Interview with Odnir Finotti, Executive President, Pró Genéricos

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When we last interviewed you in 2007, you said, “The generics business is a very exciting one,” but you “regret[ted] that the Government is not doing enough work to promote it.” At that time, generics penetration was around 10.5% – now it’s around 20%. Does this reflect some fundamental change in what the Government was doing to promote it?

The government has been supporting generics; that much is quite clear. In the very beginning, the Ministry of Health put a lot of effort behind generics because somebody needed to make the push. The dynamic of the Brazilian market is different from Europe or the United States. The main difference is who pays the bills. In Brazil, for pharmaceuticals, it’s the patients. It’s an out-of-pocket business. We do not have a single payer managing prices and putting pressure on the producers to get the best price they can. Any purchasing power is therefore diffused.
We think in that sense Brasil is innovating and in the long run the model seems to be more sustainable.

What about the SUS?

It is a good public health assistance system. People use the SUS to see physicians, not to get treatment because only very few medicines are available free of charge at SUS pharmacies. We’re doing our best to get in there, but we need more funds to finance that. For the time being, 90% of the Brazilian medicine market is out-of-pocket, therefore all these people need to have access to

affordable and trustable medicines, and this is what generics is all about. Today, many more Brazilians have access to pharmaceuticals, so people are taking better care of health than ever before thanks to Generics.
Also to guarantee that patients can get medicines free of charge, there is the so-called “Saude não tem Preço Program”, a central government program wherein about 15,000 pharmacies around the country are assigned to offer “essential” products, for example for diabetes and high blood pressure. There are nine substances given completely free. The patients visit the physicians, receive prescriptions, most of them coming from SUS, go to the pharmacies to get their medicines free.
60% of all these medicines are generics. This is another contribution of generics to make this system to work. We have been improving but we have still a lot to do.

We have seen recent M&A activity of large multinationals buying generics players. What’s your view on these companies not only acquiring market access, but also a certain knowledge and expertise they currently lack?

It’s because Brazil is a very important market. It’s about market size and upside potential. We’re talking about the seventh largest market in the world, and increasing. According to the latest data from IMS, by 2015, Brazil will be #3 in generics. It is a quite strong reason to acquire a generic company in Brasil. If you do not produce here, or control the columns that keep generics standing, you are not in the game. Brazilian companies learned very quickly how to play in generics. We can compete worldwide on the same base in cost of development and formulations, etc. In this, Brazil has the expertise. Some of the largest companies in Generics are not present in Brasil yet, for they cannot simply bring its entire portfolio from elsewhere. You need to be here – plant here, manufacturing, developing formulations, etc., here.

In terms of Brazilian companies scaling up their production, is that a scenario you see as attainable, and if so, as desirable?

The local demand is pushing it. We also that Brazil, having this market size and potential with this population, has to do something to be independent in some areas. Some strategic products, we should have local know-how, expertise and facility to control 100% of the process. That’s why the government is pushing the so-called PPPs in order to have tech transfer contract covering the essential products for the public health.

How would you rate confidence in PPPs given a public sector history of patent breaking?

To be fair, there has only been one case of compulsory license, with Merck's drug Efavirenz for AIDS treatment. Overall, the PPP model is very attractive. The government is transferring knowledge from private to state-owned companies, and empowering the state-owned laboratories. There is a strong belief in the mass-market, and that the government can benefit strongly from tech transfer.
We think PPP is a good strategy to get access to technology as long as it does not weaken the private initiative.

In 2008, 40 tonnes of counterfeit medicines were seized by the government, and in 2009 this figure was 333 tonnes. This seems to be quite an alarming increase. How much is this a concern?

First of all, we need to get access to the breakdown of these figures. If we really had that amount, we should be allocating all our resources to bring the responsible ones to justice. I don't think there's much interest in counterfeit all medicines. In some cases, for the high priced medicines you may find different versions, but most are not fake per se. It may be an issue of the drugs having been manufactured in a neighbouring country. The drug will be legal there and fully approved by local authorities. But in Brazil, you cannot sell any product without a local license and registration. What we really have to do to improve the system is work on better traceability. Brasil has joined in the fight, has a law in this regard, and is going to achieve traceability according to world standards. Pró Genéricos supports this very much, and other associations have also worked together with the government to offer solutions.

So far you seem very relaxed, as the president of the association representing one of the largest and fastest-growing generic markets in the world. What keeps you up at night or at the office working late?

I sleep quite well! Of course the market is growing. We have the same products, efficacies, safety, and the average cost is about 52% lower than the reference alternative. Obviously, this makes generics very attractive. And when you take into account we pay for our medicines out of our own pocket, it's an obvious choice. That's the bright side of the story, but there are still some challenges. One is still to improve access to medicines.
In generics, we could improve access by having a better, more balanced tax system. 35.9% of the medicine's final price is tax. VAT alone accounts for 18%. It's the highest in the world. If you bring the price down, then more people have access. Another lever is the economy of Brazil which, as it grows, allows people the capacity to buy medicines. That is not the case in Europe anymore. People there get the medicines they need. If you reduce the price, consumers do not notice, unless they have co-pays, and people don't care which product they take, therefore price reduction won't

make people buy more medicines. In Brasil is different. There are some 80 million Brazilians here to catch up, coming from the poor side to the middle class. The potential is enormous and lower prices are decisive.

Another issue is patents. Brazil has a law, we fulfill the law, and generics play by the book. It's stated that there is 20 years of exclusivity starting from the start of the patent. We do not here have any patent extensions for any reason not consistent with the law, such as data protection or linkage. We only start marketing any product after it goes off-patent. We respect it, we enforce it, and we say it everywhere. What we are faced with here are companies trying to extend the patent period, which is not fair. It brings a lot of uncertainty. It's unfortunate to see so much litigating, in many cases sham litigations, trying to buy time with legal maneuvers. It's a bit messy around this area, and until everything is proven, generics manufacturers must withdraw products from the market and stop producing.

Another of our concern right now is about biopharmaceuticals which are important for the sustainability of the generic industry as well.

We have do deal carefully with the regulations for these products in order to guarantee safe and efficient products guided by suitable and appropriate guidelines. Attempts to over regulate should be avoided for it could reinforce keeping the newcomers out of this promising market.

What are your hopes for the evolution of the Brazilian generics market?

If we keep growing at this rate, generics will in 3 years account for about 35% of the Brazilian market. It could be more, should medicine in Brazil could only be bought with a prescription.

Is this likely to change?

Well, we have until 2014. At that time, all products will have to prove bioequivalence. The rules for market authorization for similares will be the same as all others, therefore we hope the law and regulations will be then fully enforced.

What's your final message to Pharmaceutical Executive?

Some years ago we said, "Please come here." Now we keep on saying it, but we also say, "we'll go there." Brazilian companies are now discovering what American and European companies discovered many years ago which is go abroad. So they are acquiring companies in South America, establishing affiliates in Europe, doing research, obtaining patents, licensing out products. And we are just at the very beginning.

Brazilian companies have learned their lessons and now have the capacity to compete, therefore cooperations have to be dealt in another level.

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