GOVERNMENT OF INDIA
COMMERCE AND INDUSTRY
LOK SABHA

UNSTARRED QUESTION NO:2389
ANSWERED ON:27.08.2012
CHECK ON COUNTERFEIT DRUGS
Bapurao Shri Khatgaonkar Patil Bhaskarrao;Bhoi Shri Sanjay;Gaikwad Shri Eknath Mahadeo;Paranjpe Shri Anand Prakash;Ramkishun Shri

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

(a) whether the Indian drug companies have lodged a protest against a move by the European Commission to check the import of counterfeit drugs through a directive;

(b) if so, the details in this regard along with the response of Government thereto;

(c) whether the Government has sought a response from the Drug Controller General of India (DCGI) about the feasibility of training Indian Drugs Inspector on European Union (EU) standards;

(d) if so, the details thereof;

(e) whether Indian pharmaceutical companies are facing losses in exporting generic medicines through South Africa instead of EU; and

(f) if so, the details thereof and the time likely to be taken by the Government to resolve the issue?

Answer

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

a) to d): European Union has mandated through a Directive which will come into force from July 2013 that every exported consignment of active pharmaceutical ingredients (APIs) from non EU/non-listed countries is supported by a certificate issued by competent authority of that country that the consignment conforms to standards of good manufacturing practices (GMPs) as laid down in the EU or equivalent thereof.

Consultation with Government department including Drug Controller General of India, Indian pharmaceutical industry have been held on the implication of this EU Directive on the API exports from India to EU. The compatibility of this new mandate with the WTO and implications on India's exports of API to EU have been examined. The concerns of India to this new provision of EU have been raised as a specific trade concern in the Technical Barriers to Trade (TBT) Committee meeting of the WTO held in June 2012.

a) and f): Indian pharmaceutical companies, in the past, were forced to re-route their exports through South Africa, incurring more expenditure on freight, when their legitimate consignments designed to some of the African and Latin American countries were seized by the European Customs alleging counterfeits.

The matter was taken up at the diplomatic level with the EC Trade Commissioner through Embassy of India, Brussels, clearly bringing out that since there was no patent protection available to the products in India, or in the destination countries and these were not being diverted to the European markets, there was no patent violation. India also made a request to the Dispute Settlement Body of the WTO in May, 2010 seeking consultations with the EU in this regard. Consultations were held with EU in July and September 2010. Consultations have been very useful as EU has acknowledged that some provisions to the relevant EC Regulation may have been misinterpreted by the Customs authorities of EU and has shown willingness to resolve the dispute without the need to seek establishment of a Panel. As EU has indicated to resolve the dispute, India has not yet sought establishment of a Panel in this dispute.