

How Science Diplomacy can Contribute towards Pharmaceutical Sovereignty of Ecuador?



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Introduction

Science diplomacy (SD) is the use of scientific, technological and academic knowledge to build collaborations among countries, regions and societies to address common issues and to build international partnerships. Besides, SD is also to address common problems facing 21st century humanity and in a building constructive international partnerships (Federoff, 2009). This is a transversal approach to the Sustainable Development Goals (SDG) including the field of health regulations and regulatory science, Good Health and Well Being. Its aim is to achieve universal health coverage and provide access to safe and affordable medicines and vaccines to all.

Objective

The aim of this work is to describe the potential cooperations between both the Republic of Ecuador and the Republic of India focused on to develop and strengthen the friendly relationship, trade and cooperation mechanism, in order to contribute and promote the country's sovereignty of Ecuador in the field of Health Technologies.

Access to Drugs and the Situation of the Pharmaceutical Market in Ecuador

To this end, is fundamental to understand the structure and dynamics of the Ecuadorian pharmaceutical market, its segmentation between the public and private sectors, and its relationship with supply and demand, both for generic and brand-name drugs. To achieve these goals, an observational and descriptive study was conducted using the information available at free scientific, institutional, technical-administrative, and economic databases.

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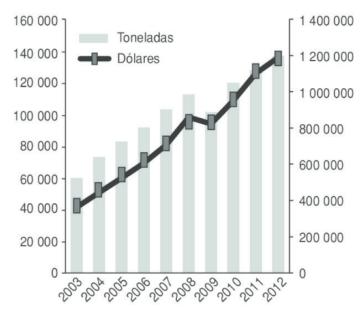
In Ecuador, 69.6 per cent of dispensed drugs are brand-name and 30.4 per cent are generics. Of all registered drugs in the country, 1,829 (13.6 per cent) are considered over-the-counter and 11,622 (86.4 per cent) are for sale under medical prescription.

In terms of sales, 93.15 per cent correspond to brand-name drugs and only 6.85 per cent to generics. 90 per cent of the pharmacies are located in urban areas while only 10 per cent in rural areas. In the last five years, prices have increased by 12.5 per cent for brand-name drugs and 0.86 per cent for generics. Brand-name drugs are dispensed and consumed 2.3 times more than generics. Furthermore, the location of most of the pharmacies shows that there is a relationship or association between purchasing power and access to drugs. Although, the regulatory authority stipulates that 13 per cent of drugs should be over the counter, approximately 60 per cent of the population acquires drugs without a medical prescription.

The access to medicines is one of the indicators used to measure the standard of living of a country, as it reflects the efficiency and strength of a health system. Currently, the pharmaceutical market

in Ecuador is undergoing state-driven changes, in compliance with its obligation to guarantee access to health for its entire population. Through the application of strategic sector policies, it has been possible to improve access and provision of medicines to the population of the comprehensive public health network (RPIS). This process has allowed the State to save, by reducing the cost of medicines by boosting the national production of active ingredients thus contributing to the change of the productive matrix. The supply of medicines in Ecuador has had an evolutionary process marked in the last fifty years: historically, some international laboratories supplied a few pharmacies. Later, and by regulations of previous governments, international laboratories were forced to install a production plant in the country as a requirement for the commercialization of their products. This led to the import substitution of finished products with that of raw materials and packaging, a model that has been maintained until now. At present, the Ecuadorian pharmaceutical market is characterized by a complex system of production, purchase, distribution and dispensing of medicines. (Prado et al, 2014)

Figure 1: Behaviour of the Ecuadorian Pharmaceutical market 2003–2012 (Tons – Dollars).



Source: Prado et al (2014)

Ecuador is a country where the demand for pharmaceutical products is designed to meet the needs of the public and private markets. However, despite the fact that the State is the main trading partner of the industry, the dispensation is made mostly through private companies, which increases the prices of medicines. This can be attributed to a disregard of the regulations in force by the prescriber or the dispenser in all Ecuadorian pharmacies. This suggests that there could be a direct relationship between capital, trade and the satisfaction of the demand of the population. Finally, and despite the fact that the regulating authority dictates that 70% of the drugs should be sold under medical prescription, this analysis shows the opposite (Figure 1).

The Pharmaceutical Industry of India

India is with current market size of \$27.57 billion

(last reported in 2016) is expected to reach a mark of \$55 billion by 2020 at a CAGR of 15.92 per cent, according to a report by the Indian Brand Equity Foundation (IBEF). In the next three years, India is projected to be among the top three pharmaceutical markets in terms of growth rate and the sixth largest market globally in absolute size (Figure 2)

"Currently the industry is growing at a rate of 9-10 per cent year-on-year, which is a healthy growth because this is largely a volume led business. This is a fundamental advantage of an emerging market economy like India; given the large base, double digit growth numbers are not observed in developed countries like United States," said Kedar Upadhye, Global Chief Financial Officer, Cipla Ltd.

In addition, India accounts for 20 per cent of global exports in generics. In FY16, India exported pharmaceutical products worth \$16.89 billion, with

Table 1: Leading Exporters of Pharmaceutical Prodcuts

Exporter	Exports in USBillions (2018)
European Union (27 countries)	136.7
Switzerland	45.3
United States of America	22
India	13.1
Canada	6.8

Source: Elaborated from the data of UN Comtrade Database. Classification HS 30

In terms of production volume, it occupies the 3rd place worldwide The Indian pharmaceutical Its generic drugs represent industry is expected to 20% of the world grow to achieve the target production of this type of of USD 55 billion by 2030. medicines. India is one of the leading countries in the global pharmaceutical industry

Figure 2: Pharmaceutical Industry of India

Source: IBEF, 2019

25.0 20.0 15.0 10.0 10.1

Table 2: Export of pharmaceutical products in USD Billions

Source: Elaborated from the data of UN Comtrade Database. Classification HS 30

the number expected to reach \$40 billion by 2020 (IBEF, 2019).

Export of pharmaceutical products

According to UN figures for 2018, India is one of the largest exporters of pharmaceutical products - 4th place – worldwide (Table 1)

Pharmaceutical exports from India, which include: bulk medicines, active ingredients, drug formulations, biological products, Ayush, herbal products and medical/surgical equipment, reached US \$ 19.14 billion in fiscal year 19 and US \$ 3.1 billion in fiscal year 20 (until June 2019). (Table 2)

Indian Generic Medicines

Indian generic medicines have contributed for the improvement of the quality of life and the increase in life expectancy of millions of patients, around the world providing excellent medicines at affordable prices. 90 per cent of the generic antiretrovirals used around the world are produced in India.

The comparative table (Table 3) depicting the cost of treatment of some diseases in Ecuador and India is given the Table below. It can be easily seen that the costs are much lower in India.

Criteria for the Selection of Pharma Companies

The following criteria are taken into consideration while selecting pharma companies for establishing an alliance with Ecuador.

- International presence in highly regulated markets.
- Annual compound growth rate in sales in the last 5 years
- Production of generic drugs and active

TREATMENT	COST ECUADOR USD	COST INDIA USD
Hepatitis C	USD 50.000,00	USD 4.500,00
Prostate cancer (Monthly Treatment)	USD 4.500,00	USD 750,00
Pulmonary fibrosis (Monthly Treatment)	USD 1.000,00	USD 90,00

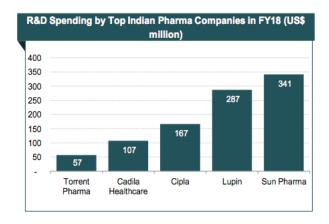
Table 3: Treatment Costs in India and Ecuador

pharmaceutical ingredients

- Investment in research and development
- -No link to proven incidents of production of counterfeit or poor quality drugs.
- Approvals and certifications in highly regulated markets for medicines and operation of production plants.
- Membership of the Indian Pharmaceutical Alliance: a group of pharmaceutical companies that have certifications in highly regulated markets, approximately 30 of the best 3,000 companies in India among producers and marketers of medicines belong to this alliance.

Examples of companies that have suitable profile for alliances with Ecuador: Sun Pharma and CIPLA.

Sun Pharma: Emphasising on Research and Development

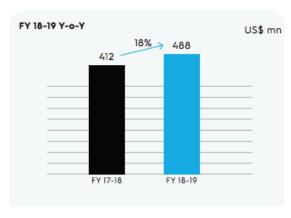


Source: IBEF (2019)

In the financial year 2018, Sun Pharma was the Indian company that invested the most in research and development (R&D). The investment of the company in the mentioned item was USD 341 million.

Cipla: Leader in highly regulated markets

Cipla is one of the main suppliers of generic medicines for the North American market. In the 2018-19 financial year, sales to the mentioned market reached USD 488 million. North America contributes to 21% of the company's total revenue.



Source: Cipla Limited. Annual Report 2018-19



Source: India Brand Equity Foundation

Ecuador - India Business Proposal

"The Agreement for Pharmaceutical Sovereignty of Ecuador" will be a government-to-government agreement, which means, a PUBLIC-PUBLIC alliance.

India proposes that the public sector company STC be the representative in negotiations with Ecuador. STC will only invite companies that have highly regulated market certifications to participate in the Project: "Ecuador in Search of Pharmaceutical Sovereignty" Ecuador, Chile and Bolivia are the

Potential Benefits of Strategic Alliance with India

Access to excellent quality medicines

100% timely coverage in terms of medicines to members

Up to 50% savings in the budget allocated for the purchase of medicines

Become pioneers in achieving Pharmaceutical Sovereignty in Latin America

- Access to excellent quality medicines.
- 100 per cent timely coverage in terms of medicines to members.
- Up to 50 per cent savings in the budget allocated for the purchase of medicines.
- Become pioneers in achieving Pharmaceutical Sovereignty in Latin America.

first 3 countries in Latin America which have been invited to participate in Pharmaceutical Sovereignty programs by India

India / STC will ensure that the quality of medicines are in accordance with the requirements stipulated by Ecuador / IESS.

Remarks

The strengths of the Indian pharmaceutical industry, and this huge experience in the production of high-quality and low-cost generic drugs, have allowed him to have a valuable presence of Indian medicines in highly regulated markets. (40 per cent of the demand for generic drugs in the United States and 25 per cent in the United Kingdom).

Indian pharmaceutical companies have developed the capabilities to compete in the international market, having the largest number of production plants outside the United States approved by the USFDA. In 2017, Indian pharmaceutical companies received 304 (ANDA-Abbreviated New Drug Application) approvals from the USFDA (US Food and Drug Administration). Year in wich the USFDA tested more than 323 generic drugs produced in several countries (100 of them in India) to assess their quality. According to the tests performed, the

323 medications met the USFDA standards.

Conclusion

Developing countries like Ecuador are often a few steps behind the one known as the first world countries. Thats why in the frame of Science Diplomcy the countries, like India and Ecuador can save lives strengthening trade and cooperation mechanisms about transfer and exchange of scientific knowledge and technological development. If India provides 40% of generic medicines to the United States. Ecuador could access a similar or preeminent figure. There are approx. 3000 laboratories in India that produce medicines. It is important to shortlist the companies that have Certificates in Highly Regulated Markets.

India can provide 60,000 generic drugs in more than 60 therapeutic specialties. An effective supplier of medicines can be generated by a strategic alliance with the Indian Government. STC is the Public Sector Trading Company of India authorized to negotiate with Ecuador.It is important to get benefits of this PUBLIC to PUBLIC alliance to make effective and support the Pharmaceutical Sovereignty for Ecuador.

To get benefit of the costs and quality of Indian medicines to adopt itself as a government focused on the welfare and recovery of members. Generating 100 per cent coverage in high quality medications. Science and technology unite us today, but cooperation and solidarity lead us towards a good living for the humanity.

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