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STANDING COMMITTEE ON CHEMICALS & FERTILIZERS (2009-10)

FIFTEENTH LOK SABHA

MINISTRY OF CHEMICALS AND FERTILIZERS (DEPARTMENT OF PHARMACEUTICALS)

DEMANDS FOR GRANTS (2009-2010)

[Action Taken by the Government on the recommendations contained in the First Report (Fifteenth Lok Sabha) of the Standing Committee on Chemicals & Fertilizers (2009-10) on Demands for Grants (2009-10) of the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals)]

TWELFTH REPORT

LOK SABHA SECRETARIAT
NEW DELHI

August, 2010/Bhadrapada, 1932 (Saka)

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Presented to Lok Sabha on 26 .08.2010

Laid in Rajya Sabha on 26.08.2010

LOK SABHA SECRETARIAT
NEW DELHI

August, 2010/ Bhadrapada, 1932 (Saka)

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COMPOSITION OF THE STANDING COMMITTEE ON CHEMICALS & FERTILIZERS
(2009-10)

SHRI GOPINATH MUNDE $ - CHAIRMAN	
MEMBERS	
LOK SABHA	
2.	Smt. Sushmita Bauri
3.	Shri Prabhatsinh P. Chauhan
4.	Shri K.D. Deshmukh
5.	Shri Ganeshrao Nagorao Dudhgaonkar
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&15.	Shri T.K.S. Elangovan
&16.	Shri Tapas Paul
**17.	Shri Udayanraje Bhonsle
*$18.	Shri Jagdambika Pal
*19.	Vacant
20 to 21.	Vacant
RAJYA SABHA	
22.	Shri Raghunandan Sharma
23.	Dr. C.P. Thakur
24.	Shri Brijlal Khabri
25.	Shri A.A. Jinnah
26.	Shri Biswajit Daimary
**27.	Prof. Anil Kumar Sahani
***28.	Shrimati Naznin Faruque
#29.	Vacant
%30.	Vacant
=31.	Vacant

* Consequent upon nomination to the Committee on Information Technology Shri Tufani Saroj, MP (LS) ceased to be Member of the Committee w.e.f. 13.10.2009.
\# Vacancy arisen due to demise of Shri Mahendra Sahni, MP (RS) w.e.f. 6 November 2009.
& Nominated w.e.f. 11.01.2010.
** Nominated w.e.f. 26.02.210.
*** Nominated w.e.f. 26.04.210.
$ Nominated w.e.f. 07.05.2010.
% Shri J.D. Seelam ceased to be Member of this Committee w.e.f. 21 June 2010 after his retirement from Rajya Sabha.
= Shri Raj Mohinder Singh Majitha ceased to be Member of this Committee w.e.f. 4 July 2010 after his retirement from Rajya Sabha.
*$ Nominated w.e.f. 04.08.2010.

SECRETARIAT

1.	Shri N. K. Sapra	-	Additional Secretary
2.	Shri Ashok Sarin	-	Joint Secretary
3.	Shri C.S. Joon	-	Director
4.	Shri Anil Kumar Srivastava	-	Deputy Secretary

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INTRODUCTION

I, the Chairman, Standing Committee on Chemicals and Fertilizers (2009-10) having been authorised by the Committee to present the Report on their behalf present this Twelfth Report on Action Taken by the Government on recommendations contained in the First Report (Fifteenth Lok Sabha) of the Standing Committee on Chemicals and Fertilizers (2009-10) on 'Demands for Grants (2009-10)' of the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals).

2. The First Report of the Committee was presented to Lok Sabha on 8 December 2009. The replies of Government to all the recommendations contained in the First Report were received on 15 March 2010. The Standing Committee on Chemicals and Fertilizers (2009-10) considered the Action Taken Replies received from the Government and adopted the Draft Action Taken Report thereon at their sitting held on 17 August 2010.

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

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

New Delhi;

17, August 2010
26, Shravana, 1932 (Saka)

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

Appendix – II

(*Vide* Para 3 of the Introduction)

ANALYSIS OF ACTION TAKEN BY THE GOVERNMENT ON THE RECOMMENDATIONS CONTAINED IN THE FIRST REPORT (FIFTEENTH LOK SABHA) OF THE STANDING COMMITTEE ON CHEMICALS AND FERTILIZERS (2009-10) ON 'DEMANDS FOR GRANTS (2009-10)' OF THE MINISTRY OF CHEMICALS AND FERTILIZERS (DEPARTMENT OF PHARMACEUTICALS)

I	Total No. of Recommendations	24
II	Observations / Recommendations which have been accepted by the Government:- (*Vide* Recommendation at Sl.Nos.2,3,4,7,9,10,12,15,16,18,19,21,22&23)	14
	Percentage of Total	58.33
III	Observation / Recommendation which the Committee do not desire to pursue in view of the Government's reply:- (*Vide* Recommendation at Sl.No.13)	01
	Percentage of Total	4.17%
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.No.20)	01
	Percentage of Total	4.17%
V	Observations / Recommendations in respect of which replies of the Government are of interim nature:- (*Vide* Recommendations at Sl.Nos. 1,5,6, 8,11,14,17 and 24)	08
	Percentage of Total	33.33%

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 First Report (Fifteenth Lok Sabha) of the Committee on Demands for Grants (2009-10) of the Ministry of Chemicals & Fertilizers (Department of Pharmaceuticals) which was presented to Lok Sabha on 8 December 2009. The Report contained 24 Observations / Recommendations.

2. The Ministry of Chemicals & Fertilizers (Department of Pharmaceuticals) were requested to furnish replies to the Observations / Recommendations contained in the First Report within three months from the date of presentation of the Report, i.e. by 8 March 2010. The Action Taken Replies of the Government in respect of all the 24 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(11)/2009-Fin.II dated 15 March, 2010. These have been categorized as follows:-

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

Sl.Nos.2,3,4,7,9,10,12,15,16,18,19,21,22&23 (Total = 14)
Chapter-II

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

Sl.No.13 (Total = 1)
Chapter-III

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

Sl.No.20 (Total = 1)
Chapter-IV

(iv) Observations / Recommendations in respect of which replies of the Government are of interim nature:-

Sl.Nos. 1,5,6, 8,11,14,17 and 24 (Total = 8)
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 the Observations / Recommendations 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 that require reiteration or merit comments.

A) Need for making Indian Pharmaceutical Industry R&D and Innovation Hub by 2020

Recommendation (Sl. No. 2, Para No.11)

5. The Committee in para 11 of their original Report had noted that the Indian Pharmaceutical Industry had been making progress globally and had been ranked third in terms of volume and fourteenth in terms of value. The Committee had also noted that the Department had prepared a 'White Paper' for consideration of Government for making India a pharma R&D and Innovation Hub by 2020. According to the Department, the document envisaged scaling up investments, undertaking deliberate action for building infrastructure for education and research, offering financial incentives to encourage and incubate innovation, shaping a favourable regulatory environment, etc. The Committee had desired that the document should be considered urgently and taken to its logical conclusions with a view to enabling the Indian pharma industry not only in ensuring abundant availability of good quality pharmaceuticals of mass consumption at reasonable prices within the country, but also in playing a meaningful role in the global market. The Committee had liked to be apprised of the updated status in this regard.

6. In reply to the aforesaid para, the Department of Pharmaceuticals have stated as under :-

> "The white paper on 'Making India a pharma R&D and Innovation Hub by 2020' was sent to Planning Commission for an in-principle approval. Planning Commission has since concurred to the Department preparing Detailed Project Report (DPR) on the white paper through a global consultant."

7. As regards the 'white paper' document which the Department had prepared for consideration of Government for making India a Pharma R&D and Innovation Hub by 2020, the Committee had desired it to be considered urgently and taken to its logical conclusion with a view to enabling the Indian pharma industry not only in ensuring abundant availability of good quality pharmaceuticals of mass consumption at reasonable prices within the country, but also in playing a meaningful role in the global market. The Department have stated that the Planning Commission has asked them to prepare a Detailed Project Report (DPR) on the white paper through a global consultant. However, the Department have not indicated as to what steps they have taken subsequent to concurrence given by the Planning Commission. The Committee

expect the Department to expeditiously finalize the Detailed Project Report (DPR) on the White Paper and also complete all other connected formalities in a time bound programme. The Committee would like the Department to intimate the progress made by them in this regard at the earliest.

B) Need to make Six Newly proposed Institutes fully Functional Expeditiously by National Institute of Pharmaceuticals Education and Research (NIPER)

Recommendation (Sl. No. 6, Para No.38)

8. The Committee in para 28 of their original Report had observed that the National Institute of Pharmaceuticals Education and Research was set up in 1998 in Mohali, Punjab to nurture and promote quality and excellence in pharmaceutical education and research. The Government had approved setting up of six more institutes under NIPER in 2007 initially for two years, which had since been extended up to 2011. These six new institutes were proposed to be established with Public-Private-Partnership (PPP) component. The Committee were informed that classes in some streams of pharmaceutical sciences had already been started in the new institutes with the help of the mentor institutes in the respective places. The Committee were, however, surprised to note that the detailed project report on the PPP model was yet to be approved. The Committee had desired that necessary formalities should be expeditiously completed so that the new institutes become fully functional and the underlying objectives for their constitution were fully met.

9. In reply to the aforesaid para, the Department of Pharmaceuticals have stated as under :-

> "The Public Private Partnership (PPP) is likely to be introduced for some revenue generating activities like hostels, auditorium, guest house, recreation and sports, maintenance etc. for which private partner will be selected wherever feasible, in consultation with the consultant and through a transparent process. A suggestion has also come for full or part running of the exclusive courses under PPP in some NIPERs. No view has been taken on this as yet. Action is being initiated in this regard".

10. The Committee had desired that necessary formalities should be expeditiously completed so that the six new institutes approved by the Government under (NIPER), which were proposed to be established at Ahmedabad, Hyderabad, Hajipur, Kolkata, Rae Bareilly and Guwahati with Public Private Partnership (PPP) component, become fully functional and the underlying objectives for their constitution were fully met. The Committee regret to point out that the Department has failed to take any firm action in making the six new institutes fully functional. While deprecating the delay on the part of the concerned authorities, the Committee desire the Department to ensure that immediate action is taken in the matter under intimation to them. The Committee may also be apprised of the complete details of the proposed "transparent process" of selection of private partners.

C) Need for Expeditious Approval by the Planning Commission of the Schemes proposed by the National Pharmaceutical Pricing Authority (NPPA)

Recommendation (Sl. No. 8, Para No.44)

11. The Committee in para 44 of their original Report had observed that the National Pharmaceutical Pricing Authority (NPPA) has been responsible for price fixation/revision of drugs and formulations. NPPA also monitors the prices of decontrolled drugs and formulations, enforce and implement the provisions of the Drugs (Prices Control) Order, (DPCO), 1995. An amount of Rs.2.25 crore had been earmarked for NPPA under plan head in BE-2009-10. The major part of this allocation was meant for the new scheme 'Proposal for Building Robust and Responsive Statistical System for NPPA'. The Committee had noted that out of the five schemes proposed by NPPA for the Eleventh Five Year Plan, four schemes were yet to get in-principle approval of the Planning Commission. In view of the fact that only two years of Eleventh Five Year Plan were left, the Committee had recommended that the Department should expeditiously take up the issue regarding early approval of the schemes proposed by the NPPA with the Planning Commission. The Committee might be apprised of the progress made in this regard at periodic intervals.

12. In reply to the aforesaid para, the Department of Pharmaceuticals have stated as under :-

> "Out of the five schemes proposed by the Department, Planning commission has accorded 'in principle' approval to only one scheme concerning "Building Robust & Responsive Statistical System for NPPA" in March, 2008. Further, it was mentioned that Planning Commission will take a view on the publicity campaign scheme after consulting with the Department of Consumer Affairs. It was also mentioned that the other schemes proposed for strengthening and monitoring of prices of drugs and pharmaceuticals would be taken up after the finalization of the Draft Pharmaceutical Policy. Department is pursuing with the Planning Commission for delinking the matter from the finalization of the draft Policy and according 'in principle' approval for the remaining schemes".

13. The Committee had observed that out of the five schemes proposed by National Pharmaceutical Pricing Authority (NPPA) for the Eleventh Five Year Plan, four schemes were yet to get in-principle approval of the Planning Commission. In view of the fact that only two years of Eleventh Five Year Plan were left, the Committee had recommended that the Department should expeditiously take up the issue regarding early approval of the schemes proposed by the NPPA with the Planning Commission and they be apprised of the progress made in this regard at periodic intervals. The Committee have now been informed that out of the five schemes proposed by the Department for strengthening NPPA, Planning Commission had accorded 'in principle' approval to only one scheme, i.e. Building Robust & Responsive Statistical System for NPPA, in March 2008. Thus, there has been no perceptible change since the Committee made their earlier recommendation more than two years ago. The

Department is stated to be pursuing with the Planning Commission for delinking the matter of granting 'in-principle' approval to remaining four schemes proposed by the Department from the finalization of the Draft Pharmaceutical Policy.

The Committee are not at all happy with the casual approach of the Planning Commission in delaying the four other schemes proposed for strengthening and monitoring of prices of drugs and pharmaceuticals. The Committee wish to be apprised of the precise reasons for not granting in-principle approval to the four schemes. The Committee also take strong exception to the lack of vigorous efforts on the part of the Department for obtaining in-principle approval of all the schemes. The Committee would also like the Department to wake up and take concrete measures at the highest level to get the in-principle approval for the important schemes. The Committee may be apprised of the progress made within three months of presentation of this report.

D. Rajiv Gandhi Aushadhi Yojana for providing Free of Cost Generic Medicines to BPL Families

Recommendation (Sl. No. 20, Para No.118)

14. The Committee in para 118 of their original Report had expressed their satisfaction that the Department of Pharmaceuticals had also planned a new scheme, viz., the Rajiv Gandhi Aushadhi Yojana for providing unbranded generic medicines free of cost to BPL families. The scheme envisages sharing of costs in the ratio of 70:30 between the Centre and the States. The Committee had noted that initially the scheme is being implemented in Rajasthan and Tamil Nadu. The Committee had, however, expressed their unhappiness over the delay in according in principle approval and additional plan outlay from the Planning Commission. The Committee had hoped that efforts would be sincerely made to extend the scheme in all the States/UTs of the country in a time-bound manner, depending upon the success of the scheme in Rajasthan and Tamil Nadu. The Committee would like to be apprised of the progress made with respect to implementation of the scheme in Rajasthan and Tamil Nadu immediately.

15. In reply to the aforesaid para, the Department of Pharmaceuticals have stated as under :-

> "Planning Commission has not supported the proposal of the Department of Pharmaceuticals for Rajiv Gandhi Aushadhi Yojana. In view of this no further progress could be made in the matter".

16. The Committee had noted that the Department have planned a new scheme, viz. the Rajiv Gandhi Aushadhi Yojana for providing unbranded generic medicines free of cost to BPL families which envisages sharing of costs in the ratio of 70:30 between the Centre and the States. As the scheme was being implemented in Rajasthan and Tamil Nadu only the Committee had expressed the hope that by making sincere efforts the scheme will be extended to all the States/UTs of the country in a time-bound manner. However, the Department in their reply has stated that Planning Commission has not supported the proposal of the Department of Pharmaceuticals for Rajiv Gandhi Aushadhi Yojana and consequently no further progress could be made in the matter.

The Committee feel concerned over the insensitivity of the Planning Commission for not giving their in-principle approval to the Rajiv Gandhi Aushadhi Yojana (RGAY) meant only for have-nots/deprived lots of the masses, i.e., the BPL families. The Committee also take a serious view of the lack of proactive approach by the Department in voicing their concern over the rejection of the newly planned scheme by the Planning Commission. The Committee would like to be apprised of the reasons advanced by the Planning Commission for not supporting the proposal of the Department.

The Committee reiterate that the Department should again approach the Planning Commission with renewed vigour for extension of this scheme in other States/ Union Territories by making necessary adjustments/changes, if required, and apprise them about the outcome of their fresh efforts at the earliest.

CHAPTER II

OBSERVATIONS / RECOMMENDATIONS WHICH HAVE BEEN ACCEPTED BY THE GOVERNMENT

Recommendation (Sl. No.2, Para No.11)

The Committee are happy to note that the Indian Pharmaceutical Industry is making progress globally and has been ranked third in terms of volume and fourteenth in terms of value. The Committee also note that the Department have prepared a 'White Paper' for consideration of Government for making India a pharma R&D and Innovation Hub by 2020. According to the Department, the document envisages scaling up investments, undertaking deliberate action for building infrastructure for education and research, offering financial incentives to encourage and incubate innovation, shaping a favourable regulatory environment, etc. The Committee desire that the document should be considered urgently and taken to its logical conclusions with a view to enabling the Indian pharma industry not only in ensuring abundant availability of good quality pharmaceuticals of mass consumption at reasonable prices within the country, but also in playing a meaningful role in the global market. The Committee would like to be apprised of the decision taken by the Government on the 'White Paper' and the action taken in this regard.

Reply of the Government

The white paper on "Making India a pharma R&D and Innovation Hub by 2020" was sent to Planning Commission for an in-principle approval. Planning Commission has since concurred to the Department preparing Detailed Project Report (DPR) on the white paper through a global consultant.

Comments of the Committee

(please see para No.7 of Chapter-I of the Report)

Recommendation (Sl. No.3, Para No.21)

The Committee note that out of an outlay of Rs.1,396.17 crore for the 11th Five Year Plan (2007-12) for the Department of Pharmaceuticals, the allocation for the first three years (2007-10) was to the extent of Rs.402.27 crore, which is less than 30% of the total plan allocation. Thus, an amount of Rs.993.90 crore which comes to about 72% will have to be released and spent under plan expenditure during the last two years of the 11th plan. Regarding the uneven allocation of resources, the Department of Pharmaceuticals contended before the Committee that they had sought to undertake many new schemes in various fields of pharmaceuticals sector and consequently a higher allocation had been sought for 2009-10 (Rs.302 crore). However, the Planning Commission conveyed its sanction for Rs.155.25 crore only. Similar had been the situation in respect of the first two years of the 11th Plan, *i.e.* 2007-08 and 2008-09 where the outlays sanctioned by the Planning Commission were well below the amounts proposed by the Department. The Committee regret to conclude that the approach of the Planning Commission in the instant case has been totally unrealistic and not conducive at all to enable the Department of Pharmaceuticals to achieve the expected plan targets. The Committee, therefore, desire that the Planning Commission should address this issue in all its seriousness and ensure that the outlays are sanctioned in the remaining two years of the plan so that the Department of Pharmaceuticals can plan and utilize the resources for achieving the laid down targets.

Reply of the Government

Planning Commission has been apprised of the concerns of the Standing Committee and the Commission is being impressed upon to appropriately address this issue. The Department is also endeavouring to make the Planning Commission allocate the requisite funds, out of its (i.e. Department's) due share sanctioned at the beginning of 11th Plan, during 2010-11 (and next year), so that it can launch the vital schemes aimed at e**nsuring availability of quality medicines and pharmaceutical products at reasonable prices for all**, besides ensuring timely and targeted implementation of its on-going schemes like creation of new NIPERs, revival/rehabilitation of pharma PSUs etc. for long-term infrastructure creation.

Recommendation (Sl. No.4, Para No.22)

What has further caused concern to the Committee is that while sanction of outlays by the Planning Commission during the first three years of the 11th Plan was unrealistic, the actual utilization of the available funds by the Department of Pharmaceuticals had been rather uninspiring. The Committee's examination revealed that as against Rs.91.77 crore sanctioned in 2007-08 (BE) and Rs.155.25 crore sanctioned in 2008-09 (BE), the utilization was Rs.77.07 crore and Rs.109.83 crore respectively. This clearly shows that the Department of Pharmaceuticals had grossly failed in proper utilization of funds, raising doubts over their capacity to plan and execute schemes, which is unfortunate, to say the least. During examination by the Committee, the Department contended that after their being created as a separate entity, they have now formulated several proposals which are being examined by the Planning Commission. They have now proposed an allocation of Rs.1,694.16 crore for the remaining two years of the Plan. The Committee desire that the Department of Pharmaceuticals should gear up their machinery and ensure that the sanctioned outlays are utilized in a methodical manner so that the planned objectives are fully achieved. The Department should also undertake appropriate monitoring at various levels in order to ensure achievement of the plan targets.

Reply of the Government

The Department of Pharmaceuticals has allocation of Rs.155.25 crore, which has been reduced to Rs..105.00 crore at RE stage. The expenditure as on 5.3.2010 is Rs.79.13 crore and the Department endeavours to achieve the objectives and utilize the sanctioned outlays as per the RE. Planning Commission has approved a few schemes like Critical Assistance for WHO-Qualifications for Pharma CPSU/R&D Projects, Proposal for setting up GLP complied Biological Labs/Chemical Labs/Animal facility and the Generic drug Campaign Schemes and efforts are already on to implement these schemes. The progress/implementation of schemes are monitored periodically by various Committees headed by Joint Secretary and Secretary level.

Recommendation (Sl. No.7, Para No.39)

The Committee note that as against a total allocation of Rs.90 crore (Rs.75 crore under plan and Rs.15 crore under non-plan) in BE 2008-09, the budgetary grant for NIPER in BE 2009-10, stands at Rs.77.47 crore (Rs.57.47 crore under plan and Rs.20 crore under non-plan). According to the Department, the decrease in allocation in 2009-10 was due to the reason that the major expenditure towards procurement and creation of infrastructure out of the total approved amount has already been completed. The Committee desire that with the augmented dimensions, NIPER should now concentrate its efforts to develop quality and excellence in pharma education and research and strive to strengthen its links with industry both at national and international levels.

Reply of the Government

The recommendation of the Committee has been noted for compliance.

Recommendation (Sl. No.9, Para No.53)

The Committee note that NPPA/ Government fixes or revises prices of the 74 scheduled bulk drugs/ formulations as per the Drugs (Prices Control) (DPCO) Order, 1995. In respect of drugs not covered therein, i.e. non-scheduled drugs, the manufacturers are free to fix the prices by themselves without seeking the approval of the Government/ NPPA. However, NPPA is required to regularly monitor the movement in prices of non-scheduled formulations and wherever increase in prices beyond 10% per annum is noticed, it is expected to get the prices brought down by such manufacturers and if not done, to take action under the DPCO, 1995. The Committee have been informed that since its inception in August 1997, NPPA has detected 655 cases of overcharging and raised demands involving Rs.1,994.16 crore as on 31 March 2009. What has, however, caused concern to the Committee is that NPPA has been able to recover only an amount of Rs.156.04 crore against the total demand of Rs.1,994.16 crore and an amount of Rs.1,763.63 crore is under litigation and thus locked up in courts. The Committee recommend that NPPA should vigorously pursue these cases and recover the dues promptly. The Committees would like to be informed of the status of the matters.

Reply of the Government

Since the inception of NPPA in August 1997 till December, 09, there is a total no. of 734 cases wherein demand notices have been issued involving total overcharged amount of Rs. 2145.61 crores. An amount of Rs. 180.29 crores has been recovered till 31.12.09 which also includes recovery through Court orders and Rs. 1877.69 crore is under litigation. During the year 2009-2010 (upto 31.12.09) Demand Notice for an amount of Rs. 151.45 crores have been issued and Rs. 24.25 crores has been recovered. As on 31.12.09, out of 69 cases referred to Collectors of various States for recovery under land and revenue arrears, 19 cases are under litigation, 46 cases are pending for recovery with Collectors of various States and in the balance 4 cases, amount has been recovered. The recovery of the overcharged amount is affected due to various Court orders passed by various High Court and also Supreme Court in various cases filed by Pharmaceuticals Companies challenging the price fixation / notification issued by NPPA / Government and criminal complaints filed by various drug control authorities against Pharma companies for not following the notified price. Inclusion of some bulk drugs under price control (Scheduled I of DPCO'95) has also been challenged by some Pharma companies. Government/NPPA is defending such cases through SG, ASGs and Senior Government Counsels. Whenever necessary NPPA files urgent applications in the Courts for vacation of interim orders and also for early hearing / disposal of the case.

Recommendation (Sl. No.10, Para No.54)

The National Pharmaceuticals Pricing Authority should also strictly monitor the prices of the non-scheduled formulations in order to check unwarranted increase in the prices of drugs. They should not hesitate to invoke the relevant provisions of the Drugs (Prices Control) Order, 1995 and fix the retail prices of such non-scheduled formulations, wherever required in public interest. The Committee would like to be apprised of the detailed action taken on this score.

Reply of the Government

In respect of drugs - not covered under the Drugs (Prices Control) Order, 1995 i.e. non-scheduled drugs, manufacturers fix the prices by themselves without seeking

the approval of Government / NPPA. Such prices are normally fixed depending on various factors like the cost of bulk drugs used in the formulation, cost of excipients, cost of R&D, cost of utilities / packing material, sales promotion costs, trade margins, quality assurance cost, landed cost of imports etc. However, As a part of its price monitoring activity, NPPA also regularly examines the movement in prices of non-Scheduled formulations. Wherever a price increase beyond 10% per annum is noticed, the concerned manufacturer is asked to bring down the price voluntarily failing which, subject to prescribed conditions, action is initiated under paragraph 10(b) of the DPCO, 1995 for fixing the price of the formulation in public interest. The Monitoring of prices of non-scheduled formulations is done by NPPA as per the following details:

1. On the basis of approved internal guidelines, the prices of Non-Scheduled formulations are monitored.
2. The monitoring of prices of non-scheduled formulation is currently done on the basis of data from ORG-IMS (about 57000 packs are analysed every month).
3. A list of formulations and their manufacturers are short listed where there is an increase in price of more than 10% (20% before 01.04.2007) in one year and the annual turnover of the formulation pack exceeds Rs.1 crore. Further, the share of formulations in that segment of the formulation is required to be at least 20% of the market or the medicine is one of the top 3 brands of that group.
4. The manufacturer and / or distributor is asked to give justification for price increase of more than 10% per annum.
5. If no information is received after the letter and reminder or the reply of the company is not satisfactory, show cause notice is issued to the manufacturer as to why action should not be initiated for price fixation under para 10(b) of DPCO'95 in larger public interest.
6. If the manufacturer voluntarily reduces the price of the subject medicine to below 10% of the price level, the case is considered for closure. Till date, 32 companies have reduced the price of 64 packs voluntarily.
7. If the manufacturer does not reduce the price to below 10% of the increase level or does not submit the required information, action is initiated by NPPA for price fixation under para 10(b) of DPCO'95 to bring it to the level of permissible level upto 10% price increase.
8. NPPA has so far fixed prices under para 10(b) in respect of 27 formulation packs and companies have reduced price voluntarily in case of 64 formulation packs. Thus in all, prices of 91 packs of non-scheduled drugs have got reduced as a result of the intervention of NPPA.

The present system of monitoring the prices of non-scheduled drugs is considered to be working well. However, creation of NPPA cells in states would make it more effective. A proposal in this regard is pending in the Planning Commission.

Recommendation (Sl. No.12, Para No.64)

The Committee appreciate the activities undertaken by the Government for carrying out of promotion of pharma export during the year 2008-09 by utilizing the funds under the Pharmaceutical Export Promotion Scheme (PEPS). The Committee are happy to note that the BE 2009-10 for PEPS under plan and non-plan heads have been doubled vis-à-vis the RE 2008-09. The Committee hope that the Department with these increased allocations will take concrete steps to encourage promotion of export of pharmaceuticals and further improve the position of Indian Pharmaceutical Industry globally.

Reply of the Government

The Department has noted recommendation of the Committee and that vigorous and sustained efforts would be made for promotion of export of pharmaceuticals.

Recommendation (Sl. No.15, Para No.92)

The Committee note that the revival scheme for Bengal Chemicals and Pharmaceuticals Ltd. (BCPL) has been approved by Government. The Committee also observe that the company is expected to be fully revived by 2016-17. The Committee recommend that the revival plan should be completed well in time to achieve the desired objectives. They also desire that periodical monitoring of the implementation of the revival plan be done at Ministry level so as to ensure that the funds are utilized for the purpose for which they are released. The Committee would therefore, expect concrete action in a time-bound framework by the Government in this behalf. The Committee also expect the Department to submit revival package to the Committee.

Reply of the Government

Every possible attempt is being made to revive the Company. Work is in progress and being monitored by sub-committees made in BCPL, frequent visit of high level officers of this Department as well as through Monthly Review Meetings.

Recommendation (Sl. No.16, Para No.101)

The Committee note that the Government have approved the rehabilitation scheme of Hindustan Antibiotics Limited (HAL). As envisaged in the approved rehabilitation scheme, cash infusion to the extent of Rs.137.59 crore has already been released to HAL. Government of India's past loans and interest thereon to the extent of Rs.259.43 crore have also been waived. Further, Government have sanctioned the scheme for upgradation of manufacturing facilities of HAL conforming to WHO- GMP standards at an estimated cost of Rs.13.31 crore. The Committee hope that with this level of revival assistance, HAL should be able to show perceptible improvement in their performance in the years to come and that the company would be able to generate profit from 2009-10, as assured by them, in addition to fulfilling their social obligations in a meaningful manner.

Reply of the Government

To get the Company fully revived in true sense, Department approved the project for setting up of new Cephalosporin powder injectable line (Phase I) and upgradation of existing Betalactum vialing line for WHO-GMP compliance (Phase II) at an estimated cost of Rs. 20.17 crore. Project activities for phase I i.e., of setting up of Cephalosporin Powder Injectable line almost completed and commercial production started from August 2009. As regards Phase II i.e., upgradation of existing Betalactum Vialing line for WHO-GMP compliance, HAL has reported that the project will be completed in March 2010. After completion of the Project, HAL will be able to generate additional profitability of approximately Rs. 11.00 crore from the first year.

Further, during 2008-09, HAL has been released Rs. 10.00 crore on 22.1.2009 for upgradation of manufacturing facilities conforming to WHO-GMP standards in Tablets & Capsules, Quality Control and Liquid syrup Sections. Every possible step is being taken to complete the Project by 31st March 2010.

To make Corporate Strategic Plan for the Company, IFCI Limited has been engaged by the Company. IFCI Limited studied the existing facilities of the Company,

its financial position, its strength and weaknesses and the overall scenario of the pharmaceutical market in India as well as abroad and prepared a roadmap for the recovery and growth of the Company. Board of HAL has considered the Strategic Analysis Consultancy Report prepared by IFCI and suggested certain modifications/additions to the Corporate Plan. As a part of the Corporate Plan, HAL has planned to undertake following projects over a period of next 7 years:-

Sl. No.	Projects	Estimated cost (Rs. In crore)
1.	Manufacturing of Erythromycin Thiocyanate in the existing fermentation facilities	40.00
2.	Multi-product sterile facilities for manufacture of Benzathine Penicillin	20.00
3.	Setting up of Captive Power Plant of 10 Megawatt capacity	54.00
4.	Expansion of IV Fluid facilities to 240 lakh bottles per annum	40.00
5.	Insulin Project	100.00
6.	Routine Repairs and replacement for maintenance of the facilities and other up-gradation	30.00
	Total	**284.00**

As a result of Government's attempt to enhance the productivity, performance of HAL in terms of production and sales can be visible by this table:-

(Rupees in crore)

CPSEs	Production				Sales			
	06-07	07-08	08-09	09-10 Upto Oct 09	06-07	07-08	08-09	09-10 Upto Oct 09
HAL	48.96	119.81	155.00	66.38	49.22	106.59	106.59	78.36

Recommendation (Sl. No.18, Para No.111)

The Committee appreciate the performance of Karnataka Antibiotics & Pharmaceuticals Limited (KAPL). The Committee recommend that the proposal of delinking KAPL from Hindustan Antibiotics Limited (HAL) may be expeditiously considered and decided so that it gives more flexibility and independence to the performing company at the earliest. The Committee also recommend that the best practices of KAPL may be set as a benchmark for other PSUs. The Committee would like the Department of Pharmaceuticals to hold orientation meetings between KAPL and other PSUs in this regard. The Committee would like to be apprised in this regard.

Reply of the Government

Consequent upon the approval of Government, BIFR approved the delinking of KAPL from HAL vide its order dated 22.6.2009. Now, KAPL have been delinked from HAL and transfer of shares held by HAL have been effected in the name of President of India w.e.f. 1st December 2009.

Observations of the Hon'ble Committee regarding Orientation meetings between KAPL and other PSUs are noted and appropriate actions are being taken.

Recommendation (Sl. No.19, Para No.117)

The Committee appreciate the efforts made by the Department for the promotion of unbranded generic medicines through their Jan Aushadhi Stores (JAS). The Committee observe that the total sale of generic medicines is about seven per cent of the total market, whereas the rest 93 per cent is branded product.

Considering the price advantage of medicines available through JAS, the Committee desire that the Government should take necessary steps for making mandatory the opening of Jan Aushadhi Stores in all Government Hospitals. Further, the Committee feel that there is an urgent need to encourage participation of State Governments in the Scheme and recommend that the Department should convince the State Governments to allot specific space for opening of Jan Aushadhi Stores at least in the State Government Hospitals. Further, Government doctors including CGHS doctors be persuaded to prescribe the generic medicines available in Jan Aushadhi Stores. The Committee also desire that the Department should conduct feasibility study for opening of Jan Aushadhi Stores in villages to achieve the objective of providing quality generic drugs at affordable prices to the common people. They also recommend that more drugs be brought under generic medicines so that the benefit of the lower cost of these medicines be made available to public at large. At the same time, the Committee would also caution that the quality of medicines should not be compromised. There is also a need for giving adequate publicity in print and electronic media to make people aware that quality medicines are available at cheaper prices in Jan Aushadhi Stores.

Reply of the Government

A decision was taken in Pharma Advisory Forum meeting held on 23rd April, 2008 for opening up of atleast one generic drug store to start with in the first phase, in District Government Hospitals wherever the State Government extends active support for selling lesser priced generic medicines through direct market intervention strategy. As per the decision, the medicines for such drug stores would be supplied by the Central Pharma PSUs (CPSUs) with minimal margins. It was felt that such drug stores can be run by Government bodies, hospitals, national/state level NGOs, co-operative/charitable organizations preferably in District Hospitals since free space can be made available by the State Governments wherein it can also direct the doctors to prescribe medicines in Generic names.

2. In order to realize the objectives of the Pharma Advisory Forum, the campaign in the name & style of 'Jan Aushadhi' Generic Drug Store was launched in November, 2008 at Amritsar in the State of Punjab so as to make qualityh medicines available at affordable prices for all. The first Jan Aushadhi Drug Store was opened on 25th November, 2009 at Amritsar Civil Hospital and by the end of December, 2009, all the twenty Districts Civil Hospitals in the State of Punjab were covered with the active support and involvement of the State government. This programme would not only ensure easy availability of quality medicines at cheaper prices to all, but also would bring down the cost of health care depending upon the duration of the period of consumption of the medicines.

3. As of now, 38 stores have been opened in the State of Punjab, Haryana, Rajasthan, Delhi, Andhra Pradesh, Chandigarh and Uttrakhand and efforts are on for opening more and more drug stores in the different parts of the country. It may be relevant to mention here that when the first Jan Aushadhi Drug Store was opened in Amritsar, the CPSUs were able to supply only 50 drugs which were meant for open sale. With the active involvement/initiatives of Department of Pharmaceuticals, the CPSUs now have a range of 380 medicines and surgical items with Jan Aushadhi package for supply to the Jan Aushadhi Outlets. Efforts are on to increase the basket of these medicines.

4. Under this Scheme, the State Government has to provide space in Government Hospital premises for the running of the outlets (JAS). Government hospitals, NGOs, Charitable Organistions and public societies like Red Cross Society, Rogi Kalyan Samitis typically constituted for the purpose can be operating agencies

for the JAS. The operating agency for JAS is nominated on the basis of the recommendations of the State government. Operational expenditure is met from trade margins admissible for the medicines. The State Govt has to ensure prescription of unbranded generic medicines by the Government doctors. The Jan Aushadhi Programme is accordingly be a self sustaining business model not dependent on government subsidies or assistance. It is run on the principle of " Not for Profits but with Minimal Profits". *In order to incentivise and provide the initial trigger for above, it is envisaged that the Central Government would provide only a one-time assistance of Rs.2.00 lakhs as furnishing and establishment costs and further Rs. 50,000 as one time start up cost to NGO etc, setting up the Jan Aushadhi Outlet.* Cooperation of the State Governments is being sought and is available for locating the outlets in the district hospital premises. Several Chief Ministers including CM Delhi, HP, Rajasthan, Punjab have strongly approved such an initiative.

5. It is proposed to launch a massive advertisement campaign in collaboration with Jago Grahak Jago campaign of Department of Consumer Affairs. Till such time it takes off, suitable publicity being undertaken by the State Governments. The Department of Pharmaceuticals and the BPPI also extended its help in this regard. In the case of Punjab, a sum of Rs.25 lakhs was released in the month of November, 2009 for Jan Aushadhi publicity campaign in the State.

6. As this campaign requires educating the public about the generic drugs, prices etc. in order to take full advantage of the same and also to remove various doubts and in particular to explode the myth that less priced drugs are not as effective as the high priced branded medicines, a 24x7 Toll-free National Helpline 1800 180 8080 has also been launched for Jan Aushadhi Campaign in collaboration with 'Consumer online Foundation' by the Bureau of Pharma PSUs of India (BPPI) with the financial support of Department of Pharmaceuticals. It may be further added here that the role of media is equally important as they can play a very crucial/useful role in disseminating and educating the public about the Jan Aushadhi campaign and its immeasurable advantages. Its role is constructive and useful so far in support of the campaign.

Recommendation (Sl. No.21, Para No.121)

The Committee observe that the purchase preference policy in respect of exclusive purchase of 102 medicines from pharma Central Public Sector Undertakings (CPSUs) has not been fully implemented. The Committee recommend that effective steps should be taken to make it mandatory for the Union Government as well as the State Governments to resort to purchase of medicines from the PSUs.

Reply of the Government

The Government instructions with regard to purchase of 102 medicines from pharma Central Public Sector Undertakings is mandatory and binding on all Central Government Departments. The Department of Pharmaceuticals keeps on reminding the Ministry of Health & Family Welfare to ensure compliance of the aforesaid decision of the Government. A meeting at the level of Joint Secretary in the Department of Pharmaceuticals was held recently in this regard. Secretary (Pharmaceuticals) will also hold a meeting with senior officers of the Ministry of Health & Family Welfare shortly to ensure the implementation of the aforesaid policy of the Government.

Recommendation (Sl. No.22, Para No.123)

The Committee also note that some companies have allegedly shifted the production of medicines that are under price control to food and nutrition supplements manufactured under Prevention of Food Adulteration Act, 1954 in order to circumvent the control mechanism. The Committee recommend that the Department should take necessary steps in co-ordination with the Ministry of Health and Family Welfare to curb such alleged malpractices of drug companies. The Committee would like to be apprised of the action taken in the matter. The Committee desire that the list of companies indulging in such malpractices and action taken against them should be submitted to the Committee.

Reply of the Government

It has come to the notice of National Pharmaceutical Pricing Authority (NPPA) that some companies have shifted manufacturing of their product from drugs to food and nutrition supplements under Prevention of Food Adulteration Act, 1954 and this has enabled them to remain out of price control. Examples observed in this regard are Evion 400mg of M/s Merck, Revital of M/s Ranbaxy, Recharge Plus of M/s Trikio, Soft Z gold of M/s Indochem etc. NPPA has taken up the matter with M/o Health & Family Welfare for appropriate action as the matter matter relating to composition of drugs under the Drugs and Cosmetics Act as well as adulteration of drugs is under the Drug Controller General of India under the Ministry of Health & Family Welfare.

Recommendation (Sl. No.23, Para No.126)

The Committee desire that the Department of Pharmaceuticals should take appropriate action in order to ensure adequate availability of Vitamin ‘C’ tablets in the country.

Reply of the Government

There is no acute shortage of Vitamin ‘C’ tablets. However, there were some reports in the media that because of the high prices of the bulk drugs, there was shortage of Vitamin ‘C’ based formulation. M/s Indian Drugs and Pharmaceuticals Limited (A Government of India Undertaking) also brought to the notice of NPPA that the bulk drug Vitamin ‘C’ was available at higher price than the notified price. NPPA vide S.O. No. 127(E) dated 20.01.2010, has revised / increased the prices of Vitamin ‘C’ bulk drugs to make it viable to produce the related formulations as per provision of the Drugs (Prices Control) Order, 1995 (DPCO, 1995). NPPA monitors the availability of the drugs in the country through State Drugs Control Administrations. Wherever required, NPPA takes remedial steps for ensuring availability of drugs by impressing upon manufacturers to rush the stocks to the places of shortage.

CHAPTER III

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

Recommendation (Sl. No.13, Para No.70)

The Public Sector Undertakings (PSUs) in the pharmaceuticals sector were expected to enable and ensure production and availability of medicines to the common people at large. The Committee are pained to observe that the present status of the pharma PSUs are, in general, extremely dismal. Out of the seven pharma PSUs under the administrative control of the Department of Pharmaceuticals, two, viz., the Smith Stanistreet Pharmaceuticals Limited (SSPL) and the Bengal Immunity Limited (BIL) have been closed and are under liquidation since 2003. Three PSUs, viz., the Indian Drugs and Pharmaceuticals Limited (IDPL), the Bengal Chemicals and Pharmaceuticals Limited (BCPL) and the Hindustan Antibiotics Limited (HAL) have been incurring continuous losses, declared sick and referred to the Board for Industrial and Financial Reconstruction (BIFR). They are under different stages of revival/ rehabilitation packages. Only two companies, viz., the Karnataka Antibiotics and Pharmaceuticals Limited (KAPL) and the Rajasthan Drugs and Pharmaceuticals Limited (RDPL) are currently making profits. Collectively, the pharma PSUs have been incurring losses continuously for the last several years. The Committee cannot but express their serious concern over the general plight of the pharma PSUs. The Department of Pharmaceuticals have assured the Committee that HAL, BCPL and IDPL have improved their performance in 2008-09 and that HAL and BCPL would be able to generate profit in 2009-10. As regards IDPL, it was stated that its revival scheme is yet to be approved by Government and that the company has undertaken to generate a net profit of Rs.3.9 crore in 2009-10. The Committee recommend that all pending proposals for the revival of pharma PSUs should be expeditiously considered and Government should extend every possible help to bring the PSUs back to the track. The Committee desire to be apprised of the updated status in this behalf.

Reply of the Government

Apart from KAPL and RDPL, joint ventures of HAL & IDPL respectively, the financial performance of pharma CPSEs as on 31st March 2006 were as under:-

(Rupees in crore)

CPSEs	Production	Sales	Profit/Loss
HAL	47.25	49.21	(34.81)
BCPL	68.76	52.23	(8.45)
IDPL	7.09	6.86	(335.58)

Government approved the Rehabilitation Scheme of HAL on 9th March 2006 which inter alia involved Cash infusion of Rs. 137.59 crore and Waiver from GoI to the extent of Rs.259.43 crore. Funds as enumerated in the Rehabilitation Scheme were made available to HAL during 2006-07. Apart from the above, to improve the manufacturing facilities and therefore the productivity, Government provided Rs. 20.17 crore to HAL for setting up manufacturing facilities of Cephalosporin and betalactum antibiotics complying to WHO-GMP standards during 2007-08 and Rs. 10 crore for upgradation of manufacturing facilities to WHO-GMP standards.

Similarly, Government also approved the Rehabilitation Scheme of BCPL on 21st December 2006, which inter alia involved Cash infusion of Rs. 207.19 crore and

Waivers of Rs. 233.19 crore. Funds as enumerated in the Rehabilitation Scheme were/are being made available to BCPL in the following manner:-

(Rupees in crore)

	2006-07	2007-08	2008-09	2009-10 (Upto January 10)	2010-11	2011-12
As per approved Scheme	117.19	30.00	25.00	20.00	15.00	-
Actual release	117.19	20.00	20.00	24.40	-	-
Short fall	Nil	10.00	5.00	-		

As a result of shortage of availability of funds, BCPL could not i) replace the existing Depot system by C&F system, ii) establish cold chain as being done by Private Players to deliver the products, iii) implement the JVs for vaccines, iv) launch of capacity addition, v) launch of new products as envisaged in revival plan. Further due to delay in implementation of revival scheme, meager fund allocation and shortage of funds, BCPL failed to generate the desired performance.

Performance of CPSEs as on 31st March 2007 and onwards

(Rupees in crore)

CPSEs	Production				Sales			
	06-07	07-08	08-09	09-10 Upto Oct 09	06-07	07-08	08-09	09-10 Upto Oct 09
HAL	48.96	119.81	155.00	66.38	49.22	106.59	106.59	78.36
BCPL	70.89	55.69	89.63	37.09	45.69	51.14	86.82	30.05
IDPL	17.90	62.13	93.25	56.52	15.97	56.70	87.40	47.54

It may be seen from the above that as a result of attempts taken by this Department, the performance of CPSEs are gradually improved and it is expected that these companies will be able to generate desired results very soon.

CHAPTER IV

OBSERVATION / RECOMMENDATION IN RESPECT OF WHICH REPLY OF THE GOVERNMENT HAVE NOT BEEN ACCEPTED BY THE COMMITTEE AND WHICH REQUIRE REITERATION

Recommendation (Sl. No.20, Para No.118)

The Committee are also happy to note that the Department of Pharmaceuticals have also planned a new scheme, viz., the Rajiv Gandhi Aushadhi Yojana for providing unbranded generic medicines free of cost to BPL families. The scheme envisages sharing of costs in the ratio of 70:30 between the Centre and the States. The Committee note that initially the scheme is being implemented in Rajasthan and Tamil Nadu. The Committee, however, express their unhappiness over the delay in according principle approval and additional plan outlay from the Planning Commission. The Committee hope that efforts will be sincerely made to extend the scheme in all the States/UTs of the country in a time-bound manner, depending upon the success of the scheme in Rajasthan and Tamil Nadu. The Committee would like to be apprised of the progress made with respect to implementation of the scheme in Rajasthan and Tamil Nadu immediately.

Reply of the Government

Planning Commission has not supported the proposal of the Department of Pharmaceuticals for Rajiv Gandhi Aushadhi Yojana. In view of this no further progress could be made in the matter.

Comments of the Committee

(please see para No.16 of Chapter-I of the Report)

CHAPTER V

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

Recommendation (Sl. No.1, Para No.6)

The Committee note that out of the nine recommendations pertaining to the Department of Pharmaceuticals contained in their 25th Report on Demands for Grants (2008-09) of the Ministry of Chemicals and Fertilizers (Department of Chemicals and Petro Chemicals), the Government have acted upon the recommendations at Sl. Nos. 8,11,13,16,17and 19, whereas the recommendation at Sl. Nos. 15 and 18 as per the latest information are at various stages of implementation. The Committee desire that the Government should implement the recommendations expeditiously and apprise them of the action taken in this regard

Reply of the Government

Recommendation S.No.10 of 25th Report

The Committee had expressed their deep anguish over the delay regarding finalization of National Pharmaceutical Policy-2006 and reiterated their earlier recommendation for early finalization of this policy so that the funds earmarked for NPPA would be utilized fully to achieve the objectives for which they are allocated.

Reply of the Government.

Following the formations of the new Government, the Department with the approval of the Minister of Chemicals and Fertilizers recommended continuation of GoM. The GoM has accordingly been re-constituted with the Ministers of the notified Departments in the earlier GoM. The anxiety of the Committee has been noted for taking further action in the matter.

Recommendation S.No.15 of 25th Report

The Committee had recommended that the Indian Drugs and Pharmaceuticals Limited (IDPL) should not only be revived but efforts should also be made to make a model drug company in the public sector.

Reply of the Government

The matter is under active consideration in the Department of Pharmaceuticals. It is the proposed to place the matter before the Union Cabinet at the earliest for which draft Cabinet Note is under preparation.

Recommendation S.No.18 of 25th Report

The Committee had desired to know the latest status regarding de-linking of Karnataka Antibiotics and Pharmaceuticals Limited (KAPL) from Hindustan Antibiotics Limited (HAL). On the issue of setting up of Cephalosporin project at KAPL, the Committee had recommended that Cephalosporin project at KAPL should be set up as early as possible so that company should increase its export.

Reply of the Government

Consequent upon the approval of Government, BIFR approved the delinking of KAPL from HAL vide its order dated 22.6.2009. Now, KAPL have been delinked from HAL and transfer of shares held by HAL have been effected in the name of President of India w.e.f. 1st October 2009.

The Company has reported that the Cephalosporin Project is at construction stage. The civil work is 40% over. Orders for other equipments viz. utility and process are being finalized and as per the present projection, the expected month of completion is September 2010.

Recommendation (Sl. No.5, Para No.28)

The Committee note that an amount of Rs.190.33 crore consisting of Rs.155.25 crore under the plan head and Rs.35.08 crore under non-plan has since been voted by Parliament to defray charges in respect of the Department of Pharmaceuticals for the year 2009-10. Out of this, Rs.160.26 crore have been allocated under Revenue and Rs.30.07 crore under Capital heads. As informed to the Committee, the Department of Pharmaceuticals were carved out of the Department of Chemicals and Petrochemicals as a separate entity on 01 July 2008 in order to provide greater focus for the growth of the pharmaceuticals industry. The Committee, however, regret to point out that neither any innovative proposal nor any marked initiative towards this end has been put forth in the Demands for Grants for the year 2009-10. The Department of Pharmaceuticals have sought to defend themselves by stating that their proposals for an enhanced allocation of Rs.302.59 crore did not find favour with the Planning Commission and the Department had to maintain the same level of outlay of Rs.155.25 crore as was in the previous year. According to them, they had to go ahead with their activities with the limited allocations. The Committee expect that the Department of Pharmaceuticals will ensure that the resources are utilized judiciously so that the pharmaceuticals sector gets its intended focus. The Department should also come out with new initiatives for the sustained growth of the pharma sector so that the creation of Department of Pharmaceuticals as a distinct entity is amply justified.

Reply of the Government

The Department has proposed a number of new initiatives viz:

i) Venture capital fund for innovative R&D in Pharmaceuticals Grant in aid/soft loan.
ii) New Schemes of 'Star Pharma colleges' for strengthening of Pharma education and training at undergraduate level.
iii) Critical assistance for WHO prequalification for Pharma CPSU/R&D.
iv) New Schemes of strengthening of NPPA.
v) Project proposal for setting up of GLP complied Biological Laboratory.
vi) Project proposal for setting up of GLP complied Chemicals Laboratory.
vii) Project proposal for setting up of GLP complied Large Animal Facility.
viii) Project proposal for inviting nominations for National Pharma Award for excellence in pharmaceutical research.
ix) Project proposal for Extra Mural Funding in Pharmaceutical Research.
x) Generic Drug Campaign Scheme.
xi) Upgradation to WHO-GMP production standards and support to State PSEs.
xii) Rajiv Gandhi Aushadhiya Yojana.

These were sent for in-principle approval of the Planning Commission.

However, the Planning Commission has conveyed approval in case of schemes only at S.Nos. (iii), (v), (vi), (vii), & (x) on which further action has been initiated by the Deptt. for implementation of the schemes.

Recommendation (Sl. No.6, Para No.38)

The National Institute of Pharmaceuticals Education and Research was set up in 1998 in Mohali, Punjab to nurture and promote quality and excellence in pharmaceutical education and research. The Government approved setting up of six more institutes under NIPER in 2007 initially for two years, which has since been extended upto 2011. These six new institutes are proposed to be established with Public-Private-Partnership (PPP) component. The Committee were informed that classes in some streams of pharmaceutical sciences have already been started in the new institutes with the help of the mentor institutes in the respective places. The Committee are, however, surprised to note that the detailed project report on the PPP model is yet to be approved. The Committee desire that necessary formalities should be expeditiously completed so that the new institutes become fully functional and the underlying objectives for their constitution are fully met.

Reply of the Government

The PPP is likely to be introduced for some revenue generating activities like hostels, auditorium, guest house, recreation and sports, maintenance etc. for which private partner will be selected wherever feasible, in consultation with the consultant and through a transparent process. A suggestion has also come for full or part running of the exclusive courses under PPP in some NIPERs. No view has been taken on this as yet. Action is being initiated in this regard.

Comments of the Committee

(please see para No.10 of Chapter-I of the Report)

Recommendation (Sl. No.8, Para No.44)

The National Pharmaceutical Pricing Authority (NPPA) is responsible for price fixation/revision of drugs and formulations. NPPA also monitors the prices of decontrolled drugs and formulations, enforce and implement the provisions of the Drugs (Prices Control) Order (DPCO), 1995. An amount of Rs.2.25 crore has been earmarked for NPPA under plan head in BE 2009-10. The major part of this allocation is meant for the new scheme 'Proposal for Building Robust and Responsive Statistical system for NPPA'. The Committee note that out of the five schemes proposed by NPPA for the Eleventh Five Year Plan, four schemes are yet to get in-principle approval of the Planning Commission. In view of the fact that only two years of Eleventh Five Year Plan are left, the Committee recommend that the Department should expeditiously take up the issue regarding early approval of the schemes proposed by the NPPA with the Planning Commission. The Committee may be apprised of the progress made in this regard at periodic intervals.

Reply of the Government

Out of the five components of the scheme proposed by the Department, Planning commission has accorded 'in principle' approval to only one component concerning "Building Robust & Responsive Statistical System for NPPA" in March, 2008. Further, it was mentioned that Planning commission will take a view on the publicity campaign scheme after consulting with the Department of Consumer Affairs. It was also mentioned that the other components proposed for strengthening and monitoring of prices of drugs and pharmaceuticals would be taken up after the finalization of the Draft Pharmaceutical Policy. Department is pursuing with the Planning Commission for delinking the matter from the finalization of the draft Policy and according 'in principle approval for the remaining schemes.

Comments of the Committee

(please see para No.13 of Chapter-I of the Report)

Recommendation (Sl. No.11, Para No.58)

The Committee find that presently life saving drugs have not been defined or specified in the DPCO, 1995. Thus, there is no effective monitoring of either their availability or prices by the NPPA. This is a matter of serious concern which need to be remedied forthwith. In this connection, the Committee note that the Supreme Court in its order dated 10 March 2003 had directed the Government to consider and formulate appropriate criteria for ensuring that essential and life saving drugs do not remain out of price control. In pursuance thereof, the Department had proposed the draft National Pharmaceuticals Policy, 2006 which *inter-alia* had taken care of the imperative need. This Committee had time and again emphasized the need to finalize the draft. The Committee are, however, unhappy to observe that the same is yet to see the light of the day. According to the Department, the matter is still pending consideration by the Government. While expressing their deep anguish over the inordinate delay in the matter, the Committee recommend that the draft policy should be finalized forthwith.

Reply of the Government

Following the formations of the new Government, the Department with the approval of the Minister of Chemicals and Fertilizers recommended continuation of GoM. The GoM has accordingly been re-constituted with the Ministers of the notified Departments in the earlier GoM. The anguish of the Committee has been noted for taking further action in the matter.

Recommendation (Sl. No.14, Para No.81)

The Committee have been informed that the revised proposal for revival of IDPL has been referred to Cabinet Secretariat for consideration of the Cabinet. The Committee wish to point out that IDPL was set up in the public sector with the objective of discharging the social responsibility of manufacturing and providing drugs to the general public at reasonable rates and as such its revival is of paramount importance. They, therefore, desire that the revival plan should be expedited so that the progress stated to have been shown by the company during the last two years may convert into bigger results for the benefit of public at large. Steps should also be taken for upgradation of manufacturing facilities in IDPL conforming to WHO-GMP standards. The Committee are of the view that by doing so IDPL would be able to effectively compete with the major pharmaceutical industries in private sector in respect of quality medicines and ultimately would instill confidence in the people. The Committee would therefore, expect concrete action in a time-bound framework by the Government in this behalf. The Committee also desire that the Department should submit the revival package to the Committee.

Reply of the Government

The matter of revival of IDPL is under active consideration in the Department of Pharmaceuticals. It is the proposed to place the matter before the Union Cabinet at the earliest for which draft Cabinet Note is under preparation. In the revival proposal of IDPL the provisions for upgradation of manufacturing facilities in IDPL conforming to WHO-GMP are already incorporated.

Recommendation (Sl. No.17, Para No.108)

The Committee note that the Appellate Authority for Industrial and Financial Reconstruction (AAIFR) has recommended the revival of sick Bengal Immunity Limited (BIL) and forwarded the proposals of five shortlisted companies for consideration of the Government. The Committee have been informed that SBI caps

have been appointed for evaluation of the proposals. The Committee desire that the matter be expeditiously decided and the Committee apprised of the outcome.

Reply of the Government

SBI Caps has submitted the draft Request for Qualification Document (containing the terms of reference for participation by the 5 short listed parties in the proposal transaction); draft expression of interest & draft Public Notice regarding re-commencement of process which are under active consideration of the Department.

Recommendation (Sl. No.24, Para No.131)

The Committee are of the considered view that the problems and concerns of the small pharmaceutical units arising out of the mandatory requirements now laid down in the Drugs and Cosmetic Rules, 1945 should be properly addressed to. The Committee are unhappy to observe that out of a total outlay of Rs.340 crore made in the 11th Plan for providing interest subsidy for the purpose, an amount of Rs.57 crore only has been allocated in the Budget Estimates during the first three years of the Plan. This was further curtailed at RE stages and the actual utilization was practically nil. This clearly shows that the Scheme has not taken off at all. Since the "Interest subsidy Scheme for schedule M compliance" was intended to help encourage small scale units to upgrade their manufacture facilities to conform to the revised norms, the Scheme should be implemented, in letter and spirit and the allocations made in this behalf should be sanctioned and properly utilized, at least in the remaining years of the 11th Plan. The Committee would like to be apprised of the latest position in this regard alongwith the list of companies which have availed of the aforesaid facility during the last three years.

Reply of the Government

There is no separate incentive scheme available for the small scale pharma units in the country. However financial assistance in the form of 15% capital subsidy limited to the project cost of upto Rs. 100 lakhs i.e. total capital subsidy limit Rs. 15 lakhs per small scale unit is available under the Credit Linked Capital Subsidy Scheme administered by the Ministry of Micro, Small and Medium Enterprises (MSME) of the Government of India for technology up-gradation.

The MSME on submission by the Department of Pharmaceuticals regarding the difficulties experienced by the small & medium units in the pharmaceutical sector in respect of the additional financial burden in implementing the mandatory measures under the revised schedule 'M' Standards relating to Good Manufacturing Practices and requirements of machineries/equipments etc., for pharmaceuticals production, issued revised Guidelines through the Second supplement dated 13th July, 2009 to the Credit Linked Capital Subsidy Scheme (CLCSS). Under the revised guidelines, the benefit of the CLCSS would be available to the small scale pharma units for an increased number of upto 179 equipments/machineries recommended for Drug and Pharmaceuticals Products, Sub-sector-wise for up-gradation to Schedule 'M' Standards as per the Drugs & Cosmetics Act, 1940. It is expected that more than 3000 small scale Pharma units will be benefited from this enhanced scheme.

New Delhi;

17, August 2010
26, Shravana, 1932 (Saka)

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

Appendix – I

MINUTES

STANDING COMMITTEE ON CHEMICALS AND FERTILIZERS (2009-10)

TWENTY-THIRD SITTING

(17.08.2010)

The Committee sat from 1530 hours to 1600 hours.

Shri Gopinath Munde - in the Chair

MEMBERS

LOK SABHA

2. Shri Prabhatsinh P. Chauhan
3. Shri K.D. Deshmukh
4. Shri Ganeshrao Nagorao Dudhgaonkar
5. Shri Ponnam Prabhakar
6. Shri Ashok Kumar Rawat
7. Shri Suresh Kumar Shetkar
8. Shri N. Cheluvaraya Swamy
9. Shri Tapas Paul
10. Shri Jagdambika Pal

RAJYA SABHA

11. Shri Raghunandan Sharma
12. Dr. C.P. Thakur
13. Shri Brijlal Khabri
14. Shri A.A. Jinnah
15. Shri Biswajit Daimary
16. Prof. Anil Kumar Sahani
17. Shrimati Naznin Faruque

SECRETARIAT

1.	Shri N. K. Sapra	-	Additional Secretary
2.	Shri C. S. Joon	-	Director
3.	Shri A.K. Srivastava	-	Deputy Secretary

2. At the outset, Hon'ble Chairman welcomed the members to the sitting of the Committee.

3. The Committee thereafter took up for consideration the Draft Action Taken Report on the Action Taken by the Government on the Recommendations contained in the First Report of the Standing Committee on Chemicals and Fertilizers (2009-10) on the Demands for Grants (2009-10) of the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals).

4. The Committee adopted the draft Report with minor amendments and authorized the Chairman to present the same to both the Houses of Parliament.

The Committee then adjourned.

Appendix – II

(*Vide* Para 3 of the Introduction)

ANALYSIS OF ACTION TAKEN BY THE GOVERNMENT ON THE RECOMMENDATIONS CONTAINED IN THE FIRST REPORT (FIFTEENTH LOK SABHA) OF THE STANDING COMMITTEE ON CHEMICALS AND FERTILIZERS (2009-10) ON 'DEMANDS FOR GRANTS (2009-10)' OF THE MINISTRY OF CHEMICALS AND FERTILIZERS (DEPARTMENT OF PHARMACEUTICALS)

I	Total No. of Recommendations	24
II	Observations / Recommendations which have been accepted by the Government:- (*Vide* Recommendation at Sl.Nos.2,3,4,7,9,10,12,15,16,18,19,21,22&23)	14
	Percentage of Total	58.33
III	Observation / Recommendation which the Committee do not desire to pursue in view of the Government's reply:- (*Vide* Recommendation at Sl.No.13)	01
	Percentage of Total	4.17%
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.No.20)	01
	Percentage of Total	4.17%
V	Observations / Recommendations in respect of which replies of the Government are of interim nature:- (*Vide* Recommendations at Sl.Nos. 1,5,6, 8,11,14,17 and 24)	08
	Percentage of Total	33.33%