

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

UNSTARRED QUESTION NO:4171
ANSWERED ON:19.08.2010
INCREASE IN PRICES OF MEDICINES
Mani Shri Jose K.

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

- (a) whether the prices of medicines have gone up after the amendment of Patent Act and introduction of product patent in place of process patent;
- (b) if so, the details thereof;
- (c) whether the Government proposes to declare a policy on Intellectual Property Right;
- (d) if so, the time by which it is likely to be declared;
- (e) whether the Government is monitoring the grant given for production of patented drugs;
- (f) if not, the reasons therefor; and
- (g) the branded and generic names of the patented medicines introduced in the country since 1st January, 2005 to 30th September, 2009 for which generic versions are not available?

Answer

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

(a) & (b): National Pharmaceutical Pricing Authority/Government fixes or revises prices of scheduled drugs /formulations as per the provisions of the DPCO, 1995. Under the provisions of the Drugs (Price Control) Order, 1995 the prices of 74 bulk drugs and the formulations containing any of these scheduled drugs are controlled.

NPPA monitors the prices of all formulations including imported scheduled formulations under price control. Under the DPCO, 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 case, a company is found selling at prices higher than the price notified/approved by the NPPA/Government, action is taken against them as per the provisions of the 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 used in the formulations, 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 part of price monitoring activity, NPPA regularly examines the movement in prices of non-scheduled formulations. The monthly reports of ORG IMS 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.

(c) & (d): Department of Commerce has constituted a Committee to examine the compatibility of intellectual property laws of India with reference Co commitments under the TRIPS Agreement.

(e)&(f): No Public Sector undertaking under the administrative control of Department of Pharmaceuticals has been given any grant for the production of Patented Drugs.

(g): Marketing approval of medicines are given by the Office of Drugs Controller General India. This Department does not monitor this information.