Interview: Paulo Climaco Lilaia – President, APOGEN, Portugal



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Paulo Lilaia, president of the board of APOGEN and CEO of Generis, highlights the need for generics in the healthcare system and the government's approach to their implementation. He also discusses the introduction of biosimilars into the Portuguese healthcare system and the cost-saving effect this has for patients and companies, which paves the way for new investments.

The goal of the Portuguese government a few years back was that generics would account for 53 percent of the market share in 2018. Where do we stand today with this goal?

The consumption of generic medications currently stands at a robust 49 percent in the current market, and there is an evident increase in this trend. This will exceed 50 percent very soon, especially with the introduction of new products into the market, along with the promotion of existing generic medicines. There is a definite trend for increased consumption of generics and an increase of general usage in market share.

Can you comment on the key measures the government initiated in recent years that have positively impacted the generics market in Portugal?

Having generics widely accepted and well known to healthcare professionals and the public has been a significant initiative. There were campaigns for the use of generics in media as well as health care centers and hospitals, which instilled a sense of trust. In addition, this campaign served

to educate stakeholders that generics are of high quality and affordably priced. As a result, today generics account for around 50 percent of the prescription market and has the potential to grow further.

Political measures, such as price competition between companies have also impacted the generic market. Consequently, the price difference between the generic product and the original drug increased, and therefore more patients sought generics as a cheaper, but equally practical, alternative.

Another fundamental measure which had a positive impact was the additional reimbursement allocated to generics. For example, generics at one point were made free for pensioners and also special reference pricing was implemented for specific homogenous groups. Medicines within a given homogeneous group had a *reference price* which is the average of the *five* lowest retail prices on the market. The state would then only reimburse medicine within a specific tier facilitating a shift from a traditional brand-oriented market to generics.

We see that in Portugal the prices of generics are some of the lowest in Europe. How was this affordable pricing structure achieved?

Before the crisis of 2010, the price of generics in Portugal was stable and in-line with that of other European countries. Due to the crisis and the intervention of the Troika, the government took action to decrease expenditures in medicines—both in retail and hospitals. Over a period lasting four years, there was immense pressure to cut costs while maintaining the volume of production and treatments. The government stated their intention to reduce prices while maintaining the availability of high-quality medicines, employees' jobs, and the medical procedures required by patients. In the face of the crisis, the government managed the situation effectively. Indeed, the consumption of medicines across Portugal did not decline thanks to these measures. However, the market value of medications lost up to a third of its value. Naturally, pharmaceutical companies were put under tremendous strain during this time and were ill-prepared for the shock fall in prices. But as is often the case in business, unfortunately, certain situations are outside of our control, and we had to accept that because of the crisis and the constant need to maintain excellent healthcare standards in Portugal, prices must fall.

The period was challenging for many players in the industry, and we adapted to meet the change in prices. Most companies had the resilience to ride out the turbulent time although smaller, local companies were hardest hit. That said, they learned the most in terms of efficiency and improvements for the future.

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And in terms of the market landscape, we see a mix of local and international generic players in Portugal. How are local companies keeping up with the competition?

The split is decreasing rapidly, and we see fewer local companies compared to the giants in this sector. For local players' success in the market, they must have an international strategy, and it will be difficult for companies in generics to survive if they do not have this international scope. To compete with multinational players in the industry, the company must operate to scale. This means either expanding internationally or focusing on a specific niche therapeutic area where competition is less intense. Commoditization and the nature of the Portuguese market require for generic companies to address their scope of operations.

How should authorities manage their health strategies to benefit the government, patients, and the industry?

It is about value creation for both generics and originators. At APOGEN, we understand that our role is to provide high-quality medication at an affordable price, even if we face pricing pressures. The risk is that patients will only be able to benefit from generics and biosimilars if the generics industry remains sustainable. We accept and understand that the government has to instill a level of competitiveness in the business environment while implementing smart reforms that ensure that the industry can continue providing affordable drugs to the healthcare system.

The Portuguese government is competent in implementing pharmacoeconomic solutions into its healthcare infrastructure, How have these solutions been received on the industry side?

Portugal is naturally at an advantage given its excellent national health care system. It is well organized and has been so for the past 40 years after the revolution paved the way for democracy. Since then, all governments have been investing in further developing the health care system to ensure that every citizen has access to healthcare and medicine. The industry is not perfect, but it is not prohibitively challenging for companies to manage the changes needed for a stable environment. In Portugal, 50 percent of healthcare spending on medicines is out-of-pocket, which affects the reimbursement process. For persistent and impacting diseases such as diabetes or hypertension, the reimbursement rate is high and in some cases, 100 percent. Conversely, the situation with we call 'comfort' diseases, the compensation scheme is lower. This approach is a good way of tackling healthcare issues and strikes a balance between price and level of care. No healthcare system is perfect but in comparison to similar countries, with similar GDP levels per

person, the Portuguese system has proven its efficiency and sustainability.

Concerning the generic market, the current system is effective in providing a choice and a level of availability. The price of a generic is based on a reference value of the five cheapest products, which is the level reimbursed. If patients wish to buy a specific brand which may be more expensive, then they are free to do so, safe in the knowledge that the reference price will be reimbursed.

How receptive is the Ministry of Health in facilitating biosimilars into the health care system?

The government is highly receptive, and we collaborate well on the subject. For example, through APOGEN, we created a list of biosimilars that could help economize up to 120 million Euros by 2020—a significant saving—to improve patient outcomes. The authorities, whether it be regulatory bodies or the Ministry of Health, are open to making progress in biosimilars and we have seen an increase in the usage of these products in hospitals. In general, we are moving in the right direction, and now that professionals are made more and more aware; biosimilars will be another success story for Portugal’s health care system.

How do you think the traditional business model of generic companies has evolved with the introduction of the complex concept that is Biosimilars?

Although biosimilars require significant amounts of investment, they are a crucial part of generic pharmaceutical companies’ business given the potential they represent. It is important for them to have a large base of buyers, and now we can see that with biosimilars, the market is becoming competitive. As always, the investment is based on the price matrix, which for the sustainability of a company needs to be as low as possible without compromising on efficiency. The government can take advantage of biosimilars in the long-term and retain the demand for new investment, by positively impacting price levels and competition gave their resources. Again, government and industry have to strike a balance where each player benefits.

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APOGEN engages in several exciting initiatives; what is the association’s current focus?

We cooperate with the Ministry of Health and regulatory bodies to assist them in finding the most scientific and pertinent information on biosimilars so that they can organize training sessions which communicate the value of generics to healthcare professionals. We have been involved in the last year in other initiatives in Lisbon, mainly focusing on awareness, but also data and evidence

discover on biosimilars, and how they increase investments and competition in the sector.

We are a member of the Medicines for Europe association where we show the authorities and professionals how they can benefit from generics and biosimilars, and how they positively impact and contribute to the sustainability of the healthcare system. The generics and biosimilars role in the healthcare system is vital: if we want to treat more patients with better value-added medicines, we have to economize in other areas. Generics and biosimilars create the necessary room to have money for investments in new and innovative products.

Finally, what are the associations' focus and goals for coming years?

Our focus is to inform healthcare professionals and the general public of the potential and advantages of biosimilars and generics and to be a specialist partner of the government and the generic and biosimilars companies to encourage good dialogue and innovation. The end goal is to increase the sustainability of the sector and provide the best outcomes to patients. We want to strike the right balance between the different stakeholders to make the industry sustainable and efficient for all involved.

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