Interview: Heitor Costa â?? Executive Director, APIFARMA, Portugal

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Heitor Costa, Executive Director for APIFARMA, the Portuguese Pharmaceutical Industry Association, outlines the recent improvements in industry and governmental agreements, the importance of non-prescription medicines, and raising societal awareness on the strengths of OTC medicines. While touching on pertinent topics that affect the entire pharmaceutical production value chain, Costa highlights the favorable investment climate we see in Portuguese healthcare today, and the recent success in both approval times and reimbursements for innovative drugs.

Can you provide our international readers with an overview of APIFARMAâ??s current standing in Portugal?

The Portuguese pharmaceutical industry enjoys a long history of cooperation with governments, especially with regards to promoting the systemâ??s sustainability. We are well aware that a sustainable system is paramount to achieving our primary goal: providing patients with access to effective medicinesâ??particularly innovative drugsâ?? and fulfilling unmet medical needs. Not only do we collaborate with government, but stakeholders across the value chain to encourage the promotion of the National Health Service (SNS), and the role of the SNS in collaboration with the private sector. Portugal, as a western democracy is a country where free initiatives in the economy are well respected, and consequently we have a robust private sector. We defend the role of the pharmaceutical industry and are examined and assessed on our results of providing the most effective drugs.

What challenges do you face in managing partnerships between government and industry?

The partnerships that we handle with the state have evolved over the years; we are no longer a static organization and develop and evolve with the countryâ??s highs and lows. The first agreement between government and industry had, at its core, an objective to limit the market. Following the crisis, Troikaâ??s restrictions took actions one step further and actively sought to downsize the market. Since Portugal exited Troika we no longer battle with these measures.

The testament to our long history of cooperation with government and stakeholders was made clear in 2016, upon signing on an agreement that no longer features a cap. The agreement established rational market developments, and as such, we pay a contribution to the systemâ??s sustainabilityâ??similar to a taxâ??, and for the past two years, we have seen steady growth. Removing the cap was the result of a natural progression of agreements made between the industry and government and aligned the market specificities with growth and our objectives. The contract for 2018, which is soon to be announced, follows a similar vein to the agreements established between 2016 to this year.

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What can you do for your members given that you represent so many different interests across the manufacturing value chain?

We represent a number of companies across the production chain with a particular focus on innovative medicines. Although the central focus of the association is not generics, we benefit from generics companiesâ?? memberships. We are the innovative association and appreciate the role that generics can play in the healthcare system and the SNS.

The golden rule with regards to generics is that we must respect patents and intellectual property; this is a non-negotiable red line for APIFARMA. If intellectual property rights are respected, then we allow room for innovation which is tantamount to the healthcare systemâ??s success. The more generics present in the market; the more innovations have headroom to developâ??this is the way the healthcare system was built. Generics are part of the management of the lifecycle of medicines, and one of the main reasons why Europe promotes generic medication.

OTC products are another crucial component of the pharmaceutical industry. OTCs give individuals the chance to take responsibility for their own state of healthâ??one of the goals of every healthcare systemâ??and with the help of educational literature and awareness campaigns, OTC medicines can efficiently target smaller, less serious illnesses, without the need for a prescription. The regulatory system is transparent in the conditions that OTCs can target, and at APIFARMA we align what is happening in Portugal with developments in other markets, concerning the development of medicines not subject to medical prescription.

APIFARMA is an active player in partnerships, and we work closely with the Directorate of the General Health, INFARMED, and Valormed (the institution dedicated to recycling medicines). We have a program on health literacy called â??Tratar de Mimâ?? â??Take Care of Myself,â?? which promotes the rational use of non-prescription medications and the practice of a healthy lifestyle. One of the primary objectives of this program is to give patients the necessary support and information concerning medicines available to them, so that they can take rational steps to combat their illnesses. Of course, a fever lasting 15 days is the matter of concern for a doctor, but by and large, OTCs have a valuable place in society.

What steps are you taking to improve Portugalâ??s reputation as a slow market access country?

Market access in Portugal is quite slow relative to European countries, but it is evolving and making substantial progress. Since the IMF, EC and ECBâ??s interventionsâ??whereby effectively Portugal was ruled in depth by third partiesâ??Portugal has experienced a revival. Our economic results perform stronger year on year, and market access and access to innovation are the cornerstones to our recent success.

The government has approved more innovative medicines in the past two years than the combined total reached during the period from 2010-2015; roughly 60 in 2017 and 51 in 2016. Nonetheless, we still operate under some of the poorest timelines in Europe. The delays are improving; the paradigm is shifting, and we must recognize that the government as the government reimburses more medicines, schedules will naturally decrease.

How ready is the Portuguese framework for the arrival of biosimilars and generics in the face of an aging population?

The Portuguese framework that we work with is European, which means that our current preoccupation is an EU-wide concern: that of the UKâ??s departure from the EU. That being said, the Portuguese system is well-prepared, and biosimilars have passed assessment examinations to enter the market. Pricing is not the driving force behind biologicsâ?? entry into the market because it is not possible to immediately swap an originator with a biosimilar innovator for a patient receiving treatment at a given time. However, new patients can receive biosimilars at the beginning of the healing process, provided the medical prescription is respected.

What is your assessment of SiNATS and the recent reforms within Portugalâ??s HTA?

Pharmacoeconomic, therapeutic and health assessments regarding the measurement of specific values within healthcare have been taking in place in Portugal for 20 years. Indeed, Portugal is the second country worldwide, after Canada, to establish an HTA. NICE, the UK HTA, was founded much later.

The new reform, under the name of SiNATS, serves to include medical devices within the scheme. SiNATS is to all intents and purposes the old system, remodeled to fit todayâ??s demands. We must be careful in our depiction of the new system: this is not a revolution, but a step in the right direction to better define the parameters for new medical devices and medicines.

The INFARMED President intends to normalize and align the approval of the new reimbursement dossiers with what we find in the law, precisely, the 180-day limit for reimbursement and approval. It is a good sign that the head of INFARMED has brought the new regulations to stakeholdersâ?? attention because it has created a sense of urgency regarding timeline compliance. The only way we can be equitable to Portuguese patients is to adhere to these rules and keep timelines in check. These reforms in the HTA system enable our patients to access the same high level of access to medicines and medical devices as other developed economies.

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The Portuguese healthcare system is highly regarded but has high levels of public debt. What can APIFARMA do to alleviate the situation?

APIFARMA is the head of an association of companies, and we have played a pivotal role in fighting public debt to the private sector. The Minister of Health would be the first person to comment that the healthcare budget is far from adequate because the healthcare system has been underfinanced for at least 20 yearsâ??since the creation of the NHS. The NHS was one of democracyâ??s main productions, and it is a robust and reliable system that is universal, transversal and equitable. The

Portuguese are proud of their system, and it is one of the best in the world.

Nonetheless, the lack of funding affects departmentsâ?? planning capabilities, which means we create unnecessary expenditure through lack of planning. During the Troika intervention, APIFARMA played its part in ensuring that all stakeholders are made aware of debt issues, and now we strive for an adequately financed system.

We see progress in this area, for example in the recent payments from the Ministry of Health this year totaling 1.4 billion euros. A unit has been created recently by the health and finance ministers who will study the sustainability of the healthcare system. We expect that with this cash injection, the pharmaceutical debt will be more or less controlled. Furthermore, we will be in a strong position to negotiate and initiate a new pathway for sustainability. We can now focus on the healthcare systemâ??s management to avoid accruing more debt in the system. Through a combined effort, we will limit the deficit, and by 2019, we will be in control of the debt function.

What is your opinion on Portugal as a testing ground for innovation?

Our healthcare system is one of the highest-rated in the world. We have medical excellence, fantastic centers for complex diseases, and we have a system that provides access to all people at little or no cost. Whatâ??s more, we are fair and equitable in our treatment of individuals and paying more does not necessarily mean better treatment because the free initiatives in place are already of excellent quality.

Secondly, the Portuguese workforce is comprised of highly-experienced individuals. Portugal has a high number of academics with doctorates, post-doctorates and all matter of distinguished degrees. Off the back of this prowess in medical sciences, Portugalâ??s Health Cluster communicates and collaborates with start-ups across the field. The evidence of Portugalâ??s success in research and innovation is that pharmaceutical companies no-longer perform large-scale medical analysis, and instead take advantage of the healthcare and start-up companies on the ground, which are set-up and ready for international exploitation. We welcome foreign companies who wish to take advantage of the innovation hotbed we see in Portugal.

What is your final message to our international readers?

APIFARMA is committed to defending the pharmaceutical industry and the promotion of the sector to international investors. Given the progressive economic steps the country is taking, the stable political government we have in place, and the fiscal incentives that are there for the taking, the time to invest in Portugal is now.

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