Henrique Tada – Executive Director, ALANAC, Brazil

The pandemic has given us the opportunity to reclaim our spot in the APIs market and not repeat the mistakes of the past

10.03.2023

Tags: Brazil, ALANAC, Generics, Association, Manufacturing

Henrique Tada of ALANAC, the association that brings together Brazil's domestic pharma companies, comments on the evolution of the Brazilian generics, biosimilars, and value-added medicines markets, local laboratories' internationalisation efforts, and the policy reforms he hopes that the country's new administration will roll out.

Could you tell us about Alanac's goals and how the association has evolved since our last interview in 2017?

Alanac is an association of national pharmaceutical laboratories with a mission to develop and increase the production of innovative medicines while improving the population's access to these medications.

Since 2017, the laboratories have developed and grown exponentially, our most important evolution has been the increased production capacity of our factories, achieved through the development of our infrastructure and the launch of new innovative products. Investing in innovation has been fundamental for our growth. As it is well known, Brazil controls the prices of medicines, so we have worked hard to revise the prices of our offering, with the goal of bringing cutting-edge products to market that meet the needs of Brazilians and others on the continent. In order to do so, it is necessary to secure patents and achieve effective solutions to health-related problems in the region, with good quality products at the lowest cost.

How does price control affect local laboratories when designing their portfolios? Are generics not an attractive opportunity due to price control?

The market for generics is quite large and highly developed in Brazil, generating up to USD 7.58 billion within the country alone. In addition to generics, we are also working on the development of drugs with incremental and even radical innovations, such as a new molecule. To further develop this project, we need the regulation of drug prices in Brazil to evolve, so we have partnered with the government to work together on these changes and achieve the incremental innovations we are looking for.

There are several types of situations where incremental innovations can be achieved, such as nanotechnology. For this type of more progressive product, as opposed to a breakthrough one, the fundamental criteria for pricing needs to be clarified, and they are not yet well defined.

How do you evaluate incremental innovations and how much independence and scientific capacity do you have to achieve this development?

We rely on the Agência Nacional de Vigilância Sanitária (ANVISA), but the pricing decision depends on a chamber formed by the Ministries of Health, Economy, Justice and Casa Civil. It is not a simple process, as many are involved and it just does not depend on one entity like in other countries.

For sanitary registration and safety checks, we turn to ANVISA, while the allocation of prices for pharmaceutical products is in the hands of these four ministries. As it is a complex process, resolution takes longer. Currently, the regulation for generics and radical innovations is very clear, but for incremental innovations unfortunately it is still not as clear-cut, limiting the possibilities for new launches. For this reason, we are working with the government to improve this aspect.

What is the outlook for biosimilars in Brazil in terms of equivalence and acceptance?

We recently attended a seminar on biosimilars in São Paulo, where we discussed the great development of these products in the global market. Today, laboratories in Brazil are in a phase of development, learning and teaching professionals about this subject, as it is very specialised. It is a market that promises much growth for national laboratories, as is the case of Bionovis, a laboratory that solely produces biological and biosimilar products.

The transfer of knowledge between experts and transnational laboratories is necessary to pass on this technology to skilled labourers, thus making it possible to produce this type of medical solution in Brazil. In other words, global companies currently have these biosimilars in their portfolios, for which Brazil has negotiated licensing and knowledge transfer agreements to develop these medicines in national laboratories.

What investment do local laboratories have and how has the economic context in Brazil influenced these decisions?

A few years ago we did not have factories, but today we have a very large laboratory that has its own manufacturing facility, Bionovis, and other national laboratories that develop their products. The diversification of these laboratories is quite accelerated. Although the economy is not very favourable, several laboratories made the decision to make large investments in order to increase the production capacity of their factories, a trend that is not going to stop in the foreseeable future. It will not stop, as there seems to be an exit movement of many multinational laboratories and others need to fill this market gap. While international manufacturing has declined, domestic manufacturers have increased their production, which is a source of pride as a lot of hard work has gone into consolidating this position in the market.

The pandemic directly influenced the increase in local production, not only of COVID-related products but also of medicines to treat other issues such as depression or other psychiatric disorders. Multinationals will seek more strategic alliances for biotechnology contracts within Brazil, while the production of synthetic chemical drugs is aimed towards other markets.

Are local manufacturers prepared to serve the Latin American market in terms of operational cost and approvals from international bodies such as the Food and Drug Administration (FDA) or the European Medicines Agency (EMA)?

We have had contracts between multinational and national laboratories to take over the production of important synthetic chemical drugs on the market. After a few years, national laboratories are expected to take over full responsibility for the production of these drugs.

We have several partner laboratories, some of which want to limit themselves to the Brazilian market, while others want to support us in our goal of internationalisation. There are currently Alanac laboratories that have interesting projects outside Brazil, with Fernando de Castro Marques’

Unión Química and Carlos Eduardo Sánchez's EMS as examples, and they have projects in the Americas, Asia and even Europe.

Why are Brazilian laboratories not particularly well-known internationally?

We are trying to position more Brazilian medicines in other countries, and hopefully, this will be the case in the near future. We have interesting Pharma projects, which already have investments and exports in other markets such as Asia. Unión Química has already launched and exported veterinary products in this market. We can say that we are working hard to achieve this notoriety.

One consequence of COVID is that countries do not want to depend on China or India for chemical raw materials for the production of medicines. What is Brazil's stand on the subject?

The pandemic showed that this dependence is not sustainable for any country. It is necessary to promote the search for and development of active pharmaceutical ingredients (APIs) in Brazil, which has already been a focal point of discussion in several meetings held with the government. In 1980, Brazil was fifth in terms of API production, so we know that it is possible to be at the top again. In those days, API production allowed Brazil to open up and import many products, but local production was not protected, a misstep that China and India took advantage of for their own benefit. These countries took the opportunities they saw and created large manufacturers, which earned them many millions of dollars in the process. The pandemic has given us the opportunity to reclaim our spot in the APIs market and not repeat the mistakes of the past.

What are the demands you will make to the government for 2023? What are the key issues to be negotiated?

Consolidate the tax reform – a very complex issue – which is necessary to allow companies to grow and generate more employment with better wages. This reform is of the most importance, as actions need to be taken in order to promote progress and innovation in the private industry, without limiting or trampling the efforts that pharmaceutical companies have worked hard for. In conclusion, our request would be to allow for a more fluid industry, competitive wages and clearer regulation on the pricing of innovative medicines. The new government must put health at the top

of the agenda for the coming years.

Is there a place for Latin American companies in the Brazilian market?

There is room, but the complexity of the market is not easy to navigate. There are many companies that have tried this but have not been successful. The tax model and public procurement procedures are very complex for foreigners. Considering that the government is the largest purchaser of medicines to ensure availability and access for the population to treat any illness they may have. The Brazilian government and Alanac aim to improve the population’s access to medicines.

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