

STANDING COMMITTEE ON CHEMICALS & FERTILIZERS (2010-11)

## FIFTEENTH LOK SABHA

# MINISTRY OF CHEMICALS AND FERTILIZERS (DEPARTMENT OF PHARMACEUTICALS)

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## DEMANDS FOR GRANTS (2010-2011)

[ Action Taken by the Government on the Observations/ Recommendations contained in the Seventh Report of the Standing Committee on Chemicals and Fertilizers (Fifteenth Lok Sabha) on Demands for Grants (2010-11) of the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals)]



# SIXTEENTH REPORT

LOK SABHA SECRETARIAT NEW DELHI

August, 2011/Sharvana, 1933 (Saka)

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Presented to Lok Sabha on 04.08.2011

Laid in Rajya Sabha on 04.08.2011



## LOK SABHA SECRETARIAT NEW DELHI

August, 2011/Sharvana, 1933 (Saka)

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## COMPOSITION OF THE STANDING COMMITTEE ON CHEMICALS & FERTILIZERS (2010-11)

| Shri | Gopinath Munde - Chairman<br>MEMBERS<br>LOK SABHA |
|------|---|
| 2    | Smt. Susmita Bauri                                |
| 3    | Shri Udayanraje Bhonsle                           |
| 4    | Shri Prabhatsinh P. Chauhan                       |
| 5    | Smt. Santosh Chowdhary                            |
| 6    | Shri K.D. Deshmukh                                |
| 7    | Adv. Ganeshrao Nagorao Dudhgaonkar                |
| 8    | Shri T.K.S. Elangovan                             |
| 9    | Shri Madhu Koda                                   |
| 10   | Shri N. Peethambara Kurup                         |
| 11.  | Shri Baidya Nath Prasad Mahato                    |
| 12   | Shri Jagdambika Pal                               |
| 13   | Shri Tapas Paul                                   |
| 14   | Shri Ponnam Prabhakar                             |
| 15   | Shri Ashok Kumar Rawat                            |
| 16   | Shri Suresh Kumar Shetkar                         |
| 17   | Shri Ajit Singh                                   |
| 18   | Shri N. Chaluvaraya Swamy                         |
| 19   | Shri Narendra Singh Tomar                         |
| 20   | <sup>#</sup> Dr. Manda Jagannath                  |
| 21   | Vacant  |
|      | RAJYA SABHA                                       |
| 22   | Shri Silvius Condpan                              |
| 23   | Smt. Naznin Faruque                               |
| 24   | Shri A.A. Jinnah                                  |
| 25   | Shri Brijlal Khabri                               |
| 26   | Prof. Anil Kumar Sahani                           |
| 27   | Shri Raghunandan Sharma                           |
| 28   | Dr. C.P. Thakur                                   |
| 29   | <sup>&amp;</sup> Shri Parshottam Khodabhai Rupala |
| 30   | <sup>8</sup> Shri Abani Roy                       |
| 31   | <sup>&amp;</sup> Shri Biswajit Daimary            |

## SECRETARIAT

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1. Shri N. K. Sapra

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- 2. Shri Ashok Sarin
- 3. Shri C.S.Joon
- 4. Shri A.K.Srivastava
- Secretary
- Joint Secretary
- Director
  - Additional Director
- & Nominated w.e.f. 21.09.2010
- # Nominated w.e.f. 04.10.2010

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#### INTRODUCTION

I, the Chairman, Standing Committee on Chemicals and Fertilizers (2010-11) having been authorised by the Committee to present the Report on their behalf present this Sixteenth Report (Fifteenth Lok Sabha) on Action Taken by the Government on the observations / recommendations contained in the Seventh Report (Fifteenth Lok Sabha) of the Standing Committee on Chemicals and Fertilizers (2010-11) on 'Demands for Grants (2010-11)' of the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals).

2. The Seventh Report (Fifteenth Lok Sabha) of the Standing Committee on Chemicals and Fertilizers was presented to Lok Sabha on 26 April, 2010. The Action Taken replies of Government to all observations / recommendations contained in the Report were received on 20 July, 2010. Subsequently, at the behest of the Committee, the Department vide LSS OM dated 3 June 2011 was requested to furnish latest/ updated Action Taken replies on the previous Action Taken replies in order to cover any new development that might have occurred. Accordingly, the Department furnished their updated Action Taken replies on 11 July 2011. The Standing Committee on Chemicals and Fertilizers (2010-11) considered and adopted this Report at their sitting held on 18 July 2011.

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

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

New Delhi; <u>28 July, 2011</u> 6 Shravana, 1933 (Saka) Gopinath Munde Chairman, Standing Committee on Chemicals and Fertilizers

#### REPORT

#### CHAPTER – I

This Report of the Standing Committee on Chemicals and Fertilizers deals with the action taken by the Government on the Observations/Recommendations contained in the Seventh Report (Fifteenth Lok Sabha) of the Committee on Demands for Grants (2010-11) of the Ministry of Chemicals & Fertilizers (Department of Pharmaceuticals) which was presented to Lok Sabha on 26.04.2010. The Report contained 11 Observations / Recommendations.

2. The Ministry of Chemicals & Fertilizers (Department of Pharmaceuticals) were requested to furnish replies to the Observations / Recommendations contained in the Seventh Report within three months from the date of presentation of the Report, <u>i.e.</u>, by 25 July 2010. The Action Taken Replies of the Government in respect of all the 11 Observations / Recommendations contained in the Report have been received from the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals) <u>vide</u> their O.M. No.16(2)/2010-Fin.II, dated 20 July 2010. Subsequently, at the instance of the Committee, the Department of Pharmaceuticals were requested on 03.06.2011 to furnish updated Action Taken Replies regarding the details about the Supplementary Demands for Grants obtained by the Department during 2010-11. Accordingly, the Department have furnished their updated Action Taken Replies of the Government is as follows:-

(i) Observations/Recommendations which have been accepted by the Government: SI.Nos. 2,6,8,9, and 11 (Total = 5)

(10tal = 5) Chapter II

(ii) Observations/Recommendations which the Committee do not desire to pursue in view of the Government's reply: SI.No. Nil (Total = NIL)

Chapter III

(iii) Observations/Recommendations in respect of which replies of the Government have not been accepted by the Committee and which require reiteration:-SI.No. 5,4,7

(Total = 3)

Chapter IV

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

SI.Nos. 1,3, and 10 (Total = 3)

Chapter V

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

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

#### Α Full utilization of the funds allocated to National Institute of Pharmaceutical Education & Research (NIPER) and development of Quality and Excellence in Pharma Education and Research

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

5. The Committee in Recommendation No.4 of their original Report had noted that the budgetary grant for NIPER during 2009-10 was Rs. 57.04 crore under plan allocation and Rs. 20 crore under non plan allocation at BE stage. The plan allocation was, however, reduced to Rs. 47.15 crore at RE stage and the actual plan expenditure upto 31 January 2010 was Rs. 39.65 crore. For this year i.e 2010-11, Rs. 61 crore has been provided as plan allocations and Rs. 19.64 crore as non plan allocation at BE stage. The Committee hope that these funds will be fully utilized and NIPER would be able to develop quality and excellence in pharma education and research so as to strengthen its links with both at National and International levels.

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

"The entire RE allocation of Plan & Non-Plan expenditure in 2009-10 for 6. NIPER head was released by year end. In 2010-11 also, Department plans to use the entire plan & non-plan allocations for NIPERs to meet targets. Agencies are in the process of being finalized to start the developmental/infrastructural work in the new NIPER(s)".

The Department of Pharmaceuticals in their Action Taken Replies dated 11 July 2011 has stated as under:-

"In 2009-10 the entire plan allocation of Rs. 47.15 crore was sanctioned & 7. released to NIPERs. Similarly, Non-Plan allocation of Rs.20.92 crore was released to NIPER in 2009-10. Details of the year 2010-11 are tabulated. Fund was released as per the requirement.

|             | BE allocation<br>(including NE) | RE allocation<br>(including NE) | Actual Release |
|-------------|---------------------------------|---------------------------------|----------------|
| Plan        | 77.50                           | 59.08                           | 30.65          |
| Non<br>Plan | 19.04                           | 24.04                           | 20.64          |

The Committee in Recommendation SI.No.4 had hoped that the funds 8 allocated would be fully utilized by NIPER and would be able to develop quality and excellence in pharma education and research so as to strengthen its links with both at National and International levels. However, the Committee are not satisfied with the updated reply furnished by the Department, as it states that the fund was released as per the requirement. As the reply is silent as to whether these actually released funds have been fully utilized and whether NIPER has been able to develop Quality and Excellence in Pharma education and research. The Committee, therefore, reiterate their earlier recommendation and would like to be apprised about the actual status on these issues through further action taken replies of the Department.

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

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

The Committee in Recommendation No.5 of their original Report had noted that 9 the National Pharmaceutical Pricing Authority (NPPA) had been responsible for price fixation/revision of drugs and formulations. NPPA also monitors the prices of decontrolled drugs and formulations, enforce and implement the provisions of the Drugs (Prices Control) Order (DPCO),1995. An amount of Rs.7.06 crore (0.99 crore under plan and Rs. 6.07 crore non plan) had been earmarked for NPPA at BE-2010-11. The major part of this allocation was meant for the new scheme 'Proposal for Building Robust and Responsive Statistical System for NPPA'. The Committee had also noted that out of the five schemes proposed by NPPA for the Eleventh Five Year Plan, four schemes were yet to get 'in principle' approval of the Planning Commission. The Committee feel that half-hearted approach can never

produce the desired results. They, therefore, strongly recommend that the Department of Pharmaceuticals should expeditiously take up the issue with the Planning Commission regarding early approval of the schemes proposed by the NPPA. The Committee may be apprised of the progress made in this regard.

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

"Out of five components of the scheme proposed by the Department, Planning Commission has accorded 'in principle' approval to only one component concerning 'Building Robust & Responsive Statistical System for NPPA' in March,2008. Further, it was mentioned that Planning Commission will take a view on the publicity campaign scheme after consulting with the Department of Consumer Affairs. It was also mentioned that the other components proposed for strengthening and monitoring of prices of drugs and pharmaceuticals would be taken up after the finalization of the Draft Pharmaceutical Policy. Department is pursuing with the Planning Commission for delinking the matter from the finalization of the draft Policy and according 'in principle' approval for the remaining schemes. The matter has again been recently taken up with the Planning Commission by Secretary (Pharmaceuticals) vide his D.O. letter dated 10.3.2010".

11 The Department of Pharmaceuticals in their Action Taken Replies dated 11 July 2011 has stated as under:-

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

12. The Committee had observed that out of five schemes for the Eleventh Five Year Plan, proposed by National Pharmaceutical Pricing Authority (NPPA) only two schemes, viz. the 'Proposal for Building Robust and Responsive Statistical System, for NPPA', and Proposal for consumer awareness and publicity through print, electronic and other Media has got in principle approval from the Planning Commission, while three schemes, namely, (i) Creation of NPPA cells in States (ii) Scheme for interaction with States and (iii) Proposal for strengthening the existing Monitoring & Enforcement work are yet to get the The Planning Commission has intimated that for in principle approval. remaining components proposal may be considered to be integrated in Twelfth Five Year Plan schemes of NPPA subject to its relevance and establishment of Accordingly, the issue is being considered by NPPA/Department of need. Pharmaceuticals. In this regard, the Committee in their earlier recommendation

had opined that half-hearted approach of the Department, for getting its pending schemes approved, can never produce the desired results and they had also recommended that the Department should expeditiously take up the issue with the Planning Commission regarding early approval of the schemes proposed by NPPA and they be apprised of the progress made in this regard.

The Committee are not satisfied with the reply furnished by the Department and strongly deplore the lethargic and bureaucratic approach of the Department as well as of the Planning Commission. This is evident from the fact that out of the five schemes proposed by the Department which were meant for implementation during Eleventh Five Year Plan only two schemes got <u>'in principle'</u> approval of the Planning Commission and remaining three schemes meant for strengthening and monitoring of prices of drugs and pharmaceuticals have been kept pending even after a lapse of more than three and a half years.

The Committee also regret to note the tardy efforts being made by the Department for pursuing the matter with the Planning Commission for delinking the issue from finalization of the Draft Pharmaceutical Policy. The Committee are also unhappy to note that linking of 'in principle' approval to the remaining schemes proposed by NPPA with finalization of the Draft Pharmaceutical Policy is creating hurdles in the path of NPPA for implementation of the remaining three schemes.

The Committee, therefore, desire to be apprised of the progress made in this regard along with the reasons for delays on the part of the Department of Pharmaceuticals as well as the Planning Commission in respect of 'in principle' approval for remaining three schemes proposed by NPPA and the time limit by which these pending schemes will get in-principle approval and be implemented. The Committee, therefore, strongly reiterate that the Department of Pharmaceuticals should make an all-out effort to get the approval and to implement the five schemes under 'Proposal for Building Robust and Responsive Statistical Scheme for NPPA'. The Committee desire that they may be apprised of the progress made in this regard within three months of presentation of this report.

C Concrete action taken by the Government for up gradation of manufacturing facilities in IDPL conforming to WHO-GMP Standards 13 The Committee in Recommendation No.7 of their original Report had noted that the Committee have been informed that at the instance of Cabinet Secretariat, a draft note is stated to have been prepared by the Department and is being finalized for consideration by the Cabinet for revival of IDPL, which had been discharging the social responsibility of manufacturing and providing drugs to the general public at reasonable rates. The revival of IDPL being of paramount importance, the Committee desire that the revival plan should be expedited at a much quicker pace. Steps should also be taken for up gradation of manufacturing facilities in IDPL conforming to WHO-GMP standards. The Committee feel that by doing so IDPL would be able to effectively compete with the major pharmaceutical industries in private sector in respect of quality medicines and ultimately would instill confidence in the people. The Committee would therefore, expect concrete action by the Government in this behalf.

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

"The draft Cabinet Note for revival of IDPL is under submission to the M(C&F). This Department is also considering the proposal for upgradation of manufacturing facilities in IDPL conforming to WHO-GMP Standards. Meanwhile proposal for making the company schedule M compliant has already been sent to Planning Commission for an in-principle approval".

15 The Department of Pharmaceuticals in their Action Taken Replies dated 11 July 2011 has stated as under:-

"IDPL has appointed consulting firm M/s E & Y for preparation of revival plan. The said consultant has since submitted the updated draft report on 08-06-2011. The revival plan has been prepared keeping in mind competition from the private sector and the Social Objective as laid down by the GoM. The same is being examined in the Ministry. This Department is also considering the proposal for up gradation of manufacturing facilities in IDPL conforming to WHO-GMP Standards".

16 The Committee note from the action taken reply as well as from updated

action taken reply of the Department to this Recommendation No.7 that the revival plan has been prepared keeping in mind competition from the private sector and the Social Objective as laid down by the GoM. The same is being examined in the Ministry. This Department is also considering the proposal for upgradation of manufacturing facilities in IDPL conforming to WHO-GMP Standards. The Committee would like to be apprised of the concrete action from the Ministry/Department on both the issues in a stipulated time frame of three months from the date of presentation of this Report to the Parliament.

#### CHAPTER II

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

#### **Recommendation No. 2**

What has caused concern to the Committee is the fact that during the Year 2009-10, the Department could spend only Rs. 76.09 crore (upto 31 January 2010) as against BE of Rs. 155.25 crore and RE Rs. 105.00 crore. This indicates that the Department has not been able to utilize even the reduced funds which have been made available to them during 2009-10. Similar was the position even in each of the three Years of the plan, a fact which was commented upon by the Committee in their earlier Report. The Committee are inclined to conclude that on the one hand Department has not been provided the requisite funds by the Planning Commission and on the other even the curtailed allocation has not been fully utilized by them. The Committee desire that the Ministry gear up their machinery and ensure that the sanctioned outlays are utilized in a proper manner during the last two Years of the plan period so that the avowed objectives are fully achieved. The new initiatives by the Department are also necessary for the sustained growth of the pharma sector so that the creation of the Department of Pharmaceuticals as a distinct entity is fully justified.

#### **Reply of the Department**

New schemes proposed by the Department got delayed in finalization due to the time taken by procedural/appraisal/approval mechanism. Therefore, utilization of funds earmarked for the schemes was delayed. However, RE allocation of Rs.105 crore was utilized to the extent of Rs.102.18 crore i.e.97.31%.

(Department of Pharmaceuticals O.M. No.16(2)/2010-Fin.II dated July 20, 2010)

#### Further reply of the Department

The Department of Pharmaceuticals in their Action Taken Replies dated 11 June 2011 has stated as under:-

"New schemes proposed by the Department got delayed in finalization due to the time taken by procedural/appraisal/approval mechanism. Therefore, utilization of funds earmarked for the schemes was delayed. However, RE allocation of Rs.105 crore was utilized to the extent of Rs.102.18 crore i.e. 97.31% in 2010-11 which is an improvement from 2009-10."

> (Department of Pharmaceuticals O.M. No.16(2)/2010-Fin.II dated July 8, 2011)

#### **Recommendation No. 6**

The Public Sector Undertakings (PSUs) in the pharmaceuticals sector were expected to enable and ensure production and availability of medicines to the common people at large. The Committee regret to note that the present status of the Pharma PSU under the administrative control of the Department of Pharmaceuticals, two undertakings viz., the Smith Stanistreet Pharmaceuticals Limited (SSPL) and the Bengal Immunity Limited (BIL) have been closed and are under liquidation since 2003. Three PSUs viz., the Indian Drugs and Pharmaceuticals Limited (IDPL), the Bengal Chemicals and Pharmaceuticals Limited (BCPL) and the Hindustan Antibiotics Limited (HAL) were declared sick and referred to the Board for Industrial and Financial Reconstruction (BIFR) as they were incurring continuous losses. They are now under different stages of revival/rehabilitation packages. Only two companies, viz., the Karnataka Antibiotics and Pharmaceuticals Limited (KAPL) and the Rajasthan Drugs and Pharmaceuticals Limited (RDPL) are currently making profits. Collectively, the Pharma PSUs have been incurring losses continuously for the last several years. The Committee cannot but express their serious concern over the general plight of the Pharma PSUs which ultimately has an adverse effect on the lives of common people in one way or the other. The Committee, therefore, recommend that all pending proposals for the revival of Pharma PSUs should be expeditiously considered and Government should extend every possible help to bring the PSUs back to the track. The Committee desire to be apprised of the updated status in this behalf.

#### **Reply of the Department**

The financial performance of HAL, BCPL & IDPL respectively as on 31<sup>st</sup> March 2006 were as under:-

|      |            |       | (Rupees in crore) |
|------|------------|-------|-------------------|
| CPSE | Production | Sales | Profit/Loss       |
| HAL  | 47.25      | 49.21 | (34.81)           |
| BCPL | 68.76      | 52.23 | (8.45)            |
| IDPL | 7.09       | 6.86  | (335.58)          |

Government approved the Rehabilitation Scheme of HAL on 9<sup>th</sup> March 2006 which inter alia involved Cash infusion of Rs. 137.59 crore and Waiver from Gol to the extent of Rs. 259.43 crore. Funds as approved in the Rehabilitation Scheme were made available to HAL during 2006-07. Further, to upgrade the manufacturing facilities to international WHO-GMP standards, and therefore ensure quality & productivity, Government provided Rs. 20.17 crore to HAL for setting up separate manufacturing facilities of Cephalosporin and Betalactum antibiotics complying to WHO-GMP standards during 2007-08 and Rs. 10 crore for upgradation of other Tablets/Capsule manufacturing facilities to WHO-GMP standards.

Similarly, Government also approved the Rehabilitation Scheme of BCPL on 21<sup>st</sup> December 2006, which inter alia involved Cash infusion of Rs. 207.19 crore and Waiver of Rs. 233.19 crore. Out of Rs. 207.19 crore of Cash Infusion, Rs. 201.59 crore has been sanctioned to BCPL as approved in the Rehabilitation Scheme, with

the targeted period of commissioning of projects as July-Aug. 2010. The rehab package of IDPL duly prepared by a consultant has been put up for the approval of the Minister of C&F.

|  | Performance of | CPSEs as from | 31 <sup>st</sup> March | 2007 ar | nd onwards |
|--|----------------|---------------|------------------------|---------|------------|
|--|----------------|---------------|------------------------|---------|------------|

|       |           |            |        |                 |                                      |           |        | ()     | Rupees in o     | crore)   |
|-------|-----------|------------|--------|-----------------|--------------------------------------|-----------|--------|--------|-----------------|--|
| CPSEs |           | Production |        |                 |                                      |           | Sales  |        |                 |  |
|       | 06-<br>07 | 07-08      | 08-09  | 09-10<br>(Prov) | % increase<br>in 09-10<br>over 06-07 | 06-<br>07 | 07-08  | 08-09  | 09-10<br>(Prov) | %<br>increa<br>se in<br>09-10<br>over<br>06-07 |
| HAL   | 48.96     | 119.81     | 155.00 | 158.09          | 223                                  | 49.22     | 106.59 | 106.59 | 160.04          | 225  |
| BCPL  | 70.89     | 55.69      | 89.63  | 89.63           | 26                                   | 45.69     | 51.14  | 86.82  | 78.24           | 71   |
| IDPL  | 17.90     | 62.13      | 93.25  | 108.10          | 504                                  | 15.97     | 56.70  | 87.40  | 96.34           | 503  |

It may be seen from the above that as a result of a continuous endeavour of the Department, the performance of CPSEs are substantially improved and it is expected that these companies will be able to generate desired results in the near future. Efforts are also on to make the PSUs Schedule-M compliant and funds for the purpose have been released to BCPL and HAL.

(Department of Pharmaceuticals O.M. No.16(2)/2010-Fin.II dated July 20, 2010)

#### Further reply of the Department

The Department of Pharmaceuticals in their Action Taken Replies dated 11 June 2011 has stated as under:-

"Apart from KAPL and RDPL, the financial performance of HAL, BCPL & IDPL respectively as on 31<sup>st</sup> March 2006 were as under:-

|      |            |       | (Rupees in crore) |
|------|------------|-------|-------------------|
| CPSE | Production | Sales | Profit/Loss       |
| HAL  | 47.25      | 49.21 | (34.81)           |
| BCPL | 68.76      | 52.23 | (8.45)            |
| IDPL | 7.21       | 6.86  | (335.58)          |

#### <u>HAL</u>

Government approved the Rehabilitation of the company on 9<sup>th</sup> March 2006 followed by BIFR approval on 5<sup>th</sup> June 2007 which inter alia involves Cash Infusion by GoI to the extent of Rs. 137.59 crore and write off of Ioan and waiver of interest to the extent of Rs. 259.43 crores. The entire cash infusion of Rs. 137.59 crores has been released to the company. Parliament has approved writing off of Ioan and waiver of interest to the extent of Rs. 259.43 crores.

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

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

HAL has completed the work on Cephalosporin in record time of 9 months. It has commenced commercial production in February, 2009 and also obtained WHO-Certification for the same. Work relating to upgradation of existing vialling facilities for Betalactum Antibiotics has also been completed and validation of equipments & facilities is in progress and production will start in July 2011. As regards the upgradation project for Tablet, Capsule and Liquid Sections complying to WHO-GMP standards at an estimated cost of Rs. 10.00 crore, HAL has reported that the project activities of upgradation of Quality Control has been completed in May, 2011 and keeping in view the utilization of existing manufacturing facilities during last quarter of the financial year, Non-Parenteral upgradation was planned after March 2011. The work of engaging consultant, conceptual layout has been completed. FDA concurrence for layout is under consideration and is expected by mid June 2011. Basic Engineering work related to Civil works, Finalizing broad specification of equipment and machinery is in progress. Also the tendering process for procurement of major equipment, tendering process for civil, electrical, mechanical and HVAC works to be carried out are in progress. Tentatively the entire project activities related to Non-Parenteral upgradation is expected to be completed within a period of six months.

Apart from the above, in order to utilize the above bulk fermentation facilities, Government sanctioned project for production of Erythromycin which was viable as per initial techno-financial survey by the company. However, the fermentation technology for Erythromycin could not be sourced by HAL on a financially viable basis in spite of global tender. Accordingly, now the setting up of the Erythromycin plan by utilization of existing fermentation facilities is being re-examined. The staff and other utility overheads expenses of the existing fermentation plant has to be however borne by the company which adds up to the losses of the company.

#### Production & Sales:

Details of Production & Sales of HAL from 2007-08 onwards are as under:

|                |                |                |                 | (Rs. In crore)  |
|----------------|----------------|----------------|-----------------|-----------------|
|                | <u>2007-08</u> | <u>2008-09</u> | <u>2009-10*</u> | <u>2010-11*</u> |
| Production     | 119.81         | 155.00         | 123.16          | 84.92           |
| Sales Turnover | 106.59         | 147.39         | 118.26          | 95.14           |

\* Provisional

#### <u>BCPL</u>

Similarly, Government approved the Revival Scheme of BCPL on 21<sup>st</sup> December 2006 which inter alia comprised cash infusion of Rs. 207.19 crore out of which Rs. 206.59 crore has already been released to BCPL. The company appointed Consultants for undertaking the work of up-gradation & modernization of plant &

machinery including compliance with Schedule 'M'/WHO GMP standard. The civil construction, commissioning of plant & machinery/utilities & ETP in Panihati has been completed and commercial production has been commenced. In Maniktala Factory, Store Building, Utilities, ETP, Roads, drains have been completed and installation & commissioning of betalactum & Cephalosporin Block and Ointment Block are in progress. ASVS and Liquid Block, Power block as reported by BCPL have been held up due to Court Case. Tablet, ORS, renovation/upgradation of existing block, Sterile Block etc in Kanpur Factory [as reported by BCPL] are in progress.

#### Production & Sales:

Details of Production & Sales of BCPL from 2007-08 onwards are as under:

|                |                |                 |                 | (Rs. In crore)  |
|----------------|----------------|-----------------|-----------------|-----------------|
|                | <u>2007-08</u> | <u>2008-09*</u> | <u>2009-10*</u> | <u>2010-11*</u> |
| Production     | 55.69          | 89.63           | 83.24           | 80.12           |
| Sales Turnover | 48.59          | 86.82           | 78.24           | 76.21           |

\* Provisional

The implementation of the Revival Package including closing down of old products & replacement with new ones is underway. This has caused mandatory reduction in stoppage of some production operations. Impact of up-gradation/modernization work will be visible in 2011-12.

#### <u>IDPL</u>

IDPL has appointed consulting firm M/s E & Y for preparation of revival plan. The said consultant has since submitted the updated draft report on 08-06-2011. The revival plan has been prepared keeping in mind competition from the private sector and the Social Objective as laid down by the GoM. The same is being examined in the Ministry. When implemented, IDPL should start making operating profit from 7<sup>th</sup> Year of implementation of the Revival Plan as per the Report. Apart from this, this Department is also considering the proposal for upgradation of manufacturing facilities in IDPL conforming to WHO-GMP Standards".

> (Department of Pharmaceuticals O.M. No.16(2)/2010-Fin.II dated July 8, 2011)

#### **Recommendation No. 8**

The Committee note that the revival scheme for Bengal Chemicals and Pharmaceuticals Limited (BCPL) has been approved by the Government. The Committee recommends that the revival plan of the company which had been engaged in manufacturing and marketing a variety of products should be expedited with a missionary zeal in a time bound programme. They also desire that periodical monitoring of the implementation of the revival plan be done at the senior-most level in the Ministry so as to ensure that the revival plan is carried out at a fast pace and also that the funds are fully utilized. The Committee would therefore, expect concrete action in a time-bound framework by the Government in this behalf.

#### **Reply of the Department**

Out of total Cash Infusion of Rs. 207.19 crore envisaged in the Revival Scheme of BCPL, Rs. 201.59 crore has been sanctioned to BCPL and balance will also be released during this financial year itself. Out of total release till 2009-10 (Rs. 181.59 crore), BCPL has reported that only Rs. 16.53 crore is unspent and the same will be utilized by July 2010.

The monitoring of the implementation of the revival plan of BCPL is being done by the Senior Officers of the Department to ensure timely implementation of Projects.

> (Department of Pharmaceuticals O.M. No.16(2)/2010-Fin.II dated July 20, 2010)

#### Further reply of the Department

The Department of Pharmaceuticals in their Action Taken Replies dated 11 June 2011 has stated as under:-

"Out of total Cash Infusion of Rs. 207.19 crore envisaged in the Revival Scheme of BCPL, Rs. 206.59 crore has been sanctioned to BCPL till 2010-11 and balance will be released during this financial year as per the requirement and utilization status of BCPL. Out of total release till 2010-11 (Rs. 206.59 crore), BCPL has reported that only Rs. 6.70 crore is unspent.

The company appointed Consultants for undertaking the work of up gradation & modernization of plant & machinery including compliance with Schedule 'M'/WHO GMP standard. The civil construction, commissioning of plant & machinery/utilities & ETP in Panihati has been completed and commercial production has been commenced. In Maniktala Factory, Store Building, Utilities, ETP, Roads and drains have been completed and installation & commissioning of betalactum & Cephalosporin Block and Ointment Block are in progress. ASVS and Liquid Blcok, Power block as reported by BCPL have been held up due to Court Case. Tablet, ORS, renovation/upgradation of existing block, Sterile Block etc in Kanpur Factory [as reported by BCPL] are in progress.

Monitoring of the implementation of the revival plan of BCPL is being done through inspection visits of senior Officers of this Department.

#### **Recommendation No. 9**

The Committee note that the Government has approved the rehabilitation scheme of Hindustan Antibiotics Limited (HAL). Further, the Government has sanctioned the scheme for upgradation of manufacturing facilities of HAL conforming to WHO-GMP standards. The Committee hope that HAL would be able to show perceptible improvement in its performance in the years to come and that the company would be able to generate profit, in addition to fulfilling its social obligations in a meaningful manner.

#### **Reply of the Department**

To get the Company fully revived in true sense, Department approved the project for setting up of new Cephalosporin powder injectable line (Phase I) and upgradation of existing Betalactum vialing line for WHO-GMP compliance (Phase II) at an estimated cost of Rs. 20.17 crore. Project activities for phase I i.e., of setting up of Cephalosporin Powder Injectable line almost completed and commercial production started from August 2009. As regards Phase II i.e., upgradation of existing Betalactum Vialing line for WHO-GMP compliance, HAL has reported that the project will be completed in Aug., 2010. After completion of the Project, HAL will be able to generate additional profitability of approximately Rs. 11.00 crore from the first year. Further, during 2008-09, HAL has been released Rs. 10.00 crore on 22.1.2009 for upgradation of manufacturing facilities conforming to WHO-GMP standards in Tablets & Capsules, Quality Control and Liquid syrup Sections. Every possible step is being taken to complete the Project by Nov., 2010.

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

(Rupees in crore)

| CPSEs | Production |        |        |                 | Sa    | ales   |        |                 |
|-------|------------|--------|--------|-----------------|-------|--------|--------|-----------------|
|       | 06-07      | 07-08  | 08-09  | 09-10<br>(Prov) | 06-07 | 07-08  | 08-09  | 09-10<br>(Prov) |
| HAL   | 48.96      | 119.81 | 155.00 | 158.09          | 49.22 | 106.59 | 106.59 | 160.04          |

(Department of Pharmaceuticals O.M. No.16(2)/2010-Fin.II dated July 20, 2010)

#### Further reply of the Department

The Department of Pharmaceuticals in their Action Taken Replies dated 11 June 2011 has stated as under:-

"To get the Company fully revived in true sense, apart from the assistance provided under Rehabilitation Scheme, HAL has been provided further financial support through Government of India Ioan for setting up of a new plant for manufacture of Cephalosporin and upgrade Production facilities of Betalactum and non-Betalactum plants as well as tablets and capsules manufacturing facilities to WHO standards so as to enhance its competitiveness and export capacity. While the Cephalosporin plant has been completed, others are under various stages of completion. The Financial Performance of the Company since 2006-07 is as under:-

|             |            | ( /         |
|-------------|------------|-------------|
| <u>Year</u> | Production | <u>Sale</u> |
| 2006-07     | 48.96      | 49.22       |
| 2007-08     | 119.81     | 106.59      |
| 2008-09     | 155.00     | 147.39      |
| 2009-10*    | 123.16     | 118.26      |

(Rs crores)

\* Provisional

It can be seen that after the sanction of Rehabilitation scheme by BIFR, the company's level of operation has improved substantially as its sales increased for the year 2007-08 by more than 100% compared to 2006-07. In the year 2008-09 also the sales exceeded Rs 147 crores. The sales in the year 2009-10, however, was Rs 121 crores as some of the major orders from the Govt. procurement agencies as per the purchase preference policy were not given to the company by the concerned procurement entities.

Further, in the projected sales turnover of the company, more than Rs 30 crores were expected from sale of utilities after leasing out the existing Penicillin plant. However, the company could not lease out its Penicillin plant due to low priced imports from China, etc., and hence no party was ready to lease the plant facilities for Penicillin production. As a result there was no income from sale of utilities and lease rent income could not be achieved. In spite of this, during 2008-09 the company achieved sales turnover of 147.39 crores. All the sales turnover of the company is from Formulation business which has very low profit margins due to controlled prices under DPCO/PPP.

#### Erythromycin Plant

In order to utilize the bulk fermentation facilities, Government sanctioned project for production of Erythromycin which was viable as per initial technofinancial survey by the company. However, the fermentation technology for Erythromycin could not be sourced by HAL on a financially viable basis in spite of global tender. Accordingly, now the setting up of the Erythromycin plan by utilization of existing fermentation facilities is being re-examined. The staff and other utility overheads expenses of the existing fermentation plant have to be however borne by the company which add up to the losses of the company.

> (Department of Pharmaceuticals O.M. No.16(2)/2010-Fin.II dated July 8, 2011)

#### **Recommendation No. 11**

The Committee appreciates the efforts made by the Department for the promotion of unbranded generic medicines through their Jan Aushadhi Stores (JAS). Considering the peculiar price advantage of medicines available through JAS, the Committee desires that the Government should take necessary steps for making mandatory the opening of Jan Aushadhi Stores in all Government Hospitals. Further, the Committee feel that there is an urgent need to encourage participation of State Governments in the Scheme and, therefore, recommend that the Department should persuade the State Governments to allot specific space for opening of Jan Aushadhi Stores at least in the State Government Hospitals. The Committee also desire that the Department should conduct feasibility study for opening of Jan Aushadhi Stores in villages as well to achieve the objective of providing quality generic drugs at affordable prices to the common people. They also recommend that more drugs be brought under generic medicines so that the benefit of the cheap medicines is percolated to the public at large. At the same time, the Committee would also caution that the quality of medicines should not be compromised. There is also a need for giving adequate publicity in print and electronic media to make people aware of the availability of quality medicines at cheaper prices in Jan Aushadhi Stores.

#### **Reply of the Department**

All efforts are being made on the recommendations of the Committee as may be seen from the following:

- Various correspondences/ meetings /visits are being done with the authorities of State Government for getting their support in opening of Jan Aushadhi Stores. Possibilities are being explored to open the Jan Aushadhi Stores in the villages also.
- ii) All Pharma CPSUs have been instructed to take necessary action for increasing the list of medicines supplied to the Jan Aushadhi Stores.
- iii) We are taking necessary action for the publicity in print and electronic media in consultation with Department of Consumer Affairs to make people aware of generic drugs and their prices in the Jan Aushadhi Stores.

#### (Department of Pharmaceuticals O.M. No.16(2)/2010-Fin.II dated July 20, 2010)

#### Further reply of the Department

The Department of Pharmaceuticals in their Action Taken Replies dated 11 June 2011 has stated as under:-

"Following efforts are being made on the recommendations of the Committee:-

i) Various correspondences/ meetings /visits are being done with the authorities of State Government for getting their support in opening of Jan Aushadhi Stores. Possibilities are being explored to open the Jan Aushadhi Stores in the villages also.

ii) All Pharma CPSUs have been instructed to take necessary action for increasing the list of medicines supplied to the Jan Aushadhi Stores.

iii) Till date, 102 Jan Aushadhi Stores have been opened in 10 States (Punjab, Haryana, Uttrakhand, Odisha, Rajasthan, Andhra Pradesh, West Bengal, Jammu & Kashmir, Union territories of Chandigarh and Delhi).

iv) Necessary action is being taken for publicity in print and electronic media in consultation with Department of Consumer Affairs to make people aware of generic drugs and their prices in the Jan Aushadhi Stores".

(Department of Pharmaceuticals O.M. No.16(2)/2010-Fin.II dated July 8, 2011)

#### **CHAPTER III**

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

NIL

#### **CHAPTER IV**

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

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

The budgetary grant for NIPER during 2009-10 was Rs. 57.04 crore under plan allocation and Rs. 20 crore under non plan allocation at BE stage. The plan allocation was, however, reduced to Rs. 47.15 crore at RE stage and the actual plan expenditure upto 31 January 2010 was Rs. 39.65 crore. For this year i.e 2010-11, Rs. 61 crore has been provided as plan allocations and Rs. 19.64 crore as non plan allocation at BE stage. The Committee hope that these funds will be fully utilized and NIPER would be able to develop quality and excellence in pharma education and research so as to strengthen its links with both at National and International levels.

#### **REPLY OF THE GOVERNMENT**

The entire RE allocation of Plan & Non-Plan expenditure in 2009-10 for NIPER head was released by year end. In 2010-11 also, Department plans to use the entire plan & non-plan allocations for NIPERs to meet targets. Agencies are in the process of being finalized to start the developmental/infrastructural work in the new NIPER(s).

> (Department of Pharmaceuticals O.M. No.16(2)/2010-Fin.II dated July 20, 2010)

#### Further reply of the Department

The Department of Pharmaceuticals in their Action Taken Replies dated 11 July 2011 has stated as under:-

"In 2009-10 the entire plan allocation of Rs. 47.15 **crore** was sanctioned & released to NIPERs. Similarly, Non-Plan allocation of Rs.20.92 crore was released to NIPER in 2009-10. Details of the year 2010-11 are tabulated. Fund was released as per the requirement.

|      | BE allocation<br>(including NE) | RE allocation<br>(including NE) | Actual Release |
|------|---------------------------------|---------------------------------|----------------|
| Plan | 77.50                           | 59.08                           | 30.65          |
| Non  | 19.04                           | 24.04                           | 20.64          |
| Plan |                                 |                                 |                |

(Department of Pharmaceuticals O.M. No.16(2)/2010-Fin.II dated July 8, 2011)

#### **Comments of the Committee**

(Please see Para No.8 of Chapter –I of the Report)

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

The Committee in Recommendation No.5 of their original Report had noted that 9 the National Pharmaceutical Pricing Authority (NPPA) had been responsible for price fixation/revision of drugs and formulations. NPPA also monitors the prices of decontrolled drugs and formulations, enforce and implement the provisions of the Drugs (Prices Control) Order (DPCO), 1995. An amount of Rs.7.06 crore (0.99 crore under plan and Rs. 6.07 crore non plan) had been earmarked for NPPA at BE-2010-11. The major part of this allocation was meant for the new scheme 'Proposal for Building Robust and Responsive Statistical System for NPPA'. The Committee had also noted that out of the five schemes proposed by NPPA for the Eleventh Five Year Plan, four schemes were yet to get 'in principle' approval of the Planning Commission. The Committee feel that half-hearted approach can never produce the desired results. They, therefore, strongly recommend that the Department of Pharmaceuticals should expeditiously take up the issue with the Planning Commission regarding early approval of the schemes proposed by the NPPA. The Committee may be apprised of the progress made in this regard.

#### REPLY OF THE GOVERNMENT

Out of five components of the scheme proposed by the Department, Planning Commission has accorded 'in principle' approval to only one component concerning 'Building Robust & Responsive Statistical System for NPPA' in March,2008. Further, it was mentioned that Planning Commission will take a view on the publicity campaign scheme after consulting with the Department of Consumer Affairs. It was also mentioned that the other components proposed for strengthening and monitoring of prices of drugs and pharmaceuticals would be taken up after the finalization of the Draft Pharmaceutical Policy. Department is pursuing with the Planning Commission for delinking the matter from the finalization of the draft Policy and according 'in principle' approval for the remaining schemes. The matter has again been recently taken up with the Planning Commission by Secretary (Pharmaceuticals) <u>vide</u> his D.O. letter dated 10.3.2010".

(Department of Pharmaceuticals O.M. No.16(2)/2010-Fin.II dated July 20, 2010)

#### Further reply of the Department

The Department of Pharmaceuticals in their Action Taken Replies dated 11 July 2011 has stated as under:-

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

(Department of Pharmaceuticals O.M. No.16(2)/2010-Fin.II dated July 8, 2011)

**Comments of the Committee** (Please see Para No.12 of Chapter –I of the Report)

#### Recommendation No.7

The Committee have been informed that at the instance of Cabinet Secretariat, a draft note is stated to have been prepared by the Department and is being finalized for consideration by the Cabinet for revival of IDPL, which had been discharging the social responsibility of manufacturing and providing drugs to the general public at reasonable rates. The revival of IDPL being of paramount importance, the Committee desire that the revival plan should be expedited at a much quicker pace. Steps should also be taken for upgradation of manufacturing facilities in IDPL conforming to WHO-GMP standards. The Committee feel that by doing so IDPL would be able to effectively compete with the major pharmaceutical industries in private sector in respect of quality medicines and ultimately would instill confidence in the people. The Committee would therefore, expect concrete action by the Government in this behalf.

#### **Reply of the Department**

The draft Cabinet Note for revival of IDPL is under submission to the M(C&F). This Department is also considering the proposal for upgradation of manufacturing facilities in IDPL conforming to WHO-GMP Standards. Meanwhile proposal for making the company schedule M compliant has already been sent to Planning Commission for an in-principle approval.

(Department of Pharmaceuticals O.M. No.16(2)/2010-Fin.II dated July 20, 2010)

#### Further reply of the Department

The Department of Pharmaceuticals in their Action Taken Replies dated 11 July 2011 has stated as under:-

"IDPL has appointed consulting firm M/s E & Y for preparation of revival plan. The said consultant has since submitted the updated draft report on 08-06-2011. The revival plan has been prepared keeping in mind competition from the private sector and the Social Objective as laid down by the GoM. The same is being examined in the Ministry. This Department is also considering the proposal for upgradation of manufacturing facilities in IDPL conforming to WHO-GMP Standards".

> (Department of Pharmaceuticals O.M. No.16(2)/2010-Fin.II dated July 8, 2011)

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

#### CHAPTER V

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

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

The Committee note that out of an outlay of Rs. 1396.17 crore for the 11<sup>th</sup> Five Year Plan (2007-12) for the Department of Pharmaceuticals, the allocation in the first four years, i.e. from 2007-08 to 2010-11 is Rs. 566.77 crore which is about 40% of the total plan allocation. Thus, an amount of Rs. 829.40 crore which comes to about 60% will have to be provided during the last year of the 11<sup>th</sup> plan i.e. 2011-12. During these years, the outlays sanctioned by the Planning commission were well below the amounts asked for by the Department. The Committee are inclined to conclude that the approach of the Planning Commission in this case has been totally unrealistic and not conducive at all to enable the Department of Pharmaceuticals to achieve the expected plan targets. The Committee, therefore, desire that the Planning Commission should ensure that the remaining outlay (60% of the plan) is provided in the last two years of the plan by increasing the allocation at 2010-11 RE stage and in 2011-12 so that the Department is able to plan and utilize the resources for achieving the laid down targets

#### **Reply of the Department**

Planning Commission has been apprised of the concerns of the Standing Committee and the Commission is being impressed upon to appropriately address this issue. The Department is also endeavouring to make the Planning Commission allocate the requisite funds, out of its (i.e. Department's) due share sanctioned at the beginning of 11<sup>th</sup> Plan, during 2010-11 (RE) and 2011-12, so that it can launch the vital schemes (and achieve the laid down targets) aimed at ensuring availability of quality medicines and pharmaceutical products at reasonable prices for all, besides ensuring timely and targeted implementation of its on-going schemes like creation of new NIPERs, revival/rehabilitation of pharma PSUs for infrastructure creation/ R&D initiatives etc.

> (Department of Pharmaceuticals O.M. No.16(2)/2010-Fin.II dated July 20, 2010)

#### Further reply of the Department

The Department of Pharmaceuticals in their Action Taken Replies dated 11 July 2011 has stated as under:-

"Planning Commission has been apprised of the concerns of the Standing Committee and the Commission is being impressed upon to appropriately address this issue. The Department is also endeavouring to make the Planning Commission allocate the requisite funds, out of its (i.e. Department's) due share sanctioned at the beginning of 11<sup>th</sup> Plan, during 2010-11 (RE) and 2011-12, so that it can launch the vital schemes (and achieve the laid down targets) aimed at ensuring availability of quality medicines and pharmaceutical products at reasonable prices for all, besides ensuring timely and targeted implementation of its on-going schemes like creation of new NIPERs, revival/rehabilitation of pharma PSUs for infrastructure creation/ R&D initiatives

etc. The planning Commission has recently given in-principle concurrence for consumer awareness scheme of NPPA which would help to spread awareness about scheduled/controlled drugs pricing, importance of MRP etc. For NIPERs, allocation has been made to Rs.125.58 cr. for 2011-12".

(Department of Pharmaceuticals O.M. No.16(2)/2010-Fin.II dated July 8, 2011)

#### Recommendation SI. No. 3

The National Institute of Pharmaceuticals Education and Research (NIPER) was set up in 1998 in Mohali, Punjab to nurture and promote quality and excellence in pharmaceutical education and research. The Government approved setting up of six more institutes under NIPER in 2007. The Committee have been informed that classes in some streams of pharmaceutical sciences have already started. Keeping in the view laudable objectives of NIPER and its performance the Committee desire that necessary formalities should be expeditiously completed so that the these six institutes become fully functional by April 2011.

#### **Reply of the Department**

Following the decision of the Cabinet at its meeting held on 10.9.2009 the following action has been taken by the Department:-

- (i) Meeting of the Expenditure Finance Committee (EFC) under the Chairpersonship of Secretary, Department of Expenditure was convened on 3<sup>rd</sup> March, 2010. it was inter-alia decided that:
  - (a) DPR for each NIPER to be updated with reference to current prices before being made available to EFC again; and
  - (b) Extent of PPP in the establishment of NIPERs to be assessed. Thereafter, proposal may be placed before the EFC again; and
  - (c) Requirement of funds for 2010-11 & 2011-12 may be re-assessed with reference to actual spending capacity.

2. The Consultant is engaged in finalizing the DPR for each NIPER with reference to current prices. The Department issued an advertisement in the Newspapers for inviting Expression of Interest (EoI) for setting up new NIPERs. The last date for receipt of EoI was 10<sup>th</sup> May, 2010. In response, 21 EoIs have been received. The Consultant is engaged in evaluating the response on Public Private Partnership (PPP) for setting up new NIPERs. The matter will be placed before the EFC duly headed by Secretary (Exp.) for its appraisal. Depending upon the appraisal

and recommendation of the EFC, the matter will be placed before the Cabinet/ CCEA for decision.

(Department of Pharmaceuticals O.M. No.16(2)/2010-Fin.II dated July 20, 2010)

#### Further reply of the Department

The Department of Pharmaceuticals in their Action Taken Replies dated 11 July 2011 has stated as under:-

"The Cabinet, at its meeting held on 23rd August,2007, accorded in-principle approval to the setting up of six new NIPERS one each at Hderabad, Ahmedabad, Hajipur, Kolkata, Guwahati and Rae Bareli and approved commencement & continuation of courses at these new NIPERs with the assistance of Mentor Institutes for two years i.e 2007-08 and 2008-09. The Cabinet also approved appointment of a Consultant of repute to prepare the Detailed Project Reports (DPRs), wherever possible, on the Public Private Partnership Model.

The Cabinet at its meeting held on 10.9.2009 approved continuation of present arrangement of running Post Graduate courses, including some more initiatives, in the new NIPERs with the help of Mentor Institutes beyond 2008-09 for a further period of two years i.e. upto 2010-11.The Cabinet further directed that finances be tied up quickly and the matter brought before the Cabinet /Cabinet Committee on Economic Affairs after appraisal by the Expenditure Finance Committee (EFC)".

(Department of Pharmaceuticals O.M. No.16(2)/2010-Fin.II dated July 8, 2011)

#### **Recommendation No. 10**

The Committee note that the Department of Pharmaceuticals is in the process of finalization a Pharma R&D Venture Fund which would cater to the requirement of Research and Development of Drug discovery and innovation. However, while allowing the Venture fund to cater to the requirement of fund for R&D the Committee expect the Department to take all care for indigenous patenting of such research and innovation. As per the scheme, the Government would provide an initial corpus that would leverage such amount in raising resources from public and private institute as well as from existing funds within India and overseas. The Committee have been given to understand that the proposal is under examination of Planning Commission for its 'in-principle' approval. While appreciating the innovative scheme for raising funds for R&D by the Department, the Committee call upon the Planning Commission

#### REPLY OF THE GOVERNMENT

The matter is being expedited.

(Department of Pharmaceuticals O.M. No.16(2)/2010-Fin.II dated July 20, 2010)

#### Further reply of the Department

The Department of Pharmaceuticals in their Action Taken Replies dated 11 July 2011 has stated as under:-

"Meetings have been held with the National Institute of Financial Policy & Planning who are now preparing a Detailed Project Report for structuring of the proposed venture fund".

(Department of Pharmaceuticals O.M. No.16(2)/2010-Fin.II dated July 8, 2011)

New Delhi;

<u>28 July, 2011</u> 6 Shravana, 1933 (Saka) GOPINATH MUNDE, Chairman, Standing Committee on Chemicals and Fertilizers.

#### <u>Appendix – I</u>

## MINUTES OF THE TENTH SITTING OF THE **STANDING COMMITTEE ON CHEMICALS & FERTILIZERS** (2010-11)

The Committee sat on Tuesday, the 31 May, 2011 from 1500 hrs. to 1630 hrs. in Committee Room 'B', Parliament House Annexe, New Delhi.

#### Present

#### Dr. Manda Jagannath

**Acting Chairman** 

#### **Members**

-

#### Lok Sabha

| 2.          | Smt. Susmita Bauri                 |  |  |
|-------------|------------------------------------|--|--|
| 3.          | Shri Prabhatsinh P. Chauhan        |  |  |
| 4.          | Smt. Santosh Chowdhary             |  |  |
| 5.          | Adv. Ganeshrao Nagorao Dudhgaonkar |  |  |
| 6.          | Shri T.K.S. Elangovan              |  |  |
| 7.          | Shri N. Peethambara Kurup          |  |  |
| 8.          | Shri Baidya Nath Prasad Mahato     |  |  |
| 9.          | Shri Jagdambika Pal                |  |  |
| 10.         | Shri Tapas Paul                    |  |  |
| 11.         | Shri Ponnam Prabhakar              |  |  |
| 12.         | Shri Ashok Kumar Rawat             |  |  |
| 13.         | Shri Narendra Singh Tomar          |  |  |
| RAJYA SABHA |                                    |  |  |
| 14.         | Shri A.A. Jinnah                   |  |  |
| 15.         | Prof. Anil Kumar Sahani            |  |  |
| 16.         | Shri Raghunandan Sharma            |  |  |
| 17.         | Shri Parshottam Khodabhai Rupala   |  |  |
| 18.         | Shri Abani Roy                     |  |  |
| 19.         | Shri Biswajit Daimary              |  |  |
|             |                                    |  |  |

#### **Secretariat**

1. Shri Ashok Sarin

2.

- Joint Secretary
- Director -
- Shri C. S. Joon Shri A.K. Srivastava 3.
- Additional Director

2. As the Chairman could not attend the sitting due to pre-occupation, the members chose Dr. Manda Jagannath, a member of the Committee, to act as the Chairman. The Acting Chairman welcomed the members to the sitting of the Committee.

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

(i) \*\*\* \*\*\* \*\*\* \*\*\* \*\*\* \*\*\* \*\*\* \*\*\* \*\*\* \*\*\* \*\*\* \*\*\* \*\*\* \*\*\* \*\*\* \*\*\* \*\*\* \*\*\* (ii)

(iii) Report on Action Taken by the Government on the recommendations contained in the Seventh Report (15<sup>th</sup> Lok Sabha) on Demands for Grants (2010-11) of the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals).

(iv) \*\*\* \*\*\* \*\*\* \*\*\* \*\*\* \*\*\* \*\*\*

4. After some deliberation the adoption/ consideration of the above mentioned Reports was deferred to a later date.

#### The Committee then adjourned.

\_\_\_\_\_

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

#### Appendix – II

#### MINUTES

#### **STANDING COMMITTEE ON CHEMICALS & FERTILIZERS** (2010-11)

#### THIRTEENTH SITTING (18.07.2011)

The Committee sat on Monday from 1500 hours to 1600 hours.

#### Present

#### Shri Gopinath Munde -Chairman

#### **Members**

#### Lok Sabha

- Smt. Susmita Bauri 2.
- Shri Prabhatsinh P. Chauhan 3.
- 4. Smt. Santosh Chowdhary
- Shri K.D. Deshmukh 5.
- Adv. Ganeshrao Nagorao Dudhgaonkar 6.
- Shri Baidya Nath Prasad Mahato 7.
- Shri Jagdambika Pal 8.
- 9. Shri Tapas Paul
- Shri Ashok Kumar Rawat 10.
- 11. Shri N. Chaluvaraya Swamy

#### Rajya Sabha

- 12. Shri Silvius Condpan
- 13. Shri Briilal Khabri
- Prof. Anil Kumar Sahani 14.
- 15. Shri Raghunandan Sharma
- Shri Parshottam Khodabhai Rupala 16.
- 17. Shri Abani Roy

#### **Secretariat**

| Shri N.K. Sapra      | - | Secretary        |
|----------------------|---|------------------|
| Shri Ashok Sarin     | - | Joint Secretary  |
| Shri C. S. Joon      | - | Director         |
| Shri A.K. Srivastava | - | Additional Direc |

Additional Director

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

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

(i) and (ii) \*\*\* \*\*\* \*\*\* \*\*\* \*\*\* \*\*\* \*\*\* \*\*\* \*\*\*

(iii) Draft Report on Action Taken by the Government on the recommendations contained in the Seventh Report (15<sup>th</sup> Lok Sabha) on Demands for Grants (2010-11) of the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals);

(iv), (v), (vi) and (vii) \*\*\* \*\*\* \*\*\* \*\*\* \*\*\* \*\*\* \*\*\*

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

#### The Committee then adjourned.

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

#### <u> Appendix – III</u>

#### (Vide Para 3 of the Introduction)

#### ANALYSIS OF ACTION TAKEN BY THE GOVERNMENT ON THE RECOMMENDATIONS CONTAINED IN THE SEVENTH REPORT (FIFTEENTH LOK SABHA) OF THE STANDING COMMITTEE ON CHEMICALS AND FERTILIZERS (2009-10) ON 'DEMANDS FOR GRANTS (2010-11)' OF THE MINISTRY OF CHEMICALS AND FERTILIZERS (DEPARTMENT OF PHARMACEUTICALS)

| I                   | Total No. of Recommendations                               | 11     |  |  |
|---------------------|--|--------|--|--|
| Ш                   | Observations / Recommendations which have been accepted    | 5      |  |  |
|                     | by the Government:-  |        |  |  |
|                     | (Vide Recommendation at SI.Nos. 2,6,8,9 and11)             |        |  |  |
|                     | Percentage of Total  | 45.46% |  |  |
|                     | Observation / Recommendation which the Committee do not    | 0      |  |  |
|                     | desire to pursue in view of the Government's reply:-       |        |  |  |
|                     | (Vide Recommendation at SI.No. Nil                         |        |  |  |
|                     |  |        |  |  |
| Percentage of Total |  |        |  |  |
| IV                  | Observation / Recommendation in respect of which reply of  | 3      |  |  |
|                     | the Government have not been accepted by the Committee     |        |  |  |
|                     | and which require reiteration:-                            |        |  |  |
|                     | (Vide Recommendation at SI.No. 5,4 and 7)                  |        |  |  |
|                     | Percentage of Total  | 27.27% |  |  |
| V                   | Observations / Recommendations in respect of which replies | 3      |  |  |
|                     | of the Government are of interim nature:-                  |        |  |  |
|                     | (Vide Recommendations at SI.Nos. 1, 3 and 10)              |        |  |  |
|                     |  |        |  |  |
| Percentage of Total |  |        |  |  |