharmaceutical sector, this should not be done at the cost of our national interest and country's capacity to produce life saving drugs at affordable prices should not be compromised. Therefore the Committee desire to be apprised about the impact of the current policy which allows 100% FDI for brown field investments in pharmaceutical sector under government approval route and also change in policy, if any, on FDI in pharmaceutical sector after the lapse of the stipulated six months period.

REPLY OF THE GOVERNMENT

It is too early to judge the impact of current policy, however, Department of Economic Affairs (Investment and Infra Division) has informed that till May, 2012, 15 proposals of Foreign Direct Investment in brown field Pharma companies have been cleared by FIPB which is likely to result in flow of approximately about Rs. 2029.51 crores in Foreign Direct Investment. They have further mentioned that a Special Group has been constituted to streamline the process for approval of FDI in brown field Pharma through FIPB.

The Department of Industrial Policy and Promotion who are the nodal Department for Foreign Direct Investment, has informed that the policy for allowing Foreign Director Investment(FDI), up to 100% in existing companies, in the pharmaceuticals sector, under the Government approval route, was introduced vide Press Note 3 of 2011, dated 08.11.2011. This provision has since been incorporated under *"Circular 2 of 2011-Consolidated FDI Policy"*, effective from 10.04.2012.

[Department of Pharmaceuticals O.M.No. 16(3)/2012-Fin.II dated 20.7.2012]

RECOMMENDATION NO.10

The Committee note that innovative Research & Development is critical in the Pharmaceutical industry. Particularly, New Drug Discovery Research (NDDR) is important yet expensive affair. The Committee also note that many Indian companies, often in collaboration with multi national Pharma companies, are making significant effort in the area NDDR. However, as R&D, particularly NDDR is expensive; the Committee recommended that an interest free venture fund should be institute to promote NDDR with India-specific focus. The Committee is worried to note that most of the Pharma PSUs are not investing in R&D. The Committee desire that Department to develop a frame PSUs can collaborate with private sector, universities and research institution in R&D work. The Committee note that the Department has awarded assignment to Ernst & Young (E&Y) as global level consultant for preparation of Detailed Project Report (DPR) for developing India as a Drug Discovery and Pharma Innovation Hub 2020. As the DPR is expected in six months, the Committee desire to be apprised about the recommendation in the DPR and action taken by the Department in this regard.

REPLY OF THE GOVERNMENT

The Detailed Project Report (DPR) has not been submitted. The first and second drafts were discussed with a broad-based Advisory Committee consisting of representatives of Industry, Scientific Organizations and other stake holders. Taking into account the views expressed at the meeting, E&Y will finalize the DPR.

New Delhi;
17 DECEMBER, 2012
26 AGRAHAYANA,1934 (SAKA)

GOPINATH MUNDE,
CHAIRMAN,
STANDING COMMITTEE ON CHEMICALS AND FERTILIZERS

APPENDIX – I

MINUTES

MINUTES OF THE FOURTH SITTING OF THE STANDING COMMITTEE ON CHEMICALS & FERTILIZERS (2012-13)

The Committee sat on Monday, the 10 December, 2012 from 1500 hrs. to 1615 hrs. in Room No.63, Parliament House, New Delhi.

PRESENT

Shri A.A. Jinnah - *In the Chair*

MEMBERS

LOK SABHA

2.	Shri Gajanan D. Babar
3.	Shri Sakti Mohan Malik
4.	Shri Ashok Kumar Rawat
5.	Shri Kamlesh Paswan
6.	Shri Amarnath Pradhan
7.	Shri Tufani Saroj
8.	Shri G.M. Siddeshwara
RAJYA SABHA	
9.	Shri Brijlal Khabri
10.	Shri Pyarimohan Mohapatra

SECRETARIAT

Smt. Rashmi Jain	-	Joint Secretary
Shri A.K. Srivastava	-	Additional Director

2. As the Chairman could not attend the sitting due to pre-occupation, the members chose Shri A.A Jinnah, MP and a member of the Committee, to act as the Chairman. The Acting Chairman welcomed the members to the sitting of the Committee.

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

(i) *******
(ii) *******
(iii) Draft Report on Action Taken by the Government on the recommendations contained in the Twenty-seventh Report (15th Lok Sabha) on Demands for Grants (2012-13) of the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals); and
(iv) *******

4. After some discussion, the draft Reports were adopted by the Committee.

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 TWENTY-SEVENTH REPORT (FIFTEENTH LOK SABHA) OF THE STANDING COMMITTEE ON CHEMICALS AND FERTILIZERS (2011-12) ON 'DEMANDS FOR GRANTS (2012-13)' OF THE MINISTRY OF CHEMICALS AND FERTILIZERS (DEPARTMENT OF PHARMACEUTICALS)

I	Total No. of Recommendations	10
II	Observations / Recommendations which have been accepted by the Government:- (*Vide* Recommendation at Sl.Nos.2,3,4 and 6)	4
	Percentage of Total	40%
III	Observation / Recommendation which the Committee do not desire to pursue in view of the Government's reply:- NIL	0
	Percentage of Total	NIL
IV	Observation / Recommendation in respect of which reply of the Government have not been accepted by the Committee and which require reiteration:- (*Vide* Recommendation at Sl.Nos. 1 and 9)	2
	Percentage of Total	20%
V	Observations / Recommendations in respect of which replies of the Government are of interim nature:- (*Vide* Recommendations at Sl.Nos.5,7,8 and10)	4
	Percentage of Total	40%