

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

UNSTARRED QUESTION NO:1748
ANSWERED ON:01.12.2011
UNAPPROVED/OVERPRICED FORMULATIONS
Mahtab Shri Bhartruhari

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

- (a) whether the National Pharmaceutical Pricing Authority has come across with unapproved formulations and overpriced formulations in the list of medicines of the drug companies;
- (b) if so, the details thereof alongwith the names of the companies; and
- (c) the action taken/proposed to be taken by the Government against those companies?

Answer

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

(a) to (c): Yes Sir, It is mandatory on the part of manufacturers to get prior price approval for scheduled formulations from the National Pharmaceutical Pricing Authority (NPPA). However, prior price approval under paragraph 8 of the DPCO 1995 is not required in case of Small Scale Industry (SSI) units fulfilling requirements of exemption notification S.O. No. 134(E) dated 02.03.95.

Based on market surveillance by the NPPA, complaints from individuals/ NGOs and reports from State Drug Controllers (SDCs) as and when NPPA comes to know cases of scheduled formulations being marketed without price approval, their prices are immediately fixed and action is initiated against such companies under the provisions of the DPCO 1995 read with the Essential Commodities Act, 1955. So far NPPA has referred 39 cases to SDCs for taking action against such companies. Of this, thirty three formulations pertain to M/s Cadila Healthcare Ltd., two formulations to M/s Alembic Ltd., two formulations to M/s Medley Pharmaceuticals Ltd. and one formulation each to M/s Lupin Ltd. and Wockhardt Ltd.