Interview: Henrique Tada â?? Executive Director, ALANAC, Brazil

â??Our main competitive advantage on international markets relates to the proven quality of the pharmaceutical products developed and manufactured in Brazil.â?•

01.12.2017

Tags:

Brazil, ALANAC, Pharma, Association

Henrique Tada, executive director of ALANAC, the association gathering Brazilian pharmaceutical companies, provides an historical overview of the rapid and eye-catching growth of the local pharmaceutical industry and documents the new development opportunities envisioned by domestic manufacturers with regards to botanical and biological drugs as well as their competitive advantages in international markets.

Over the past few years, how has the importance of domestic pharmaceutical companies been evolving among the Brazilian healthcare ecosystem?

In order to understand where domestic companies stand in 2017, we first need to go back to a founding event that occurred 18 years ago: the promulgation of the Generic Law in 1999, which authorized laboratories to develop and sell generics of original products that have lost their ten-year patent. This law has deeply transformed the Brazilian market, while generic consumption in the country has more than five folded in the meantime. Furthermore, we saw that the fast-growing consumption of generics has mainly benefitted to domestic companies, which now account for around 71 percent (in units) and 68 percent (in value) of all generics sold in Brazil.

Overall, domestic pharmaceutical companies make up around 67 percent (in volume) and 58 percent (in value) of the total retail market in the country, while they only accounted for 38 percent of the total retail marketâ??s volume in 2002. Although we expect domestic manufacturersâ?? market share to stabilize at some point, we believe that the abovementioned figures will continue to increase in the short and mid term. Despite this positive context, domestic companies however did not rest on their laurels, and most of them significantly invested over the past few years to expand and/or upgrade

their manufacturing capacities and improve their cost-effectiveness profile.

In the meantime, Brazilian pharmaceutical companies are leveraging double digit revenue growth rates to venture into new development avenues, including botanical and biological drugs. This endeavor has fostered the dawn of eye-catching initiatives, such as Bionovis, a biopharmaceutical joint venture composed of four leading Brazilian companies â?? AchÃ© LaboratÃ³rios, EMS, Hypermarcas and UniÃ£o QuÃmica â?? which hold the objective to provide Brazilâ??s public health system (SUS) with complex, locally produced biotech products.

Entering the biosimilar segment stands as a very promising opportunity for domestic companies. What are the main obstacles that still lie ahead?

[Featured_in]

In Brazil as in other advanced markets around the world, the interchangeability of biosimilars with the products of reference remains a sensitive subject. Nevertheless, enacting biosimilar interchangeability is absolutely critical to foster the development of a strong domestic, biological industry and prevent multinational companies from keeping a monopole position in this market niche. At the moment public authorities are focused on bolstering the competitiveness of Brazilâ??s pharmaceutical market and aim to accessing life-changing medicines at a fair price, restricting competition in the biological area would clearly go against this fundamental objective.

On the other hand, multinationals still claim that biosimilars and reference products stand as different formulations and therefore ask to rule out interchangeability â?? without bringing technical evidences to support this claim. In this regard, the context surrounding biologicals is similar to what happened more than twenty years ago when regulatory agencies decided to open their markets to generic products. At that time, proven analytical methods stating that generics were chemically identical to original products in terms of efficacy and safety did not prevent multinational companies from offering strong resistance to genericsâ?? market entry.

Nevertheless, in Brazil, the regulatory basis framing biological and biosimilar products is already particularly strong and advanced, and ANVISA has been actively liaising with its international counterparts to set up high-level standards for these productsâ?? registration.

The domestic pharmaceutical industry has been performing particularly well in comparison to other sectors of the Brazilian economy over the past few years. How are you working with the Brazilian government to further propel the growth of local companies?

[related_story]

In this regard, we are involved in a specific committee gathering experts from ANVISA, the Ministry of Health, the Ministry of Industry, Foreign Trade and Services as well as from the Ministry of Science, Technology, Innovation and Communication. As part of this committeeâ??s activities, we discuss new growth scenarios for the pharmaceutical industry, encompassing new drug development as well as Productive Development Partnerships (PDP), which are collaborative agreements between public institutions and public or private entities for the development or transfer of technologic and productive capacities, with a focus on strategic products that are aligned with the demand of the public health system.

In this context, I want to highlight that the Ministry of Health and ANVISA are particularly open to dialogue and to any new initiatives that would imply domestic companies. Overall, the Brazilian government really strives to propel the development of the Brazilian pharmaceutical industry and is careful not to implement regulations that would hinder its growth. In the meantime, Brazilian

companies can thrive within a strong and predictable regulatory framework which overarches all aspects of the value chain, from manufacturing and quality standards to product development, clinical trials and market access regulations. Finally, ANVISA is particularly proactive when it comes to upgrading our countryâ??s regulatory standards, and Brazilâ??s agency is always careful to avoid implementing abrupt regulatory updates that would disrupt the development of the industry, which is also extremely important.

Given that domestic companies already hold a 67 percent market in the Brazilian retail market, increasing these companiesâ?? international presence has become even more crucial. What are the competitive advantages of Brazilian companies to gain market share in international markets?

Our main competitive advantage on international markets relates to the proven quality of the pharmaceutical products developed and manufactured in Brazil. Again, this strength emanates from the stringent standards imposed by ANVISA, which proudly stands as one of the most recognized regulatory agencies in the world, while we see that many other Latin American companies still struggle to get approval for their products or bioequivalence studies by advanced marketsâ?? regulatory agencies.

As a matter of fact, ANVISA officially became in November 2016 a member of the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH), alongside the US FDA, the EU EMA, Japanâ??s PMDA, Swissmedic, and Health Canada. Furthermore, ANVISA proudly belongs to the five Latin American regulatory agencies accredited by the World Health Organization *[alongside its Mexican, Argentinian, Cuban, and Colombian counterparts â?? Ed..]*

As executive director of ALANAC, what are your strategic priorities?

My fundamental objective is two fold: fuel the sustained growth of our companies and bolster innovation by mixing an incremental and radical development approach. Innovation-oriented projects such as the aforementioned joint venture Bionovis are still relatively recent but they have already accumulated interesting successes, whether they concern the registration and production of biopharmaceutical products or to encouraging technology transfers. Overall, I want to stress that innovation is extremely important for Brazilian companies; we have honed a top-notch expertise for the development and manufacturing of generics, and we are now ready to move forward through incremental and radical innovation-oriented projects.

Finally, we recently opened ALANACâ??s door to animal health companies, a market segment that has experienced an extremely strong growth over the past decade. As ALANAC, we will continue to work alongside our members to ensure they can fully seize the eye-catching development opportunities that the Brazilian market holds in the veterinary field.

What would be your final message to our international readers?

Brazilian pharmaceutical products meet the highest quality standards as they have been developed, tested, and manufactured within a world-class regulatory framework enacted by one of the most reputed regulatory agencies internationally. Leveraging our companiesâ?? decades of experience in technical, scientific, and regulatory matters, all conditions are met to allow Brazilian companies to further develop their international footprint and sharpen their competitiveness in our domestic market.

See more interviews