

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

UNSTARRED QUESTION NO:924
ANSWERED ON:28.11.2011
SEIZURE OF DRUGS
Reddy Shri K. Jayasurya Prakash

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

(a) whether India and European Union have any consultations to resolve disputes concerning seizure of generic drugs of leading Indian pharma companies; and

(b) if so, the details alongwith the present status thereof?

Answer

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

(a) & (b): India initiated dispute settlement consultations on 11 May 2010 at the World Trade Organisation ("WTO") with the European Union (EU) on the issue of detention of Indian generic medicines while in transit through EU. The detentions were made by invoking the EC's Regulation 1383/2003 which contains customs procedures for taking action against goods suspected of infringing intellectual property rights (IPRs). India and Brazil jointly held two rounds of consultations with the EU on 7-8 July, 2010 and 13-14 September 2010. During these consultations, EU acknowledged that some provisions of the EC Regulation 1383 were misinterpreted by the customs authorities while detaining the Indian generic drugs. EU showed willingness to resolve this dispute without our resorting to the WTO dispute panel.

After several rounds of extensive consultations, India and EU reached an "Understanding" to guide border enforcement of intellectual property in the EU. This inter-alia, includes the core principle of the Understanding that the mere fact that medicines are in transit through EU territory, and that there is a patent title applicable to such medicines in the EU territory, does not in itself constitute enough grounds for customs authorities in any Member State of EU to suspect that the medicines at stake infringe patent rights. EU also agreed to issue guidelines to confirm the principles contained in the Understanding.

EU also agreed to reflect the principles contained in the Understanding in its proposal for a new Regulation to replace Regulation 1383/2003. The European Commission has adopted a proposal for a new Regulation to replace Regulation 1383/2003 and the proposed new Regulation is under consideration of EU's Parliament. India has conveyed its views to the EU on the proposed Regulation. In the meanwhile, so long as the EU and its Member States adhere to the principles contained in the Understanding with respect to generic drugs in transit through the EU, India has assured not to request the establishment of a dispute settlement panel at the WTO.