

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

UNSTARRED QUESTION NO:1616  
ANSWERED ON:07.03.2013  
PRICE OF CANCER DRUGS  
Viswanathan Shri P.

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

- (a) the details of the generic drug for cancer which is equivalent to Nexavar manufactured in the country and its price;
- (b) whether the Government is under pressure to keep the price of Indian cancer drug at par with the price of the same drug made by the American manufacturer;
- (c) if so, the comments of the Government thereto; and
- (d) the steps being taken by the Government to control the prices of such life saving drugs?

**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 (c) As per IMS Health data available with National Pharmaceutical Pricing Authority (NPPA), the details of Nexavar which is an anti-cancer drug are not reported. In respect of drugs not covered under the Drugs (Prices Control) Order, 1995 (DPCO, 1995) i.e. non-scheduled drugs, manufacturers fix the launch prices by themselves without seeking the approval of Government/NPPA. Anti-cancer medicines are non-scheduled drugs. Under the present framework of price fixation, there are no controls on the launch price of non-scheduled medicines.

It has been informed by Department of Industrial Policy and Promotion that M/s Natco Pharma Ltd. had applied to the Controller General of Patents Design & Trade Marks (CGPDTM) in July, 2011 for grant of Compulsory License for the drug "Sorafenibtosylate" patented by M/s Bayer Ltd under Section 84 of the Patents Act, 1970. The Controller General Patents Designs and Trade Marks, after examining the application, granted the Compulsory License to M/s Natco Pharma Ltd in March, 2012. However, M/s Bayer Ltd filed an appeal before IPAB (Intellectual Property Appellate Board) against the said orders of the CGPDTM.

(d) There is no classification of Life Saving Drugs in DPCO, 1995. Recently, the Government has notified New Pharmaceutical Pricing Policy, 2012 (NPPP-2012) on 7th Dec, 2012. NPPP-2012 provides for price fixation of cancer drugs specified in the National List of Essential Medicines-2011 (NLEM-2011) of the prescribed strengths and dosage forms. As envisaged in the NPPP-2012, prices of these specified anti-cancer drugs would be fixed after promulgation of the new DPCO by the Government.

Further, to bring down the prices, Ministry of Health & Family Welfare has recommended three cancer drugs, namely, Trastuzumab, lxabepilone and Dasatinib to the Department of Industrial Policy & Promotion to put them under Compulsory Licensing under the provisions of the Indian Patents Act, 1970.