Interview with Dirceu Barbano, Director, ANVISA

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10 days ago, your Swedish counterpart Mats Larsson made a technical visit here at ANVISA and said he had a lot to learn. What is it about ANVISA that can be learned by some of the richest, most developed countries in the world?

I think that there is something very significant that has happened in the regulatory activity here in ANVISA. ANVISA is twelve years old. It is an agency that has bilateral relations with many other institutions. Over these twelve years, and though it might seem as if we are only beginning our activities, we have presided over a period of rapid and significant changes here in Brazil. What's important is what the agency, in this period, has inserted in this period of economic change. It poses an agenda of a dialogue in economic and industrial development. Other countries are already developed and act in a stable environment, and have health concerns much more focused on big health problems of the population. They don't necessarily internally move and prepare daily for new happenings. In Brazil, Anvisa has emphasized risk questions and has opened new perspectives towards development.

ANVISA makes a great contribution that combines economic development with the development of medicines and medical devices. We have a young workforce mostly hired after 2005 that has been qualified for health activities. This great change in industry has resulted in a greater competitiveness of the generics industry and innovation demands of the multinationals. Thus, the value of ANVISA is very significant for other countries.

We have a situation where the products produced here in Brazil are mainly ones used locally. Our industry, whether of foreign or local capital, largely manufactures for the local market. Another

factor of responsibility for ANVISA is that a big part of this production is acquired by public resources, e.g. Ministry of Health, Secretary of State, or Municipalities.

At ABIQUIFi, we spoke of the focal points of promoting Brazilian industry abroad, and Mr. Correia da Silva said the number one selling point is Brazil's world class regulatory environment. Private industry, on the other hand, says there is some unfortunate lack of speed. What's ANVISA's opinion on the matter?

We're speaking of two types of performance here. One is related to quality and rigour in our regulatory actions. The other is about efficiency. ANVISA can accept that the performance of rigour interferes with the efficiency, but not the other way around. ANVISA counts over 2,000 workers who seek to preserve rigour while enhancing efficiency. There are cases that indicate a way to make these two performances closer. This involves an improvement in norms, and searching for a focus on health risks.

In the case of medical devices, ANVISA has identified lower risks of registration and in these instances has implemented a simplified registration process. This permits the team analyzing the relevant documents to allocate more time for products of greater risks. Two years ago, the standard for the approval of medical devices was one and a half years. Now , it's 60 days, and there is a ceiling set, to a maximum of 120 days. In the case of implants, the limit is eight months. This is a lot faster than the past. With medicines, we are going through a similar process, with special norms for products with lower risks. Our priority is to work on registration of new products, and the associated analysis of clinical trial data. With generic drugs, the focus is on strategic products, with the highest priority assigned to new products which break monopolies and allow new products to compete at lower prices. The second priority in generics is those products which are in a less competitive market. Another priority is products considered strategic for the public health system. These are objects of the PPPs. The PPPs involve another strategy of the government, which is the possibility of the nationalization and vertical integration of the production chain. This involves a private pharmaceutical company, a private API company, and a public laboratory.

We speak of a change in regulatory process towards risk assessment, alterations in the work processes, and also using information technology to simplify all of the steps mentioned. At the end of this year, ANVISA will start a process of electronic registration of new drugs. This will simplify the prior requirement of hard copies of documents.

This is just one of the many initiatives that will see a closer match between ANVISA's ambitions of rigour and efficiency, without one compromising the other. Meanwhile, some companies call for so-called "fast track" procedures. It's important to note that in reality, considering technical criteria,

this doesn’t exist anywhere in the world. What we understand is that in special situations where questions of health demand specific and particular interests, ANVISA can stop other activities to solve that problem. We did that in the case of influenza, and in 60 days a vaccine was registered. But that was a specific situation to be solved. We have a very clear orientation from the government, and it is one you will hear from the Ministry of Health: every time there is a question of whether to put public or private sector interests first, we don’t hesitate for even half a second to opt for the public interest.

Clearly, the strong growth in generics has been in the public interest. Recently we’ve seen issues with Lundbeck’s Lexapro, for instance, resulting in repealing the rights of Aché’s generic which had been on the market since 2009. You called it a “dangerous precedent”. How do you see this as an impediment to further growth?

Naturally, MNCs who have invested a lot of money in innovation have interests, especially considering how these innovations have been reduced over time. This reaction is comprehensible. However, in Brazil, we passed a patent law when the country joined the WTO in 1996. Our generic drug policy was developed with the most absolute respect for these laws. Therefore, we understand that Brazilian society has gained a lot from generics. There are many examples of access to medicines due to reductions in price when generics arrive in the market. Now, of the 10 biggest pharmaceutical companies in Brazil, five are Brazilian. Five or six years ago, these same companies occupied insignificant market positions. They have made great investments in great plants – even under rigid health surveillance control of ANVISA. They have enhanced their participation in the market and conquered foreign markets very easily with foreign companies. On the other hand, it seems to us unacceptable the lack of compromise that has resulted in some companies adopting increasingly creative means to extend patents. The most common are patents of second use, polymorphous, and the use of data from clinical studies.

There are two important things to note here. The first is that ANVISA does not use the same data from dossiers to register a reference drug as a generic drug. What we do is an analogy, an inference. If they are identical, they will have the same effect.

The precedent is a very dangerous one, because it comes from the principle that these clinical trials for new product registration – which are also published in magazines and whose data are used daily so that physicians can prescribe the medicines properly and understand how they work – would be the property of the laboratories. In this sense, we reaffirm that in Brazil, generics are registered when they demonstrate bioequivalence to the reference products no longer protected by patents, and are therefore guaranteed safe and secure.

In 2004, you were the Director of the committee that introduced Farmacia Popular. Though it is not directly part of your portfolio, how do you view the success of this program and other initiatives to achieve universal access to medicines?

First, it’s important to note that the Farmacia Popular program is part of a larger program of pharmaceutical assistance financed by the Brazilian Health System. In terms of financing, the Farmacia Popular program doesn’t represent more than 8% of the total expenditures of the Ministry in its acquisition of drugs. The Farmacia Popular program represents a strategy of the government to ensure those drugs already financed and distributed by public health care units arrive easily to citizens. We found out that in the first years of President Lula’s term, logistics at the Ministry could be reduced. Therefore, a strategy was developed for this target, which resulted in this program that increased capacity in the system to offer medicines through another way . The program is not going to substitute public financing as it is done today, and it won’t substitute dispensation already done in the universal manner for any Brazilian in public service health care units. The Farmacia Popular program is the first experience in Brazil of financing dispensation. Initially it was a co-financing operation. However now, President Dilma has said that in the cases of hypertension and diabetes, the state will pay for the whole value in the pharmacy. This tendency means that, in addition to hypertension and diabetes, we want to deal with other diseases and treatments deemed strategic with entire payment. It’s important to understand that this program, today, allows the possibility for Brazilians to access throughout 15,000 private pharmacies, whose functioning and workers are paid by the company’s owners, where users of public or private system may obtain medications for hypertension and diabetes without problem. This is an obvious health priority action given that maladies of this type of disease have high treatment costs when they go untreated. Naturally, we will not see 100% of drugs in this program. We want a public system acquiring products, principally products of high cost, and use the buying power of the Ministry for a reduction in cost. These are products used in a restricted group of people, such as Hepatitis C sufferers numbering 14,000, Gaucher’s disease numbering 600 carriers, and around 1,000 Multiple Sclerosis patients who receive their drugs via the public service. We understand that lower cost products and a most comprehensive treatment may be available in these units of the Farmacia Popular program in a co-payment system, such as what happens with contraceptives, medications for high cholesterol, or in a totally free way for drugs we consider strategic. It is a model that resembles the NHS model in England, with the difference that we also have a system of private dispensation

We first came to Brazil four years ago. If we were to return in four years, what would you hope we would see?

In 2015, you will probably see me somewhere else – because of mandate requirements. In fact, my mandate is up for renewal this October, and can only last to a maximum of 2014. Therefore I welcome you back at 2014 for the best time to find me here!

I have a number of ambitions, as much as a Brazilian citizen as the Director of ANVISA. ANVISA has a very important role to play for Brazil at this moment. We have a perspective that the economy continues to grow, and that this growth transforms, simultaneously, into greater social justice. President Dilma has a phrase that is very profound, though it appears very simple: “We want to live in a country that is effectively rich.” This means a country where people don’t feel deprived of necessities of health and education. My ambition is that we are in a condition to help. Helping means, on one hand, understanding that it’s possible to be rigourous in health regulation and at the same time support development. We must be as rigourous now as we have been over the past 10 years, because this is one of the values that have helped Brazilian companies as they move towards globalization.

ANVISA needs to maintain a frank and open dialogue with companies. The more qualified the companies are, the more easily their products will be registered, the more easily they can grow their sales, the more easily people will have access to drugs.

There’s another important task: ANVISA coordinates the system of health vigilance that involves 27 states and more than 5,500 municipalities. The entire network must understand its role, and that its centralized nature represents a strength. It is fundamental for ANVISA to support its development. I hope that in 2014 when you come back we will have advanced in these issues, in addition to more and more steps of new product development. We hope Brazilian companies will continue growing in the generic markets, and commercializing biotechnology – that can occupy an important share of the market. We also hope ANVISA continues to place itself among its worldwide peers as an institution closely linked with Brazilian industry that is no longer merely a national authority, but a trustworthy institution that is indeed responsible for the safety of these products appearing all over the world.

And this path, as we understand it, always implies identifying strategic health authorities and establishing bilateral cooperation. Whether this be relations with our European equivalents in Sweden, France, or Portugal, where we have already had more progress, or Canada, Australia, and of course, the United States, as well as our ongoing partnerships with Latin American agencies.

What is your final message to Pharmaceutical Executive readers?

There is one thing I would like to share with executives in all the pharmaceutical companies: I think there is a necessity that transnational industries establish an action dynamic that actually makes closer the demands of the market and public health. It’s clear that a market logic has shown good

evidence over time, which may indicate I’m wrong. It is also true that many companies have discovered some products for minimally relevant health problems and made a lot of money in them. But on the other hand, unless the industry action is an opening action, which comprehends the dynamic of the different health systems of different countries in the context of the greater demands of the public health in the whole world, maybe there are excellent opportunities and profits as well that will be lost. Brazil is an excellent laboratory for that. We have an excellent regulatory regime, an expanding internal market, and a public health system that guarantees access to drugs. Brazil will consume pharmaceutical products and it’s very interesting to ensure they are the most effective from the point of view of efficacy, safety, and access. Sometimes I have the impression that company executives understand very little of this. If they could spare some time from analyzing profit and loss graphs, they would discover these opportunities. Everyone needs to know: Brazil is a very clear option. Our market is open. Our companies’ actions in the world will continue to be open. But we have a very clear position and interest in the production and development of new pharmaceutical products here in Brazil, with the most verticalized value chain possible. The explanation is simple. We have a tremendous trade deficit generated by the consumption of both API and ready products. We prefer if this money would stay in Brazil. On the other hand, we need engineers, pharmacists, chemists, graduated in Brazilian schools paid for by Brazilian taxpayers through public universities to remain here as well, so that afterward they can create their own companies. We make airplanes, and extract oil from the bottom of the ocean – surely we can do this as well.

At the end of 2010, ANVISA approved health norms for the registration of biological products through RDC 55/10. This norm, as we understand it, should over the next 10 years have the same significance that the generics law of 1999 had in the production of generics for producing copies of biotech products. The interest in the government is to work with Brazilian companies who can actually copy and patent drugs, so that a blockbuster may one day originate from Brazilian industry.

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