

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

UNSTARRED QUESTION NO:4453
ANSWERED ON:03.05.2012
MANUFACTURING OF GENERIC VERSION OF DRUGS
Jindal Shri Naveen;Singh Alias Pappu Singh Shri Uday

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

- (a) whether the Government has recently decided to invoke the flexibility it had under the World Trade Organisation (WTO) agreement on trade related Intellectual Property Rights for compulsory licensing of patented drugs to ensure availability of life saving drugs at affordable prices to the people;
- (b) if so, the details thereof;
- (c) the details of the firms to which the Government is likely to allow the manufacturing of generic version of other drugs; and
- (d) the extent to which the steps taken by the Government are likely to ensure the availability of life saving drugs at affordable prices?

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): Yes Sir.

(b) & (c): Department of Industrial Policy and Promotion has 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). The details are given as under;

The Compulsory license has been granted by the Controller General of Patents, Designs and Trade Marks for the anti-cancer drug in which the compound is 'Sorafenib Tosylate' (Patent No. 215758). The patent was granted to M/s Bayer Corporation, USA on 03.03.2008 by Indian Patent Office, consequent to their filing a national phase application in India.

M/s Bayer Corporation, USA developed the drug under trade name 'NEXAVAR' and received regulatory approval for importing and marketing the drug in India and launched it in India in the year 2008.

The Compulsory license for the drug has been granted to M/s Natco Pharma Ltd., Hyderabad, Andhra Pradesh.

(d): As per the orders of the Controller of Patents, Mumbai compulsory license has been granted to M/s Natco for manufacture of '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.