

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

UNSTARRED QUESTION NO:1918

ANSWERED ON:11.08.2011

ESSENTIAL LIFE SAVING DRUGS UNDER PRICE CONTROL

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

- (a) the details of essential drugs covered under the National List of Essential Medicines (NLEM);
- (b) whether the Supreme Court, in a directive had urged the Government to formulate an appropriate criteria to bring all essential and life- saving drugs under the price control;
- (c) if so, whether the National Pharmaceutical Pricing Authority (NPPA) is exploring the possibility of invoking the `people's interest' clause enshrined in the Drug Price Control Order (DPCO), 1995 to make changes in the pricing of these drugs and to bring them under the price control;
- (d) if so, the details thereof alongwith the steps taken in this regard; and
- (e) the steps taken by the Government against such companies indulging to duck the price control mechanism by manipulating the description of the composition of medicines/formulations and charge exorbitant prices on their drugs?

Answer

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

(a)&(b): The Supreme Court in its interim order dated 10.3.2003 in SLP(C) No. 3668/2003 directed the Government, inter alia, to `consider and formulate appropriate criteria for ensuring essential and life saving drugs not to fall out of price control and further directed to review drugs which are essential and life saving in nature till 2nd May, 2003'. As per the directions of the Supreme Court, the Ministry of Health and Family Welfare reviewed the National Essential Drugs List 1996 and brought out the National List of Essential Medicines, 2003(NLEM 2003). Keeping in view the directions of the Supreme Court it has been proposed in the Draft National Pharmaceutical Policy, 2006 which is at present before the Group of Ministers for a decision, that basket of drugs for price control would be the essential medicines as contained in the NLEM 2003 (subject to certain conditions and exemptions) in addition to the 74 drugs which are at present under price control under the Drugs (Prices Control) Order, 1995,

(c) to (e): 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. No one can sell any scheduled drug /formulation at a price higher than the price fixed by NPPA/Govt. Essential/Life Saving Drugs are not defined in DPCO, 1995,

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. Such prices are normally fixed depending on various factors like the cost of bulk drugs under in the formulation, cost of excipients, cost of R&D, cost of utilities/packing material, sales promotion costs, trade margins, quality assurance cost, landed cost of imports etc.

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. This is an ongoing process.

Based on monitoring of prices of non-scheduled formulation, NPPA has fixed prices in case of 30 formulation packs under para 10(b) and companies have reduced price voluntarily in case of 65 formulation packs. This is an ongoing process.