

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

UNSTARRED QUESTION NO:5863
ANSWERED ON:02.05.2013
LIFE SAVING DRUGS
Das Shri Khagen

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

- (a) whether the life saving drugs have not been defined in the Drugs (Prices Control) Order, 1995;
- (b) if so, the reasons therefor and its impact on the common people, who are in need of life saving drugs;
- (c) the manner in which the National Pharmaceuticals Pricing Authority (NPPA) monitors the prices of all formulations including imported formulations; and
- (d) the mechanism followed by NPPA in calculating the prices of domestic or imported drugs or formulations?

Answer

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

(a) to (c) There is no classification as 'life saving drugs/medicines' under Drugs (Prices Control) Order, 1995 (DPCO, 1995). Under the provisions of the DPCO, 1995, the prices of 74 scheduled bulk drugs and the formulations containing any of these scheduled drugs are controlled. National Pharmaceutical Pricing Authority (NPPA) fixes or revises prices of scheduled drugs/ formulations as per the provisions of the DPCO, 1995. No one is authorized to sell any scheduled drug / formulation at a price higher than the price fixed by NPPA / Govt.

In respect of drugs not covered under the DPCO, 1995 i.e. non scheduled drugs, manufacturers fix the prices without seeking the approval of Government/NPPA. However, as a part of price- monitoring activity, NPPA regularly examines the movement in prices of non-scheduled formulations. Wherever a price increase beyond 10% per annum on moving basis is noticed, 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.

The NPPA monitors the prices of all formulations including imported scheduled formulations that are under price control. To ensure that companies adhere to the prices fixed by NPPA, the State Drug Controllers are sensitized and asked to forward the cases relating to non-compliance of the notified price. As a part of continuous market surveillance, NPPA also procures samples of various scheduled formulations to check the compliance of the notified ceiling price by the companies.

(d) NPPA fixes or revises prices of domestic scheduled formulations as per formula contained in para 7 of the DPCO, 1995 which provides for 100% Maximum Post Manufacturing Expenses (MAPE) to cover all costs incurred by the manufacturer from the stage of ex-factory cost to retailing and includes trade margin and margin to the manufacturer. The prices of imported scheduled formulations are fixed/revised as per proviso to para 7 of the DPCO, 1995 which provides for a maximum margin of 50% on the landed cost to cover selling and distribution expenses including interest and importer's profit.