

India's Access to the Pharmaceutical Market in Argentina

Introduction

In today's global trading system, regulatory processes pose as much a challenge to accessing markets as tariff-related measures. Addressing some of these barriers is, therefore, sometimes dependent on the ability of the embassies of a country to make use of both its soft skills and extensive networks to arrive at mutually beneficial solutions. To do this often requires a significant amount of political astuteness, and, at times, pressure.

The following case study illustrates how the Indian Embassy in Buenos Aires, Argentina, under the leadership of Ambassador Amarendra Khatua, through its extensive political know-how and do-how, played a key role in the opening up of the Argentinian market to India's pharmaceutical products.

Context

For the past 30 years, Indian pharmaceutical products had very limited access to the Argentinian market. Only countries that were listed on the Presidential Annexes enjoyed access to the market. However, in spite of continued efforts, the Indian government had been unable to include India in these Annexes. In July 2012 this issue was resolved.

As the third largest pharmaceutical market in Latin America after Brazil and Mexico, India's limited access to the Argentinian market had been a major problem for India's

pharmaceutical exporters. Including the import of fine chemicals and generics import, the annual market size of Argentina is valued at almost US\$4.5bn. However, in spite of India's competitive advantage in many pharmaceutical products, India's share of this market stood negligible.

Given the size of this potential market, the Indian government, through the Indian Embassy in Argentina, had continuously raised this issue with the Argentinian government. The exclusion of India in the Annexes meant that the inspection of all Indian drugs and medicines had

to be undertaken by the regulatory body, ANMAT (*Administración Nacional de Medicamentos, Alimentos y Tecnología Médica* – National Administration of Drugs, Food Products and Medical Technology), and this often resulted in lengthy processing times, sometimes spanning years. And even then, approval was not certain.

As a result, India's exports of pharmaceutical products to Argentina were limited to raw materials and fine chemicals for production of medicines by state and private

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sector laboratories. Very few specialised drugs were selected through inspection by ANMAT and these were often permitted on the basis of *ad-hoc* market demand. The limited generic drugs exporters included Lupin, Ranbaxy and a few vaccine manufacturers.

A number of factors contributed to the difficulties that India faced in accessing this market. First, the market itself was tightly controlled and dominated by the local distributors of multinationals from the US, European Union and Switzerland. These distributors included both state and private

The new Decree saw India's inclusion in Annex II; thus, opening up the Argentine market for the export of Indian pharmaceuticals

sector laboratories. Secondly, tenders were often awarded to non-producing suppliers due to the power of lobby groups that sought to keep out new entrants.

This system existed because many of the existing players

benefitted from supply-constrained profit margins that were more lucrative than those that would have existed in an open market; however the intransigent thinking by the Ministries and provincial authorities also proved to be a constraint.

Trade Promotion

In August 2012, the Indian Embassy in Buenos Aires decided to form an advisory committee to the Ambassador in order to find ways to address this issue. The committee comprised of a few ex-Health Ministers of Argentina and a few ex-Chiefs of ANMAT. In building this committee, the then Indian Ambassador met almost all the 30 state and private sector laboratories to convince them that imports from India would not cut down their profit margin, and that India was willing to produce locally with investment and technology through joint venture initiatives and as such would not supplant the local industry.

The consultations between Argentina and India were initiated at the World Health Organisation and the issue was further discussed in 2013 at the first Argentina-India Joint Commission Meeting, which was held in New Delhi after seven years, with the Argentine Foreign Minister. It was also raised with all the 23 Governors of Argentine states under the Indian Embassy's Regional Action Plan. In addition to this, the Indian Embassy also insisted that the Argentine Health Minister pay a visit to India which eventually resulted in softening of Argentina's stand towards Indian pharmaceuticals.

The then Indian Ambassador's personal relationships with the presidency as well as others members of the Argentinian national leadership also helped in publicising this issue with people who worked in the media, think-tank bodies, non-governmental organisations and chambers of commerce and industry. Three export promotion events and buyer-seller meets by the Pharmaceutical Exports Promotion Council of India (Pharmexcil) were organised and attended by officials from the Department of Commerce, Government of India.

All this was done in an effort to request Argentina to consider including India to the Presidential Annexes on the basis of the quality and price of Indian pharmaceutical products as this could further foster goodwill between India and Argentina, and facilitate long-term cooperation in the sector.

Market Access

Prior to August 2014, changes in a Presidential Decree in Argentina had been unheard of but the consolidated efforts of the Indian Embassy over the three year period placed pressure on all the relevant stakeholders including the Ministry of Health, regulatory body ANMAT, the major laboratories in the private sector who are closely linked to multinational pharmaceutical companies as distributors, state governments and public sector laboratories. The final break-through occurred with the issuance of the Presidential Decree on August 08, 2014. The new Decree saw India's inclusion in Annex

II; thus, opening up the Argentine market for the export of Indian pharmaceuticals.

The Decree has allowed for a number of benefits to India's pharmaceutical companies. First, Indian companies with US Federal Drug Authority (USFDA) and EU certification can now export freely to Argentina.

Secondly, the ANMAT inspection procedure has become streamlined for Indian companies. India can now concentrate on registering those drugs that it does not export to the US, EU, etc. with ANMAT.

Thirdly, an assessment of the possibility of setting up joint ventures for local and regional sales and distribution can now be undertaken. Finally, adjacent markets such as Uruguay, Paraguay, Ecuador, Bolivia and Peru can also be accessed.

Following this Decree amending Annex II, the Argentinian Health Minister accompanied by a high powered team visited India in September, 2015 to hold talks with the Commerce and Industry Minister of India, Pharmexcil and pharma industry on a number of issues including:

- the immediate import of generic drugs, essential medicines, vaccines and latex products from India to bring down the rising price in the Argentine market;
- identifying and preparing a list of drugs and medicines for which India can participate in single tenders for urgent and immediate supply;
- working with ANLAB (National Administration of Laboratories), a body created by the Argentine Ministry for future Joint Venture manufacturing of medicines in Argentina, technology transfer and export of drugs and medicines to Argentina; and
- increasing collaboration between Indian pharmaceutical manufactures and

Argentine public and private sector laboratories.

Following this, in collaboration with the Ministry of Commerce & Industry of the Government of India and Pharmexcil, the Indian Embassy in Argentina brought 40 Indian pharmaceutical manufacturers and exporters for a road show, buyer-seller meet and market intervention event in September 2015. Indian participants had wide ranging talks with the Ministry of Health, public and private sector laboratories, regulatory body ANMAT, state governments, and importing and joint venture body ANLAB.

ANLAB will visit India to explore joint venture possibilities and acquire technology transfer and long-term raw material supply

Based on these meetings, Argentina is now in the process of submitting a list of 20 drugs for immediate import from India. The process and procedure to implement the exports will be worked out by Ministry of Commerce & Industry, Government of India. ANLAB will shortly visit India to explore joint venture possibilities and acquire technology transfer and long-term raw material supply. This is currently being coordinated by the Ministry of Commerce & Industry, Government of India.

With proper coordination and existing goodwill, and as a result of this success, in next two to three years, India's exports of pharmaceutical products to Argentina touch a target of US\$15mn to US\$20mn.

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