

Interview: Heitor Costa, Executive Director, Apifarma, Portugal



02.05.2014

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Dr. Heitor Costa, Executive Director at Apifarm, Portugal, discusses the country's economic situation and the presence of international pharmaceutical companies despite the recession. He further discusses the current policy and influence of generics on the pharmaceutical industry, and why he feels investment in Portugal is so crucial at a time like this.

What is the most important issues on your agenda today?

The most important issues on our agenda are similar to those of everyone in Europe for the industry, which are centered on dealing with austerity measures. The situation in Portugal is somewhat worse than the rest of Europe because of the bailout. As a result, the Ministry of Health has elected the pharmaceutical industry as the main contributor to the adjustment of its current financial dilemma. As an example, between 2011 and 2012 the industry contributed €600 million, which represents more than half of the adjustment made by the entire Ministry. Restoration measures with the pharmaceutical industry tend to be quite easy; decreasing prices, imposing the lowest prices in Europe based on reference countries, creating restrictive access measures and refusing to compensate new medicines are all easier than merging hospitals or changing policy at the level of the Ministry. Of course, the Portuguese pharmaceutical industry is the main stakeholder in the sustainability of the system, whose stability directly affects the industry. Therefore,

companies operating in Portugal have been cooperating well with the government. There are of course limits, because the sustainability of the system cannot endanger the sustainability of local or multinational companies.

Apifarma has 120 members, and is somewhat unique compared to similar associations throughout Europe in that it not only covers pharmaceutical companies, but also generic companies, OTC companies, medical devices in the field of in vitro diagnostics (IVD), and veterinary medicines.

How do you ensure that you can address the interests of all these different groups?

Businesses like IVD have their peculiarities, and Apifarma runs special divisions that allow these segments some autonomy. However, as members under the Apifarma umbrella they must still be represented under the same association and budget. The association must also balance between inpatient and outpatient medicines, which have different markets, payment methods, access, and business models. You have to balance between companies operating in markets outside of human medicine. Therefore, one of Apifarma's biggest challenges is to defend its members and encourage their commitment to Portuguese patients while merging different interests and creating a common position that holds everyone together. While it is not always easy to communicate the pharmaceutical industry's message, Apifarma has successfully demonstrated to the healthcare sector that innovation is an important investment rather than expenditure.

The troika (Central European Bank, the IMF, and the European Commission) have imposed a MoU on Portugal to cut total pharmaceutical expenditure (both inpatient and outpatient) to one percent of GDP, which is the average for other countries, for outpatient markets only. This would downgrade Portugal's per capita expenditure to one of the lowest in Europe.

Access to innovative medicines in Portugal is one of the lowest in Europe. What can the industry do to ameliorate this situation?

The industry can share the responsibility with the state in terms of providing new medicines needed for patients while respecting the sustainability of Portugal's healthcare system. This country needs access to innovative medicines like anywhere else, but there has been a lack of new reimbursements in Portugal for two and a half years apart from those ones recently reimbursed under the framework of the Agreement Government-APIFARMA of 2013. I know some risk sharing agreements have been designed for the introduction and approval of some medicines, but some of them are still not in the market. Access is only provided through special authorization, which is not ideal.

Hospital debt is another challenge for Apifarma and the industry, which has financed the system for two years. This cannot continue anymore. Portugal has been in Europe for a long time, but it seems like the country is leaving Europe because of this lack of access to new medicines to fulfill unmet medical needs. Sustainability is one of the main preoccupations of all companies here and elsewhere in Europe. The industry should share risks in sustainability while still maintaining access to innovation; the state currently designs the market for each company, which creates uneven competitiveness and is generally incomprehensible.

Additionally, Portugal has significantly expanded its generic market in recent years to almost 40 percent market share in count units. The development of this market provides headroom for innovation, and given this tremendous development of the generic market, innovation should not have been frozen for two and a half years. This must be changed.

Given Portugal's current situation, could generics penetrate the market even more to levels of countries like the UK? What is the current policy towards generics?

I do not think it is possible to reach UK levels. While that was the target originally imposed by the troika, I think generics have their own place for treating patients who are the main occupation of all pharmaceutical companies. We must be clear that generics have their place in the therapeutic area of each patient. Portugal lacks access to innovative medicines that fulfill unmet medical needs, and generics exist to allow more room for that innovation. That being said, 40 percent generic market share in ten years is extraordinary. The work done by government, industry and doctors to achieve that was incredible. But Portugal does not have the maturity to have some active substances as generics. For example, there are some active substances with prices that are not attractive to a generics company wanting to invest in the commercialization of generics. Because of the reference pricing method, the prices of originators are so low that commercializing a generic would not be profitable. Every company should be profitable; it is the nature of private initiatives. This is because the implementation of a generic policy in Portugal only happened ten years ago, and many old molecules of branded medicines were set at a price in which companies would not invest.

Despite the recession, pharmaceutical companies have continued operations in Portugal. How have they managed to stay afloat?

Indeed, many international pharmaceutical companies are here, paying taxes and providing jobs to the economy, and the industry has been very cooperative with the Portuguese government. One of Apifarma's main objectives is to maintain that status quo. A pharmaceutical company could continue to sell medicines here through a distributor and avoid paying taxes. But Apifarma's

members want to continue to invest in Portugal, which also means staying here with an affiliate.

How has the manufacturing industry evolved since the start of the recession?

The manufacturing industry has expanded greatly, and is the main contributor of health sector exports. There is potential to grow more, and the export of medicines in Portugal has rapidly increased in recent years. By the end of 2013, Portugal will have exported over €700 million in medicines, and total sales in 2012 were €600 million, more than port wine. Including other contributions like medical devices, Portugal exports more than €1 billion per year in the health sector. The industry is also looking to increasingly diversifying markets. PharmaPortugal, an Apifarma project for product export that combines all pharma companies with factories in the country, has been targeting markets beyond Europe to regions like the Middle East and Latin America.

Has that increase in manufacturing incentivized multinationals to come back here and do it again?

In order to make Portugal attractive to a multinational, the country needs to do more than just reduce taxes. Despite recently improved labor laws, our system of justice is very slow to make decisions, which is a big problem for all industries wishing to invest here.

Portugal has implemented a system to protect intellectual property. Today, there is an obligatory arbitration system, which is not optimal. The country has created an intellectual property court, but this field of action was not extended to medicine. On the other hand, you are not going to invest in a country that is not innovation-friendly. This must be improved.

What are your expectations for the pharmaceutical industry in the next five years?

I would like the industry to be growing here. The recession cycle in Portugal broke in the third quarter of 2013, indicating hope for continual growth in 2014. For the years ahead, the Portuguese pharmaceutical industry has reached its limit in terms of reducing the size of the market.

Portugal should have more money allocated to pharmaceutical expenditure as well. Expenditure per capita is very low and it would be desirable to invest in new medicines if they are affordable. Portugal has one of the oldest systems of pharmacoeconomic assessment, so the system should provide access to cost-effective medicines.

Portugal is part of the European market, and faces similar challenges to everyone across the continent. The development of new medicines and risk sharing will come in time. Portugal needs a

normal and predictable system for companies developing new medicines to provide access to patients.

I would also add that the industry has an initiative called the Bank of Medicines, in which companies provide free medication to nonprofit organizations. It is an example of companies assuming their social responsibility in Portugal, rather than simply financing the system for a couple years. Many Portuguese citizens are being supported by charities through these pharmaceutical services. In total, almost twenty companies have provided 130,000 packages in medication from their portfolio to more than 60 organizations.

I would also like to see continued investment in Portugal, because being here is important for Portuguese patients and indeed the entire country. Without pharmaceutical companies' medicines they will not be properly treated. Companies here are contributing to our economy not just through patients but as employers as well.

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