

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

STARRED QUESTION NO:174
ANSWERED ON:19.08.2013
. IPR FOR COMPULSORY LICENSING
Rao Shri Konakalla Narayana

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

- (a) whether the Government proposes to invoke the flexibility under the World Trade Organization 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 of the firms which have been allowed generic version of drugs along with steps taken by the Government for availability of life saving drugs at affordable prices;
- (c) whether the Government has finalised the draft National Intellectual Property Rights (IPR) Strategy; and
- (d) if so, the details thereof along with the measures suggested to protect both product and process patents?

Answer

THE MINISTER OF COMMERCE AND INDUSTRY (SHRI ANAND SHARMA)

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

Statement referred to in reply to Lok Sabha Starred Question No. 174 for answer on 19th August, 2013 by Shri Konakalla Narayana Rao regarding IPR for Compulsory Licensing.

(a): The provisions under the World Trade Organization agreement on Trade Related Intellectual Property Rights (TRIPS) for Compulsory Licensing of patented products and the flexibilities thereof, have already been incorporated in the Patents Act, 1970 (as amended in 2005). The decision of the Government to invoke the relevant provisions of the Act will depend on the facts and circumstances of each case.

(b): A compulsory license has been granted under Section 84 of the Patents Act, 1970 by the Controller General of Patents, Design and Trade Marks for Sorafenib Tosylate to M/s. Natco Pharma Ltd. on 9th March, 2012. National Pharmaceutical Pricing Policy, 2012 (NPPP,2012) notified by the Government on 7th Dec,2012 addresses the issue of making life-saving drugs available at reasonable prices. The policy includes provisions for bringing medicines of various strengths and dosage forms as specified in National List of Essential Medicines-2011 (NLEM-2011) under price control. Subsequently, Drug (Prices Control) Order (DPCO), 2013 has also been notified on 15th May 2013.

(c): No, Madam.

(d): Does not arise.