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STANDING COMMITTEE ON CHEMICALS AND FERTILIZERS (2015-2016)

SIXTEENTH LOK SABHA

MINISTRY OF CHEMICALS AND FERTILIZERS (DEPARTMENT OF PHARMACEUTICALS)

DEMANDS FOR GRANTS (2015-2016)

[Action Taken by the Government on the Observations/Recommendations contained in the SixthReport of the Standing Committee on Chemicals and Fertilizers (Sixteenth Lok Sabha) on Demands for Grants (2015-2016) of the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals)]

THIRTEENTH REPORT

सत्यमेव जयते

LOK SABHA SECRETARIAT
NEW DELHI

November, 2015/*Kartika,* 1937 *(Saka)*

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Presented to Lok Sabha on 27.11.2015
Laid in Rajya Sabha on 27.11.2015

सत्यमेव जयते

LOK SABHA SECRETARIAT
NEW DELHI
November, 2015/*Kartika,* 1937 *(Saka)*

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INTRODUCTION

I, the Chairperson, Standing Committee on Chemicals and Fertilizers (2015-2016) having been authorised by the Committee to present the Report on their behalf, present this Thirteenth Report (Sixteenth Lok Sabha) on Action Taken by the Government on the observations/ recommendations contained in the Sixth Report (Sixteenth Lok Sabha) of the Standing Committee on Chemicals and Fertilizers (2014-2015) on Demands for Grants (2015-2016) of the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals).

2. The Sixth Report (Sixteenth Lok Sabha) of the Standing Committee on Chemicals and Fertilizers was presented to Lok Sabha on 20.4.2015. The Action Taken replies of Government to all observations/ recommendations contained in the Report were received on 31.7.2015. The Standing Committee on Chemicals and Fertilizers (2015-2016) considered and adopted this Report on Action Taken Replies at their sitting held on 22.9.2015.

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

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

NEW DELHI;
5 *October*, 2015
13 *Asvina*, 1937 *(Saka)*

ANANDRAO ADSUL,
Chairperson,
Standing Committee on
Chemicals and Fertilizers.

CHAPTER I

REPORT

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 Sixth Report (Sixteenth Lok Sabha) of the Committee on Demands for Grants (2015-16) of the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals) which was presented to Lok Sabha on 20.4.2015. In all, the Committee made 8 Observations/Recommendations in the Report.

2. Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals) were requested to furnish replies to the Observations/ Recommendations contained in the Sixth Report within three months from the date of presentation of the Report, *i.e.*, by 20.7.2015. The Action Taken Replies of the Government in respect of all the 8 Observations/ Recommendations contained in the Report have been received from the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals) *vide* their O.M. No. 23003/2/2015-Fin.II dated 31.7.2015. These Replies have been categorized as follows:—

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

Sl. Nos. 2, 3, 5, 6, 7 and 8

(Total : 06)
Chapter - II

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

Sl. No. -Nil-

(Total : 00)
Chapter - III

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

Sl. No. -Nil-

(Total : 00)
Chapter - IV

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

Sl. Nos. 1 and 4

(Total : 02)
Chapter - V

3. The Committee desire that the Action Taken Notes on the Observations/Recommendations contained in Chapter-I of this Report and the Final Replies in respect of Observations/Recommendations contained in Chapter V for which replies are of interim nature should be furnished expeditiously.

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

A. Need to encourage Indigenous Production by Pharma Companies

Recommendation No. 1

5. While stressing that Government should boost and incentivize domestic bulk drugs and discourage Indian Pharmaceutical firms from importing, the Committee had recommended as under:—

"The Committee note that the annual turnover of the Indian Pharmaceutical Industry is estimated to be about Rs. 128044.29 crore during the year 2013-14. This segment of Industry has shown tremendous progress in terms of infrastructure development, technology base and wide range of products. The industry has developed excellent GMP (Good Manufacturing Practices) compliant facilities for the production of different dosage forms. The Indian pharmaceutical companies maintain highest standards in Purity, Stability and International Safety, Health and Environmental (SHE) protection in production and supply of bulk drugs. The country is almost self-sufficient in case of formulations. However, the Committee note with concern that a large sum of money is being spent on imports by the country. During the year 2013-14, Rs. 17944.05 crore was spent to import medicinal and pharmaceuticals products. According to the Department, the imports are being made on quality and economic considerations and not necessarily due to non-availability from domestic sources. However, the Committee is not satisfied with the explanation of the Department on this issue. The Committee are of the strong view that to realize the dream of 'Make in India' concept in pharmaceutical sector, the Government should boost and incentivize domestic bulk drug industry and discourage Indian pharmaceutical firms from importing. It is also essential that revival of closed/sick public sector units may be expedited to create capacity of bulk drugs in the country itself and to make the country self-reliant in bulk drugs as also recommended by the Committee in their 2nd Report. Incentives should be given for Research and Development in the pharmaceutical sector. In this context, the Committee note that the Government had constituted a committee under the chairmanship of Secretary, Department of Health and Research. The mandate of this Committee was to carefully study the whole issue of Active Pharmaceutical Ingredients (APIs) of critical importance by identifying important APIs and then working out a package of interventions/concession required to build domestic production capabilities and examine the cost implications. The said Committee has reportedly submitted its report. Based on the recommendations of the said Committee and consultations with stakeholders, the Department would come up with a policy on promotion of production of APIs in India. The Committee now expect from the Department to expedite the process of formulation of the policy on promotion of production of APIs in India. The Committee hope that as a result of the proposed policy, Indian pharmaceutical companies will be encouraged to produce bulk drugs in the country and consequently cheap and quality drugs will be available to the consumers in India. The Committee would like to know the initiatives taken to expedite the policy and the progress made in the matter so far."

Reply of the Government

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

The Government is examining the Katoch Committee recommendation for formulation of a policy for promotion of manufacturing of bulk drugs for being placed before the Cabinet.

Comments of the Committee

7. The Committee note that the Government is examining the Katoch Committee recommendation for formulation of a policy for promotion of manufacturing of bulk drugs for placing the same before the Cabinet. The Committee hope that as a result of the proposed policy, Indian pharmaceutical companies will be encouraged to produce bulk drugs in the country and consequently cheap and quality drugs

will be available to the consumers in India. The Committee, therefore, recommend that the examination of the Katoch Committee recommendations may be done in a time-bound manner and they may be implemented at the earliest. The Committee also recommend that the imports may be resorted by companies only when the same is absolutely necessary for the industry. The Committee would like to know the initiatives taken to expedite the policy and the progress made in the matter so far.

B. Need to allocate funds commensurate to the outlays proposed by the Department

Recommendation No. 2

8. While stressing that the allocation made by the Planning Commission should commensurate to the outlays proposed by the Department, the Committee had recommended as under:—

"The Committee are constrained to note that an outlay of Rs. 12341.89 crore was proposed by the Department for the 12th Five Year Plan covering various Schemes to the Planning Commission, against which an allocation of Rs. 2968 crore was approved. However, for the first three years of the 12th Five Year Plan, against a proposed outlay of Rs. 2566.86 crore (Rs 1127.45 crore for 2012-13, Rs. 567.60 crore for 2013-14 and Rs. 871.81 crore for 2014-15) sought by the Department, the Planning Commission allocated a Plan provision of Rs. 583 crore only *i.e.* Rs. 188 crore each for 2012-13 and 2013-14, and Rs. 207 crore for 2014-15. The balance outlay available for this Department, out of the total approved 12th Plan outlay of Rs. 2968 crore, is Rs. 2385 crore. According to the Department, the allocation made to them falls far short of the urgent funds requirements projected by them for carrying out its laid down mandate and its Vision for development of Indian Pharmaceuticals Industry under 'Make in India' initiative, to make India a largest global provider of quality medicines. According to the Department, the funds allocated for NIPER will be insufficient if NIPER buildings are to be completed in two years. Notwithstanding the position stated above, the Committee's examination revealed that the Department has not been able to spend the plan outlay allocated to them over a period of time and the actual utilization of funds by the Department had remained unsatisfactory. The Committee find that as against the Plan outlay of Rs. 188 crore in BE 2012-13 which was slashed to Rs. 85 crore at RE stage, only Rs. 51.26 crore was spent. For the year 2013-14, the actual expenditure was only Rs. 74.02 crore against Rs. 188 crore in BE 2013-14 which was reduced to Rs. 75 crore at RE stage. The Plan outlay for the year 2014-15 was Rs. 207 crore at BE stage which was curtailed to Rs. 87.49 crore at RE stage and out of which only Rs. 65.86 crore was spent by the Department. Rs. 20 crore was allocated to NIPER, Mohali in BE 2014-15 but the same could not be released for want of Third Pay Evaluation and EFC approval of these schemes. Delay in expenditure was the reason for reduction from Rs. 30 crore in BE 2014-15 to Rs. 26.49 core at RE stage for project based support to PSUs. Cluster Development Programme for Pharma sector was approved in January 2014 but there was delay in selection of Project Management consultant and therefore, due to delay in selection, the BE 2014-15 was reduced at RE stage. Similarly, funds could not be released for setting up of National Centre for R&D in Bulk Drugs at NIPER, Hyderabad. Under Plan Revenue Head for Other Schemes, BE 2014-15 was Rs. 64 crore which was reduced to Rs. 20.70 crore at RE 2014-15 stage but the Actual Expenditure during the year 2014-15 was only Rs. 0.71 crore and a large sum of funds under Plan for Other Schemes could not be spent. Against the allocated funds of Rs. 2.44 crore for the scheme on targets specific new drugs discovery for Anti TB and Kalaazar, a sum of Rs. 0.71 crore was released in last fiscal year 2014-15 and balance amount could not be released as the Utilisation Certificate was not be provided by NIPER, Mohali. All these facts illustrated above clearly speaks about the poor performance of the Department in utilization of its plan allocation. In fact, the Department was candid enough to accept the fact that they could not spend the allotted funds in the past. The Committee, therefore, feel that the Department can not achieve its avowed objectives and targets set for various schemes/programmes unless the funds are utilized by the Department optimally and efficiently. The Committee, therefore, recommend that the Department should make earnest efforts for optimum utilisation of funds allocated to them. The Committee would like to be apprised of the initiatives undertaken by the Department in this regard."

Reply of the Government

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

"The Plan outlay for the year 2014-15 was Rs. 207 crore at BE stage which was reduced to Rs. 87.49 crore at RE stage. Actual expenditure incurred for the year was Rs. 85.28 crore *i.e.* 97.69% of RE. The initiatives undertaken by the Department for timely and optimal utilization of Plan funds of Rs. 210 crore for 2015-16 are as follows:—

The allocation of Rs. 177 crore under Plan Scheme out of which Rs. 87 crore for NIPERs at BE Stage 2014-15 was keeping in view of the proposed construction of New campuses for NIPERs of Guwahati, Gandhinagar and Hyderabad. However, these could not be materialized due to delay in selection of PMC, approval of design and estimates and signing of MoU. Now PMC for Gandhinagar and Guwahati have been finalized and construction work is going to start shortly. The foundation stone ceremony of NIPER, Guwahati was held on 30.05.2015. For NIPER, Hyderabad MoU is under process and the construction work will start after signing of MoU. As far as proposal for Setting up of National Centre for R&D in Bulk Drugs at NIPER, Hyderabad is concerned, it has been approved by SFC and finalization of MoU with PMC is under process. After signing of MoU with PMC, construction activity will be undertaken to utilize the funds allocated for 2015-16. Efforts will be made for optimum utilization of funds allocated for 2015-16.

To implement the Cluster Development Programme for Pharma Sector Scheme, Project Development India Limited (PDIL) has been appointed as the Project Management Consultant (PMC) to implement this scheme. The first meeting of Scheme Steering Committee (SSC) was held on 23.06.2015 wherein Expression of Interest (EoI) was finalized.

The proposed 'Cluster Development Programme for Pharma Sector' Scheme would be a central sector scheme to be implemented as Public Private Partnership (PPP) format for developing Pharma cluster. Rs. 125 crores has been approved for this scheme during the current plan. As each SPV will cost about Rs. 20 crore, to implement 3-4 SPVs. Department would require at least Rs. 75 crore during the current financial year. However, the fund allocated in BE 2015-16 is Rs. 15 crore under the head New Scheme of Pharmaceuticals. As the fund allotted under the head is too meager, Rs. 75 crore has been requested during the current financial year for implementing the scheme.

As for creation of IPR Facilitation Centre Scheme, no fund was allotted in BE 2015-16. As the two IPR's have already been approved and for this purpose an estimate of Rs. 2 crore is required for running the said facilitation centres. As such, Rs. 2 crore has been requested to be provided during current financial year for implementing this scheme.

An allocation of Rs. 5 crore has been made during 2015-16 for the Consumer Awareness Scheme which is anticipated to be fully utilized and an annual plan for release of advertisement through print and electronic media for the purpose has been chalked out.

Keeping in view the delay in finalization of Strategic Action Plan 2015, Jan Aushadhi Stores with new format which was to be launched from June 21, 2015 has been postponed and is expected to be launched in August 2015. The final shape of policy regarding opening of new stores is being SAP 2015. Basket of drugs has been increased to 500 medicines. About 160 items of consumables and disposable surgical has also been finalized and planned to be made available at Jan Aushadhi Stores in SAP 2015.

As regards the Scheme for target specific new drugs discovery for Anti-TB and Kala Azar, the entire amount allocated for 2014-15 *i.e.* Rs. 2.44 crore was released by the end of the fiscal year after obtaining utilization certificate from NIPER Mohali. Further, a Committee has been formed to review the progress of the Scheme on six monthly basis.

Implementation of Plan Schemes and progress of utilization of funds is continuously being monitored at regular intervals. Plan expenditure is monitored Scheme wise at the level of Secretary, Department of Pharmaceuticals in Coordination meetings convened twice a month, as also on a case to case basis. Targeted activities are broken up into individual timelines of achievements, hurdles identified and pace of expenditure speeded up under various Plan Schemes. Process of timely obtaining of requisite appraisals/ approvals from concerned agencies, convening of EFC Meetings etc. is being speeded up."

Comments of the Committee

10. The Committee noted that Planning Commission has approved an allocation of Rs. 2968 crore for 12th Five Year Plan. However, the actual budget allocation was Rs. 583 crore *i.e.* Rs. 188 crore each for 2012-13 and 2013-14 and Rs. 207 crore for 2014-15. The balance outlay available for this Department, for last two years out of the total approved 12th Plan outlay of Rs. 2968 crore, is Rs. 2385 crore. According to the Department, the allocation made to them falls far short of the urgent funds requirements projected by them for carrying out its laid down mandate and its Vision for development of Indian

Pharmaceuticals Industry under "Make in India" initiative, to make India a largest global provider of quality medicines.

The Committee noted from the Action Taken Replies that out of allocation of Rs. 177 crore under Plan Scheme, Rs. 87 crore was earmarked for NIPERs at BE stage 2014-15 keeping in view the proposed construction of New Campuses for NIPERs at Guwahati, Gandhinagar, and Hyderabad. However, the same could not be utilised due to various reasons *viz.* delay in selection of PMC, approval of design and estimates and signing of MoU. They have also stated that PMC for Guwahati and Gandhinagar has been finalised and construction work is going to start shortly. The foundation stone for Guwahati has been laid on 30.05.2015. As regards NIPER, Hyderabad, MoU is under process and the construction will start after signing of MoU. Similarly, the proposal for setting up of National Centre for R&D in Bulk Drugs at NIPER, Hyderabad has been approved by SFC and finalization of MoU with PMC is under process. It has been further stated that after signing MoU with PMC construction activity will be undertaken and efforts will be made for optimum utilisation of funds allocated for 2015-16. While noting the above points, the Committee express their displeasure over the facts that many formalities are yet to be finalised and only after that construction work will start and therefore, the Committee is apprehensive about utilisation of funds. As such the Committee desire that earnest efforts should be made by the Department for completing all the formalities urgently in a time bound manner so that the BE 2015-16 for the establishment of NIPERs is utilised fully.

As regards 'Cluster Development Programme for Pharma Sector', the Department in Action Taken Reply stated that Rs. 125 crore has been approved for this scheme during the current plan. Accordingly, each SPV will cost about Rs. 20 crore and to implement 3-4 SPVs the Department would require at least Rs. 75 crore during the current financial year. However, the fund allocated in BE 2015-16 is Rs. 15 crore under the head New Scheme of Pharmaceuticals. As the fund allotted under the head is too meagre, Rs. 75 crore has been requested during the current financial year for implementing the scheme. The Committee feel that Cluster Development Programme is an innovative programme with a view to catalyze and encourage quality, productivity and innovation in Pharma Sector and to enable the Indian Pharmaceutical Industry, especially SMEs to play a leading role in a competitive global market. The Committe, therefore, urge that such innovative and developmental scheme should not suffer for want of money and

recommend that efforts should be made at the highest level to get the requisite funds for the Cluster Development Programme.

C. Need for optimum utilization of funds

Recommendation No. 3

11. While observing that funds allocated to the Department are utilized optimally and evenly during the year to enable them to achieve the physical targets, the Committee had recommended as under:—

> "The Committee note that total budgetary allocation was reduced from Rs. 247.87 crore in BE 2014-15 to Rs. 137.04 crore in RE 2014-15 by Ministry of Finance. The Department had sought an enhanced provision of Rs. 236.26 crore for RE 2014-15, against which only Rs. 87.49 crore was actually made available to them. For Plan BE 2015-16, at RE stage, in November 2014, the Department had sought Rs. 871.63 crore. This request for Plan BE 2015-16 was subsequently enhanced by this Department after finalization of Plan proposals to Rs. 1590.78 crore in February 2015, to address the long pending pressing needs of development of 6 old NIPERs and 3 new NIPERs, upgradation/modernization of CPSUs, Jan Aushadhi Yojana, new schemes etc. As against the request of the Department, only Rs. 210 crore was actually provided for Plan BE 2015-16 by Ministry of Finance. In the total allocation of Rs. 259.02 crore for BE 2015-16, 81% *i.e.* Rs. 210 crore is accounted for by Plan provisions. NIPER has been allocated Rs. 126.44 crore in BE 2015-16 which according to the Department is insufficient against the proposal of Rs. 1128.57 crore. In addition to 6 NIPERs, the Budget speech for 2015-16 lists three new NIPERs at Maharastra, Rajasthan and Chhattisgarh. The Committee also note that Plan allocation of Rs. 155 crore in BE 2014-15 was reduced to Rs. 56 crore at RE stage for Phamaceutical industries. Under Critical Assistance to Pharma CPSEs for WHO (GMP) Compliance scheme, Rs. 6.84 crore was allocated in RE 2014-15 and Rs. 10 crore allocated in Supplementary Budget Grant (SBG), out of which Rs. 3.3 crore could be sanctioned and the Planning Commission did not approve projects totaling Rs. 3.16 crore of IDPL. Similarly, Rs. 9.67 crore was allocated at RE stage for the year 2014-15 for Jan Aushadhi Scheme as against Rs. 30 crore at BE stage and actual expenditure was Rs. 9.67 crore only.
>
> In view of the foregoing, the Committee strongly feel that the funds allocated to the Department by the Ministry of Finance is abysmally low with reference to their proposals. In the absence of adequate funds available with them, the plan schemes/programmes

undertaken by the Department would be adversely affected. The Committee, therefore, strongly feel that the Ministry of Finance should allocate the funds as per the proposed requirement of the Department and would like that the Department may strongly take up the matter with the Ministry of Finance. At the same time, the Department, on their part, should ensure that funds allocated to them are utilized optimally and evenly during the year to enable them to achieve the physical targets set for various schemes/ programmes which would in turn boost the sustained growth and development of pharma sector in the country. The Committee would like to be apprised of the initiatives undertaken by the Department in this regard."

Reply of the Government

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

"The matter regarding allocation of funds has been taken up with the Budget Division, Department of Economic Affairs, Ministry of Finance. Department is also trying to get additional allocation of funds as admissible through supplementary Demand for Grants. The efforts will be made for allocation of more funds as per the requirement of the Department at the stage of formulation of Revised Estimates—2015-16.

As mentioned in reply to Recommendation No. 2 above the implementation of Plan Schemes and progress of utilization of funds is continuously being monitored at regular intervals. Plan expenditure is monitored Scheme wise at the level of Secretary, Department of Pharmaceuticals in Co-ordination meetings convened twice a month, as also on a case to case basis. Targeted activities are broken up into individual timelines of achievements, hurdles identified and pace of expenditure speeded up under various Plan Schemes. Process of timely obtaining of requisite appraisals/ approvals from concerned agencies, convening of EFC Meetings etc. is being speeded up."

Comments of the Committee

13. The Department in Action Taken Reply stated that the total budgetary allocation was reduced from Rs. 247.87 crore in BE 2014-15 to Rs. 137.04 crore in RE 2014-15 by Ministry of Finance. For Plan BE 2015-16, at RE stage, in November 2014, the Department had sought for Rs. 871.63 crore. This request for Plan BE 2015-16 was subsequently

enhanced by the Department after finalization of Plan proposals to Rs. 1590.78 crore in February, 2015. As against the request of the Department only Rs. 210 crore was actually provided for BE 2015-16 by Ministry of Finance. The Committee noted that the Department has taken up the matter regarding allocation of funds with the Budget Division, Department of Economic Affairs, Ministry of Finance. The Department is also trying to get additional allocation of funds as admissible through supplementary Demand for Grants. The efforts will also be made for demand of more funds as per the requirement of the Department at the stage of formulation of Revised Estimates—2015-16. Further, the Committee also noted that the implementation of Plan Schemes and progress of utilization of funds is continuously being monitored at regular intervals. Plan expenditure is monitored Scheme wise at the level of Secretary, Department of Pharmaceuticals in Co-ordination meetings convened twice a month, as also on a case to case basis. Targeted activities are broken up into individual timelines of achievements, hurdles identified and pace of expenditure speeded up under various Plan Schemes.

The Committee are of the opinion that without the availability of proper funds for all the schemes of the Department, it will not be possible in toto to implement the schemes of Department of Pharmaceuticals. Further the Department should look into the challenges and shortcomings on an urgent basis. The Committee, therefore, reiterate its earlier recommendation that the Department should impress upon Ministry of Finance to allocate required fund by highlighting the actions being undertaken by the Department of Pharmaceuticals. The Committee would like to be apprised of the initiatives undertaken by the Department in this regard.

D. National Institute of Pharmaceutical Education and Research (NIPER)

Recommendation No. 4

14. While observing that to impress upon the State Governments to provide land for NIPER without any delay, the Committee had recommended as under:—

> "NIPER was declared as an "Institute of National importance" under the Act of Parliament on 26th June, 1998. NIPER is a member of Association of Indian Universities. In addition to NIPER, SAS Nagar, Mohali the Government had set up six new NIPERs at Hyderabad, Hajipur, Ahmedabad, Rae Bareli, Guwahati and Kolkata. These New NIPERs will cater to the growing demand of the pharmaceutical

industry for highly trained manpower for continuous growth of the pharmaceuticals sector with increased focus on R&D, particularly after the amendment of Indian Patent Act. At present, new NIPERs are functioning with the assistance of the Mentor Institutes. However, the six New NIPERs are yet to be provided with buildings and regular faculty. In the year 2015-16 it is proposed to construct buildings and provide regular faculties for the six NIPERs. However, the budgetary provision is very limited to take up the same. Thus a supplementary demand is being proposed. Further the Department proposed setting up of three new NIPERs at Andhra Pradesh, Madhya Pradesh and Karnataka. The Budget Speech for 2015-16 lists three new NIPERs at Maharashtra, Rajasthan and Chhattisgarh. The Committee further observed that the work relating to construction of NIPER Campus at Guwahati and Gandhinagar has since been awarded to Engineering Projects (India) Ltd. and Hindustan Steelworks Constructions Ltd. respectively. Further, the Committee noted that Department has not spent the money because it got into all the procedural difficulties. To construct one NIPER the State Governments have to give 100 acres of land free of cost and then only NIPER is sanctioned. The Committee have been apprised that State Governments do not provide adequate land that is why construction activities cannot be started immediately. The Committee, therefore, recommend that the Department of Pharmaceuticals should take up the matter with State Governments at the highest level and impress upon them to provide land for NIPER without any delay. Further they may also take up the matter with the Finance Ministry for required fund allotment after substantial work is in progress. The Committee would like to be apprised of the progress made in this regard.

Reply of the Government

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

"The Department has since awarded the work of construction of NIPER campus from concept to completion at Guwahati to Engineering Project India Ltd. (EPIL) and Gandhinagar to Hindustan Steelworks Constructions Ltd. (HSCL). Memorandum of Understanding (MoU) is to be signed by NIPER, Hyderabad with the National Project Construction Corporation (NPCC) Ltd. After signing the MoU, funds would be released to NIPER for making available to the concerned PSU so as to enable them to commence work relating to construction of NIPER campus at Gandhinagar and Hyderabad. The construction of NIPERs Guwahati, Ahmedabad and Hyderabad will start during the current year. However, construction could not be taken up as sufficient fund has not been provided. Department is planning for supplementary demands/ budgets proposal for additional funds to undertake construction properly.

The issue of allotment of land with respect to NIPERs at Hajipur, Kolkata and Rae Bareli are yet to be resolved.

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

National Institute of Pharmaceutical Education and Research (NIPER), Kolkata was set up after the State Government committed to provide 100 acres of land free of cost. Subsequently, State Government allotted 35 acres land free of cost at Baruipur. However, out of 35 acres, NIPER was required to spare 10 acres for common facilities, which leaves a very small piece of land for setting up of an Institute of national importance. In addition, State Government wanted Government of India to pay for the External Development Charges (EDC). Since, Union Cabinet approved setting up of NIPERs in other parts of country, including Kolkata, on the premise that 100 acres of land would be provided free of cost by the State Governments. Therefore, it is not possible to pay for EDC. The matter has been followed up vigorously with the State Government for allotment of 100 Acres of land near Kolkata free of cost and free from all encumbrances. A letter has also been written on 29.12.2014 by Hon'ble Minister (C&F) to the Chief Minister of West Bengal. However, response from the State Government is yet to be received.

Status of land allocation at NIPER, Hajipur (Bihar)

I. Based on the firm assurances given in writing by the State Government of Bihar for allotment of 100 acres land free of cost, this Department set up NIPER at Hajipur in 2007 under the mentorship of Rajendra Memorial Research Institute of Medical Sciences (RMRIMS), Patna. Since, 2007, NIPER is functioning in the EPIP Campus, BIADA Industrial Area, Hajipur. State Government has, however, not yet allotted the land for setting up full-fledged NIPER Campus at Hajipur, in spite of the matter being followed up with the State Government at Chief Minister and Chief Secretary level.

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

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

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

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

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

NIPER, Raebareli

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

Setting up of Three new NIPERs

The Hon'ble Finance Minister in his Budget Speech for 2015-16 announced setting up of three new NIPERs. However, no budget allocation has been made. The matter is being taken up with Ministry of Finance for allocation of fund."

Comments of the Committee

16. The Committee noted that in addition to NIPER, SAS Nagar, Mohali the Government had set up six new NIPERs at Hyderabad, Hajipur, Ahmedabad, Raebareli, Guwahati and Kolkata. At present, new NIPERs are functioning with the assistance of the Mentor Institutes. The Committee observed that in the year 2015-16, it is proposed to construct buildings and provide regular faculties for the six NIPERs. The Committee also observed that to construct one NIPER, the State Governments have to give 100 acres of land free of cost and then only NIPER is sanctioned. The Committee were further apprised that State Governments do not provide adequate land due to which construction activities cannot be started immediately.

The Committee note from the action taken replies of the Department, that the construction work of NIPER Guwahati, Gandhinagar and Hyderabad has been pending due to the various reasons in spite of allotment of land. Further, the issue of allotment of land with respect to NIPERs at Hajipur and Kolkata and Raebaerali is yet to be resolved.

The Committee, therefore, recommend that the Department should vigorously pursue with the respective State Governments to allocate land of requisite dimension within a fixed timeframe and for this purpose the Department may consider to create a Special Cell to monitor and pursue vigorously with the States for acquisition of land. The Committee also recommend that the process of construction work in respect of NIPERs for which land has already been acquired should be expedited and be completed within a fixed timeframe. The Committee would like to be apprised of the initiatives taken by the Department in this regard.

E. National Pharmaceutical Pricing Authority

Recommendation No. 5

17. With the objective to make all drugs available especially Life Saving Drugs, the Committee had recommended as under:—

"The Committee note that the functions of NPPA, *interalia* include fixation and revision of prices of scheduled drug under the Drugs (Prices Control) Order (DPCO), as well as monitoring and enforcement of prices. NPPA also provides inputs to Government for policy formulation on other specific issues concerning making available affordable medicines to the consumers. The Government has notified DPCO, 2013 on 15th May, 2013 in supersession of DPCO, 1995 and as per the order the prices of scheduled formulations which are based on National List of Essential Medicines (NLEM)-2011 issued by the Ministry of Health and Family Welfare are to be fixed based on market based data. No one is permitted to sell any scheduled drug/formulation at a price higher than the ceiling price fixed by NPPA/Government. NPPA has fixed the ceiling prices of 509 formulation packs under DPCO, 2013. NPPA is in the process of collecting market based information for fixing the prices of remaining formulations. The Committee were surprised to know that all the medicines are not listed in National List of Essential Medicines. The Committee are of the view that all medicines are essential and is taken only when it is needed by the patient. All these medicines including Life Saving Drugs should be available in the market at affordable cost. To keep this in view, the Committee recommend that the scope of price control needs to be enlarged to make all the drugs available especially Life Saving Drugs in all parts of the country. The Government should also expedite the process of notifying the ceiling prices of the remaining medicines. The Committee would like the department to act accordingly and be apprised of the targets achieved in the matter."

Reply of the Government

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

"Drug Price Control Order, 2013 is an offshoot of NPPP-2012 which was approved by the Cabinet on 22.11.2012. The Objective of NPPP-2012 is to put in place a regulatory framework for pricing of drugs so as to ensure availability of required medicines—"essential medicines" at reasonable prices even while providing sufficient opportunity to innovation and competition to support the growth of pharma industry thereby meeting the goals of employment and shared economic well-being for all.

Life Saving Drugs are neither defined in the National Pharmaceutical Pricing Policy (NPPP), 2012 nor in the First Schedule of the Drugs (Prices Control) Order, 2013 (DPCO, 2013) issued pursuant to NPPP, 2012. All essential drugs specified in the National List of Essential Medicines, 2011 (NLEM-2011) are included in Schedule-I of the DPCO, 2013 and are under price control.

NPPA is empowered to fix/notify the ceiling price of all essential medicines. Out of 680 medicines (628 net) specified in Schedule-I of DPCO, 2013, ceiling prices have been fixed in respect of 530 essential medicines under provisions of the said order. In spite of the best efforts made by NPPA, ceiling prices of 98 medicines could not be fixed due to non-availability of the data in the retail sector.

NPPA is empowered to fix/revise the prices of non-scheduled formulations, not covered under price control, under para 19 of DPCO, 2013. NPPA *vide* price notifications dated 10.07.2014 capped the MRP of 106 non-scheduled single ingredient drug formulations used in the treatment of diabetes and cardiovascular diseases.

As regards enlargement of the scope of price control, it is mentioned that Ministry of Health and Family Welfare has constituted a Core Committee for revision of NLEM-2011 under the chairmanship of Dr. V.M. Katoch, former Secretary, Department of Health Research and DG, ICMR. The said Core-Committee (on which both the Department of Pharmaceuticals and NPPA are also represented) will be submitting its recommendations to the Government with regard to revision of the list of essential medicines.

Regarding availability of medicines, it is mentioned that NPPA regularly monitors shortages of essential medicines mainly through Drug Controllers of the State Governments. Whenever shortage is reported by the State Drugs Controller, or when any such shortage comes to the notice of NPPA, NPPA takes remedial steps for ensuring availability of drugs by impressing upon manufacturers to rush the stocks to the places of shortage.

Also, there is a mechanism for monitoring the stock and availability of the essential drugs/scheduled drugs under para 21 (i) of DPCO, 2013 that provides for submission of quarterly return in respect of production/import and sales of scheduled medicines (NLEM medicines) and Active Pharmaceutical Ingredients contained in scheduled formulations as stated in Form- III of the said order by the manufacturer/importer/marketer. Further, any manufacturer/importer wanting to discontinue manufacture/import of a scheduled formulation has to apply to NPPA in Form-IV of Schedule IV of DPCO, 2013 at least 6 months in advance, and NPPA can direct the applicant to continue production/import upto 1 year.

NPPA has recently launched ‘Pharma Jan Samadhan’, a web enabled system which provides consumers and others with an online facility to redress their complaint relating to pricing and availability of medicines. The primary objective of 'Pharma Jan Samadhan' is to put in place a speedy and effective complaint redressal system with regard to non-availability or shortage of any medicine, refusal of supply or sale of any medicine without good and sufficient reason, overpricing of medicines etc.

Further, a web-enabled application called Integrated Pharmaceutical Database Management System (IPDMS) has been developed with the help of NIC and is being operationalized. Besides its usage for price fixation, IPDMS will also serve the objective of price regulation and price monitoring, and will help check price rise of scheduled and non-scheduled formulations, help enforce notified prices, detect price rise violations, and help in recovery of overcharged amounts along with interest from the defaulter companies.

Comments of the Committee

19. The Committee had noted that the functions of NPPA, *inter-alia* include fixation and revision of prices of scheduled drug under the Drugs (Prices Control) Order (DPCO), as well as monitoring and enforcement of prices. NPPA also provides inputs to Government for policy formulation on other specific issues concerning making available affordable medicines to the consumers. The Committee further, note that NPPA is empowered to fix/notify the ceiling price of all essential medicines. Out of 680 medicines (628 net) specified in Schedule-I of DPCO, 2013, ceiling prices have been fixed in respect of 530 essential medicines under provisions of the said order. In spite of the best efforts made by NPPA, ceiling prices of 98 medicines could not be fixed due to non-availability of the data in the retail sector.

In this regard, the Committee are disappointed to note that despite of all efforts by NPPA, the ceiling price of 98 medicines could not be fixed due to non-availability of data. The Committee also note that reasons for non-availability of data in respect of 98 medicines have not been clearly stated. The Committee, therefore, strongly recommend that the Department should ensure to get the collection of the data of the remaining 98 medicines expeditiously in order to fix their price without any further delay.

Further, the Committee are of the view that all the medicines are essential and is taken only when it is needed by the patient. All

medicines including Life Saving Drugs should be available in the market at affordable cost and the Committee expect that recommendations submitted by the Core Committee under the Chairmanship of Dr. V.M. Katoch should be looked into as it is regarding the scope of Price Control of Essential Drugs and scope for bringing more drugs under essential list of medicines. The Committee also recommend that wide publicity be given to web-enabled application called 'Pharma Jan Samadhan' which provides consumers and others with an online facility to redress their complaint relating to pricing and availability of medicines. The other web based application 'Integrated Pharmaceutical Database Management System' which will serve the objective of price regulation and price monitoring may also be operationalised at the earliest. The Committee would like to be apprised of the achievements made in this regard.

F. Recovery of Overcharged Amount by NPPA

Recommendation No. 6

20. With the objective to the recovery of overcharged amount the Committee had recommended as under:—

> "The Committee note that since inception of NPPA till 28.2.2015 there are 1138 cases (1087 cases under DPCO 1995 and 51 cases under DPCO 2013) where demand notices amounting to Rs. 4052.03 crore have been issued by NPPA to Pharmaceutical companies for selling their medicines at prices higher than the price fixed by NPPA/Government of which Rs. 371.60 crore has been recovered till 28.02.2015 leaving a balance of Rs. 3680.43 crore. Out of the balance amount of Rs. 3680.43 crore, Rs. 3485.01 crore is pending in various High Courts and Supreme Court, Rs. 51.86 crore is pending for recovery with Collectors of various States under DPCO 1995, Rs. 5.05 crore is pending with BIFR/Official liquidators under DPCO 1995 and Rs. 139.50 crore is under process. The Committee are given to understand that action for recovery of the overcharged amount along with interest thereon is a continuous process and NPPA takes action as per the provisions of DPCO'1995/DPCO, 2013 read with EC Act, 1955. However, the process of recovery is affected due to orders passed by the various High Courts and also by Supreme Court in cases filed by the pharmaceutical companies challenging the price fixation order/notification issued by NPPA/Government under DPCO, 1995. Inclusion of some Bulk Drugs

under Price Control (schedule-I of DPCO, 1995) has also been challenged by the pharma companies in different courts of India. NPPA/Government is defending such cases through senior Government Counsels. Whenever necessary, NPPA files urgent application in the Courts for vacation of interim orders and also for early hearing/disposal of the case. While appreciating these efforts, the Committee recommend that NPPA should vigorously pursue all the recovery cases and recover the overcharged amount from the companies. The Committee would also like to be apprised of the action taken in this regard."

Reply of the Government

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

"Since inception of NPPA till 30.04.2015, there are 1180 cases (1118 cases under DPCO, 1995 and 62 cases under DPCO, 2013) where demand notices amounting to Rs. 4072.31 crore (Rs. 3918.83 crore under DPCO, 1995 and Rs. 153.48 crore under DPCO 2013) have been issued by NPPA to Pharmaceutical companies for selling their medicines at prices higher than the price fixed by NPPA/ Government. Out of the above, Rs. 373.56 crore (Rs. 309.42 crore under DPCO 1995 and Rs. 64.14 crore under DPCO 2013) has been recovered till 30.04.2015 leaving a balance of Rs. 3698.75 crore (Rs. 3609.41 crore under DPCO 1995 and Rs. 89.34 crore under DPCO 2013). The amount recovered under DPCO 2013 also includes an amount of Rs. 8.32 crore deposited by M/s Biological Evans Ltd. in the Hon'ble High Court of Delhi. Out of the balance amount of Rs. 3698.75 crore, Rs. 3477.82 crore is pending for collection on account of litigation in various High Courts and the Supreme Court; Rs. 54.58 crore is pending for recovery with Collectors of various States; Rs. 5.05 crore is pending with BIFR/Official liquidators under DPCO 1995; and recovery of Rs. 161.30 crore is in process.

Recovery of the overcharged amount gets pending on account of stay orders passed by the various High Courts and the Supreme Court. All efforts have been made to recover the overcharged amounts from the companies through the following steps *viz.* urgent filing of application for vacation of interim orders by various Courts; pursuing cases with the concerned State Drug Controllers

(SDCs) to urge upon the companies for early recovery of the overcharged amounts etc.”

Comments of the Committee

22. The Committee note from the action taken replies of the Department that the recovery of the overcharged amount has been adversely affected due to stay orders passed by the High Courts and the Hon'ble Supreme Court in cases filed by pharmaceutical companies. The Committee are given to understand that action for recovery of the overcharged amount along with interest thereon is a continuous process and NPPA takes action as per the provisions of DPCO, 1995/DPCO, 2013 read with EC Act, 1955. Inclusion of some Bulk Drugs under Price Control (Schedule-I of DPCO, 1995) has also been challenged by the pharma companies in different Courts of India. NPPA/Government is defending such cases. The Committee also note that all efforts have been made to recover the overcharged amounts from the companies through the following steps *viz*. urgent filing of application for vacation of interim orders by various Courts; pursuing cases with the concerned State Drug Controllers (SDCs) to urge upon the companies for early recovery of the overcharged amounts etc. The Committee reiterate that NPPA should vigorously pursue all the recovery cases and recover the overcharged amount from the companies. The Committee would like to be apprised of the action taken in this regard.

G. Public Sector Undertakings

Recommendation No. 8

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

“The Committee note that the Department has 5 running PSUs under its administrative control *viz.* Karnataka Antibiotics and Pharmaceuticals Limited (KAPL), Rajasthan Drugs and Pharmaceuticals Limited (RDPL), Bengal Chemicals and Pharmaceuticals Limited (BCPL), Hindustan Antibiotics Limited (HAL) and Indian Drugs and Pharmaceuticals Limited (IDPL). Out of these KAPL is profit making, while RDPL has reported losses for the first time in 2013-14 and BCPL, HAL and IDPL are BIFR referred Companies. However consistent with the policy to ensure availability of good quality life saving drugs at reasonable prices, Government of India has since approved rehabilitation scheme for revival of HAL and BCPL.

As the HAL is still incurring losses, the 2nd Rehabilitation Plan of HAL including the sale of some portion of surplus land has been approved by the Government. The Committee note that proceeds from sale of surplus land could generate a substantial amount for the revival of the company. The Committee expressed their displeasure that no significant progress on the proposal has been made. The Committee now expect that necessary action would be taken by the Government in the matter and the formalities would be finalised expeditiously to implement the 2nd rehabilitation Plan of HAL for the early revival of company and to ensure welfare of its employees.

As regard the sickness and revival of BCPL the revival package for BCPL was approved by the Government on 21st December 2006. As envisaged in the Revival Scheme of BCPL, Government has so far released Rs. 207.19 crore in full as cash infusion component. The company has appointed Consultants for undertaking the work of up gradation and modernization of plant and machinery including compliance with Schedule 'M'/WHO GMP standards. The company is on the path of revival. The production sale and gross margin during the last 9 months of 2014-15 surpassed the production and sale during the last two financial year.

IDPL was declared as a sick industrial company on 12th August, 1992. After failure to privatize IDPL, BIFR ordered its winding–up on 4.12.2003. AAIFR set aside the impugned order of BIFR dated 4.12.2003 and remanded the matter back to BIFR for taking further action for rehabilitation of IDPL and to pass further orders in accordance with law. GoM in its meeting held on 11.10.2007 advised that IDPL's revival plan should be based on public interest goals and ensuring the viability of the Company. Based on the observations made by GoM, in its meeting held on 11.10.2007, IDPL appointed a leading consultant Company E&Y to carry out the feasibility study. E&Y submitted its report to the Ministry/DoP. A revised updated Draft Rehabilitation Scheme (DRS) has been prepared taking cut off date 31.3.2014 and submitted to the DoP/Ministry in January, 2015 for consideration and approval. The DRS of IDPL is self-financing in nature in other words no fund will be sought from the Government rather the present assets will be sold off and the fund released will be used to payoff secured creditors. The Committee are given to understand that Government has also decided to sell surplus land of IDPL , Gurgaon to generate revenue. The Committee hope that with the sale of land, the IDPL would generate revenue which would help them to revive IDPL, Gurgaon.

The Committee are, however, unhappy with the slow pace of progress to revive the sick PSUs in spite of their repeated recommendations in this regard. The Committee once again reiterate its recommendation that the Department should make vigorous efforts in coordination with all concerned to expedite the revival of the sick PSUs in time bound manner. The Committee would like to be apprised of the action plan by the Department in this regard."

Reply of the Government

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

"Hindustan Antibiotic Ltd.

IDBI, the Operating Agency appointed by BIFR for HAL has prepared and submitted the Modified Draft Rehabilitation Scheme (MDRS) in February, 2015. The same has been approved by Board of Directors of HAL. Action is being taken to prepare Cabinet Note and obtain necessary approval before approaching BIFR for sanctioning the second rehabilitation package for HAL.

Bengal Chemicals and Pharmaceuticals Ltd.

As regard the sickness and Revival of BCPL the revival package for BCPL was approved by the Government on 21st December, 2006. As envisaged in the Revival Scheme of BCPL, Government has so far released Rs. 207.19 crore in full as cash infusion component. The company has appointed consultants for undertaking the work of upgradation and modernization of plant and machinery including compliance with Schedule 'M'/WHO GMP standards. The Company has taken initiative to commission Ointment, Cephalosporin and Betalactum Blocks which is as per Ministry's approval in its Appraisal Meeting for Revised Cost Estimate, held on 13.01.2015. The Company is on the path of revival. The Production, Sales and Gross Margin during the financial year

2014-15 surpassed the Production and Sales achieved during the last two financial years (*i.e.*, 2013-14 and 2012-13)."

	Financial Year 2014-15 (Rs. in Cr.) Unaudited	Financial Year 2013-14 (Rs. in Cr.) Audited	Financial Year 2012-13 (Rs. in Cr.) Audited
Production	64.11	19.71	36.33
Sales	53.00	19.04	30.03
Gross Margin	(7.33)	(20.36)	(22.90)

Indian Drugs and Pharmaceuticals Ltd.

On the directions of BIFR, the Operating Agency *i.e.* IDBI drafted the Modified Draft Rehabilitation Scheme (MDRS) and submitted to the Department.

MDRS has since been approved by the Board of Directors of IDPL in their Board meeting dated 05.05.2015. Cabinet Note is under finalization and is expected to be circulated for inter-ministerial consultation shortly."

Comments of the Committee

25. The Committee noted that the Department has 5 running PSUs under its administrative control. Out of these KAPL is profit-making, while RDPL has reported losses for the first time in 2013-14 and BCPL, HAL and IDPL are BIFR referred Companies. However, consistent with the policy to ensure availability of good quality life saving drugs at reasonable prices, Government of India has since approved rehabilitation scheme for revival of IDPL, HAL and BCPL. In the case of HAL IDBI, the Operating Agency appointed by BIFR for HAL has prepared and submitted the Modified Draft Rehabilitation Scheme (MDRS) in February, 2015. The same has been approved by Board of Directors of HAL. Action is being taken to prepare Cabinet Note and obtain necessary approval before approaching BIFR for sanctioning the second rehabilitation package for HAL With regard to revival of BCPL, the revival package for BCPL was approved by the Government on 21st December 2006. The company has appointed consultants for undertaking the work of upgradation and modernization of plant and machinery including compliance with Schedule 'M'/WHO GMP standards. Now, the production sale and gross margin during the

last 9 months of 2014-15 surpassed the production and sale during the last two financial years 2013-14 and 2012-13.

In the case of IDPL on the directions of BIFR, the Operating Agency *i.e.* IDBI drafted the Modified Draft Rehabilitation Scheme (MDRS) and submitted to the Department. MDRS has since been approved by the Board of Directors of IDPL in their Board meeting dated 05.05.2015. Cabinet Note is under finalization and is expected to be circulated for inter-ministerial consultation shortly.

The Committee are, however, unhappy with the slow pace of progress to revive the sick PSUs in spite of their repeated recommendations in this regard. The Committee once again reiterate its recommendation that the Department should make vigorous efforts in coordination with all concerned to expedite the revival of the sick PSUs in a time bound manner and if felt necessary the Department may also consider to overhaul the management of sick units. The Committee would like to be apprised of the action plan by the Department in this regard.

CHAPTER II

OBSERVATIONS/RECOMMENDATIONS WHICH HAVE BEEN ACCEPTED BY THE GOVERNMENT

Recommendation No. 2

The Committee are constrained to note that an outlay of Rs. 12341.89 crore was proposed by the Department for the 12th Five Year Plan covering various Schemes to the Planning Commission, against which an allocation of Rs. 2968 crore was approved. However, for the first three years of the 12th Five Year Plan, against a proposed outlay of Rs. 2566.86 crore (Rs. 1127.45 crore for 2012-13, Rs. 567.60 crore for 2013-14 and Rs. 871.81 crore for 2014-15) sought by the Department, the Planning Commission allocated a Plan provision of Rs. 583 crore only *i.e.* Rs. 188 crore each for 2012-13 and 2013-14, and Rs. 207 crore for 2014-15. The balance outlay available for this Department, out of the total approved 12th Plan outlay of Rs. 2968 crore, is Rs. 2385 crore. According to the Department, the allocation made to them falls far short of the urgent funds requirements projected by them for carrying out its laid down mandate and its Vision for development of Indian Pharmaceuticals Industry under "Make in India" initiative, to make India a largest global provider of quality medicines. According to the Department, the funds allocated for NIPER will be insufficient if NIPER buildings are to be completed in two years. Notwithstanding the position stated above, the Committee's examination revealed that the Department has not been able to spend the plan outlay allocated to them over a period of time and the actual utilization of funds by the Department had remained unsatisfactory. The Committee find that as against the Plan outlay of Rs. 188 crore in BE 2012-13 which was slashed to Rs. 85 crore at RE stage, only Rs. 51.26 crore was spent. For the year 2013-14, the actual expenditure was only Rs. 74.02 crore against Rs. 188 crore in BE 2013-14 which was reduced to Rs. 75 crore at RE stage. The Plan outlay for the year 2014-15 was Rs. 207 crore at BE stage which was curtailed to Rs. 87.49 crore at RE stage and out of which only Rs. 65.86 crore was spent by the Department. Rs. 20 crore was allocated to NIPER, Mohali in BE 2014-15 but the same could not be released for want of Third Pay Evaluation and EFC approval of these schemes. Delay in expenditure was the reason for reduction from Rs. 30 crore in BE 2014-15 to Rs. 26.49 crore at RE stage for project based support to PSUs. Cluster Development Programme for Pharma sector was approved in January 2014 but there was delay in selection of Project Management consultant and therefore, due to delay in selection, the BE 2014-15 was reduced at RE stage. Similarly, funds could not be released for setting up of National Centre for R&D in Bulk Drugs at NIPER, Hyderabad. Under Plan Revenue Head for Other Schemes, BE 2014-15 was Rs. 64 crore which was reduced to Rs. 20.70 crore at RE 2014-15 stage but the Actual Expenditure during the year 2014-15 was only Rs. 0.71 crore and a large sum of funds under Plan for Other Schemes could not be spent. Against the allocated funds of Rs. 2.44 crore for the scheme on targets specific new drugs discovery for Anti-TB and Kala Azar, a sum of Rs. 0.71 crore was released in last fiscal year 2014-15 and balance amount could not be released as the Utilisation Certificate was not be provided by NIPER, Mohali. All these facts illustrated above clearly speaks about the poor performance of the Department in utilization of its plan allocation. In fact, the Department was candid enough to accept the fact that they could not spend the allotted funds in the past. The Committee, therefore, feel that the Department can not achieve its avowed objectives and targets set for various schemes/programmes unless the funds are utilized by the Department optimally and efficiently. The Committee, therefore, recommend that the Department should make earnest efforts for optimum utilisation of funds allocated to them. The Committee would like to be apprised of the initiatives undertaken by the Department in this regard.

Reply of the Government

The Plan outlay for the year 2014-15 was Rs. 207 crore at BE stage which was reduced to Rs. 87.49 crore at RE stage. Actual expenditure incurred for the year was Rs. 85.28 crore *i.e.* 97.69% of RE. The initiatives undertaken by the Department for timely and optimal utilization of Plan funds of Rs. 210 crore for 2015-16 are as follows:—

The allocation of Rs. 177 crore under Plan Scheme out of which Rs. 87 crore for NIPERs at BE Stage 2014-15 was keeping in view of the proposed construction of New campuses for NIPERs of Guwahati, Gandhinagar and Hyderabad. However, these could not be materialized due to delay in selection of PMC, approval of design and estimates and signing of MoU. Now PMC for Gandhinagar and Guwahati have been finalized and construction work is going to start shortly. The foundation stone ceremony of NIPER, Guwahati was held on 30.05.2015. For NIPER, Hyderabad MoU is under process and the construction work will start after signing of MoU. As far as proposal for Setting up of National Centre for R&D in Bulk Drugs at NIPER, Hyderabad is concerned, it has been approved by SFC and finalization of MoU with PMC is under process. After signing of MoU with PMC, construction activity will be undertaken to utilize the funds allocated for 2015-16. Efforts will be made for optimum utilization of funds allocated for 2015-16.

To implement the Cluster Development Programme for Pharma Sector Scheme, Project Development India Limited (PDIL) has been appointed as the Project Management Consultant (PMC) to implement this scheme. The first meeting of Scheme Steering Committee (SSC) was held on 23.06.2015 wherein Expression of Interest (EoI) was finalized.

The proposed 'Cluster Development Programme for Pharma Sector' Scheme would be a central sector scheme to be implemented as Public Private Partnership (PPP) format for developing Pharma cluster. Rs. 125 crore has been approved for this scheme during the current plan. As each SPV will cost about Rs. 20 crores, to implement 3-4 SPVs Department would require at least Rs. 75 crore during the current financial year. However, the fund allocated in BE 2015-16 is Rs. 15 crore under the head New Scheme of Pharmaceuticals. As the fund allotted under the head is too meager, Rs. 75 crore has been requested during the current financial year for implementing the scheme.

As for creation of IPR Facilitation Centre Scheme, no funds was allotted in BE 2015-16. As the two IPR's have already been approved and for this purpose an estimate of Rs. 2 crore is required for running the said facilitation centres as such, Rs. 2 crore has been requested to be provided during current financial year for implementing this scheme.

An allocation of Rs. 5 crore has been made during 2015-16 for the Consumer Awareness Scheme which is anticipated to be fully utilized and an annual plan for release of advertisement through print and electronic media for the purpose has been chalked out.

Keeping in view the delay in finalization of Strategic Action Plan 2015, Jan Aushadhi Stores with new format which was to be launched from June 21, 2015 has been postponed and is expected to be launched in August, 2015. The final shape of policy regarding opening of new stores is being SAP 2015. Basket of drugs has been increased to 500 medicines. About 160 items of consumables and disposable surgical has also been finalized and planned to be made available at Jan Aushadhi Stores in SAP 2015.

As regards the Scheme for target specific new drugs discovery for Anti-TB and Kala Azar, the entire amount allocated for 2014-15 *i.e.* Rs. 2.44 crore was released by the end of the fiscal year after obtaining utilization certificate from NIPER Mohali. Further, a Committee has been formed to review the progress of the Scheme on six monthly basis.

Implementation of Plan Schemes and progress of utilization of funds is continuously being monitored at regular intervals. Plan expenditure is monitored Scheme-wise at the level of Secretary, Department of Pharmaceuticals in Coordination meetings convened twice a month, as also on a case to case basis. Targeted activities are broken up into individual timelines of achievements, hurdles identified and pace of expenditure speeded up under various Plan Schemes. Process of timely obtaining of requisite appraisals/approvals from concerned agencies, convening of EFC Meetings etc. is being speeded up.

Comments of the Committee

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

Recommendation No. 3

The Committee note that total budgetary allocation was reduced from Rs. 247.87 crore in BE 2014-15 to Rs. 137.04 crore in RE 2014-15 by Ministry of Finance. The Department had sought an enhanced provision of Rs. 236.26 crore for RE 2014-15, against which only Rs. 87.49 crore was actually made available to them. For Plan BE 2015-16, at RE stage, in November, 2014, the Department had sought Rs. 871.63 crore. This request for Plan BE 2015-16 was subsequently enhanced by this Department after finalization of Plan proposals to Rs. 1590.78 crore in February, 2015, to address the long pending pressing needs of development of 6 old NIPERs and 3 new NIPERs, upgradation/modernization of CPSUs, Jan Aushadhi Yojana, new schemes etc. As against the request of the Department, only Rs. 210 crore was actually provided for Plan BE 2015-16 by Ministry of Finance. In the total allocation of Rs. 259.02 crore for BE 2015-16, 81% *i.e.* Rs. 210 crore is accounted for by Plan provisions. NIPER has been allocated Rs. 126.44 crore in BE 2015-16 which according to the Department is insufficient against the proposal of Rs. 1128.57 crore. In addition to 6 NIPERs, the Budget speech for 2015-16 lists three new NIPERs at Maharashtra, Rajasthan and Chhattisgarh. The Committee also note that Plan allocation of Rs. 155 crore in BE 2014-15 was reduced to Rs. 56 crore at RE stage for Pharmaceutical Industries. Under Critical Assistance to Pharma CPSEs for WHO (GMP) Compliance scheme, Rs. 6.84 crore was allocated in RE 2014-15 and Rs. 10 crore allocated in Supplementary Budget Grant (SBG), out of which Rs. 3.3 crore could be sanctioned and the Planning Commission did not approve projects totalling Rs. 3.16 crore of IDPL. Similarly, Rs. 9.67 crore was allocated at RE stage for the year 2014-15 for Jan Aushadhi Scheme as against Rs. 30 crore at BE stage and actual expenditure was Rs. 9.67 crore only.

In view of the foregoing, the Committee strongly feel that the funds allocated to the Department by the Ministry of Finance is abysmally low with reference to their proposals. In the absence of adequate funds available with them, the plan schemes/programmes undertaken by the Department would be adversely affected. The Committee, therefore, strongly feel that the Ministry of Finance should allocate the funds as per the proposed requirement of the Department and would like that the Department may strongly take up the matter with the Ministry of Finance. At the same time, the Department, on their part, should ensure that funds allocated to them are utilized optimally and evenly during the year to enable them to achieve the physical targets set for various schemes/ programmes which would in turn boost the sustained growth and development of pharma sector in the country. The Committee would like to be apprised of the initiatives undertaken by the Department in this regard.

Reply of the Government

The matter regarding allocation of funds has been taken up with the Budget Division, Department of Economic Affairs, Ministry of Finance. Department is also trying to get additional allocation of funds as admissible through supplementary Demand for Grants. The efforts will be made for allocation of more funds as per the requirement of the Department at the stage of formulation of Revised Estimates—2015-16.

As mentioned in reply to Recommendation No. 2 above the implementation of Plan Schemes and progress of utilization of funds is continuously being monitored at regular intervals. Plan expenditure is monitored Scheme-wise at the level of Secretary, Department of Pharmaceuticals in Coordination meetings convened twice a month, as also on a case to case basis. Targeted activities are broken up into individual timelines of achievements, hurdles identified and pace of expenditure speeded up under various Plan Schemes. Process of timely obtaining of requisite appraisals/approvals from concerned agencies, convening of EFC Meetings etc. is being speeded up.

Comments of the Committee

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

Recommendation No. 5

The Committee note that the functions of NPPA, *inter-alia* include fixation and revision of prices of scheduled drug under the Drugs (Prices Control) Order (DPCO), as well as monitoring and enforcement of prices. NPPA also provides inputs to Government for policy formulation on other specific issues concerning making available affordable medicines to the consumers. The Government has notified DPCO, 2013 on 15th May, 2013 in supersession of DPCO, 1995 and as per the order the prices of scheduled formulations which are based on National List of Essential Medicines (NLEM)-2011 issued by the Ministry of Health and Family Welfare are to be fixed based on market based data. No one is permitted to sell any scheduled drug/formulation at a price higher than the ceiling price fixed by NPPA/Government. NPPA has fixed the ceiling prices of 509 formulation packs under DPCO, 2013. NPPA is in the process of collecting market based information for fixing the prices of remaining formulations. The Committee were surprised to know that all the medicines are not listed in National List of Essential Medicines. The Committee are of the view that all medicines are essential and is taken only when it is needed by the patient. All these medicines including Life Saving Drugs should be available in the market at affordable cost. To keep this in view, the Committee recommend that the scope of price control needs to be enlarged to make all the drugs available especially Life Saving Drugs in all parts of the country. The Government should also expedite the process of notifying the ceiling prices of the remaining medicines. The Committee would like the department to act accordingly and be apprised of the targets achieved in the matter.

Reply of the Government

Drug Price Control Order, 2013 is an offshoot of NPPP-2012 which was approved by the Cabinet on 22.11.2012. The Objective of NPPP-2012 is to put in place a regulatory framework for pricing of drugs so as to ensure availability of required medicines—"essential medicines" at reasonable prices even while providing sufficient opportunity to innovation and competition to support the growth of pharma industry thereby meeting the goals of employment and shared economic well-being for all.

Life Saving Drugs are neither defined in the National Pharmaceutical Pricing Policy (NPPP), 2012 nor in the First Schedule of the Drugs (Prices Control) Order, 2013 (DPCO, 2013) issued pursuant to NPPP, 2012. All essential drugs specified in the National List of Essential Medicines, 2011 (NLEM-2011) are included in Schedule-I of the DPCO, 2013 and are under price control.

NPPA is empowered to fix/notify the ceiling price of all essential medicines. Out of 680 medicines (628 net) specified in Schedule-I of DPCO, 2013, ceiling prices have been fixed in respect of 530 essential medicines under provisions of the said order. In spite of the best efforts made by NPPA, ceiling prices of 98 medicines could not be fixed due to non-availability of the data in the retail sector.

NPPA is empowered to fix/revise the prices of non-scheduled formulations, not covered under price control, under para 19 of DPCO, 2013. NPPA *vide* price notifications dated 10.07.2014 capped the MRP of 106 non-scheduled single ingredient drug formulations used in the treatment of diabetes and cardiovascular diseases.

As regards enlargement of the scope of price control, it is mentioned that Ministry of Health and Family Welfare has constituted a Core Committee for revision of NLEM 2011 under the chairmanship of Dr. V.M. Katoch, former Secretary, Department of Health Research and DG, ICMR. The said Core-Committee (on which both the Department of Pharmaceuticals and NPPA are also represented) will be submitting its recommendations to the Government with regard to revision of the list of essential medicines.

Regarding availability of medicines, it is mentioned that NPPA regularly monitors shortages of essential medicines mainly through Drugs Controllers of the State Governments. Whenever shortage is reported by the State Drugs Controller, or when any such shortage comes to the notice of NPPA, NPPA takes remedial steps for ensuring availability of drugs by impressing upon manufacturers to rush the stocks to the places of shortage.

Also, there is a mechanism for monitoring the stock and availability of the essential drugs/scheduled drugs under para 21 (i) of DPCO, 2013 that provides for submission of quarterly return in respect of production/ import and sales of scheduled medicines (NLEM medicines) and Active Pharmaceutical Ingredients contained in scheduled formulations as stated in Form-III of the said order by the manufacturer/importer/marketer. Further, any manufacturer/importer wanting to discontinue manufacture/ import of a scheduled formulation has to apply to NPPA in Form-IV of Schedule-IV of DPCO, 2013 at least 6 months in advance, and NPPA can direct the applicant to continue production/import upto 1 year.

NPPA has recently launched 'Pharma Jan Samadhan', a web enabled system which provides consumers and others with an online facility to redress their complaint relating to pricing and availability of medicines. The primary objective of 'Pharma Jan Samadhan' is to put in place a speedy and effective complaint redressal system with regard to non-availability or shortage of any medicine, refusal of supply or sale of any medicine without good and sufficient reason, overpricing of medicines etc.

Further, a web-enabled application called Integrated Pharmaceutical Database Management System (IPDMS) has been developed with the help of NIC and is being operationalized. Besides its usage for price fixation, IPDMS will also serve the objective of price regulation and price monitoring, and will help check price rise of scheduled and non-scheduled formulations, help enforce notified prices, detect price rise violations, and help in recovery of overcharged amounts along with interest from the defaulter companies.

Comments of the Committee

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

Recommendation No. 6

The Committee note that since inception of NPPA till 28.2.2015 there are 1138 cases (1087 cases under DPCO-1995 and 51 cases under DPCO-2013) where demand notices amounting to Rs. 4052.03 crore have been issued by NPPA to Pharmaceutical companies for selling their medicines at prices higher than the price fixed by NPPA/Government of which Rs. 371.60 crore has been recovered till 28.02.2015 leaving a balance of Rs. 3680.43 crore. Out of the balance amount of Rs. 3680.43 crore, Rs. 3485.01 crore is pending in various High Courts and Supreme Court, Rs. 51.86 crore is pending for recovery with Collectors of various States under DPCO-1995, Rs. 5.05 crore is pending with BIFR/Official liquidators under DPCO-1995 and Rs. 139.50 crore is under process. The Committee are given to understand that action for recovery of the overcharged amount along with interest thereon is a continuous process and NPPA takes action as per the provisions of DPCO-1995/DPCO-2013 read with EC Act, 1955. However, the process of recovery is affected due to orders passed by the various High Courts and also by Supreme Court in cases filed by the pharmaceutical companies challenging the price fixation order/notification issued by NPPA/Government under DPCO-1995. Inclusion of some Bulk Drugs under Price Control (Schedule-I of DPCO-1995) has also been challenged by the pharma companies in different courts of India. NPPA/

Government is defending such cases through senior Government Counsels. Whenever necessary, NPPA files urgent application in the Courts for vacation of interim orders and also for early hearing/disposal of the case. While appreciating these efforts, the Committee recommend that NPPA should vigorously pursue all the recovery cases and recover the overcharged amount from the companies. The Committee would also like to be apprised of the action taken in this regard.

Reply of the Government

Since inception of NPPA till 30.04.2015, there are 1180 cases (1118 cases under DPCO 1995 and 62 cases under DPCO 2013) where demand notices amounting to Rs. 4072.31 crore (Rs. 3918.83 crore under DPCO 1995 and Rs. 153.48 crore under DPCO 2013) have been issued by NPPA to Pharmaceutical companies for selling their medicines at prices higher than the price fixed by NPPA/Government. Out of the above, Rs. 373.56 crore (Rs. 309.42 crore under DPCO 1995 and Rs. 64.14 crore under DPCO 2013) has been recovered till 30.04.2015 leaving a balance of Rs. 3698.75 crore (Rs. 3609.41 crore under DPCO 1995 and Rs. 89.34 crore under DPCO 2013). The amount recovered under DPCO 2013 also includes an amount of Rs. 8.32 crore deposited by M/s Biological Evans Ltd. in the Hon'ble High Court of Delhi. Out of the balance amount of Rs. 3698.75 crore, Rs. 3477.82 crore is pending for collection on account of litigation in various High Courts and the Supreme Court; Rs. 54.58 crore is pending for recovery with Collectors of various States; Rs. 5.05 crore is pending with BIFR/Official liquidators under DPCO 1995; and recovery of Rs. 161.30 crore is in process.

Recovery of the overcharged amount gets pending on account of stay orders passed by the various High Courts and the Supreme Court. All efforts have been made to recover the overcharged amounts from the companies through the following steps *viz*. urgent filing of application for vacation of interim orders by various Courts; pursuing cases with the concerned State Drug Controllers (SDCs) to urge upon the companies for early recovery of the overcharged amounts etc.

Comments of the Committee

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

Recommendation No. 7

The Committee note that under the Strategic Action Plan 2015, a pilot initiative will be launched during 2015-16 to reach out all sections of society with results and will be expanded across the country in the coming 3 years covering all therapeutic groups. The Committee were informed regarding Jan Aushadhi Scheme that the said Scheme will be launched in a new format from June 21st onwards in six States in the first phase. Rest of the States would be covered in second and third phases. Over a period of another one year time, Jan Aushadhi Stores are expected to be opened throughout the country in the medical colleges and district hospitals in the first phase. The Committee were further informed that the organisation which is responsible to implement this particular Jan Aushadhi scheme, the Bureau of Public Sector Pharmacy Companies is very weak organisation. Now the Department is strengthening that organisation. The Department is telling them to see that drugs are procured and stored adequately. Now, the Department is increasing the number of products also. Earlier there were 350 products, now the Department want to raise it to 500 plus products including surgical carton, syringes, etc.

The Committee, would like the Department to sort out all procedural issues well before actually launching the Strategic Action Plan 2015. The Committee would like to be apprised of the progress in the matter ensuring that generic drugs are made available at cheaper rate to the common man throughout the country at the earliest.

Reply of the Government

BPPI has been actively working to finalize Strategic Action Plan 2015 to ensure its role out as soon as possible. Keeping in view the delay in finalization of Strategic Action Plan Jan Aushadhi Stores with new format which was to be launched from June 21, 2015 has been postponed and is expected to be launched in August 2015.

BPPI is planning to open 3000 stores in Medical colleges, district Hospitals and by Charitable/NGOs/Entrepreneurs/Pharmacist in coming two years. The final shape of policy regarding opening of new stores is being finalized in SAP 2015. Through SAP 2015, BPPI is also strengthening organizational structure of BPPI to ensure that Jan Aushadhi scheme is made successful. Basket of drugs has already been increased to 500 medicines. Approx-160 items of consumables and disposable surgical has also been finalized and planned to be made available at Jan Aushadhi stores in SAP 2015. BPPI has also started strengthening its supply chain structure to ensure timely availability of medicines at Jan Aushadhi Stores.

Through this planning and effective implementation, BPPI is confident that generic drugs at cheaper rate will be made available to the common man throughout the country at the earliest.

Recommendation No. 8

The Committee note that the Department has 5 running PSUs under its administrative control *viz.* Karnataka Antibiotics and Pharmaceuticals Limited (KAPL), Rajasthan Drugs and Pharmaceuticals Limited (RDPL), Bengal Chemicals and Pharmaceuticals Limited (BCPL), Hindustan Antibiotics Limited (HAL) and Indian Drugs and Pharmaceuticals Limited (IDPL). Out of these KAPL is profit making, while RDPL has reported losses for the first time in 2013-14 and BCPL, HAL and IDPL are BIFR referred Companies. However, consistent with the policy to ensure availability of good quality life saving drugs at reasonable prices, Government of India has since approved rehabilitation scheme for revival of HAL and BCPL.

As the HAL is still incurring losses, the 2nd Rehabilitation Plan of HAL including the sale of some portion of surplus land has been approved by the Government. The Committee note that proceeds from sale of surplus land could generate a substantial amount for the revival of the company. The Committee expressed their displeasure that no significant progress on the proposal has been made. The Committee now expect that necessary action would be taken by the Government in the matter and the formalities would be finalised expeditiously to implement the 2nd rehabilitation Plan of HAL for the early revival of company and to ensure welfare of its employees.

As regard the sickness and Revival of BCPL the revival package for BCPL was approved by the Government on 21st December 2006. As envisaged in the Revival Scheme of BCPL, Government has so far released Rs. 207.19 crore in full as cash infusion component. The company has appointed Consultants for undertaking the work of up gradation and modernization of plant and machinery including compliance with Schedule 'M'/WHO GMP standards. The company is on the path of revival. The production sale and gross margin during the last 9 months of 2014-15 surpassed the production and sale during the last two financial year.

IDPL was declared as a sick industrial Company on 12th August, 1992. After failure to privatize IDPL, BIFR ordered its winding–up on 4.12.2003. AAIFR set aside the impugned order of BIFR dated 4.12.2003 and remanded the matter back to BIFR for taking further action for rehabilitation of IDPL and to pass further orders in accordance with law. GoM in its meeting held on 11.10.2007 advised that IDPL's revival plan should be based on public interest goals and ensuring the viability of the Company. Based on the observations made by GoM, in its meeting held on 11.10.2007, IDPL appointed a leading consultant Company E&Y to carry out the feasibility study. E&Y submitted its report to the Ministry/ DoP. A revised updated Draft Rehabilitation Scheme (DRS) has been prepared taking cut off date 31.3.2014 and submitted to the DoP/Ministry in January 2015 for consideration and approval. The DRS of IDPL is self-financing in nature in other words no fund will be sought from the Government rather the present assets will be sold off and the fund released will be used to payoff secured creditors. The Committee are given to understand that Government has also decided to sell surplus land of IDPL , Gurgaon to generate revenue. The Committee hope that with the sale of land, the IDPL would generate revenue which would help them to revive IDPL, Gurgaon.

The Committee are, however, unhappy with the slow pace of progress to revive the sick PSUs in spite of their repeated recommendations in this regard. The Committee once again reiterate its recommendation that the Department should make vigorous efforts in coordination with all concerned to expedite the revival of the sick PSUs in time bound manner. The Committee would like to be apprised of the action plan by the Department in this regard."

Reply of the Government

Hindustan Antibiotic Ltd.

IDBI, the Operating Agency appointed by BIFR for HAL has prepared and submitted the Modified Draft Rehabilitation Scheme (MDRS) in February, 2015. The same has been approved by Board of Directors of HAL. Action is being taken to prepare Cabinet Note and obtain necessary approval before approaching BIFR for sanctioning the second rehabilitation package for HAL.

Bengal Chemicals and Pharmaceuticals Ltd.

As regard the sickness and Revival of BCPL the revival package for BCPL was approved by the Government on 21st December, 2006. As envisaged in the Revival Scheme of BCPL, Government has so far released Rs. 207.19 Crore in full as cash infusion component. The company has appointed Consultants for undertaking the work of upgradation and modernization of plant and machinery including compliance with

Schedule 'M'/WHO GMP standards. The Company has taken initiative to commission Ointment, Cephalosporin and Betalactum Blocks which is as per Ministry's approval in its Appraisal Meeting for Revised Cost Estimate, held on 13.01.2015. The Company is on the path of revival. The Production, Sales and Gross Margin during the financial year 2014-15 surpassed the Production and Sales achieved during the last two financial years (*i.e.*, 2013-14 and 2012-13)."

	Financial Year 2014-15 (Rs. in cr.) Unaudited	Financial Year 2013-14 (Rs. in cr.) Audited	Financial Year 2012-13 (Rs. in cr.) Audited
Production	64.11	19.71	36.33
Sales	53.00	19.04	30.03
Gross Margin	(7.33)	(20.36)	(22.90)

Indian Drugs and Pharmaceuticals Ltd.

On the directions of BIFR, the Operating Agency *i.e.* IDBI drafted the Modified Draft Rehabilitation Scheme (MDRS) and submitted to the Department.

MDRS has since been approved by the Board of Directors of IDPL in their Board meeting dated 05.05.2015. Cabinet Note is under finalization and is expected to be circulated for inter-ministerial consultation shortly."

Comments of the Committee

(Please *see* Para No. 25 of Chapter I of the Report)

CHAPTER III

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

-Nil-

CHAPTER IV

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

-Nil-

CHAPTER V

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

Recommendation No. 1

The Committee note that the annual turnover of the Indian Pharmaceutical Industry is estimated to be about Rs. 128044.29 crore during the year 2013-14. This segment of Industry has shown tremendous progress in terms of infrastructure development, technology base and wide range of products. The industry has developed excellent GMP (Good Manufacturing Practices) compliant facilities for the production of different dosage forms. The Indian Pharmaceutical companies maintain highest standards in Purity, Stability and International Safety, Health and Environmental (SHE) protection in production and supply of bulk drugs. The country is almost self-sufficient in case of formulations. However, the Committee note with concern that a large sum of money is being spent on imports by the country. During the year 2013-14, Rs. 17944.05 crore was spent to import medicinal and pharmaceuticals products. According to the Department, the imports are being made on quality and economic considerations and not necessarily due to non-availability from domestic sources. However, the Committee is not satisfied with the explanation of the Department on this issue. The Committee are of the strong view that to realize the dream of 'Make in India' concept in pharmaceutical sector, the Government should boost and incentivize domestic bulk drug industry and discourage Indian pharmaceutical firms from importing. It is also essential that revival of closed/sick public sector units may be expedited to create capacity of bulk drugs in the country itself and to make the country self-reliant in bulk drugs as also recommended by the Committee in their 2nd Report. Incentives should be given for Research and Development in the pharmaceutical sector. In this context, the Committee note that the Government had constituted a committee under the chairmanship of Secretary, Department of Health and Research. The mandate of this Committee was to carefully study the whole issue of Active Pharmaceutical Ingredients (APIs) of critical importance by identifying important APIs and then working out a package of interventions/concession required to build domestic production capabilities and examine the cost implications. The said committee has reportedly submitted its report. Based on the recommendations of the said committee and consultations with stakeholders, the Department would come up with a policy on promotion of production of APIs in India. The Committee now expect from the Department to expedite the process of formulation of the policy on promotion of production of APIs in India. The Committee hope that as a result of the proposed policy, Indian pharmaceutical companies will be encouraged to produce bulk drugs in the country and consequently cheap and quality drugs will be available to the consumers in India. The Committee would like to know the initiatives taken to expedite the policy and the progress made in the matter so far.

Reply of the Government

The Government is examining the Katoch Committee recommendation for formulation of a policy for promotion of manufacturing of bulk drugs for being placed before the Cabinet.

Comments of the Committee

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

Recommendation No. 4

NIPER was declared as an "Institute of National importance" under the Act of Parliament on 26th June 1998. NIPER is a member of Association of Indian Universities. In addition to NIPER, SAS Nagar, Mohali the Government had set up six new NIPERs at Hyderabad, Hajipur, Ahmedabad, Raebareli, Guwahati and Kolkata. These New NIPERs will cater to the growing demand of the pharmaceutical industry for highly trained manpower for continuous growth of the pharmaceuticals sector with increased focus on R&D, particularly after the amendment of Indian Patent Act. At present, new NIPERs are functioning with the assistance of the Mentor Institutes. However, the six New NIPERs are yet to be provided with buildings and regular faculty. In the year 2015-16 it is proposed to construct buildings and provide regular faculties for the six NIPERs. However, the budgetary provision is very limited to take up the same. Thus a supplementary demand is being proposed. Further the Department proposed setting up of three new NIPERs at Andhra Pradesh, Madhya Pradesh and Karnataka. The Budget Speech for 2015-16 lists three new NIPERs at Maharashtra, Rajasthan and Chhattisgarh. The Committee further observed that the work relating to construction of NIPER Campus at Guwahati and Gandhinagar has since been awarded to Engineering Projects (India) Ltd. and Hindustan Steelworks Constructions Ltd. respectively. Further, the Committee noted that

Department has not spent the money because it got into all the procedural difficulties. To construct one NIPER the State Governments have to give 100 acres of land free of cost and then only NIPER is sanctioned. The Committee have been apprised that State Governments do not provide adequate land that is why construction activities cannot be started immediately. The Committee therefore recommend that the Department of Pharmaceuticals should take up the matter with State Governments at the highest level and impress upon them to provide land for NIPER without any delay. Further they may also take up the matter with the Finance Ministry for required fund allotment after substantial work is in progress. The Committee would like to be apprised of the progress made in this regard.

Reply of the Government

The Department has since awarded the work of construction of NIPER campus from concept to completion at Guwahati to Engineering Project India Ltd. (EPIL) and Gandhinagar to Hindustan Steelworks Constructions Ltd. (HSCL). Memorandum of Understanding (MoU) is to be signed by NIPER, Hyderabad with the National Project Construction Corporation (NPCC) Ltd. After signing the MoU, funds would be released to NIPER for making available to the concerned PSU so as to enable them to commence work relating to construction of NIPER campus at Gandhinagar and Hyderabad. The construction of NIPERs Guwahati, Ahmedabad and Hyderabad will start during the current year. However, construction could not be taken up as sufficient fund has not been provided. Department is planning for supplementary demands/budget proposal for additional funds to undertake construction properly.

The issue of allotment of land with respect to NIPERs at Hajipur, Kolkata and Raebareli are yet to be resolved.

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

National Institute of Pharmaceutical Education and Research (NIPER), Kolkata was set up after the State Government committed to provide 100 acrec of land free of cost. Subsequently, State Government allotted 35 acres land free of cost at Baruipur. However, out of 35 acres, NIPER was required to spare 10 acres for common facilities, which leaves a very small piece of land for setting up of an Institute of national importance. In addition, State Government wanted Government of India to pay for the External Development Charges (EDC). Since, Union Cabinet approved setting up of NIPERs in other parts of country, including Kolkata, on the premise that 100 acres of land would be provided free of cost by the State Governments. Therefore, it is not possible to pay for

EDC. The matter has been followed up vigorously with the State Government for allotment of 100 acres of land near Kolkata free of cost and free from all encumbrances. A letter has also been written on 29.12.2014 by Hon'ble Minister (C&F) to the Chief Minister of West Bengal. However, response from the State Government is yet to be received.

Status of land allocation at NIPER, Hajipur (Bihar)

I. Based on the firm assurances given in writing by the State Government of Bihar for allotment of 100 acre land free of cost, this Department set up NIPER at Hajipur in 2007 under the mentorship of Rajendra Memorial Research Institute of Medical Sciences (RMRIMS), Patna. Since, 2007, NIPER is functioning in the EPIP Campus, BIADA Industrial Area, Hajipur. State Government has, however, not yet allotted the land for setting up full-fledged NIPER Campus at Hajipur, in spite of the matter being followed up with the State Government at Chief Minister and Chief Secretary level.

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

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

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

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

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

NIPER, Raebareli

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

Setting up of Three new NIPERs

The Hon'ble Finance Minister in his Budget Speech for 2015-16 announced setting up of three new NIPERs. However, no budget allocation has been made. The matter is being taken up with Ministry of Finance for allocation of fund.

Comments of the Committee

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

NEW DELHI;
5 *October*, 2015
13, *Asvina*, 1937 *(Saka)*

ANANDRAO ADSUL,
Chairperson,
Standing Committee on
Chemicals and Fertilizers.

APPENDIX I

MINUTES

MINUTES OF THE SECOND SITTING OF THE STANDING COMMITTEE ON CHEMICALS AND FERTILIZERS (2015-16)

The Committee sat on Tuesday, the 22nd September, 2015 from 1500 hrs. to 1530 hrs. in Committee Room 'C', Parliament House Annexe, New Delhi.

PRESENT

Shri Anandrao Adsul — *Chairperson*

MEMBERS

Lok Sabha

2. Shri Idris Ali
3. Shri Anju Bala
4. Shri Sankar Prasad Datta
5. Shri K. Ashok Kumar
6. Shri Chhedi Paswan
7. Shri Chandu Lal Sahu
8. Dr. Kulamani Samal
9. Shri Tasleem Uddin
10. Smt. Rekha Arun Verma
11. Shri Kotha Prabhakar Reddy

Rajya Sabha

12. Shri Narayan Lal Panchariya
13. Shri K. Parasaran

14. Shri Mansukh L. Mandaviya

15. Shri Abdul Wahab

SECRETARIAT

1. Smt. Rashmi Jain — *Joint Secretary*
2. Shri A.K. Srivastava — *Director*

2. At the outset, the Hon'ble Chairperson welcomed the members of the Committee.

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

(a) Action Taken Report on Demands for Grants (2015-16) of the Ministry of Chemicals and Fertilizers (Department of Chemicals and Petrochemicals); and

(b) Action Taken Report on Demands for Grants (2015-16) of the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals).

4. Both the draft Action Taken Reports were adopted by the Committee without any amendment.

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

6. The Committee decided to undertake a study tour to Kochi, Munnar, Chennai, Mumbai, Vadodra and Dahej from 2nd to 6th November, 2015. The Committee also decided to hold the next sitting on 07 October, 2015.

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 SIXTH REPORT (SIXTEENTH LOK SABHA) OF THE STANDING COMMITTEE ON CHEMICALS AND FERTILIZERS (2014-15) ON 'DEMANDS FOR GRANTS (2015-16)' OF THE MINISTRY OF CHEMICALS AND FERTILIZERS (DEPARTMENT OF PHARMACEUTICALS)

I. Total No. of Recommendations 8

II. Observations/Recommendations which have been accepted by the Government:

(*Vide* Recommendation Nos. 2, 3, 5, 6, 7 and 8)

Total : 06
Percentage : 75%

III. Observations/Recommendations which the Committee do not desire to pursue in view of the Government's reply:

-Nil-

Total : 00
Percentage : 00

IV. Observations/Recommendations in respect of which reply of the Government have not been accepted by the Committee and which require reiteration:

-Nil-

Total : 00
Percentage : 00

V. Observations/Recommendations in respect of which final replies of the Government are still awaited:

(*Vide* Recommendation No. 1 and 4)

Total : 02
Percentage : 25%