

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

UNSTARRED QUESTION NO:3890

ANSWERED ON:02.12.2010

LICENCE TO DRUG MANUFACTURERS

Bapurao Shri Khatgaonkar Patil Bhaskarrao;Natarajan Shri P.R.

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

- (a) whether the TRIPS agreement legally recognized the compulsory licence for supply of a generic version of the patent drugs;
- (b) if so, whether the Government proposes to issue compulsory licence to domestic drug manufacturers to make low cost versions of patented essential medicines;
- (c) if so, the details alongwith the objective thereof; and
- (d) the action taken by the Government to overcome barriers in assessing affordable medicines?

Answer

THE MINISTER OF STATE IN THE MINISTRY OF CHEMICALS AND FERTILIZERS (SHRI SRIKANT KUMAR JENA)

(a) to (d): Article 4 of `The Declaration on the TRIPS Agreement and Public Health` adopted in Doha in November 2001 affirms that the TRIPS agreement does not and should not prevent member countries from taking measures to protect public health. Accordingly, it allows for interpretation and implementation of the TRIPS agreement in a manner supportive of the WTO's members right to protect public health and in particular, promote access of medicines to all. Article 6(b) of the Doha Declaration recognizes that the flexibilities of the TRIPS agreement include the right of each Member to grant compulsory licenses and the freedom to determine the grounds under which such licenses are granted. Article 6(c) recognizes the right of each Member to determine what constitutes a national emergency or other circumstances of extreme urgency.

These flexibilities have been incorporated in the Patents Act 1970 as amended in 2005 which is fully consistent with TRIPS. Chapter XVI of this Act entitled `Working of Patents, Compulsory Licenses and Revocation` deals with the issue of compulsory licenses. Sections 84, 85, 91, 92, and 92A enumerate the various circumstances under which Compulsory Licenses may be issued. Chapter XVII contains provisions for use of inventions for the proposes of government and the acquisition of inventions by the Central Government. Chapter VIII of the Patent Rules 2003 as amended in 2006 provides for the modalities of issue and maintenance of Compulsory Licenses. Rule 97 discusses the action to be taken when a prima facie case has not been made out. Rule 98 enables a notice of opposition to the Compulsory License to be made out while Rule 100 provides for amendment to the terms of the Compulsory License. Besides this, the Pharmaceutical policy as amended from time to time also envisages making available quality medicines at affordable price to the masses.