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India, EU reach understanding on seizure of Indian generic drugs at EU ports

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India and the European Union (EU) have reached an interim settlement on the long pending issue of seizure of Indian generic drug shipments at the EU ports, en route to Latin American and other countries, on charges of counterfeiting and patents infringement. The settlement will ensure that none of the 27 members of the economic and trading bloc will detain 'Made in India' consignments of generic medicines, which are transiting through EU ports.

As per the understanding between the India and the EU, the European Commission will come up with a new Regulation to replace Regulation 1383/2003, under which the EU countries were detaining the Indian generic drugs on charges of counterfeiting and patents infringement.

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 the EU that India will not request the establishment of a dispute settlement panel at the WTO. With the exchange of these letters, India and the EU have reached, for the present, an informal settlement of this dispute. India would watch with interest EU's further steps in implementing its commitments. India's options to revive the dispute remain intact in case the EU does not abide by the core principles agreed to in the Understanding.

India had initiated dispute settlement consultations on 11 May 2010 at the World Trade Organization (WTO) with the EU on this issue. The dispute was triggered by the repeated instances of detentions/seizure at EU ports, particularly in the Netherlands, of Indian generic drugs destined for export to Latin American and other countries. 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). These detentions were made during the period October – December 2008 at Schiphol airport, Netherlands. The consignments were initially detained and later, either destroyed or returned to India or allowed to proceed to the destination.

The detentions by the customs authorities of these generic medicine consignments were in violation of the obligations of the EU and the Netherlands under Article V of GATT which enshrines freedom of transit of goods through the territory of each contracting party of GATT via the routes most convenient for international transit. The detentions were also inconsistent with the EU and its Member States' obligations under Articles 41

and 42 of the TRIPS Agreement as these detentions created barriers to legitimate trade, led to abuse of the rights conferred on the owner of a patent, were unfair and inequitable, unnecessarily burdensome and complicated and created unwarranted delays.

Moreover, these detentions were inconsistent with certain fundamental obligations of the EU under Article 31 of the TRIPS Agreement read together with the provisions of the Decision of the General Council of August 30, 2003 on the Implementation of Paragraph 6 of the Doha Declaration on the Trips Agreement and Public Health to ensure access to medicines for members of the WTO ("Members") with insufficient or no capacity in the pharmaceutical sector to enable them to address their public health problems.

India was joined by Brazil in this dispute; Brazil also filed a similar complaint against the EU before the Dispute Settlement Body of the WTO. India and Brazil jointly held two rounds of consultations with the EU on 7-8 July 2010 and 13-14 September 2010 in Geneva. 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 resorting to the WTO dispute panel.

Thereafter, India engaged in extensive consultations with the EU with the assistance of legal experts. Finally, after several rounds of discussions, India and EU reached an "Understanding" which, inter-alia, contains the principles to guide border enforcement of intellectual property in the EU.