

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

UNSTARRED QUESTION NO:4843
ANSWERED ON:25.04.2013
PROTECTION OF GENERIC DRUG PRODUCERS
Biswal Shri Hemanand

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

- (a) whether the Government is taking steps to protect the interests of generic drug producers in the country;
- (b) if so, the details thereof;
- (c) whether the price of pharmaceutical products in India are much higher when compared to other countries and if so, the details thereof; and
- (d) the steps being taken by the Government to develop the pharmaceutical industry in the country?

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) & (b): The Government has been providing fiscal and non-fiscal benefit to the Indian pharmaceutical sector mainly generic medicine manufacturers, like Excise Free Zones, Tax benefit on Research and Development Activities, Credit Linked Capital Subsidy Scheme under Ministry of Micro, Small and Medium Enterprises etc.

(c): Under the Drugs (Prices Control) Order, 1995(DPCO, 1995), no person can sell any formulation (medicines) of price controlled category to a consumer at a price exceeding the price notified/approved by the NPPA/ Government. 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 used 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. Wherever a price increase beyond 10% per annum is noticed, subject to prescribed conditions, the manufacturer is asked to bring down the price voluntarily failing which 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.

(d): The Department of Pharmaceuticals has notified the National Pharmaceutical Pricing Policy-2012 on 07.12.2012 with the objective to put in place a regulatory framework for pricing of drugs so as to ensure availability of required medicines—"essential medicines" – at reasonable prices even while providing sufficient opportunity for innovation and competition to support the growth of industry, thereby meeting the goals of employment and shared economic well being for all.