

**GOVERNMENT OF INDIA  
COMMERCE AND INDUSTRY  
LOK SABHA**

UNSTARRED QUESTION NO:4384  
ANSWERED ON:19.12.2014  
COMPULSORY LICENSING ON PATENTED DRUGS  
Singh Deo Shri Kalikesh Narayan

**Will the Minister of COMMERCE AND INDUSTRY be pleased to state:**

- (a) the patented drugs against which Compulsory License has been granted by the Government so far in the country;
- (b) whether the Government proposes to implement compulsory licensing on certain other patented drugs, and if so, the details thereof; and
- (c) whether the Government has received any proposals in this regard, and if so, the details thereof along with the action taken/proposed to be taken by the Government thereon?

**Answer**

THE MINISTER OF STATE (INDEPENDENT CHARGE) OF THE MINISTRY OF COMMERCE AND INDUSTRY (SHRIMATI NIRMALA SITHARAMAN)

(a): So far, one Compulsory License has been granted by the Controller General of Patents, Designs and Trade Marks for the anti-cancer drug containing the compound 'Sorafenib Tosylate' which is used for treatment of kidney and liver cancer to a drug manufacturing company, namely M/s Natco Pharma Ltd. The grant is under section 84 of the Patent Act, 1970 (as amended). The patent was originally granted to M/s Bayer Corporation, USA by the Indian Patent Office.

(b): Compulsory license provisions are enshrined in the Patents Act and these provisions will be implemented in a situation befitting the issue.

(c): In January, 2013, Ministry of Health & Family Welfare forwarded to this Department, minutes of the meeting of the Committee set up under that Ministry for invoking provisions of Compulsory Licensing of Drugs in India in which it was recommended to put three drugs namely Herceptin, Dasatinib and Lxabepilone under Compulsory Licensing as per the provisions of Section 92 of the Patents Act, 1970. The said recommendations were examined in detail in this Department and the Ministry of Health and Family Welfare was requested to furnish the relevant information. Subsequently patent on Herceptin was not renewed by the patentee and lxabepilone was considered unsafe by the Ministry of Health and Family Welfare. Ministry of Health and Family Welfare was requested to furnish further information on Dasatinib.