

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

UNSTARRED QUESTION NO:1196
ANSWERED ON:04.03.2010
ESSENTIAL /LIFE SAVING DRUGS UNDER PRICE CONTROL
Ram Shri Purnmasi

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

- (a) whether the Supreme Court in its order dated 10-03-2003 had directed the Government to consider and formulate appropriate criteria for ensuring that essential and life saving drugs do not remain out of price control;
- (b) if so, the action taken thereon by the Government;
- (c) whether the Government has not defined/specified life saving drugs in the DPCO, 1995;
- (d) if so, the reasons thereof; and
- (e) the measures taken by the Government to monitor the availability of life saving drugs and to control their prices ?

Answer

THE MINISTER OF STATE IN THE MINISTRY OF CHEMICALS AND FERTILIZERS (SHRI SRIKANT KUMAR JENA)

(a) and (b): The Supreme Court vide its order dated 10-03-2003 directed the Government, to consider and formulate appropriate criteria for ensuring essential and life saving drugs not to fall out of the price control and further directed to review drugs, which are essential and life saving in nature till 2nd May, 2003, Ministry of Health and Family Welfare has brought out the National List of Essential Medicines, 2003 after the review of the National Essential Drugs List, 1996. The Draft Pharmaceutical Policy 2006 which is under consideration of the Government, proposes to include essential drugs as contained in the in the National List of Essential Medicines (NLEM) 2003 under price control.

(c) and (d): Each drug has its own utility keeping in mind the requirement of the patient taking the drug. Ministry of Health and Family Welfare have a National List of Essential Medicines. As per the Drug Policy 1994 the bulk drugs have been kept under price control on the basis of the following criteria as laid down in its para 22.7,2 span of control as stated below:-

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

(ii) Drugs of popular use in which there is a monopoly situation be kept under price control. For this purpose 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 be kept in check by the forces of market competition. The Government may determine the ceiling levels beyond which increase in prices would not be permissible.

Based on the above criteria at present 74 bulk drugs and formulations based thereon are under price control for which prices are fixed by the National Pharmaceutical Pricing Authority (NPPA) under the provisions of Drugs (Prices Control) Order 1995.

(e): Price Control on Drugs is done under the Drugs (Prices Control) Orders issued by this Department from time to time. Presently, the Drugs (Prices Control) Order, 1995 is in force. The 74 bulk drugs specified in the First Schedule of the Drugs (Prices Control) Order, 1995 (DPCO, 95) and the formulations based thereon are under price control and their prices are fixed / revised by the National Pharmaceutical Pricing Authority (NPPA) in accordance with the provisions of the DPCO, 1995.

Prices of non-Scheduled formulations are fixed by the manufacturers themselves keeping in view the various factors like cost of production, marketing/selling expenses, R&D expenses, trade commission, market competition, product innovation, product quality etc. The Government takes corrective measures where the public interest is found to be adversely affected.

Whenever any shortage is reported of any drug from any part of the country, Government takes measures to see that these shortages are met urgently.