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STANDING COMMITTEE ON CHEMICALS & FERTILIZERS (2012-13)

FIFTEENTH LOK SABHA

MINISTRY OF CHEMICALS AND FERTILIZERS (DEPARTMENT OF PHRMACEUTICALS)

REPORT ON NATIONAL PHARMACEUTICAL PRICING AUTHORITY (NPPA)

TWENTY-NINTH REPORT

LOK SABHA SECRETARIAT
NEW DELHI

December, 2012/ Agrahayana 1934, (Saka)

CC&F No. -29

REPORT

STANDING COMMITTEE ON CHEMICALS AND FERTILIZERS (2012-13)

FIFTEENTH LOK SABHA

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REPORT ON NATIONAL PHARMACEUTICAL PRICING AUTHORITY (NPPA)

Presented to Lok Sabha on 17.12.2012

Laid in Rajya Sabha on 17.12.2012

LOK SABHA SECRETARIAT
NEW DELHI

December, 2012/Agrahayana, 1934 (Saka)

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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 Radadiya Vitthalbhai Hansrajbhai
8.	Shri Sk. Nurul Islam
9.	Shri Sakti Mohan Malik
10.	Shri Paswan Kamlesh
11.	Shri Amarnath Pradhan
12.	Shri Ashok Kumar Rawat
13.	Shri Tufani Saroj
14.	Shri Suresh Kumar Shetkar
15.	Shri Raju Shetti
16.	Shri G.M. Siddeshwara
17.	Shri D. Venugopal
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.	Dr. Vijay Mallya
27.	Shri Pyarimohan Mohapatra
28.	Shri Dilipbhai Pandya
29.	Shri Raghunandan Sharma
30.	Vacant
31.	Vacant

SECRETARIAT

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

Shri P. Balaram Naik appointed as a minister of state

IV-(b)

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

$ Shri Gopinath Munde - Chairman	
Members	
Lok Sabha	
2	Smt. Sushmita Bauri
3	Shri Prabhatsinh P. Chauhan
4	Shri K.D. Deshmukh
5	Shri Ganeshrao Nagorao Dudhgaonkar
6	Shri Madhu Koda
7	Shri N. Peethambara Kurup
8	Shri Baidyanath Prasad Mahato
9	Shri Ponnam Prabhakar
10	Shri Ashok Kumar Rawat
11.	Shri Suresh Kumar Shetkar
12	Shri Ajit Singh
13	Shri N. Cheluvaraya Swamy
14	Shri Narendra Singh Tomar
&15	Shri T.K.S. Elangovan
&16	Shri Tapas Paul
**17	Shri Udayanraje Bhonsle
18 to 21	Vacant
Rajya Sabha	
22	Shri Raghunandan Sharma
23	Dr. C.P. Thakur
24	Shri Brijlal Khabri
25	Shri A.A. Jinnah
26	Shri Biswajit Daimary
**27	Prof. Anil Kumar Sahani
***28	Shrimati Naznin Faruque
#29	Vacant
%30	Vacant
=31	Vacant

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* Consequent upon nomination to the Committee on Information Technology Shri Tufani Saroj, MP (LS) ceased to be Member of the Committee w.e.f. 13.10.2009.

\# Vacancy arisen due to demise of Shri Mahendra Sahni, MP (RS) w.e.f. 6 November 2009.

& Nominated w.e.f. 11.01.2010.

** Nominated w.e.f. 26.02.2010.

*** Nominated w.e.f. 26.04.2010.

$ Nominated w.e.f. 07.05.2010.

% Shri J.D. Seelam ceased to be Member of this Committee w.e.f. 21 June 2010 after his retirement from Rajya Sabha.

= Shri Raj Mohinder Singh Majitha ceased to be Member of this Committee w.e.f. 4 July 2010 after his retirement from Rajya Sabha.

IV-(c)

COMPOSITION OF THE STANDING COMMITTEE ON CHEMICALS & FERTILIZERS (2008-09)

Shri Anant Gangaram Geete - Chairman	
Members	
Lok Sabha	
2.	Shri Ajit Singh
3.	Shri Sunil Khan
4.	Shri Shrichand Kripalani
5.	Shri Subhash Maharia
6.	Shri A. Narendra
7.	Shri Anand Paranjpe
8.	Shri Prasanta Pradhan
9.	Shri P. Chalapathi Rao
10.	Shri Ashok Kumar Rawat
11.	Shri Anantha Venkata Rami Reddy
12.	Shri Devwrat Singh
13.	Shri Narsingrao H. Suryawanshi
14.	Shri Mansukhbhai Dhanjibhai Vasava
15.	Shri D. Venugopal
16.	Shri Bhanu Pratap Singh Verma
*17.	Vacant
**18.	Vacant
***19.	Vacant
@**20**	Vacant
21.	Vacant
RAJYA SABHA	
22.	Shri B.S. Gnanadesikan
23.	Shri A.A. Jinnah
24.	Shri Raj Mohinder Singh Majitha
25.	Shri Om Prakash Mathur
26.	Shri V. Hanumantha Rao
27.	Shri Mahendra Sahni
28.	Shri Gireesh Kumar Sanghi
29.	Shri Raghunandan Sharma
%30.	Dr. Barun Mukherji
#31.	Shri Brijlal Khabri

** Consequent upon his disqualification for being Member of the Lok Sabha, Shri Jai Prakash (Constituency – Mohanlal Ganj) ceased to be Member of this Committee w.e.f. 12.09.2008.*

***Consequent upon his disqualification for being Member of the Lok Sabha, Shri Ramswaroop Prasad ceased to be Member of this Committee w.e.f. 03.10.2008.*

**** Consequent upon his resignation from Lok Sabha, Shri Punnu Lal Mohale ceased to be Member of this Committee w.e.f. 17.12.2008.*

*% Nominated w.e.f. 09.12.2008 **vice** Shri Debabrata Biswas, MP (RS) who had resigned from Rajya Sabha on 23.09.2008.*

 # Nominated w.e.f. 27.01.2009

@ Consequent upon his resignation from Lok Sabha, Shri Afzal Ansari ceased to be Member of this Committee w.e.f. 12.03.2009.

IV-(d)

COMPOSITION OF THE STANDING COMMITTEE ON CHEMICALS & FERTILIZERS (2006-07)

Shri Anant Gangaram Geete - Chairman	
Members	
Lok Sabha	
2.	Shri Ajit Singh
3.	Shri Suresh Angadi
4.	Shri Afzal Ansari
5.	Shri Jaiprakash (Mohanlal Ganj)
6.	Shri Sunil Khan
*7.	Shri Shrichand Kripalani
8.	Shri Subhash Maharia
9.	Shri Punnu Lal Mohale
$10.	Shri A. Narendra
11.	Shri Prasanta Pradhan
#12.	Shri Ramswaroop Prasad
13.	Shri P. Chalapathi Rao
14.	Shri Ashok Kumar Rawat
15.	Shri Anantha Venkata Rami Reddy
&16.	Shri Devwrat Singh
17.	Shri Narsingrao H. Suryawanshi
18.	Shri Mansukhbhai Dhanjibhai Vasava
19.	Shri D. Venugopal
20.	Shri Bhanu Pratap Singh Verma
+21.	Vacant
Rajya Sabha	
22.	Shri Devdas Apte
%23.	Shri Debabrata Biswas
24.	Shri Gireesh Kumar Sanghi
25.	Shri V. Hanumantha Rao
@26.	Shri Mahendra Sahni
27.	Shri Dilip Singh Judev
28.	Shri R. Shunmugasundaram
29.	Shri Raj Mohinder Singh Majitha
30.	Shri T.R. Zeliang
**31.	Vacant

** Nominated w.e.f. 31.08.2006.*
$ Nominated w.e.f. 25.09.2006
@ Nominated w.e.f. 04.10.2006
 # Nominated w.e.f. 08.12.2006
+ Consequent upon nomination to the Committee on Transport, Tourism and Culture, Shri Prahlad Joshi, MP (LS) ceased to be Member of the Committee w.e.f. 20.03.2007
% Nominated w.e.f. 03.05.2007
& Nominated w.e.f. 25.07.2007
** Shri B.S. Gnanadesikan, MP (RS) ceased to be Member of Rajya Sabha w.e.f. 24.07.2007

INTRODUCTION

I, the Chairman, Standing Committee on Chemicals and Fertilizers (2012-13) having been authorised by the Committee to submit the Report on their behalf present this Twenty-Ninth Report on the subject 'National Pharmaceutical Pricing Authority (NPPA)'.

2. The Subject, National Pharmaceutical Pricing Authority (NPPA)' was first taken up for examination by the Committee on Chemicals and Fertilizers (2006-2007). Accordingly, a sitting of the Committee was held on 26 September, 2006 to have a briefing on the subject. The subject was again taken up for examination by the Committee (2008-09). During that time a sitting of the Committee was held on 27 January, 2009 to have a briefing on the subject. As the examination of the subject remained inconclusive, the subject was again taken up for examination by the Committee (2009-10) and accordingly a sitting was held on 4 November, 2009 for taking oral evidence of the representatives of the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals).

3. The Committee considered and adopted the Report at their sitting held on 10 December 2012.

4. The Committee wished to express their thanks to the Officers of the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals) for furnishing the material and other information, which the Committee desired in connection with the examination of the subject. The Committee also expressed their thanks to the earlier Committees for their work on the subject.

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

6. The Committee also place on record their appreciation for the invaluable assistance rendered to them by the Officials of the Lok Sabha Secretariat attached to the Committee.

New Delhi;

14 December, 2012
26 Agrahayana, 1934 (Saka)

GOPINATH MUNDE
CHAIRMAN,
STANDING COMMITTEE ON
CHEMICALS AND FERTILIZERS

REPORT

PART-I

CHAPTER –I

INTRODUCTORY

1.1 The National Pharmaceutical Pricing Authority (NPPA) was established as an independent body of experts under the Ministry of Chemicals and Fertilizers by Gazette notification dated 29.08.1997. The Authority is entrusted with the task of price fixation / revision of the 74 scheduled drugs and formulation containing any of the scheduled drugs under the Drugs (Prices Control) Order, 1995 as well as monitoring and enforcement of prices. NPPA also provides in-puts to the Government for policy formulation and on other specific issues concerning affordable medicines to the consumer. The NPPA comprise of a Chairman in the rank of Additional Secretary to the Government of India, a Member Secretary in the rank of Joint Secretary and three ex-officio-Member viz. Economic Adviser, Department of Economic Affairs, Ministry of Finance, Advisor (Cost), Department of Expenditure, Ministry of Finance and the Drug Controller General (India), Ministry of Health.

1.2 The functions of the National Pharmaceutical Pricing Authority (NPPA) are:-

(i) To implement and enforce the provisions of the Drugs (Prices Control) Order (DPCO), 1995 in accordance with the power delegated to it.

(ii) To undertake and/or sponsor relevant studies in respect of pricing of drugs/formulations.

(iii) To monitor the availability of drugs, identify shortages, if any, and to take remedial steps.

(iv) To collect/maintain data on production, exports and imports, market share of individual companies, profitability of companies etc. for bulk drugs and formulations.

(v) To deal with all legal matters arising out of the decisions of the Authority.

(vi) To render advice to the Central Government of changes/revisions in the drug policy.

(vii) To render assistance to the Central Government on matters relating to drug pricing.

CHAPTER –II

PERFORMANCE OF NPPA

2.1 The details of BE,RE and the Actual Expenditure (Both Plan and Non-Plan) for National Pharmaceutical Pricing Authority for the years 2009-10, 2010-11 and 2011-12 and BE 2012-13 are as follows:-

A. BUDGET ALLOCATION

Details of Plan Allocation

(Rupees in lakh)

BE 2009-10	RE 2009-10	Actual Expenditure 2009-10	BE 2010-11	R.E. 2010-11	Actual Expenditure 2010-11	BE 2011-12	R.E. 2011-12	Actual Expenditure 2011-12	B.E. 2012-13
225.00	85.00	43.20	99.00	70.00	37.90	240.00	205.00	7.64	400.00

Details of Non-Plan Allocations

(Rupees in lakh)

Sl. No.	Object Head	BE 2009-10	RE 2009-10	Actual Exp. 2009-10	BE 2010-11	RE 2010-11	Actual Exp. 2010-11	BE 2011-12	RE 2011-12	Actual Exp. 2011-12	BE 2012-13
1	Salary	280.00	280.00	257.98	260.00	224.00	218.45	245.00	245.00	238.21	260.00
2	Medical Treatment	10.00	10.00	9.52	15.00	15.00	1.85	16.00	16.00	5.10	20.00
3	Domestic Travel	20.00	15.00	12.46	22.00	22.00	14.40	22.00	20.00	18.44	25.00
4	Foreign Travel	7.00	6.00	0.00	8.00	8.00	0.00	8.00	8.00	0.00	8.00
5	Rent, Rates and Taxes	115.00	96.00	95.72	110.00	110.00	99.57	110.00	110.00	110.11	125.00
6	Office Expenses	127.00	110.00	88.66	120.00	90.00	90.00	110.00	100.00	99.59	110.00
7	Other Admn. Exp.	5.00	4.00	0.47	5.00	5.00	1.07	5.00	5.00	2.98	5.00
8	Professional Service	50.00	15.00	14.41	20.00	20.00	16.91	20.00	20.00	13.93	20.00
9	Wages	10.00	40.00	38.38	45.00	45.00	42.10	50.00	50.00	49.98	60.00
10	OTA	2.00	1.00	0.95	2.00	2.00	1.35	2.00	2.00	1.31	2.00
	Total	**626.00**	**577.00**	**518.55**	**607.00**	**541.00**	**485.70**	**588.00**	**581.00**	**539.00**	**635.00**

2.2 The Committee enquired about the reasons for lesser utilization of funds for the years 2009-10, 2010-11 and 2011-12 under the Revenue Head and Capital Head regarding Plan Expenditure, the Department of Pharmaceuticals in its written reply stated as under: -

> "There has been low utilization of the approved funds during the above said period under the On-going Scheme of Computerization of NPPA. The software called Integrated Management System (IMS) developed by NIC for computerization of the functions of the NPPA is under testing / implementation.
>
> The funds provided under the Schemes were not fully utilized due to delay in submission of the reports by M/s. ICRA Management Consultant Services Ltd. who were assigned the work for two studies in the year 2010-11 namely (i) First Pharmaceutical Census of India, and (ii) Collection of annual turnover data from the Bulk Drug manufacturing units. It is expected work on the both schemes would be completed during the year 2012-13.
>
> In principle approval for the Scheme Consumer Awareness and Publicity through Print, Electronic and other medium was received in February, 2011. The scheme is to be implemented through Department of Consumer Affairs. However, no expenditure could take place in 2011-12 since the modalities for joint publicity campaign were being finalized. Department of Consumer Affairs sent the Media Plan for NPPA on 9th January, 2012. As DAVP has a payment cycle of two months no expenditure could be incurred".

2.3 Further, while explaining the Revised Expenditure (Plan) for the year 2011-12 for the schemes being implemented by NPPA the Department of Pharmaceuticals in a written note, informed the Committee as under :-

> "The allocation of Rs.205 lakh (Plan) under the RE for the year 2011-12 includes Rs.25 lakh for Ongoing Scheme of Computerization of NPPA, Rs.10 lakh for the scheme "Building Robust & Responsive Statistical System for NPPA", and Rs.170 lakh for the Scheme "Consumer Awareness through print, electronic and other media". Out of this, an amount of Rs.16.00 lakh have been released to National Informatics Centre (NIC) under the Ongoing Scheme of Computerization of NPPA. Out of Rs.16.00 lakh NIC could utilize only Rs.7.64 lakh. Under the scheme "Building Robust & Responsive Statistical System for NPPA" , the work on two studies, i.e., (i) First Pharmaceutical Census of India, and (ii) Collection of annual turnover data from the Bulk Drug manufacturing units, has been taken up and is likely to be completed during the year 2012-13. The Scheme "Consumer Awareness through print, electronic and other media" is to be implemented through Department of Consumer Affairs. Modalities for joint publicity campaign and two ads for print media have been finalized. The work for development of ad films on the role and functions of NPPA is in process. Funds under the scheme have not been utilized as yet. It is hoped that NPPA will start utilizing the funds under the scheme from the beginning of the next year".

2.4 As regards the Budget Expenditure (Plan) for the year 2012-13, the Department of Pharmaceuticals in a written note stated as under:-

> "For the year 2012-13 an amount of Rs.400 lakh (Plan) has been provided.
>
> NPPA in 2007 has sent following five New Plan Schemes amounting to Rs.49.95 crores for the plan period 2007-08 to 2011-12:-

Sl. No.	Scheme	Amount (Rupee in lakh)
1.	Building Robust & Responsive Statistical System for NPPA	215.00
2.	Creation of NPPA Cells in States	2638.00
3.	Scheme for Interaction with States	152.00
4.	Proposal for Consumer Awareness and Publicity through Print, electronic and other medium	1828.00
5.	Proposal for strengthening the existing Monitoring and Enforcement work	162.60
	Total	**4995.60**

> Out of these, Building Robust & Responsive Statistical System for NPPA was initially approved by the Planning Commission and implemented during the 11th Five Year Plan (2007-08 to 2011-12). In-principle approval of the Planning Commission in respect of scheme at Sl No. 4 was received in February, 2011. NPPA has been provided an amount of Rs.400 lakh (Plan) for the year 2012-13. The scheme-wise allocation of funds is as under:

Sl. No.	Scheme	Amount (Rupee in lakh)
A.	**On-going Scheme of Computerisation of NPPA**	**38.00**
B.	**Other Plan Schemes**	
1.	Building Robust & Responsive Statistical System for NPPA	**20.00**
2.	Creation of NPPA Cells in States	
3.	Scheme for Interaction with States	
4.	Consumer Awareness and Publicity through Print, electronic and other medium	**342.00**
5.	Strengthening the existing Monitoring and Enforcement work	
	Total	**400.00**

B. ACHIEVEMENTS OF NPPA

(i) Ongoing Scheme of Computerization of NPPA

2.5 The scheme envisages to bring in automation/computerization in the functioning of NPPA. Required hardware have been purchased through National Informatics Centre and a software called Integrated Management System has been developed by National Informatics Centre for NPPA. The software would help NPPA in scrutinizing the overcharging cases and further follow up required for the purpose such as issue of the notices/demand notices to the defaulting companies. The fixation of the prices of the scheduled bulk drugs and formulations would also be undertaken through the help of this software. Presently, the software is under testing/implementation in the NPPA.

(ii) Building Robust & Responsive Statistical System for NPPA

2.6 The first Directory of Pharmaceutical Manufacturing Units in India 2007 has been prepared. This contains State wise addresses of 10,563 pharmaceutical manufacturing units in alphabetical order, their telephone numbers, email addresses and website wherever available across the country. It is available on the website of NPPA. Moreover the details relating to composition of the Pharmaceutical units, their products, data relating to investment, R&D, employment, etc are being compiled to bring out exhaustive directory to provide reliable and effective input for policy purposes. For this purpose, the work on two studies, i.e., (i) First Pharmaceutical Census of India, and (ii) Collection of annual turnover data from the Bulk Drug manufacturing units, has been assigned to M/s ICRA Management Consultancy Services Ltd. and is likely to be completed during the year 2012-13.

(iii) Consumer Awareness and Publicity through Print, electronic and other medium

2.7 The scheme “Consumer Awareness and Publicity through Print, electronic and other medium” was approved in February, 2011. The aim of the scheme is to familiarize the general public about the role and functions of the NPPA and the Government’s decisions. The scheme is to be implemented through Department of Consumer Affairs on cost sharing basis. For Joint Publicity Campaign two print advertisements have been released on 11.07.2012 and 19.07.2012. As amount of Rs.52,00,000/- only (Fifty Two Lakh Only) was released for publishing two print ads, in color, during the financial year 2012-13.

2.8 The Committee further enquired about overall performance of NPPA since its inception (upto 15.10.2012), the Department of Pharmaceuticals in its written reply stated as under:-

> "NPPA has fixed / revised the prices of scheduled bulk drug 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. Of these, the prices of 7 scheduled bulk drugs and 3 derivatives and 477 formulations were fixed / revised during the period from 01.04.12 to 30.11.2012."

CHAPTER –III

MONITORING OF DRUGS

A. Monitoring of Scheduled Drugs

3.1 National Pharmaceutical Pricing Authority (NPPA) fixes / revises the price of 74 bulk drugs, specified in the First Schedule of Drugs (Prices Control) Order (DPCO), 1995 and the formulation containing any of these scheduled drugs. The prices of scheduled formulations are fixed or revised in accordance with the paragraph 7 of the DPCO, 1995. Under paragraph 8 of DPCO, non-ceiling company specific/product specific prices are notified. Under paragraph 9 of DPCO, the ceiling prices applicable to all similar scheduled formulation manufactured by different formulators are notified. The prices are notified in The Gazette of India Extraordinary. No one can sell any scheduled drugs/formulations at a price higher than that fixed by NPPA/Government.

3.2 The price of scheduled bulk drugs and formulation packs fixed during the last four years and since inception of NPPA are given below:

I. BULK DRUGS PRICES

Particulars	2009-10	2010-11	2011-12	2012-13 (upto November, 2012)	Since inception of NPPA (August, 1997)
No. of Bulk Drugs Where Price Increased	15	10	19	06	158
No. of Bulk Drugs Where Price Decreased	10	07	01	04	347
No. of Bulk Drugs Where price fixed For First Time	02	01	0	0	17
No change In Price	01	03	1	0	10
Total	**28**	**21**	**21**	**10**	**532**

II. FORMULATION PACKS

Particulars	2009-10	2010-11	2011-12	2012-13 (upto November, 2012)	Since Inception of NPPA
Price Increased	184	223	257	73	1862
Price Decreased	450	60	50	86	3495
Price fixed for first time	1155	371	239	253	6315
No change in prices	35	59	61	65	465
Total	**1824***	**713***	**607***	**477***	**12137***

* Including in Pro-rata pricing

3.3 Further, in reply to Lok Sabha Unstarred Question No.310 dated 9.8.2012, wherein details of percentage of increase in the prices of schedule drugs during the last three years were sought, the Department of Pharmaceuticals has stated as under:-

> "The prices of the medicines containing the drug Sulphamethoxazole, Nalidixic Acid, Asprin, Pheniramine Maleate, Rifampicin, Iodochlorohydroxyquinoline, Cloxacillin sodium, Dextropropoxyphene, Cefotaxime Sodium, Chloroquin, Carbamazapine and Vitamin E were increased and the prices revised in this regard are applicable to all the manufacturers of these medicines. The details of the price fixed by the National Pharmaceutical Pricing Authority (NPPA) for scheduled formulations during the last three years and the current year and the percentage of increase is given below:

Particulars	2009-10	2010-11	2011-12	2012-13 (upto 31st July, 12)
Price Increased	184	223	257	72
	10.09%	**31.28%**	**42.34%**	**20.45%**
Price Decreased	450	60	50	83
	24.67%	**8.42%**	**8.24%**	**23.58%**
Price fixed for first time	1155	371	239	165
	63.32%	**52.03%**	**39.37%**	**46.88%**
No change in prices	35	59	61	32
	1.92%	**8.27%**	**10.05%**	**9.09%**
Total	**1824**	**713**	**607**	**352**

3.4 In the above mentioned Unstarred Question, when it was asked whether the pharmaceutical companies have sought permission from the NPPA to increase the prices of some scheduled drugs, the Department of Pharmaceuticals has provided following details:-

> "There are 74 bulk drugs specified under First Schedule of DPCO,1995. Of these, prices of bulk drugs and their salts / esters / derivatives / stereo-isomers manufactured indigenously are fixed / revised from time to time under Para 3 of DPCO,1995. As per provisions of said paragraph, any manufacturer, who desires revision of the maximum sale price of a bulk drug fixed, is required to make an application to the Government/ NPPA in Form I of DPCO,1995. Accordingly, prices of scheduled bulk drugs are fixed / revised after examination of the requisite data / information and by allowing a post tax return, as applicable under the said paragraph. The price of scheduled bulk drugs are also fixed / revised under Para 11 of DPCO,1995 where any manufacturer of a bulk drug fails to submit an application for price fixation / revision, as the case may be. During the last three year i.e., 2009-2010, 2010-2011 and 2011-2012, NPPA has fixed / revised the prices in the case of 28, 21 and 21 drugs respectively as per details given in the **Annexure** (Page 21 to 24)**.** This includes both upward and downward price revision based on the application / Form-I / data received from the respective manufacturers. The prices have been increased as per the provisions of the DPCO, 1995. The price fixation / revision is a continuous process under the DPCO, 1995. The prices are revised based on the applications of the companies and by applying the formula given in para 7 of DPCO, 1995".

3.5 The Committee enquired about the difficulty being faced by NPPA in price fixation and revision of scheduled bulk drugs and their derivative formulations, the Department of Pharmaceuticals in their written reply stated as under:-

> "Price fixation and revision of scheduled bulk drugs and their derivative formulations is carried out as per provisions contained in DPCO, 1995. While doing so, the major difficulty being faced by NPPA is non-submission of the requisite data/information by the manufacturing units. In most of the cases where reduction in the input cost (including raw-materials) takes place, the concerned manufacturing units do not come forward with the pricing applications as required under DPCO, 1995. NPPA endeavors to overcome this through interaction with State Drug Controllers who in turn impress upon the manufacturing units to submit the requisite data/information".

3.6 The Department of Pharmaceuticals have further informed that the State Drugs Controllers help the National Pharmaceutical pricing Authority (NPPA) in monitoring the prices and enforcing the provisions of Drugs (Price Control) Order, 1995. The State Governments are authorized to take action under Essential Commodities (EC) Act, 1995 for violation of the provisions of the DPCO, 1995. However, prosecution under EC Act, 1995 sometimes does not lead to stringent action against defaulters. At present, there are no

provisions of fines or penalties for the violation of the DPCO,95 for non submission of requisite data, price list and for not allowing officers of NPPA to visit and inspect the manufacturing premises.

3.7 Further, according to the Department of Pharmaceuticals, NPPA monitors the prices of scheduled drugs on the basis of references of overcharging and other violations received from various State Drug Controllers, complaints from public and NGOs, suo-motu purchase of drug sample packs by NPPA during market surveillance. The Department have also stated that the Pharma Companies frequently change, the composition/strength of their formulations to circumvent the provision of DPCO, 1995. They added that the flooding of retail market of medicines by the Dietary Supplements licensed under the Prevention of Food Adulteration Act (PFA) Act is a novel device initiated by the Pharma Companies for escaping the provisions of DPCO, 1995.

Further when asked clarification from NPPA, In addition to above, NPPA in its e-mail have said as under:-

> "NPPA has come across certain practices aiming at relating to circumventing the price control mechanism by some manufactures by shifting scheduled drugs to the category of Food & Nutrition Supplement manufactured under PFA Act, 1954 and selling them as Vitamin tablets/capsules/food supplements. A reference was made by NPPA to the Ministry of Health & Family Welfare for appropriate action to curtail such practices.
>
> In this regard Secretary, Ministry of Health & Family Welfare, convened a meeting on 01.05.2012 wherein inter alia the following decisions were also taken:
>
> The definition of "drug" under Section 3(b)(i) under Drugs & Cosmetics Act 1940 clearly specifies "intended to be sued". Thus the intent of the manufacturing companies is clearly to prevent, treat or mitigate disease or disorder. The CDSCO would therefore collect material from the prescriptions, literature accompanying the food supplements in mass media carried out by these companies and show cause the manufacturers as to why their products should not be treated as "drugs" under the Drugs & Cosmetics Act 1940.
>
> Simultaneously, CDSCO will forward a proposal to the Ministry for making suitable amendments to the definition of "drugs" under Section 3(b)(i) of the Drugs & Cosmetics Act 1940 and schedule 'K' of the Drugs & Cosmetics Rules.

From the above, it may be noted that the subject matter is currently dealt by Ministry of Health & Family Welfare for appropriate action".

3.8 During the course of evidence, while speaking regarding affordability and availability of medicines, the Secretary, Department of Pharmaceuticals, informed the Committee that:-

> **"**We are involved in the control of prices. There has been regime of control on prices ever since 1962. Policies have changed over a period of time. The last control order was issued in 1995. There have been subsequent draft policies which have been circulated but not implemented. Now the proposal is before the Group of Ministers.... the recommendations of the GoM will go to the Cabinet and the Cabinet in their wisdom will approve the policy. The proposal is that we have identified 348 essential drugs and medicines which are put in certain formulations and based on those drugs prices are recommended to be controlled. At present of course there are only about 74 drugs which are controlled and the formulations are more. Hopefully, even on the affordability and availability of medicines, the Cabinet would soon take a decision".

Further In reply to Lok Sabha Unstarred Question No.135 dated 22.11.2012 wherein details regarding finalization of new pharmaceutical policy were sought, the Department of Pharmaceuticals stated as under:-

"The Department of Pharmaceuticals had prepared a draft National Pharmaceutical Pricing Policy, 2011 (NPPP-2011) based on the criteria of essentiality and requirements as stipulated by the Ministry of Health and Family Welfare. The draft National Pharmaceutical Pricing Policy, 2011 (NPPP-2011) was circulated among the concerned Ministries/Stakeholders. The draft policy was also available for comments of any other interested persons on the Department's website www.pharmaceuticals.gov.in till 30.11.2011. The views/inputs received on the draft NPPPA-2011 were examined and the matter was placed before the Group of Ministers (GoM) which met on 25.4.2012. The Group of Ministers (GoM) in the meeting held on 27.9.2012, gave its final recommendation on pricing of National List of Essential Medicines -2011 based on which National Pharmaceutical Pricing Policy 2012 has been prepared and sent to the Cabinet on 15.10.2012 for its approval.

In addition the Department of Pharmaceuticals in its reply to Unstarred Question No.947 dated 29.11.2012 have stated that:-

".....Based on the recommendations of the GoM, National Pharmaceuticals Pricing Policy-2012 (NPPP 2012) was formulated and placed before the Cabinet. The Cabinet considered NPPP-2012 in its meeting held on 22.11.2012 and approved the same with certain modifications".

Further in the reply to Lok Sabha Unstarred Question No.2163 dated 6 December, 2012 when asked regarding implementation of New Pharmaceutical Policy, the reason for delay in approving the said policy and the names of 348 essential medicines that are proposed to be brought under the policy. The Department of Pharmaceuticals stated as under:-

"The Department of Pharmaceuticals had prepared a draft National Pharmaceutical Pricing Policy, 2011 (NPPP-2011) based on the criteria of essentiality as per the medicines as under National List of Essential Medicines-2011 (348 drugs with specified dosage and strengths), as stipulated by the Ministry of Health and Family Welfare which was placed before the Group of Ministers (GoM). Based on the recommendations of the GoM, National Pharmaceutical Pricing Policy-2012 (NPPP-2012) was formulated and placed before the Cabinet. The Cabinet considered NPPP-2012 in its meeting held on 22.11.2012 and approved the same with certain modifications. .....further action to notify NPPP-2012 has been undertaken. NPPP-2012 has not yet been notified."

3.9 Regarding the setting up of Drugs (Prices Control) Order Cells by the Government in all the States for proper monitoring of price of drugs and pharmaceuticals in a time bound manner, the Department in a written note stated as under:-

> "The proposal for setting up of the DPCO/NPPA Cells in States is part of the new schemes for Eleventh Plan for strengthening of NPPA which was sent for seeking 'in principle' approval of Planning Commission. It has been observed by Planning Commission that some of the components proposed in the scheme for strengthening of NPPA including setting up of DPCO/NPPA Cells in States proposed for strengthening and monitoring of prices of drugs and Pharmaceuticals would be taken up after the finalization of the Draft Pharmaceutical Policy. Draft National Pharmaceutical Policy, 2006 was considered by the Cabinet and the Cabinet has sent the policy for consideration of the Group of Ministers. The Group of Ministers has not made any recommendations to the Cabinet so far. As the draft policy has not been finalized as yet the proposal for setting up of DPCO Cells in States could not be materialized. Planning Commission, who has earlier linked the 'in principle' approval to the finalization of Draft Pharmaceutical Policy, has been requested to de-link them and again consider the proposal of new scheme for strengthening of NPPA".

B. Monitoring of prices of Non Scheduled Formulations

3.10 In respect of drugs - not covered under the Drugs (Prices Control) Order, 1995 i.e. non-scheduled drugs, manufacturers themselves fix the prices without seeking the approval of Government / NPPA. Such prices are normally fixed by the manufacturers depending on various factors like the cost of bulk drugs used in the formulation, cost of excipients, cost of R&D, cost of utilities / packing material, trade margins, quality assurance cost, landed cost of imports etc.

3.11 The monitoring of prices of non-scheduled formulations is currently done on the basis of data from IMS (Health) (about 61000 packs are analysed every month). 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, 95 in larger public interest.

3.12 The Department of Pharmaceuticals have further elaborated in their written reply as under:-

> "In case a company refuses to lower the price, NPPA under the powers delegated by Government under paragraph 10 of DPCO,1995 fixes the retail prices of such non-scheduled formulations in public interest under para 10(b) of the DPCO,95".

3.13 As per the Audit Report of IMS (Health) the percentage number of packs whose prices have increased in 2010-2011 was in the range of 0.01% to 2.46%, and in 2011-2012 (January 2012) the increase was 0.01% to 5% while in the remaining number of packs, prices have decreased or remained stable.

3.14 NPPA has so far fixed prices under para 10(b) in respect of 30 formulation packs and companies have reduced price voluntarily in case of 65 formulation packs. Thus in all, prices of 95 packs of non-scheduled drugs got reduced as a result of the intervention of NPPA.

3.15 Further, in replies to queries regarding fixing of prices of scheduled and non-scheduled drugs, during the course of evidence, the Member Secretary, NPPA informed the Committee that:-

> "Operating the DPCO 1995, there are 74 scheduled drugs defined in the first schedule of the DPCO. These scheduled drugs as well as any formulations containing these drugs are controlled by the NPPA. We fix their prices on cost based formula which is given in the DPCO in para 7. The prices fixed by us of the scheduled drugs are final and nobody can sell the drugs over and above the prices which we are fixing. You have mentioned about the paracetamol. It is a non-scheduled drug. We have no control over the launch price. Every company launch this under their own cost. What we are doing, as Secretary has rightly pointed out, we do not allow it to exceed 10 per cent in a year. That is what we are doing. In the non-scheduled category, we have noticed that there is much more margin.

But because of our constraints we cannot do anything. We have brought this matter to the notice of the Government also. We have our constraints in this area".

When asked to further clarify the points, regarding fixing of prices of scheduled and non-scheduled drugs, the NPPA via e-mail has stated as under:-

"Under the provisions of the Drugs (Prices Control) Order, 1995 the prices of 74 bulk drugs and the formulations containing any of these scheduled drugs are controlled. NPPA / Govt. fixes or revises prices of scheduled drugs / formulations as per the provisions of the DPCO,1995. The NPPA monitors the prices of all formulations including imported scheduled formulations under price control. Under the provisions of DPCO 95, no person can sell any scheduled formulation (medicine) to a consumer at a price exceeding the price notified/approved by the NPPA/Government.

In respect of drugs not covered under the Drugs (Prices Control) Order, 1995 i.e. non-scheduled drugs, manufacturers fix the prices by themselves without seeking the approval of Government / NPPA. In respect of non scheduled formulations there is no control on the launch price of the formulations.

As a part of price-monitoring activity, NPPA regularly examines the movement in prices of non-scheduled formulations. The monthly reports of IMS Health and the information furnished by individual manufacturers are utilized for the purpose of monitoring prices of non-scheduled formulations. Wherever a price increase beyond 10% per annum is noticed, the manufacturer is asked to bring down the price voluntarily failing which, subject to prescribed conditions, action is initiated under paragraph 10(b) of the DPCO, 1995 for fixing the price of the formulation in public interest".

3.16 The Committee desired to know about the feedback/suggestions received from drug industry regarding the functioning of NPPA, the Department of Pharmaceuticals in their written note informed the Committee as under :-

"Whenever, NPPA receives any feed back or suggestion from the drug industry, it examines them and takes appropriate action. A recent example is that the industry brought to the notice of NPPA the difficulty faced by it in getting price approvals in time for imported drugs for earlier consignment. NPPA decided that where the import is done in rupee terms and the value remains unchanged (i.e. the CIF price is in Rupees), the companies need not obtain prior approval of NPPA for each consignment subject to fulfilling certain conditions.

NPPA also gets suggestions from NGOs and individuals. These are mostly in the nature of bringing more drugs/formulations/devices under price control for obvious reasons at variance with the drug industry which favours decontrol".

CHAPTER –IV

MISCELLANEOUS

A. Availability of Drugs

4.1 NPPA is also entrusted with the job of monitoring the availability of drugs and to identity shortage, if any, and to take remedial steps to make the drugs available. NPPA is carrying out this responsibility mainly through monthly field reports from the State Drugs Controllers and other available information. As and when the reports for shortage of particular drug(s), in any part of the country are received, the concerned company is asked to rush the stock and to make the drugs available. Generally shortage reported is brand specific. However, in most cases alternative brands are available.

4.2 The Committee enquired about the efforts taken by Department of Pharmaceuticals to make available Life Saving Drugs at affordable prices, the Department in its written reply has stated as under:-

> "While, there may not be a textual definition of life saving drugs, every drug can be life saving depending upon the particular situation. However, the drugs are classified as Essential Commodities under Essential Commodities Act.
>
> NPPA is also entrusted with the job of monitoring the availability of drugs and to identity shortages, if any, and to take remedial steps to make the drugs available. NPPA is carrying out this responsibility mainly through the State Drugs Controllers and other available information. As and when the reports for shortages of particular drug(s), in any part of the country are received, the concerned company is asked to rush the stock and to make the drugs available".

B. Monitoring of Quality of Drugs

4.3 Quality of drugs and check on spurious drugs is monitored by Drugs Controller of India which is under the administrative control of Ministry of Health and Family Welfare. On the other side, prices and availability of drugs is monitored by Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals). When the Committee desired to know whether this arrangement is confusing and faulty and non-conducive for the growth of Pharmaceutical Industry, the Department of Pharmaceuticals, in its written reply, appraised the Committee as under :-

> "This Department had received a reference from Cabinet Secretariat wherein they have forwarded a letter from Dr.Sujan Chakraborty, MP (Lok Sabha) who had suggested to the Prime Minister that the office of the Central Drug Control Organization under the Ministry of Health be also taken under the purview of the Department of Pharmaceuticals without which the purpose of creating the Department of Pharmaceuticals will remain unfulfilled. After examining the VIP reference this Department felt that as the issues relating to pricing and availability and quality of medicines are closely interlinked, Central Drugs Control Organisation (CDSCO) should be a part of the Department of Pharmaceuticals so that it may be able to play its role more effectively to achieve its main objective to ensure availability of life saving drugs at, reasonable prices as envisaged in the drug policy.
>
> Quality is an essential parameter while considering the pricing and availability of medicines. In the absence of jurisdiction over the issue of quality of medicines, the Department of Pharmaceuticals finds itself handicapped to do full justice to the role assigned to it. It is, therefore, extremely important to bring the quality control set up i.e Central Drugs Standard Control Organisation (CDSCO) under

the purview of this Department. Since the function of price control and the administrative control of National Pharmaceutical Pricing Authority is already vested with the Department, this Department would be well equipped to address the significant issues related to the Pharmaceuticals. The above view of the Department has been conveyed to the Cabinet Secretariat and PMO earlier.

The view of this Department is that the very purpose of creating a separate Department is to bring all important functions under the single Department to facilitate growth of Pharma Industry. However, the functions of CDSCO for quality, marketing and other regulatory matters and issues related to Drug & Cosmetics Act are still being handled by the Ministry of Health & Family Welfare. As the issues of pricing, availability and quality of medicines are closely interlinked, the Government may consider bringing the price control and regulatory mechanisms under one umbrella, i.e. the Department of Pharmaceuticals, so that the work towards achieving the prime objective of making available quality drugs at reasonable prices to the common man and ensuring the quality and efficacy of the medicines at the same time could be carried out in a more focused, smooth, and effective manner".

4.4 In reply to Lok Sabha unstarred Question No.445 dated 9.8.2012 wherein details regarding any survey that has been conducted to assess the extent and quantum of spurious drugs, especially in rural and non-metro cities of the country were sought, the Department of Pharmaceuticals stated as under:-

"A survey to assess the extent of spurious drugs in the country was conducted in the year 2009 by the Ministry of Health through Central Drugs Standard Control Organization. Samples were drawn from different stratum in various regions in the country.

24,136 samples of 62 brands of drugs belonging to 9 therapeutic categories of 30 manufacturers from over 100 different pharmacy outlets in different regions of the country and located in each stratum viz. Metros, big cities, district, towns and villages were collected. The survey revealed that the extent of drugs found spurious was 0.046% only. The report of the survey is available on the CDSCO website www.cdso.nic.in."

4.5 Further, under the above stated question, when it was asked to provide the details of corrective action to weed out the menace of spurious drugs, the Department stated as under:-

"The Government has taken following steps to check the menace of Spurious/Sub-standard Drugs.

(i) The Drugs and Cosmetics Act, 1940 was amended under Drugs & Cosmetics (Amendment) Act 2008. Stringent penalties for manufacture of spurious and adulterated drugs have now been provided to make it deterrent for the antisocial elements to indulge in manufacture of spurious drugs. Certain offences have also been made cognizable and non-bailable.

(ii) Whistle Blower Policy has been announced by Government of India to encourage vigilant public participation in the detection of movement of spurious drugs in the country. Under this policy the informers would be suitably rewarded for providing concrete information in respect of movement of spurious drugs to the regulatory authorities. The details of policy are available at the website CDSCO (www.cdsco.nic.in).

(iii) Guidelines for taking action on samples of drugs declared spurious or not of standard quality in the light of enhanced penalties under the Drugs & Cosmetics (Amendment) Act, 2008 were

forwarded to the State Drugs Controllers for implementation. The guidelines are available on the website of CDSCO (www.cdsco.nic.in)

(iv) The Inspectorate staff has been instructed to keep vigil and draw samples of drugs for test and analysis to monitor the quality of drugs moving in the country.

(v) The State/UTs were requested to set up special courts for trial of offences under the Drugs and Cosmetics Act for speedy disposal of cases. Some of the States have already set up designated special Courts for trial of cases related to spurious and substandard drugs."

C. Functioning of Enforcement Division in NPPA

4.6 A separate Enforcement Division was created during the year 2007-08 to facilitate suo-motu detection of violation of DPCO, 1995 with the following objectives :

(i) Market Surveillance of prices of scheduled drugs

- Purchase of samples by NPPA officers all over India to ensure compliance;
- Examine complaints by individuals / NGOs/VIP references.

(ii) Based on analysis, specific cases are identified for

- Recovery of overcharged amounts;
- Fixation of prices, wherever required.

4.7 **Achievements of Enforcement Division of NPPA**

Year	No. of Samples Collected	Prima Facie Violations detected	Referred for Overcharging	Identified for Price fixation Para 8(6) violation
2007-08	1450	840	456	384
2008-09	520	284	172	112
2009-2010	464	246	208	38
2010-2011	553	225	216	9
2011-2012	559	156	152	4
2012-2013 (upto 30th November, 2012)*	365	67	65	2

**56 cases are under process.*

D. Status of Cases Relating To Overcharging

4.8 The Drugs Price Control Order, 1995 under para 13 provides as under:-

"Power to recover overcharged amount:- Notwithstanding anything contained in this order, the Government shall by notice, require the manufacturers, importers or distributor, as the case may be to deposit the amount accrued due to charging of prices higher than those fixed or notified by the Government under the provisions of Drugs (Prices Control) Order, 1987 and under the provisions of this order."

4.9 Since the inception of NPPA in August 1997 till November 2012, demand notices have been issued 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. A list of these cases is available on the Website of NPPA i.e. www.nppaindia.nic.in. It is added here that Rs. 2267.75 crore is under litigation. 84 cases have been referred to Collectors of various States for recovery under land and revenue arrears, out of which 30 cases are under litigation, 47 cases are pending for recovery with Collectors of various States and in the balance 7 cases amount has been recovered. The recovery of the overcharged amount is affected due to various Court orders passed by various High Court and also Supreme Court in various cases filed by Pharmaceuticals Companies challenging the price fixation / notification issued by NPPA / Government and complaints filed by various drug control authorities against Pharma companies for not following the notified price. Inclusion of some bulk drugs under price control (scheduled 1 of DPCO'95) has also been challenged by the Pharma companies. NPPA / Government is defending such cases through SG, ASG's and Senior Government Counsels. Whenever necessary NPPA files urgent application in the Courts for vacation of interim orders and also for early hearing / disposal of the case.

Year wise Break Up of overcharged amount from Inception (October 1997) of NPPA to 2012-2013 (upto November 2012)

		During The Year		Cummulative (Total since inception)		Amount Recovered	
S No.	Year	No. of cases	Estimated overcharged amount including interest			During the year	Cummulative (Total since inception)
			(Rs. in crores)	No. of cases	(Rs.in Crores)	(Rs. in crores)	(Rs. in crores)
1	Since Inception (Aug. 97) upto 31.03.05	285	670.63	285	670.63	87.36	87.36
2	2005-2006	50	29.59	335	700.22	11.80	99.16
3	2006-2007	67	38.01	402	738.23	0.96	100.12
4	2007-2008	118	820.31	520	1558.54	4.51	104.63
5	2008-2009	135	435.62	655	1994.16	51.41	156.04
6	2009-2010	89	156.22	744	2150.38	35.41	191.45
7	2010-2011	42	146.93	786	2297.31	17.26	208.71
8	2011-2012	40	164.94	826	2462.25	10.69	219.40
9	2012-2013 (upto November 2012)	76	115.19	902	2577.44	14.59	233.99

4.10 Further, The Committee desired to know the precise steps being taken by NPPA to recover the excess amount charged by retailers, the Department in their note has stated as under:-

> "Under Paragraph 13 of DPCO, the Government is vested with the powers to recover the overcharged amounts. Under this provision Government shall by notice require the manufacturers, importers or distributors as the case may be to deposit the amount accrued due to charging of prices higher than those fixed of notified by the Government under the provisions of Drug (Price Control) Order, 1987 and under the provision of this order (DPCO' 95). NPPA asks the companies to deposit

the overcharged amount with the Government and in case they fail to do so, takes action to recover the dues through the District Collector as a land revenue recovery."

4.11 On being enquired about the proposal regarding devising a mechanism to utilize over-charged amount for the benefit of customers instead of depositing it in the Government accounts, the Department in their note has stated as under:-

"In the draft National Pharmaceutical Policy, 2006 it has been proposed to create a fund in which the overcharged amount will be deposited. The proposed fund would be housed in NPPA but it would be operated by an Empowered Committee headed by Secretary, Department of Pharmaceuticals. The fund will be utilized for the benefit of consumers and creating consumer awareness".

E. Updating The List Of Drugs Under Price Control

4.12 The Committee enquired about the system of updating the list of drugs under price control, the Department of Pharmaceuticals in a note stated as under:-

"The following criteria has been specified in para 22.7.2 of the Modifications in Drug Policy, 1986' announced in September, 1994.

(i) The criterion of including drugs under price control will be the minimum annual turnover of Rs.400 lakhs.

(ii) Drugs of popular use, in which there is a monopoly situation will be kept under price control. For this purpose, if for any bulk drug, having an annual turnover of Rs. 100 lakhs or more there is a single formulator having 90% or more market share in the Retail Trade (as per ORG) a monopoly situation would be considered as existing.

(iii) Drugs in which there is sufficient market competition viz. at least 5 bulk drug producers and at least 10 formulators and none having more than the 40% market share in the Retail Trade (as per ORG) may be kept outside the price control. However, a strict watch would be kept on the movement of prices as it is expected that their prices would forces of market competition. The Government may determine the ceiling levels beyond which would not be permissible.

(iv) Government will keep a close watch on the prices of medicines which are taken out of price control. In case, the prices of these medicines rise unreasonably, the Government would take appropriate measures, including reclaiming of price control.

(v) For applying the above criteria, to start with, the basis would be the data upto 31st March, 1990 collected for the exercise of the Review of the Drug Policy. The updating of the data will be done by the National Pharmaceutical Pricing Authority as detailed in para 22.7.4 (i). Of the "Modifications in Drug Policy, 1986".

(vi) Genetically engineered drugs produced by recombinant DNA technology and specific cell/tissue targeted drug formulations will not be under price control for 5 years from the date of manufacture in India.

All the bulk drugs have been kept under price control on the basis of the above criteria. Price Control is presently exercised on drugs included in the Schedule-I of DPCO, 1995 and their formulations. For these, the prices are fixed by the NPPA. In respect of non-scheduled formulations, the NPPA monitors their price movements to ensure that the annual price rise is not more than 10% subject to certain prescribed conditions. Where the price rise is noticed to be beyond the above limit, NPPA asks the concerned company to reduce the price and in the event of their not complying, fixes the price in public interest under paragraph 10(b) of DPCO 1995".

PART-II

OBSERVATIONS / RECOMMENDATIONS

FUNCTIONING OF NATIONAL PHARMACEUTICAL PRICING AUTHORITY (NPPA)

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.

(Recommendation Sl.No.1)

SCHEMES OF NPPA

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.

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@19th Report on Demands for Grants 2011-12 and 27th Report on Demands for Grants 2012-13

(Recommendation Sl.No.2)

MONITORING OF PRICES OF SCHEDULED DRUGS

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.

(Recommendation Sl.No.3)

MONITORING OF PRICES OF NON- SCHEDULED DRUGS

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.

(Recommendation Sl.No.4)

AVAILABILITY OF DRUGS

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.

(Recommendation Sl.No.5)

MONITORING OF QUALITY OF DRUGS

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.

(Recommendation Sl.No.6)

RECOVERY OF OVERCHARGED AMOUNT

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.

(Recommendation Sl.No.7)

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

GOPINATH MUNDE
CHAIRMAN
STANDING COMMITTEE ON
CHEMICALS AND FERTILIZERS

ANNEXURE

On

http://164.100.47.132/Annexture/lsq15/11/au310.htm

APPENDICES-I

MINUTES

STANDING COMMITTEE ON CHEMICALS & FERTILIZERS (2006-07)

SECOND SITTING (26.09.2006)

The Committee sat from 1530 hrs. to 1630 hrs.

PRESENT

Shri Anant Gangaram Geete - Chairman

Members

LOK SABHA

2. Shri Sunil Khan
3. Shri Subhash Maharia
4. Shri Prasanta Pradhan
5. Shri Narsingrao H. Suryawanshi
6. Shri Bhanu Pratap Singh Verma

RAJYA SABHA

7. Shri Dilip Singh Judev
8. Shri Devdas Apte
9. Shri Raj Mohinder Singh Majitha

SECRETARIAT

1.	Shri P. Sreedharan	-	Joint Secretary
2.	Shri Brahm Dutt	-	Director
3.	Shri S.C. Kaliraman	-	Under Secretary
4.	Shri Santosh Kumar	-	Assistant Director

Representatives of the Ministry of Chemicals & Fertilizers (Department of Chemicals & Petrochemicals)

(1)	Ms. Satwant Reddy	-	Secretary
(2)	Shri K.C. Misra	-	Joint Secretary
(3)	Shri G.S. Sandhu	-	Joint Secretary
(4)	Shri Gurdeep Singh	-	Director
(5)	Shri Surjeet Bhujbal	-	Director
(6)	Ms. Harmeet S. Singh	-	Director

Representatives of National Pharmaceutical Pricing Authority (NPPA)

(1)	Shri Ashok Kumar	-	Chairman
(2)	Shri Arun Jha	-	Member Secretary
(3)	Shri L.M. Kaushal	-	Director
(4)	Shri B.S. Raghunathan	-	Director

2. At the outset, the Chairman welcomed the Members and the representatives of the Ministry of Chemicals & Fertilizers (Department of Chemicals & Petrochemicals) and National Pharmaceutical Pricing Authority (NPPA) to the sitting of the Committee. He briefly informed that the sitting was convened to have a briefing by the representatives of

the Department/NPPA on '*Functioning of National Pharmaceutical Pricing Authority (NPPA)*'.

3. Thereafter, the representatives of the Department of Chemicals & Petrochemicals/NPPA made a briefing highlighting the various aspects relating to the subject, which are as under:-

(i) Price fixation/revision by NPPA;
(ii) Monitoring of prices of decontrolled drugs;
(iii) Implementation of DPCO, 1995;
(iv) Overcharging of prices by drug companies;
(v) Availability of drugs;
(vi) Compilation and collection of data by NPPA;
(vii) Computerization in NPPA;
(viii) Role of PSUs in stabilising prices;
(ix) Menace of manufacturing drugs without license;
(x) Finalization of new pharma policy; and
(xi) Implementation of the recommendations contained in the 7th Report of the Committee.

4. Thereafter, clarifications sought by the Committee were replied to by the representatives of the Department of Chemicals & Petrochemicals/NPPA.

5. A verbatim record of the proceedings has been kept.

The Committee then adjourned.

APPENDICES-II

MINUTES

STANDING COMMITTEE ON CHEMICALS AND FERTILIZERS (2008-09)

FOURTH SITTING (27.01.2009)

The Committee sat from 1100 hours to 1320 hours.

PRESENT

Shri Sunil Khan - In the Chair

MEMBERS

LOK SABHA

2. Shri Shrichand Kripalani
3. Shri Subhash Maharia
4. Shri P. Chalapathi Rao
5. Shri Ashok Kumar Rawat
6. Shri Anantha Venkatarami Reddy
7. Shri Narsingrao H. Suryawanshi
8. Shri D. Venugopal
9. Shri Bhanupratap Singh Verma

RAJYA SABHA

10. Shri B.S. Gnanadesikan
11. Shri A.A. Jinnah
12. Shri Raj Mohinder Singh Majitha
13. Shri Om Prakash Mathur
14. Shri Gireesh Kumar Sanghi
15. Shri Raghunandan Sharma
16. Shri Barun Mukharji

SECRETARIAT

1.	Shri N.K. Sapra	-	Additional Secretary
2.	Shri P. Sreedharan	-	Joint Secretary
3.	Shri A.S. Chera	-	Director
4.	Shri A.K. Srivastava	-	Deputy Secretary-II
5.	Smt. Balwant Kaur Saimbhi	-	Under Secretary

Representatives of the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals)

1.	Shri Ashok Kumar	-	Secretary (Pharma)
2.	Shri Mathew C. Kunnumkal	-	Additional Secretary and FA
3.	Smt. Neelkamal Darbari	-	Joint Secretary
4.	Shri A.K. Vishandas	-	Dy. Director General
5.	Shri V.P. Rajiv Sebastian	-	Economic Advisor

National Pharmaceutical Pricing Authority

1.	Shri A.K. Banerjee	-	Chairman
2.	Shri A.K. Singhal	-	Advisor (Pricing)

2. At the outset, in the absence of Chairman, the Committee choose Shri Sunil Khan, a Member of the Committee to act as Chairman in accordance with Rule 258 (3) of the Rules of Procedure and Conduct of Business in Lok Sabha. Then he welcomed the Members to the sitting of the Committee.

3. Then the acting Chairman invited officials of the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals) and National Pharmaceutical Pricing Authority to the sitting of the Committee and draw attention of the witnesses to the provisions contained in Direction 55(1) of the Directions by the Speaker regarding confidentially of proceedings of the Committee.

4. Secretary (Pharma), Chairman (NPPA) and other representatives of the Department of Pharmaceuticals / National Pharmaceutical Pricing Authority were introduced to the Committee. Then, the Committee were briefed and an audio-visual presentation was also made before them in this regard on the subject 'Functioning of National Pharmaceutical Pricing Authority'.

5. The following issues were discussed during the sitting:-

i) Pricing/modification by the NPPA;
ii) Monitoring of prices of the decontrolled drugs;
iii) Overcharging by the Pharmaceutical Companies and recoveries thereof;
iv) Availability of Life Saving Drugs;
v) Introduction of generic drug stores in several states under 'Jan Aushadhi Scheme'
vi) Re-designing of NPPA website;
vii) Monitoring of prices of Scheduled/Non-Scheduled drugs;
viii) Interactions held with the State Governments, Industries, Consumers and Non-Government organizations on pricing of pharmaceuticals and over charging etc; and
ix) Computerization in the NPPA.

6. During briefing, the acting Chairman and some members of the Committee raised some queries which were replied to by the Secretary (Pharma) and Chairman (NPPA) and they also assured to send requisite information in writing on the points to which replies were not readily available with them.

7. A verbatim record of the proceedings of the sitting has been kept.

The Committee then adjourned.

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APPENDICES-III

MINUTES

STANDING COMMITTEE ON CHEMICALS & FERTILIZERS (2009-10)

SEVENTH SITTING (04.11.2009)

The Committee sat from 1500 hours to 1630 hours.

PRESENT

Shri Ananth Kumar - Chairman

MEMBERS

LOK SABHA

2. Smt. Sushmita Bauri
3. Shri Prabhatsinh P. Chauhan
4. Shri Ganeshrao Nagorao Dudhgaonkar
5. Shri N. Peethambara Kurup
6. Shri Ashok Kumar Rawat
7. Shri Suresh Kumar Shetkar
8. Shri N. Cheluvaraya Swamy

RAJYA SABHA

9. Shri J. D. Seelam
10. Dr. C. P. Thakur
11. Shri Raj Mohinder Singh Majitha
12. Shri Biswajit Daimary

SECRETARIAT

1. Shri N. K. Sapra - Additional Secretary
2. Shri P. Sreedharan - Joint Secretary
3. Shri A.K. Srivastava - Deputy Secretary

I. MINISTRY OF CHEMICALS AND FERTILIZERS (DEPARTMENT OF PHARMACEUTICALS)

1. Shri Ashok Kumar, Secretary
2. Shri Mathew C. Kunnumkal, Additional Secretary & Financial Adviser
3. Shri Devendra Chaudhry, Joint Secretary
4. Shri Arun Jha, Joint Secretary

II. REPRESENTATIVES OF NATIONAL PHARMACEUTICAL PRICING AUTHORITY (NPPA)

1. Dr. S.M. Jharwal - Chairman
2. Shri Om Prakash, - Member Secretary

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

3. Thereafter, he called the officials of the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals), and representatives of the National Pharmaceutical Pricing Authority (NPPA) and invited their attention to the provisions contained in Direction 55(1) of the Directions by the Speaker regarding confidentiality of the Committee's proceedings.

4. Then the officials of the Department and others introduced themselves. Thereafter, the Secretary, Department of Pharmaceuticals briefed the Committee about the subject 'National Pharmaceutical Pricing Authority' and also gave an audio-visual presentation.

5. Subsequent to the power-point presentation, the Chairman and members of the Committee raised some questions which were answered by the Secretary (Department of Pharmaceuticals), and Chairman (NPPA). They also promised to furnish the requisite information in writing which was not readily available with them. Apart from various aspects concerning National Pharmaceutical Pricing Authority the following issues were also discussed :-

(a) Drugs Price Control ;

(b) Availability of Life Saving Drugs;

(c) Generic Drug Campaign ;

(d) Finalization of National Pharmaceuticals Policy

6. The Committee also decided to hold their next sitting on 11 November 2009 to hear the views of the Fertilizers Association of India on the subject Fertilizers Education Project.

7. A verbatim record of the proceedings of the sitting has been kept.

The Committee then adjourned.

MINUTES

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

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

PRESENT

Shri A. A. Jinnah - In the Chair

MEMBERS

LOK SABHA

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

SECRETARIAT

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

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

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

(i) *****
(ii) *******
(iii) *******
(iv) Draft Report on the subject 'National Pharmaceutical Pricing Authority (NPPA)' pertaining to the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals).

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

The Committee then adjourned.

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