

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

STARRED QUESTION NO:284

ANSWERED ON:30.08.2012

PRICES OF PATENTED AND IMPORTED MEDICINES

Hussain Shri Syed Shahnawaz;Rao Shri Kavuri Samba Siva

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

- (a) whether the Government has taken note of exorbitant prices of patented and imported medicines used for the treatment of diseases like cancer;
- (b) if so, the reaction of the Government thereto;
- (c) whether control over the prices of such medicines are outside the purview of the National Pharmaceutical Pricing Authority;
- (d) if so, the reaction of the Government thereto; and
- (e) the corrective steps taken by the Government in this regard?

Answer

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

(a) to (e): A Statement is laid on the Table of the House.

STATEMENT REFERRED IN REPLY TO PARTS (a to (e) OF THE LOK SABHA STARRED QUESTION NO. 284 FOR ANSWER ON 30.08.2012 REGARDING PRICES OF PATENTED AND IMPORTED MEDICINES

(a) to (c): Patented Drugs are not defined in the Drugs(Prices Control) Order, 1995 (DPCO, 1995). Under the provisions of the DPCO, 1995, 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.

Anti-cancer medicines are non-scheduled drugs and therefore both the domestically produced as well as imported anti-cancer medicines are not covered under DPCO, 1995. In respect of non-scheduled drugs, manufacturers are at liberty to fix the prices by themselves without seeking the approval of Government /NPPA.

(d) & (e): The Department of Pharmaceuticals had prepared a draft National Pharmaceutical Pricing Policy, 2011 (NPPP-2011) based on the criteria of essentiality and requirements as stipulated by the Ministry of Health & Family Welfare which included anti-cancer drugs also. The draft National Pharmaceutical Pricing Policy, 2011 (NPPP-2011) was circulated among the concerned Ministries/Stakeholders. The draft Policy was also available for comments of any other interested person on the Department's website www.pharmaceuticals.gov.in till 30.11.2011. The views/inputs received on the draft NPPP-2011 were examined and the matter was placed before the Group of Ministers (GoM) which met on 25.04.2012. Subsequent to this two meetings have been held by the GoM.

The Indian Patents Act as amended in 2005 contains provisions for issue of Compulsory License for patented drugs. Department of Industrial Policy and Promotion had informed that so far one Compulsory license has been granted by the Controller General of Patents, Designs and Trade Marks to a drug manufacturing company since the amendment of the Patents Act in 2005 for an application filed under Section 84 of the Patents Act (as amended in 2005). As per the orders of the Controller of Patents, Mumbai compulsory license has been granted to M/s Natco for manufacture of an anti-cancer drug 'NEXAVAR'. M/s Natco Pharma Ltd, are required to sell this drug at a price not exceeding Rs. 8880/- for a pack of 120 tablets, required for a month's treatment which was earlier being sold by M/s Bayer Corporation at Rs. 2,80,428/- for one month treatment.