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India issues demarche to Argentina on drug laws

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New Delhi: Angry over Argentina's insistence on denying Indian drugs access to its market, New Delhi has issued a demarche to the country asking it to relax laws.

Argentina, the third largest market in Latin America after Brazil and Mexico, is the only country in the region, which, through law, forbids Indian companies from supplying drugs. This comes at a time when Brazil is considering changes in legislation to facilitate increased supply of generics, a move which would prove favourable for Indian players.

India's generic drug industry is incidentally one of the strongest in the world. Indian companies supply drugs to the highly-regulated markets of the US and EU, with many of them even aggressively seeking market exclusivity for their products invoking the relevant legal instruments.

Brazil has also teamed up with India to move to World Trade Organisation against EU's action of seizing perfectly legitimate Indian drugs in transit. Officials say that the issue was raised earlier in the week by the delegation led by minister of state for external affairs, Preneet Kaur, on her visit to Argentina.

Under the Argentine presidential decree, imports are allowed from two sets of countries enlisted in separate annexures. Annexure-I contains a list of matured markets with established regulatory systems such as USA, Japan, Sweden, Switzerland, Israel and Canada, among others. The second annexure names eleven countries—Australia, Mexico, Brazil, Cuba, Finland, Hungary, Ireland, China, Luxembourg, Norway and New Zealand—from where imports are allowed if the plants of firms from these countries are approved by one of the countries included in annexure I. "For all other countries outside these two annexures, there is a complicated procedure which makes it virtually impossible to import from them," said a government official. Since India is not a part of either annexure, Indian firms are unable to export to Argentina.

The fact that India exports to all matured markets included in the first annexure implies that Indian drugs meet the stringent quality standards of their regulatory framework. India also has the largest number of US Food & Drug Administration-approved laboratories outside USA. India has taken up the matter repeatedly with Argentina, batting for its inclusion. The Indian industry believes that local drug cartels are wielding their influence to prevent

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- Indian pharma goods have held a declining share of Argentina's pharma imports, from 0.85% in 2004 to 0.30% in 2008

their entry. “If Indian players are allowed to enter the Argentine market, they could wean away a significant market share of local players by offering the same drugs at competitive prices. Also low prices of Indian drugs could force generic players to reduce the costs of drug, thus affecting their margins and profitability significantly,” said a domestic player.

Argentine pharma companies earn around \$2.5 million through their exports to India. This figure includes the export from Indian drug firm Glenmark’s subsidiary in Buenos Aires. Surprisingly, Argentina is significantly dependent on India for pharma raw material. Also, Indian drugs find their way to Argentina through indirect channels. For instance, vaccines supplied by the Serum Institute of India are bought by the Pan-American Health Organisation in Panama and is distributed in Latin American countries, including Argentina.

India’s stance is supported by independent market analysts. In a recent report, Business Monitor International noted, “Argentina has started imposing trade tariffs on imports from outside the Mercosur trade bloc, with additional regulations that will favour domestic drug firms. According to the UN Commodities Trade Statistics Database, Argentina’s pharma imports touched \$1.14 billion in 2008, a 109% jump from 2004. The imports are projected to touch \$1.25 billion in 2009 and \$2.01 billion by 2014, with a CAGR of 10%. Pharmaceutical imports, mainly comprising raw materials from India, witnessed a decline from \$6.8 million in 2005 to \$3 million in 2008. Indian pharma goods have held a declining share of Argentina’s pharma imports, from 0.85% in 2004 to 0.30% in 2008.