

38**STANDING COMMITTEE ON
CHEMICALS & FERTILIZERS
(2012-13)****FIFTEENTH LOK SABHA****MINISTRY OF CHEMICALS AND FERTILIZERS
(DEPARTMENT OF PHARMACEUTICALS)****NATIONAL PHARMACEUTICALS PRICING AUTHORITY**

[Action Taken by the Government on the Observations/Recommendations contained in the Twenty-Ninth Report of the Standing Committee on Chemicals and Fertilizers (Fifteenth Lok Sabha) on National Pharmaceuticals Pricing Authority of the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals)]

**THIRTY EIGHTH REPORT****LOK SABHA SECRETARIAT
NEW DELHI****August, 2013/Shravana, 1935 (Saka)**

THIRTY EIGHTH REPORT

**STANDING COMMITTEE ON CHEMICALS AND FERTILIZERS
(2012-13)**

FIFTEENTH LOK SABHA

**MINISTRY OF CHEMICALS AND FERTILIZERS
(DEPARTMENT OF PHARMACEUTICALS)**

NATIONAL PHARMACEUTICALS PRICING AUTHORITY

*[Action Taken by the Government on the Observations/Recommendations
contained in the Twenty Ninth Report of the Standing Committee on Chemicals and Fertilizers
(Fifteenth Lok Sabha) on National Pharmaceuticals Pricing Authority of the
Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals)]*

Presented to Lok Sabha on 13.08.2013

Laid in Rajya Sabha on 13.08.2013



LOK SABHA SECRETARIAT

NEW DELHI

August, 2013/Shravana, 1935 (Saka)

**COMPOSITION OF THE STANDING COMMITTEE ON CHEMICALS & FERTILIZERS
(2012-13)**

| Shri Gopinath Munde - Chairman | |
|---------------------------------------|------------------------------|
| MEMBERS | |
| LOK SABHA | |
| 2. | Shri S. Alagiri |
| 3. | Shri Gajanan D. Babar |
| 4. | Shri P.P. Chauhan |
| 5. | Shri K.D. Deshmukh |
| 6. | Shri Sher Singh Ghubaya |
| 7. | Shri Sk. Nurul Islam |
| 8. | Shri Sakti Mohan Malik |
| 9. | Shri Paswan Kamlesh |
| 10. | Shri Amarnath Pradhan |
| 11. | Shri Ashok Kumar Rawat |
| 12. | Shri Tufani Saroj |
| 13. | Shri Suresh Kumar Shetkar |
| 14. | Shri Raju Shetti |
| 15. | Shri G.M. Siddeshwara |
| 16. | Shri D. Venugopal |
| 17.^ | Shri Sai Prathap Annayyagari |
| 18.* | Vacant |
| 19. # | Vacant |
| 20. | Vacant |
| 21. | Vacant |
| RAJYA SABHA | |
| 22. | Shri Biswajit Daimary |
| 23. | Shrimati Naznin Faruque |
| 24. | Shri A.A. Jinnah |
| 25. | Shri Brijlal Khabri |
| 26. | Shri Dilipbhai Pandya |
| 27. | Shri Raghunandan Sharma |
| 28. % | Vacant |
| 29. ^ | Vacant |
| 30. ^# | Vacant |
| 31. | Vacant |

SECRETARIAT

| | | | |
|----|----------------------------|---|---------------------|
| 1. | Smt Rashmi Jain | - | Joint Secretary |
| 2. | Shri U.B.S. Negi | - | Director |
| 2. | Shri Anil Kumar Srivastava | - | Additional Director |
| 3. | Smt. Emma C. Barwa | - | Under Secretary |

* Shri P. Balam Naik appointed as a minister of state

#Shri Vitthalbhai Hansrajbhai (LS) has resigned w.e.f. 03 .01.2013

^ Shri Sai Prathap Annayyagarin (LS) nominated w.e.f. 09.01.2013.

% Dr. Vijay Mallya (RS) has resigned w.e.f. 26.02.2013

^ Shri K.C. Tyagi (RS) nominated w.e.f. 07.03.2013.

^ Shri Pyarimohan Mohapatra (RS) has resigned w.e.f. 22.03.2013

Shri K.C. Tyagi (RS) has resigned w.e.f. 01.04.2013

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INTRODUCTION

I, the Chairman, Standing Committee on Chemicals and Fertilizers (2012-13) having been authorised by the Committee to present the Report on their behalf, the Thirty-Eighth Report (Fifteenth Lok Sabha) on Action Taken by the Government on the observations/recommendations contained in the Twenty-Ninth Report (Fifteenth Lok Sabha) of the Standing Committee on Chemicals and Fertilizers (2012-13) on 'National Pharmaceuticals Pricing Authority (NPPA)' of the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals).

2. The Twenty-Ninth Report (Fifteenth Lok Sabha) of the Standing Committee on Chemicals and Fertilizers was presented to Lok Sabha on 17 December, 2012. The Action Taken Replies of Government to all observations/recommendations contained in the Report were received on 3 June, 2013. The Standing Committee on Chemicals and Fertilizers (2012-13) considered the Action Taken Report and adopted the same at their sitting held on 6 August, 2013.

3. An analysis of the Action Taken by the Government on the observations/recommendations contained in the Twenty-Ninth 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;

12 August, 2013
21 Shravana, 1935 (Saka)

GOPINATH MUNDE
Chairman,
Standing Committee on
Chemicals and Fertilizers

CHAPTER – I

This Report of the Standing Committee on Chemicals and Fertilizers deals with the action taken by the Government on the Observations/Recommendations contained in the Twenty-Ninth Report (Fifteenth Lok Sabha) of the Committee on the subject Report on National Pharmaceuticals Pricing Authority (2012-13) of the Ministry of Chemicals & Fertilizers (Department of Pharmaceuticals) which was presented to Lok Sabha on 17.12.2012. The Report contained seven Observations / Recommendations.

2. The Ministry of Chemicals & Fertilizers (Department of Pharmaceuticals) were requested to furnish replies to the Observations / Recommendations contained in the Twenty-Ninth Report within three months from the date of presentation of the Report, i.e., by 16.03.2013. The Action Taken Replies of the Government in respect of all the seven Observations / Recommendations contained in the Report have been received from the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals) vide their O.M. No.31026/20/2013-PI.I dated 03.06.2013. These have been categorized as follows:-

- (i) Observations/Recommendations that have been accepted by the Government :-
 Sl. Nos. 1, 2 and 3 (Total =3)
 This may be included in Chapter II of the Draft Report.
- (ii) Observations/Recommendations which the Committee do not desire to pursue in view of the Government's reply :-
 Sl. Nos. Nil (Nil)
 This may be included in Chapter III of the Draft Report.
- (iii) Observations/Recommendations in respect of which replies of the Government have not been accepted by the Committee :-
 Sl. Nos. 4,5, 6 and 7 (Total =4)
 This may be included in Chapter IV of the Draft Report.
- (iv) Observations/Recommendations in respect of which final replies of the Government are awaited:-
 Sl. Nos. Nil (Nil)
 These may be included in Chapter V of the Draft Report.

3. The Committee desire that the Action Taken Notes on the Observations / Recommendations contained in Chapter-I of this Report and the final replies in respect of the Observation / Recommendations contained in Chapter IV which have not been accepted by the Committee 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.

RECOMMENDATION NO.2

A SCHEMES OF NPPA

5. Emphasizing the early need for implementation of all the schemes of NPPA the Committee had recommended as under:-

“The Committee note that during the Eleventh Five Year Plan period (2007-2012), NPPA had proposed five new schemes amounting to Rs. 4995.60 lakh. These schemes are (i) Building Robust and Responsive Statistical System for NPPA; (ii) Creation of NPPA Cells in States; (iii) Scheme for Interaction with States; (iv) Proposal for Consumer Awareness and Publicity through Print, Electronic and other medium; and (v) Proposal for strengthening the existing Monitoring and Enforcement work. The Committee also note that out of these five schemes, only one scheme viz Building Robust and Responsive Statistical System for NPPA has already been approved by the Planning Commission and implemented during the Eleventh Plan period. Further, in-principle approval in respect of the scheme, namely Proposal for Consumer Awareness and Publicity through Print, Electronic and other medium was given in February, 2011 and in the budget allocation for the year 2012-13, funds are allocated only for these two schemes. In this regard, this Committee have time and again recommended that the Department should earnestly pursue the issue with the Planning Commission and make all out efforts towards getting in-principle approval for rest of the three schemes of NPPA. The Committee strongly feel that the above three schemes of NPPA are vital for fulfilling the mandate of the organization and again recommend that the Department should make earnest effort to get in-principle approval of these three schemes from Planning Commission. The Committee would like to be informed about follow up action taken in this matter”.

REPLY OF THE GOVERNMENT

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

“With the notification of National Pharmaceutical Pricing Policy 2012 and Drugs (Price Control) Order, 2013, (DPCO, 2013) the relevance of the Schemes has been reviewed in consultation with NPPA and the status of each scheme is as under :

- (i) Creation of NPPA Cells in States: In view of the changes in norms for pricing as envisaged in DPCO, 2013, it is felt that separate cells in States may not be required.
- (ii) Scheme for Interaction with States: NPPA has already taken initiative in this regard by having regional meetings with States on regular basis. It is felt that a special scheme for the purpose is not required.

- (iii) Proposal for strengthening the existing Monitoring and Enforcement work: it has been decided to revisit the provisions of this scheme by NPPA and a view will be taken keeping in view the requirement under DPCO, 2013.

COMMENTS OF THE COMMITTEE

7. The Committee had observed that out of five schemes proposed by NPPA during the Eleventh Five Year Plan, only one scheme namely Building Robust and Responsive Statistical System for NPPA has been implemented. Besides this, in-principle approval in respect of the scheme, namely Proposal for Consumer Awareness and Publicity through Print, Electronic and other medium was given in February, 2011 and in the budget allocation for the year 2012-13, funds were allocated only for these two schemes. The remaining three schemes namely (i) Creation of NPPA Cells in States (ii) Scheme for Interaction with States and (iii) Proposal for strengthening the existing Monitoring and Enforcement work were to get in-principle approval of the Planning Commission.

In its Action Taken Replies, the Committee have now been informed that with the notification of National Pharmaceutical Pricing Policy, 2012 and Drugs (Price Control) Order, 2013, (DPCO, 2013) the relevance of the said three Schemes has been reviewed by the Department in consultation with NPPA and according to them, separate NPPA cells in the States are not required in view of the changes in norms for pricing as envisaged in DPCO, 2013. Similarly, special scheme for interaction with States is also not required as NPPA has already taken initiative in this regard by having regional meetings with States on regular basis. The Committee, however, still feel that proposed schemes namely Creation of NPPA Cells in States and the Scheme for Interaction with States are well intended and the same could be an effective institutional mechanism to carry out the mandate of the Department. The Committee, therefore, desire that the relevance of the proposed schemes against the backdrop of DPCO, 2013 should be re-looked into. As regards the third scheme namely, Proposal for strengthening the existing Monitoring and Enforcement work, the Committee note that the provisions of this scheme will be revisited by NPPA and a view will be taken keeping in view the requirement under DPCO, 2013. The Committee expect the Department to expedite the process and the relevance of the proposed scheme may be examined comprehensively keeping in view the requirement under DPCO, 2013. The Committee would like to be apprised of the final decision taken in the matter.

B MONITORING OF PRICES OF SCHEDULED DRUGS

RECOMMENDATION. NO.3

8. Emphasizing the need for periodic monitoring of the prices of Scheduled drugs the Committee had recommended as under:-

“National Pharmaceutical Pricing Authority fixes/ revises the prices of 74 bulk drugs and the formulations containing any of the scheduled drugs under the provisions of the Drugs specified in the first schedule of the Drug (Prices Control) Order, 1995. The Committee find that scheduled drugs/formulations cannot be sold at a price higher than that fixed by NPPA/Government. According to the Department of Pharmaceuticals, non-submission of the requisite data/information by the manufacturing units particularly in cases of reduction in the input cost is the major difficulty being faced by NPPA. The Committee observe that NPPA endeavours to overcome this problem through interaction with State Drug Controllers to impress upon the manufacturing units to submit the requisite data/information. The Committee are of the view that there is an urgent need for taking definite steps to encourage the manufacturing units to submit the data in time and desire that NPPA should chalk out mechanism in co-ordination with State Enforcement Agencies in this regard.

The Committee also note that the Pharma Companies frequently change, the composition/strength of their formulations to circumvent the provisions of DPCO, 1995. In order to escape the provisions of the DPCO, 1995 pharma companies are also using the via-media of Dietary Supplements under the Prevention of Food Adulteration Act 1954 and flooding the retail market by medicines of dietary supplements. While expressing their concern over such strategy adopted by the pharma companies, the Committee recommend that the Department should expeditiously identify the concerned pharma companies and take up the issue strongly with the Ministry of Health and Family Welfare. The Committee also desire that NPPA should not hesitate to invoke the relevant provisions of the DPCO, 1995 to curb such alleged malpractices by the drug companies. Thus, the circumventing of the price control mechanism by some manufacturers by shifting schedule drugs to the category of Food and Nutrition Supplement manufacture under Prevention of Food Adulteration Act 1954 should also be monitored by the NPPA. In this regard, NPPA cannot shirk away from its responsibility and leave the matter at the behest of the Ministry of Health and Family Welfare. The Committee would like to be apprised of the action taken in the matter. The Committee also desire that the list of companies indulged in such malpractices and action taken against them should be furnished to the Committee within three months of presentation of the Report.

The Committee further note that the State Drugs Controllers help NPPA in monitoring the prices and enforcing the provisions of DPCO, 1995. The State Governments are authorized to take action under Essential Commodities (EC) Act, 1995 for violation of the provisions of the DPCO, 1995. The Committee observe that prosecution under Essential Commodities Act, 1995 sometimes does not lead to stringent action against defaulters. The Committee find that at present, there are no provisions of fine or penalties for the violation of the DPCO, 1995 for non-submission of requisite data, price list and for not allowing officers of NPPA to visit and inspect manufacturing premises. The Committee, therefore, desire that DPCO, 1995 should be amended suitably to incorporate provisions for compounding offences by stringent fines or penalties therein”.

REPLY OF THE GOVERNMENT

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

“With change in pricing norms under DPCO, 2013 from the cost based pricing to market based pricing, the cost data will no more be required. Moreover, forms have been further simplified in DPCO, 2013 to make the process of collection easy. Para 16 of the said order provides for submission of information / data by the industry mandatorily in respect of revision of the prices within 15 days and it also provides that the company would be liable for an action under the said order if it fails to submit the same within 15 days’ time. The provision has also been made with regard to monitoring of availability of scheduled formulations vide Para 21 of the said order. Manufacturers are also required to file

quarterly production returns with the NPPA in Form-III. In respect of discontinuation of the production of the scheduled formulation manufacturers should file returns in Form IV of the said order. The companies are also required to file price list in Form-V with the NPPA.

The issue of circumventing the price control mechanism through dietary supplements has already been taken up by this Department with the Ministry of Health & Family Welfare and a reminder has also been sent on 29.4.2013.

DPCOs are subordinate legislation and sufficient penal provisions already exist in the parent Act i.e. Essential Commodities Act, 1955”.

COMMENTS OF THE COMMITTEE

10. The Committee noted that National Pharmaceutical Pricing Authority fixes/ revises the prices of 74 bulk drugs and the formulations containing any of the scheduled drugs under the provisions of the Drugs specified in the first schedule of the Drug (Prices Control) Order, 1995. The Committee also noted that the Pharma Companies frequently change, the composition/strength of their formulations to circumvent the provisions of DPCO, 1995. In order to escape the provisions of the DPCO, 1995 pharma companies are also using the via-media of Dietary Supplements under the Prevention of Food Adulteration Act 1954 and flooding the retail market by medicines of dietary supplements. The Committee, therefore, recommended that the the Department should identify such pharma companies and take up the issue strongly with the Ministry of Health and Family Welfare.

In its Action Taken Replies, the Committee have been informed by the Department that the issue of circumventing the price control mechanism through dietary supplements has already been taken up by the Department with the Ministry of Health & Family Welfare and a reminder has also been sent to that Ministry on 29.4.2013. The Committee, however, desire that the Department should vigorously pursue the issue with the Ministry of Health & Family Welfare to its logical conclusion. The Committee would like to be apprised of the action taken by the Department in this regard.

C MONITORING OF PRICES OF NON-SCHEDULED DRUGS

RECOMMENDATION NO.4

11. Stressing the need to make Department to take necessary steps to make NPPA self-sufficient and resourceful to carry out its activities regarding monitoring of prices of non-scheduled drugs independently and effectively the Committee had recommended as under:-

“The Committee note that prices of non-scheduled drugs are fixed by manufacturers themselves without seeking the approval of Government / NPPA. NPPA, however, regularly monitors the prices of non-scheduled formulations based on the data from IMS (Health). The Committee in this regard regret to point out that NPPA depends entirely on IMS (Health) data and does not have their own specific system for data collection. The Committee, therefore, recommend that Department should take necessary steps to

make NPPA self-sufficient and resourceful to carry out its activities regarding monitoring of prices of non-scheduled drugs independently and effectively.

Regarding monitoring of the prices of non-scheduled drugs, the Committee note that a list of formulations and their manufacturers are short-listed where there is an increase in price of more than 10% in one year and the annual turnover of the formulation pack exceeds Rs.1 crore. Further, the share of formulations in that segment of the formulation is required to be at least 20% of the market or the medicine is one of the top 3 brands of that group. The manufacturer and / or distributor is asked to give justification for price increase of more than 10% per annum. If no information is received after the letter and reminder or the reply of the company is not satisfactory, show cause notice is issued to the manufacturer stating as to why action should not be initiated for price fixation under para 10(b) of DPCO, 1995 in larger public interest. In this regard, Committee feel that such a process of monitoring of prices of non-schedule drugs is not satisfactory and deterrent as the manufacturers have the advantage of fixing the prices first provisionally. The present mechanism does not provide any relief to masses in case it is found that prices were arbitrarily fixed. Hence, the Committee recommend that NPPA should devise a mechanism to proactively monitor the rise in prices of non-scheduled drugs so that the same does not go beyond the permissible limit”.

REPLY OF THE GOVERNMENT

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

“NPPA has already taken initiative to collect information directly from the manufacturers. Almost 7,000 manufacturers have already been addressed to submit required information. Moreover, making a provision for filing of information online will further facilitate collection of information. This would definitely reduce dependence on IMS Health in long run.

In the new DPCO, 2013, there is a provision to amend the list of Scheduled Formulations based on the communication from the Ministry of Health and Family Welfare. Hence, para 10(b) of DPCO, 95 has lost its relevance”.

COMMENTS OF THE COMMITTEE

13. **The Committee had noted that the manufacturers have the advantage for fixing the prices of non-scheduled drugs without seeking the approval of the Government / NPPA and this mechanism does not provide any relief to the public, in case it was found that the prices of the drugs were fixed arbitrarily. The Committee, therefore, recommended that NPPA should devise a mechanism to proactively monitor the rise in prices of non-scheduled drugs so that the same does not go beyond the permissible limit. The Committee are not fully convinced with the reply given by the Department of Pharmaceuticals that a provision has been made in DPCO, 2013 to amend the list of scheduled formulation based on the communication received from the Ministry of Health and Family Welfare. The Committee feel that though new list of scheduled drugs would empower NPPA to control the prices of some more drugs in the country even then there will be a large number of drugs which may not be included in scheduled category for which no prices could be fixed by NPPA being non-scheduled drugs. It is, therefore, imperative that a mechanism may be evolved to regulate the prices of non-scheduled drugs at reasonable level. The Committee, therefore, recommend that in addition to**

taking up the matter vigorously with Ministry of Health and Family Welfare to amend the list of scheduled formulation to the largest extent possible, the Department should also take initiative to evolve a price mechanism for non-scheduled drugs with a view to ensure the availability of all such drugs to the consumers at affordable prices.

D AVAILABILITY OF DRUGS

RECOMMENDATION NO.5

14. Emphasizing the need to ensure regular and normal supply of medicines in all States, the Committee had recommended as under:-

“The Committee are happy to note that NPPA has been monitoring the availability of drugs in the country regularly and taking remedial steps whenever required. NPPA is carrying out this responsibility mainly through monthly field reports from the State Drugs Controllers and other available information and whenever, there are reports of shortage of certain brands of drugs in some States, the concerned company is asked to rush the stock and to make the drugs available. The Committee, therefore, desire that to ensure regular and normal supply of medicines in all States, specifically in remote and hilly regions, NPPA should devise effective distribution and delivery system in coordination with State Drugs Controllers. While devising such mechanism, NPPA should incorporate provisions for check on availability of spurious / fake and sub-standard drugs in the market which is becoming health hazard for the common people. The Committee would like to be apprised of the action taken in the matter within three months of presentation of this report”.

REPLY OF THE GOVERNMENT

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

“Monitoring of spurious / fake and sub-standard drugs in the market is looked after by the Drugs Controller General (India) and State Drugs Controllers in the country. The concerns of the Hon’ble Committee have been communicated to Ministry of Health & Family Welfare”.

E. MONITORING OF QUALITY OF DRUGS

RECOMMENDATION NO.6

16. Emphasizing the need regarding bringing the quality control and regulatory mechanism under one umbrella, the Committee had recommended as under:-

“Quality is an essential parameter while considering the pricing and availability of medicines. In this regard, the Committee are surprised to note that the quality of drugs and check on spurious drugs is monitored by Drugs Controller of India which is under the jurisdiction of Ministry of Health and Family Welfare whereas the pricing and availability of drugs fall within the purview of the Department of Pharmaceuticals. The Committee further note that the Central Drugs Standard Control Organisation (CDSCO) is within the purview of the Ministry of Health and Family Welfare. In this regard, the Committee strongly feel that monitoring the quality of drugs and check on spurious drugs are interlinked with pricing and availability of drugs and Department of Pharmaceuticals may not be able to do full justice to its role regarding pricing and availability of drugs if

the quality control set up does not come within its purview. The Committee, therefore, desire that the Department of Pharmaceuticals should take up the matter regarding bringing the quality control and regulatory mechanism under one umbrella i.e. the Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers. The Committee would like to be apprised of the action taken in this regard.

Regarding the menace of spurious drugs, Committee note that a survey to assess the extent of spurious drugs in the country was conducted in the year 2009 by the Ministry of Health and Family Welfare through Central Drugs Standard Control Organization and samples were drawn from different stratum in various regions in the country. The survey revealed that the extent of drugs found spurious was 0.046% only. In this regard, the Committee feel that such random surveys are not sufficient to monitor the extent and check the menace of spurious drugs in the country. Hence, the Committee recommend that Department of Pharmaceuticals along with the Ministry of Health and Family Welfare should conduct regular surveys along with random checks in different parts of the country and ensure stringent and quick legal action against the manufacturers of spurious drugs so that common man's life and health is not put into jeopardy".

REPLY OF THE GOVERNMENT

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

"The Department has taken up the matter in the year 2009 with the Cabinet Secretariat regarding transferring the subject matter pertaining to quality control of medicines along with relevant infrastructure i.e. CDSCO to the Department of Pharmaceuticals.

As regards the recommendation regarding checks on spurious drugs, the subject matter falls entirely within the jurisdiction of Ministry of Health & Family Welfare. The concerns of the Hon'ble Committee have been communicated to Ministry of Health & Family Welfare. Till such time the subject matter is transferred to this Department, it will not be feasible for this Department to intervene in the matters of quality control of medicines".

COMMENTS OF THE COMMITTEE

18 The Committee noted that NPPA has been monitoring the availability of drugs in the country regularly and taking remedial steps whenever required. NPPA is carrying out this responsibility mainly through monthly field reports from the State Drugs Controllers and other available information and whenever, shortage of certain brands of drugs is reported in some States, the concerned company is asked to rush the stock and to make the drugs available. In its action taken replies, the Department has stated that Monitoring of spurious / fake and sub-standard drugs in the market is looked after by the Drugs Controller General (India) and State Drugs Controllers in the country. The Department in its reply to the Recommendation No.6, have further stated that till the subject matter is transferred to the Department of Pharmaceuticals it will not be feasible for the Department of Pharmaceuticals to intervene in the matters of quality control of medicines.. According to the Department, they have taken up the matter in the year 2009 with the Cabinet Secretariat regarding transferring the subject matter pertaining to quality control of medicines along with relevant infrastructure to the Department of Pharmaceuticals. However, the Department is silent about the present status of the matter and whether or not the matter is still being pursued by them. The Committee

regret to observe that the reply of the Department in the matter is evasive and unsatisfactory. The Committee are of view that the Department of Pharmaceuticals, being the nodal authority for regulating the production and pricing of drugs, cannot escape its responsibility to monitor the sale of spurious/fake drugs in the market. In addition to this the Committee feel as it is mandatory for all the pharmaceutical company to fully adhere to the quality of drugs and no compromise can be made by them in maintaining the Good Manufacturing Practice (GMP) since the issue regarding quality of drugs cannot be seen in isolation with the manufacturing of medicines. The Committee, therefore, reiterate its recommendation that the Department should evolve a mechanism in cooperation with Ministry of Health and Family Welfare/Drugs Controller General of India and State Drugs Controller to check sale of spurious/sub-standard drugs in the country. The Committee also reiterate that the Department should also actively pursue the matter with the Ministry of Health and Family Welfare and other departments concerned to bring the issue of quality control and regulatory mechanism under the control of the Department of Pharmaceuticals.

F. RECOVERY OF OVERCHARGED AMOUNT

RECOMMENDATION NO.7

19. Expediting the process of pursuing cases relating to overcharged amount and prompt recovery, the Committee had recommended as under:-

“The Committee note that NPPA, since its inception in August 1997, till November, 2012 has issued demand notices in 902 cases involving total overcharged amount of Rs.2577.44 crore out of which an amount of Rs.233.99 crore has been recovered which also includes recovery through court orders. The Committee are, however, surprised to note that NPPA has been able to recover only an amount of Rs.233.99 crore against the total demand notices of Rs.2577.44 crore and an amount of Rs.2267.75 crore is under litigation and thus locked up in courts. The Committee, therefore recommend that NPPA should vigorously pursue these cases and recover the dues promptly. The Committee desire to be apprised of the detailed action taken in this regard. The Committee also desire to be apprised about the way the recovered amount is utilized by the NPPA”.

REPLY OF THE GOVERNMENT

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

“The recovery of the overcharged amount has been adversely affected due to orders passed by High Courts and the Hon’ble Supreme Court in cases filed by the pharmaceutical companies challenging the price fixation / notification issued by the NPPA / Government. Inclusion of some bulk drugs under price control (schedule 1 of DPCO’95) has also been challenged by the a few pharma companies. In some cases, the High Courts and Supreme Court have restrained the Govt. / NPPA to recover the overcharged amount or directed the companies to make part payment of the overcharged amount until the matter is finally decided by them. This has led to an increase in the long outstanding overcharged amount alongwith interest thereon from the

companies. In some cases, the Hon'ble Courts have also directed not to take coercive action for recovery of amount.

NPPA / Government is defending all these cases which are under litigation in the various Courts through Central Agency/Branch Secretariat, Department of Legal Affairs. Urgent applications for vacation of interim orders and also for early hearing / disposal of the case are also filed in various courts. Further, matters are pursued with the District Collectors for initiating action for early recovery of the outstanding dues from the Pharma companies. Besides, the Pharma companies are also insisted through regular follow up to pay the demanded amount.

Presently, the amount recovered from the Pharmaceutical companies for overcharging in normal course is deposited in the 'Consolidated Fund of India'."

COMMENTS OF THE COMMITTEE

21 The Committee also note from the action taken replies of the Department that the recovery of the overcharged amount has been adversely affected due to orders passed by the High Courts and the Hon'ble Supreme Court in cases filed by the pharmaceutical companies challenging the price fixation / notification issued by the NPPA / Government. Inclusion of some bulk drugs under price control (schedule 1 of DPCO'95) has also been challenged by a few pharma companies. In some cases, the High Courts and Supreme Court have restrained the Government / NPPA to recover the overcharged amount or directed the companies to make part payment of the overcharged amount until the matter is finally decided by them. The Committee strongly feel that the above situation would not have arisen in the first place if a mechanism for proactively monitoring the prices of drugs had been devised by the NPPA before the introduction of drugs in the market and had ensured that the prices of drugs were not arbitrarily fixed by the pharma companies. The mechanism to first allow the pharma companies to fix the price and recover the enhanced price if the same was found arbitrarily high was not a sound proposition enunciated by the NPPA as in the whole process the consumer was put at a disadvantageous position such he would not have the benefit of recovery of overcharged amount. The Committee, therefore, recommend that a mechanism for proactively monitoring the prices of drugs should be devised by NPPA before the introduction of drugs in the market. Besides these alternate dispute resolution method like arbitration should be adopted also to mitigate the litigation cases.

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

National Pharmaceutical Pricing Authority (NPPA) has been constituted as an independent body of experts in the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals) by Gazette Notification with the task of price fixation/revision of prices of 74 scheduled bulk drugs/ formulation under the Drugs (Price Control) Order 1995 and other related matters. The Committee note that NPPA provides inputs to the Government for policy formulation and on other specific issues concerning affordable medicines to the consumers and also monitors availability of drugs, identifies shortage and takes remedial steps accordingly. The Committee observe that NPPA has fixed/ revised the prices of scheduled bulk drugs in 532 cases, which includes 342 bulk drugs and 190 derivatives of scheduled bulk drugs and also fixed/ revised the prices of 12137 formulation packs since its inception. The Committee are concerned to note that NPPA's mandate regarding fixing of prices is limited to only 74 bulk drugs/ formulations. The Committee strongly feel that the present mandate of NPPA is narrow and hence the Committee recommend that the mandate of NPPA regarding fixing / revision of pricing of drugs should be broadened to include all the 348 essential drugs and medicines listed by the Department of Pharmaceuticals. As per the latest reply to the Unstarred Question No.2163 dated 6.12.2012 whereby the Department of Pharmaceuticals has informed that the Cabinet has approved the National Pharmaceutical Pricing Policy-2012 (NPPP-2012) with certain modifications. Also it is stated that NPPP-2012 has not yet been notified. Therefore, in view of the above, the Committee desire to know about the 'Certain modifications' carried out in NPPP-2012. Further, the Committee also recommends that the Department of Pharmaceuticals should expedite the process of notification of NPPP-2012. Further, the Committee recommend that the prices fixed/ revised by NPPA should be printed on the medicine packet bottle alongwith the Maximum Retail Price (MRP) of the medicines so that common man may know if there is any over pricing by the manufacturers. The Committee would like to be apprised of steps taken in this regard within three months of presentation of Report.

REPLY OF THE GOVERNMENT

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

"The Cabinet in its meeting held on 22.11.2012 approved the proposal regarding National Pharmaceutical Pricing Policy covering essential medicines with the following modification in paragraph 3.1(c) of the supplementary note dated 21.11.2012 which read as under:

"If a manufacturer of a NLEM drug with dosages and strengths as specified in NLEM, launches a new drug by combining the NLEM drug with another NLEM drug or by changing the strength and dosages of the same NLEM drug, such manufacturers shall be required to seek price approval from the Government before launching the new drug."

that the words "or a non-NLEM drugs" be inserted after the words "another NLEM drug".

National Pharmaceutical Pricing Policy-2012 (NPPP-2012) has been notified on 07.12.2012. The new Drugs (Prices Control) Order, 2013 has been notified vide S.O.122(E) dated 15th May, 2013.

Printing of MRP on packaging is regulated as per Weights and Measures Act, which does not provide for printing of MRP on medicine strips. Therefore, a special provision for compulsory printing of MRP on medicine strips was made under DPCO, 1995. Further, Para 24 (2) of the DPCO, 2013 also provides for printing of Maximum Retail Price (MRP) of a

formulation based on the ceiling price notified in the official Gazette or ordered by the Government in this behalf”.

[Department of Pharmaceuticals O.M. No.31026/20/2013-PI.I dated 3.06.2013]

RECOMMENDATION NO.2

The Committee note that during the Eleventh Five Year Plan period (2007-2012), NPPA had proposed five new schemes amounting to Rs. 4995.60 lakh. These schemes are (i) Building Robust and Responsive Statistical System for NPPA; (ii) Creation of NPPA Cells in States; (iii) Scheme for Interaction with States; (iv) Proposal for Consumer Awareness and Publicity through Print, Electronic and other medium; and (v) Proposal for strengthening the existing Monitoring and Enforcement work. The Committee also note that out of these five schemes, only one scheme viz Building Robust and Responsive Statistical System for NPPA has already been approved by the Planning Commission and implemented during the Eleventh Plan period. Further, in-principle approval in respect of the scheme, namely Proposal for Consumer Awareness and Publicity through Print, Electronic and other medium was given in February, 2011 and in the budget allocation for the year 2012-13, funds are allocated only for these two schemes. In this regard, this Committee have time and again recommended that the Department should earnestly pursue the issue with the Planning Commission and make all out efforts towards getting in-principle approval for rest of the three schemes of NPPA. The Committee strongly feel that the above three schemes of NPPA are vital for fulfilling the mandate of the organization and again recommend that the Department should make earnest effort to get in-principle approval of these three schemes from Planning Commission. The Committee would like to be informed about follow up action taken in this matter”.

REPLY OF THE GOVERNMENT

With the notification of National Pharmaceutical Pricing Policy 2012 and Drugs (Price Control) Order, 2013, (DPCO, 2013) the relevance of the Schemes has been reviewed in consultation with NPPA and the status of each scheme is as under :

- (i) Creation of NPPA Cells in States: In view of the changes in norms for pricing as envisaged in DPCO, 2013, it is felt that separate cells in States may not be required.
- (ii) Scheme for Interaction with States: NPPA has already taken initiative in this regard by having regional meetings with States on regular basis. It is felt that a special scheme for the purpose is not required.
- (iii) Proposal for strengthening the existing Monitoring and Enforcement work: it has been decided to revisit the provisions of this scheme by NPPA and a view will be taken keeping in view the requirement under DPCO, 2013.

COMMENTS OF THE COMMITTEE

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

RECOMMENDATION. NO.3

National Pharmaceutical Pricing Authority fixes/revises the prices of 74 bulk drugs and the formulations containing any of the scheduled drugs under the provisions of the Drugs specified in the first schedule of the Drug (Prices Control) Order, 1995. The Committee find that scheduled drugs/formulations cannot be sold at a price higher than that fixed by NPPA/Government. According to the Department of Pharmaceuticals, non-submission of the requisite data/information by the manufacturing units particularly in cases of reduction in the input cost is the major difficulty being faced by NPPA. The Committee observe that NPPA endeavours to overcome this problem through interaction with State Drug Controllers to impress upon the manufacturing units to submit the requisite data/information. The Committee are of the view that there is an urgent need for taking definite steps to encourage the manufacturing units

to submit the data in time and desire that NPPA should chalk out mechanism for co-ordination with State Enforcement Agencies in this regard.

The Committee also note that the Pharma Companies frequently change, the composition/strength of their formulations to circumvent the provisions of DPCO, 1995. In order to escape the provisions of the DPCO, 1995 pharma companies are also using the via-media of Dietary Supplements under the Prevention of Food Adulteration Act 1954 and flooding the retail market by medicines of dietary supplements. While expressing their concern over such strategy adopted by the pharma companies, the Committee recommend that the Department should expeditiously identify the concerned pharma companies and take up the issue strongly with the Ministry of Health and Family Welfare. The Committee also desire that NPPA should not hesitate to invoke the relevant provisions of the DPCO, 1995 to curb such alleged malpractices by the drug companies. Thus, the circumventing of the price control mechanism by some manufacturers by shifting schedule drugs to the category of Food and Nutrition Supplement manufacture under Prevention of Food Adulteration Act 1954 should also be monitored by the NPPA. In this regard, NPPA cannot shirk away from its responsibility and leave the matter at the behest of the Ministry of Health and Family Welfare. The Committee would like to be apprised of the action taken in the matter. The Committee also desire that the list of companies indulged in such malpractices and action taken against them should be furnished to the Committee within three months of presentation of the Report.

The Committee further note that the State Drugs Controllers help NPPA in monitoring the prices and enforcing the provisions of DPCO,1995. The State Governments are authorized to take action under Essential Commodities (EC) Act, 1995 for violation of the provisions of the DPCO, 1995. The Committee observe that prosecution under Essential Commodities Act, 1995 sometimes does not lead to stringent action against defaulters. The Committee find that at present, there are no provisions of fine or penalties for the violation of the DPCO,1995 for non-submission of requisite data, price list and for not allowing officers of NPPA to visit and inspect manufacturing premises. The Committee, therefore, desire that DPCO, 1995 should be amended suitably to incorporate provisions for compounding offences by stringent fines or penalties therein.

REPLY OF THE GOVERNMENT

With change in pricing norms under DPCO, 2013 from the cost based pricing to market based pricing, the cost data will no more be required. Moreover, forms have been further simplified in DPCO, 2013 to make the process of collection easy. Para 16 of the said order provides for submission of information / data by the industry mandatorily in respect of revision of the prices within 15 days and it also provides that the company would be liable for an action under the said order if it fails to submit the same within 15 days' time. The provision has also been made with regard to monitoring of availability of scheduled formulations vide Para 21 of the said order. Manufacturers are also required to file quarterly production returns with the NPPA in Form-III. In respect of discontinuation of the production of the scheduled formulation manufacturers should file returns in Form IV of the said order. The companies are also required to file price list in Form-V with the NPPA.

The issue of circumventing the price control mechanism through dietary supplements has already been taken up by this Department with the Ministry of Health & Family Welfare and a reminder has also been sent on 29.4.2013.

DPCOs are subordinate legislation and sufficient penal provisions already exist in the parent Act i.e. Essential Commodities Act, 1955".

[Department of Pharmaceuticals O.M. No.31026/20/2013-PI.I dated 3.06.2013]

COMMENTS OF THE COMMITTEE

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

CHAPTER – III

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

NIL

CHAPTER – IV**OBSERVATIONS/RECOMMENDATIONS IN RESPECT OF WHICH REPLIES OF THE GOVERNMENT HAVE NOT BEEN ACCEPTED BY THE COMMITTEE AND WHICH REQUIRE REITERATION****RECOMMENDATION NO.4**

The Committee note that prices of non-scheduled drugs are fixed by manufacturers themselves without seeking the approval of Government / NPPA. NPPA, however, regularly monitors the prices of non-scheduled formulations based on the data from IMS (Health). The Committee in this regard regret to point out that NPPA depends entirely on IMS (Health) data and does not have their own specific system for data collection. The Committee, therefore, recommend that Department should take necessary steps to make NPPA self-sufficient and resourceful to carry out its activities regarding monitoring of prices of non-scheduled drugs independently and effectively.

Regarding monitoring of the prices of non-scheduled drugs, the Committee note that a list of formulations and their manufacturers are short-listed where there is an increase in price of more than 10% in one year and the annual turnover of the formulation pack exceeds Rs.1 crore. Further, the share of formulations in that segment of the formulation is required to be at least 20% of the market or the medicine is one of the top 3 brands of that group. The manufacturer and / or distributor is asked to give justification for price increase of more than 10% per annum. If no information is received after the letter and reminder or the reply of the company is not satisfactory, show cause notice is issued to the manufacturer stating as to why action should not be initiated for price fixation under para 10(b) of DPCO, 1995 in larger public interest. In this regard, Committee feel that such a process of monitoring of prices of non-schedule drugs is not satisfactory and deterrent as the manufacturers have the advantage of fixing the prices first provisionally. The present mechanism does not provide any relief to masses in case it is found that prices were arbitrarily fixed. Hence, the Committee recommend that NPPA should devise a mechanism to proactively monitor the rise in prices of non-scheduled drugs so that the same does not go beyond the permissible limit.

REPLY OF THE GOVERNMENT

NPPA has already taken initiative to collect information directly from the manufacturers. Almost 7,000 manufacturers have already been addressed to submit required information. Moreover, making a provision for filing of information online will further facilitate collection of information. This would definitely reduce dependence on IMS Health in long run.

In the new DPCO, 2013, there is a provision to amend the list of Scheduled Formulations based on the communication from the Ministry of Health and Family Welfare. Hence, para 10(b) of DPCO, 95 has lost its relevance.

[Department of Pharmaceuticals O.M. No.31026/20/2013-PI.I dated 3.06.2013]

COMMENTS OF THE COMMITTEE

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

RECOMMENDATION NO.5

The Committee are happy to note that NPPA has been monitoring the availability of drugs in the country regularly and taking remedial steps whenever required. NPPA is carrying out this responsibility mainly through monthly field reports from the State Drugs Controllers and other available information and whenever, there are reports of shortage of certain brands of drugs in some States, the concerned company is asked to rush the stock and to make the drugs available. The Committee, therefore, desire that to ensure regular and normal supply of medicines in all States, specifically in remote and hilly regions, NPPA should devise effective distribution and delivery system in coordination with State Drugs Controllers. While devising

such mechanism, NPPA should incorporate provisions for check on availability of spurious / fake and sub-standard drugs in the market which is becoming health hazard for the common people. The Committee would like to be apprised of the action taken in the matter within three months of presentation of this report.

REPLY OF THE GOVERNMENT

Monitoring of spurious / fake and sub-standard drugs in the market is looked after by the Drugs Controller General (India) and State Drugs Controllers in the country. The concerns of the Hon'ble Committee have been communicated to Ministry of Health & Family Welfare.

[Department of Pharmaceuticals O.M. No.31026/20/2013-PI.I dated 3.06.2013]

COMMENTS OF THE COMMITTEE

(Please see Para No.18 of Chapter I of the Report)

RECOMMENDATION NO.6

Quality is an essential parameter while considering the pricing and availability of medicines. In this regard, the Committee are surprised to note that the quality of drugs and check on spurious drugs is monitored by Drugs Controller of India which is under the jurisdiction of Ministry of Health and Family Welfare whereas the pricing and availability of drugs fall within the purview of the Department of Pharmaceuticals. The Committee further note that the Central Drugs Standard Control Organisation (CDSCO) is within the purview of the Ministry of Health and Family Welfare. In this regard, the Committee strongly feel that monitoring the quality of drugs and check on spurious drugs are interlinked with pricing and availability of drugs and Department of Pharmaceuticals may not be able to do full justice to its role regarding pricing and availability of drugs if the quality control set up does not come within its purview. The Committee, therefore, desire that the Department of Pharmaceuticals should take up the matter regarding bringing the quality control and regulatory mechanism under one umbrella i.e. the Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers. The Committee would like to be apprised of the action taken in this regard.

Regarding the menace of spurious drugs, Committee note that a survey to assess the extent of spurious drugs in the country was conducted in the year 2009 by the Ministry of Health and Family Welfare through Central Drugs Standard Control Organization and samples were drawn from different stratum in various regions in the country. The survey revealed that the extent of drugs found spurious was 0.046% only. In this regard, the Committee feel that such random surveys are not sufficient to monitor the extent and check the menace of spurious drugs in the country. Hence, the Committee recommend that Department of Pharmaceuticals along with the Ministry of Health and Family Welfare should conduct regular surveys along with random checks in different parts of the country and ensure stringent and quick legal action against the manufacturers of spurious drugs so that common man's life and health is not put into jeopardy.

REPLY OF THE GOVERNMENT

The Department has taken up the matter in the year 2009 with the Cabinet Secretariat regarding transferring the subject matter pertaining to quality control of medicines along with relevant infrastructure i.e. CDSCO to the Department of Pharmaceuticals.

As regards the recommendation regarding checks on spurious drugs, the subject matter falls entirely within the jurisdiction of Ministry of Health & Family Welfare. The concerns of the Hon'ble Committee have been communicated to Ministry of Health & Family Welfare. Till such time the subject matter is transferred to this Department, it will not be feasible for this Department to intervene in the matters of quality control of medicines.

[Department of Pharmaceuticals O.M. No.31026/20/2013-PI.I dated 3.06.2013]

COMMENTS OF THE COMMITTEE

(Please see Para No. 18 of Chapter I of the Report)

RECOMMENDATION NO.7

The Committee note that NPPA, since its inception in August 1997, till November, 2012 has issued demand notices in 902 cases involving total overcharged amount of Rs.2577.44 crore out of which an amount of Rs.233.99 crore has been recovered which also includes recovery through court orders. The Committee are, however, surprised to note that NPPA has been able to recover only an amount of Rs.233.99 crore against the total demand notices of Rs.2577.44 crore and an amount of Rs.2267.75 crore is under litigation and thus locked up in courts. The Committee, therefore recommend that NPPA should vigorously pursue these cases and recover the dues promptly. The Committee desire to be apprised of the detailed action taken in this regard. The Committee also desire to be apprised about the way the recovered amount is utilized by the NPPA.

REPLY OF THE GOVERNMENT

The recovery of the overcharged amount has been adversely affected due to orders passed by High Courts and the Hon'ble Supreme Court in cases filed by the pharmaceutical companies challenging the price fixation / notification issued by the NPPA / Government. Inclusion of some bulk drugs under price control (schedule 1 of DPCO'95) has also been challenged by the a few pharma companies. In some cases, the High Courts and Supreme Court have restrained the Govt. / NPPA to recover the overcharged amount or directed the companies to make part payment of the overcharged amount until the matter is finally decided by them. This has led to an increase in the long outstanding overcharged amount alongwith interest thereon from the companies. In some cases, the Hon'ble Courts have also directed not to take coercive action for recovery of amount.

NPPA / Government is defending all these cases which are under litigation in the various Courts through Central Agency/Branch Secretariat, Department of Legal Affairs. Urgent applications for vacation of interim orders and also for early hearing / disposal of the case are also filed in various courts. Further, matters are pursued with the District Collectors for initiating action for early recovery of the outstanding dues from the Pharma companies. Besides, the Pharma companies are also insisted through regular follow up to pay the demanded amount.

Presently, the amount recovered from the Pharmaceutical companies for overcharging in normal course is deposited in the 'Consolidated Fund of India'.

[Department of Pharmaceuticals O.M. No.31026/20/2013-PI.I dated 3.06.2013]

COMMENTS OF THE COMMITTEE

(Please see Para No.21 of Chapter I of the Report)

CHAPTER – V

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

NIL

**NEW DELHI;
12 AUGUST, 2013
21 SHRAVANA, 1935 (SAKA)**

**GOPINATH MUNDE
CHAIRMAN;
STANDING COMMITTEE ON
CHEMICALS AND FERTILIZERS**

APPENDIX I**MINUTES****MINUTES OF THE FOURTEENTH SITTING OF THE
STANDING COMMITTEE ON CHEMICALS & FERTILIZERS
(2012-13)**

The Committee sat on Tuesday, the 06 August, 2013 from 1500 hrs. to 1530 hrs. in Committee Room 'E', Parliament House Annexe, New Delhi.

Shri Gopinath Munde - Chairman

MEMBERS**LOK SABHA**

2. Shri Gajanan D. Babar
3. Shri K.D. Deshmukh
4. Shri Sher Singh Ghubaya
5. Shri Kamlesh Paswan
6. Shri Tufani Saroj
7. Shri Suresh Kumar Shetkar

RAJYA SABHA

8. Smt. Naznin Faruque
9. Shri A.A. Jinnah

SECRETARIAT

| | | |
|----------------------|---|---------------------|
| Smt. Rashmi Jain | - | Joint Secretary |
| Shri U.B.S. Negi | - | Director |
| Shri A.K. Srivastava | - | Additional Director |

2. At the outset, the Chairman welcomed the members of the Committee.
3. The Committee thereafter took up for consideration the following draft Reports:
 - I. XXXXX XXXXX XXXXX
 - II. Draft Action Taken Report on the action taken by the Government on the observations/ recommendations contained in the Twenty-ninth report (15th LS) on 'National Pharmaceuticals Pricing Authority' (Department of Pharmaceuticals)
4. Both the reports were adopted by the Committee without any amendment.
5. The Committee then authorized the Chairman to present the same to both the Houses of Parliament.
6. It was decided that the following Members would present/lay the Reports in Lok Sabha/ Rajya Sabha on 13.08.2013.

In Lok Sabha
Shri Gopinath Munde
Shri Shakti Mohan Malik

In Rajya Sabha
Shri A.A. Jinnah
Shri Dilipbhai Pandya

The Committee then adjourned.

XXXXX Matters not related to this Report

APPENDIX II

(Vide Para 3 Of The Introduction)

ANALYSIS OF ACTION TAKEN BY THE GOVERNMENT ON THE RECOMMENDATIONS CONTAINED IN THE TWENTY-NINTH REPORT (FIFTEENTH LOK SABHA) OF THE STANDING COMMITTEE ON CHEMICALS AND FERTILIZERS (2012-13) ON NATIONAL PHARMACEUTICALS PRICING AUTHORITY (NPPA)' OF THE MINISTRY OF CHEMICALS AND FERTILIZERS (DEPARTMENT OF PHARMACEUTICALS)

| | | |
|---------------------|--|-----|
| I | Total No. of Recommendations | 7 |
| II | Observations / Recommendations which have been accepted by the Government:- (Vide Recommendation at Sl.Nos.1,2 and 3) | 3 |
| Percentage of Total | | 43% |
| III | Observation / Recommendation which the Committee do not desire to pursue in view of the Government's reply:- NIL | 0 |
| Percentage of Total | | NIL |
| IV | Observation / Recommendation in respect of which reply of the Government have not been accepted by the Committee and which require reiteration:- (Vide Recommendation at Sl.Nos. 4,5,6 and 7) | 4 |
| Percentage of Total | | 57% |
| V | Observations / Recommendations in respect of which replies of the Government are awaited:- NIL | 0 |
| Percentage of Total | | NIL |