

**GOVERNMENT OF INDIA
CHEMICALS AND FERTILIZERS
LOK SABHA**

UNSTARRED QUESTION NO:798

ANSWERED ON:04.08.2011

CHARGING OF EXORBITANT PRICES ON DRUGS

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Will the Minister of CHEMICALS AND FERTILIZERS be pleased to state:

- (a) the details regarding mechanism for revising the prices of bulk drugs;
- (b) whether some pharmaceutical companies charge exorbitant prices of their drugs and formulations without any control/check;
- (c) if so, the steps taken to monitor the prices of drugs;
- (d) the number of cases detected by the drug regulator involving price violations during the last three years and the current year along with the action taken against the erring pharmaceutical companies;and
- (e) the measures taken to ensure availability of life saving drugs in sufficient quantity at the reasonable prices in the country?

Answer

MINISTER OF THE STATE (INDEPENDENT CHARGE) IN THE MINISTRY OF STATISTICS AND PROGRAMME IMPLEMENTATION AND MINISTER OF STATE IN THE MINISTRY OF CHEMICALS AND FERTILIZERS (SHRI SRIKANT KUMAR JENA)

(a): National Pharmaceutical Pricing Authority (NPPA) fixes/revises price of scheduled drugs/formulations as per the provisions of Drugs (Prices Control) Order, 1995 (DPCO, 1995). Under the provisions of the DPCO, 1995 the prices of 74 bulk drugs included in its Schedule-I and the formulations containing any of these scheduled drugs are controlled. The prices of scheduled bulk drugs are fixed / revised under para 3 of DPCO, 1995 by a detailed Cost cum Techno- Economic Study done based on the information / data furnished by the manufacturers. The mechanism involved in fixing / revising the prices of bulk drugs is as follows;

- i.Collection of data by issuing questionnaire to the manufactures,
- ii. Verification of the data submitted by the manufacturers.
- iii. Preparation of the cost statement based on technical parameters and cost details considered in the study.
- iv. Approval of the price thus worked out by the members of the Authority,
- v. Notification of the maximum sale price of bulk drug in official gazette.

However, under certain circumstances when the manufacturers fail to furnish information for price fixation / revision, the price of the bulk drug is fixed / revised as per the available information under para 11 of DPCO, 1995.

In respect of drugs - not covered under DPCO, 1995 i.e. non-scheduled drugs, manufacturers fix the prices by themselves without seeking the approval of Government/NPPA.

(b) & (c): NPPA fixes/revises price of scheduled drugs/formulations as per the provisions of DPCO, 1995. As a part of price monitoring activity, NPPA regularly examines the movement in prices of non-scheduled formulations also. 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. No one can sell any drugs/formulation at a price higher than the price fixed by NPPA.

However, a number of drug companies have been found to be selling medicines at a higher price to consumers in violation of the prices notified by NPPA. In such cases, NPPA initiates action for overcharging based on the report from State Drug Controllers (SDCs), complaints from individuals, verification of price list submitted by companies and suo-moto purchase of samples of scheduled packs. In case, a company is found selling drugs / formulations at a price higher than the prices fixed by NPPA, appropriate action is initiated against them by NPPA under para 13 of the DPCO, 1995 and the Essential Commodities Act, 1955, The demand notices are issued to the Pharma companies in case of confirmed overcharging cases.

Further, since its inception in August, 1997 NPPA has fixed prices in case of 30 formulation packs under para 10(b) of DPCO, 1995 based on monitoring of prices of non-scheduled formulation, and companies have reduced price voluntarily in case of 65 formulation

packs. Thus in all, prices of 95 packs of non-scheduled drugs have got reduced as a result of intervention of NPPA.

(d): During the last three years and the current year (upto 31st July, 2011), details of the demand notices NPPA issued to the Pharmaceuticals companies, based on detection of overcharging cases, alongwith the details of overcharged amount including interest demanded as well as the amount recovered from the Pharmaceuticals companies during the relevant years are given below:

SI. No.	Year	No. of Cases	Overcharged Amount received	Amount including interest
			(Rs. in crores)	(Rs. in crores)

1	2008-09	135	435.62	51.41
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2	2009-10	89	156.22	35.41
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3	2010-11	49	188.17	17.26
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4	2011-12 (upto 19 July 11)	19	18.69	2.54
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(e): Life saving drugs are not defined in the DPCO, 1995. NPPA is, however, entrusted with the responsibility of monitoring the availability of drugs and to identify 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 Controller 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.

Further, a Campaign in the name of 'Jan Aushadhi Campaign' has been launched by the Department of Pharmaceuticals with the purpose to make available medicines at affordable prices for all. Under this campaign less priced quality unbranded generic medicines are made available through Jan Aushadhi Stores. At present 105 Jan Aushadhi Stores have been opened till July.2011 in various states in the country.