

Original: English

**ARGENTINA – MEASURES AFFECTING THE IMPORT  
OF PHARMACEUTICAL PRODUCTS**

Request for Consultations by India

The following communication, dated 25 May 2001, from the Permanent Mission of India to the Permanent Mission of Argentina and to the Chairman of the Dispute Settlement Body, is circulated in accordance with Article 4.4 of the DSU.

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My authorities have instructed me to request consultations with the Government of Argentina pursuant to Article 4 of the Understanding on Rules and Procedures Governing the Settlement of Disputes (DSU), Article 14 of the Agreement on Technical Barriers to Trade (Agreement on TBT) and Article XXIII of the General Agreement on Tariffs and Trade 1994 (GATT 1994) regarding Argentina's Law/Act No. 24.766 and Decree No. 150/92, which constitute unnecessary obstacles to international trade and prevent Indian medicines, drugs and other pharmaceuticals from entering into the Argentinean market thus discriminating against Indian drugs *vis-à-vis* like products of other countries and of Argentina.

The above-mentioned Law and Decree relating to export and import of medicines, require that before entering the Argentinean market, all drugs and other pharmaceuticals must be registered with the National Administration of Drugs, Foodstuffs and Medical Technology under the Ministry/Department of Health of Argentina. The Decree (text ordered by Decree 177/93) contains two Annexes listing countries. In respect of Annex-I countries, pharmaceutical products are required to be manufactured in facilities approved by the relevant governmental bodies of these countries or by the Argentinean Ministry/Department of Health and meet the National Health Authority's manufacturing and quality control requirements. In respect of Annex-II countries, manufacturing facilities for such countries are required to be inspected and approved by the Ministry/Department of Health of Argentina before export of these pharmaceutical products into Argentina.

India does not figure in either of these two Annexes. This discrimination has led to total lack of market access for Indian drugs and pharmaceutical products in Argentina. The Government of India considers that the above Law and Decree of Argentina are in violation of Article 5.1.1 of the Agreement on TBT and violates the fundamental MFN provisions under Articles I and III of GATT 1994. The Government of India considers that the Argentinean Law No. 24.766 and Decree No. 150/92 have also violated obligations under Article 5.2 of the Agreement on TBT thus constituting unnecessary obstacles to international trade.

As per Article XVI:4 of the Agreement Establishing the WTO, the Government of Argentina is under an obligation to ensure conformity of its laws, regulations and administrative procedures with the WTO covered agreements. Maintenance of the above-mentioned Act/Law and Decree is in violation of this fundamental obligation. Besides, in implementing these laws/decrees, Argentina has

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not taken into consideration the status of India as a developing country Member and has not provided special and differential treatment as required under Article 12 of the Agreement on TBT.

The Government of India considers that infringement of the following provisions have taken place:

- (i) Articles 2 (especially 2.2), 5 (especially 5.1 and 5.2) and 12 of the Agreement on TBT
- (ii) Articles I and III of the GATT 1994
- (iii) Article XVI:4 of the Agreement Establishing the WTO.

The Government of India reserves its right to raise further factual claims and legal issues during the course of the consultations.

We look forward to receiving your reply to this request and to fixing a mutually convenient date for consultations.

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