

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

UNSTARRED QUESTION NO:2469  
ANSWERED ON:09.08.2010  
LICENCING OF GENERIC DRUGS  
Natarajan Shri P.R.

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

(a) whether the Trade Related Aspects of Industrial Property Rights (TRIPS) agreement legally recognise the compulsory licence for supply of a generic version of a Patent drugs;and

(b) if so, the details thereof and the action taken by the Government in accessing affordable medicines?

**Answer**

THE MINISTER OF STATE IN THE MINISTRY OF COMMERCE AND INDUSTRY(SHRI JYOTIRADITYA M. SCINDIA)

(a) & (b): The Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS Agreement) and the Doha Declaration on the TRIPS Agreement and Public Health provide for certain flexibilities in devising patent legislations by Member States so as to incorporate provisions for 'other use of patent without authorisation of the right holder', subject to certain conditions.

Chapter XVI of the Indian Patents Act, 1970 as amended in 2005 incorporates the flexibilities available under the TRIPS Agreement and provides for issue of compulsory licenses subject to certain safeguards.

Further, the National Pharmaceutical Pricing Authority (NPPA) under the provisions of Drugs (price & Control) Order, 1995 controls the prices of 74 bulk drugs and formulations containing any of these scheduled drugs. NPPA also monitors the movement in prices of non-scheduled formulations and intervenes whenever a price increase beyond 10% per annum is noticed.