Interview: João Madeira, General Manager, Mylan Portugal

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João Madeira, General Manager of Mylan Portugal provides an overview of the state of generics in Portugal today, discussing structural issues related to Portugal's low generic medicines penetration, ways to better promote healthcare savings, and Mylan's own contributions to ensuring a sustainable marketplace in Portugal.

Prior to Mylan, you worked for a number of years at Pfizer. What have been the most notable differences in moving from an innovative company to a generic medicines company?

Between 2002 and 2010, a significant number of Pfizer's products lost exclusivity. Therefore, although indirectly, generic medicines have been part of my professional life for some time not only with Pfizer but also in other previous professional experiences with originator medicines companies where I managed products and business units that were being challenged by generic medicines entrances. The experience I've had tells me that the generic market in Portugal is a faster paced and more volatile environment than the innovative market, where the formulas you've successfully used yesterday do not guarantee you success tomorrow. There are more opportunities but also more challenges and a higher number of direct competitors.

For less than 15 years, the generic medicines market in Portugal has evolved significantly. However, it should be more developed today than it currently is. In the early days, upon entrance into the Portuguese market, generic medicines' prices were generally higher than the average pharmaceutical product because generic medicines companies chose exactly which molecules to produce and market. This led to an unusual situation in which the average prices of generic medicines was higher than the average of retail originators' prices. Everybody knew this was not sustainable in the long-term. So in 2008, the first measures for a more aggressive price control and healthcare expense management was enforced. Consequently, the price of generic medicines has eroded about 75 percent since 2008, and 55 percent since 2010. Contrastingly, as per a local market analytics and sales data provider (hmR), originator prices have only decreased 6.1 percent since 2009, and with over 100 generic medicines brands in Portugal, the market is very polarized and unsustainable.

The generic medicines business model was focused on high prices and the commercial terms you could offer to pharmacies in particular. Of course, when you do not have the market developed to the point of pharmacy-based decisions (which you would expect in a substitution market), and when you start adopting strategies and tactics that do not correlate with the profile of that market, you will fail. Focusing business on pricing and commercial strategies alone, without creating the landscape to de-stigmatize generic medicines and increase its understanding by physicians and patients is dangerous. At the time, generic medicines were still under a branded prescription-based business: physicians prescribed, drugs were shipped to pharmacies with a script, and pharmacies would typically dispense whatever was in that script. That definitely did not help to build the generic medicines marketplace in Portugal, and did not allow for a proper understanding of the value of having a developed generic medicines market in Portugal nor the need for the authorities to leverage this market.

Due to recent crises in Europe and especially in Portugal, generic medicines have been critical to support healthcare budgets. Affordability more than ever becomes fundamental and companies like Mylan, who carries a wide portfolio (more than 1300 products) that covers a significant number of medical and treatment needs, can play a significant role if they provide reliability of service and high quality of medication.

What has Mylan done to ensure that Portuguese are aware of generic medicines quality?

Firstly, quality is an obsession at Mylan. We apply one global quality standard across our more than 30 facilities, and across our product line regardless of the market. Quality has been in our DNA for more than 50 years.

Six years ago Mylan entered Portugal through the generic medicines portfolio acquisition of Merck, who had already enjoyed significant penetration in the marketplace. Merck had already created significant awareness, but Mylan added some of its own special spice to this mixture, working strongly with stakeholders and authorities to leverage generic medicines penetration and awareness. We have strong training programs that teach pharmacies how to better substitute generics medicines over the counter and to educate patients regarding medication they need but can no longer afford. Mylan also partners with physicians to further increase awareness and value of generic medicines, and is one of the few to do so.

Mylan also partners with Portuguese health authorities. Portugal has been an INN prescription-driven market since June 2012. A significant measure in 2014 will be the dematerialization of the script, which will live virtually in the healthcare system. Mylan is partnering with groups like the Portuguese Pharmacy Association to create a set of tools that allows patients to have greater access to medication by using the new dematerialized script system, which reinforces our commitment to partnering with authorities and assist them in preventing reimbursement fraud, having better control over prescriptions and dispensaries, and ensuring a higher usage through INN prescription. Although measures in Portugal are introduced and laws published, it takes longer than usual for these to be fully captured by the market players and stakeholders.

The generic medicines market is growing in Portugal, but there is no coherent government policy to support this when value continues to drop. How have you responded to the gap between volume and value?

We estimate that Mylan alone as a partner of the Portuguese Government and patients has helped to save about €110 million over the last three years. We did this by operationally managing our portfolio via the decisions that we take, launching new generic medicines offers to the market and fostering the development of a better understood generic medicines concept, while working closely with pharmacies to mitigate some of the constraints generated by the significant price erosion affecting all the players in the Portuguese pharmaceutical value chain. We also have strategic drivers, such as biosimilars, respiratory, injectables and antiretrovirals, that we expect will allow Mylan to continue to play an important role for the system, government and patients to reduce expense. From a portfolio management perspective, it is true that the generic business is growing, but this growth has declined in recent years (12.6 percent in 2013 versus 18.6 in 2012). Based on the government’s commitments with Troika we plan to double our market share between 2014 and 2015. With a 28 percent market share in volume last month, you have to question if this is an achievable target or if the market is growing as much as it could be.

The government tends to be optimistic about generic medicines penetration within the retail market, and, to some extent, some of the signals are indeed positive, particularly when we already witness a substitution rate superior to 60 percent on the molecules that can be substituted by a generic medicines option; the problem is that, when an original molecule has generic medicines options, there are still many physicians that tend to shift the prescription to other non-generic molecules that, in some cases, do not bring significant added value to the patient that justifies the increase of the treatment costs. This does not create the savings that healthcare authorities planned to achieve. Even molecules with generic medicines options have many discrepancies in the marketplace. Some key generic molecules have substitution rates as high as 90 percent, and other molecules that have been in the marketplace with a generic option for a couple years still have a 30 percent substitution rate. This imbalance within the generic medicines market is partially due to the government's measures to promote healthcare savings' measures that are not aligned with the different performances of different molecules across several therapeutic areas and medical conditions.

The Ministry of Health recently passed legislation allowing drug makers to introduce generic molecules on a monthly rather than quarterly basis. Does that help Mylan?

It helps Mylan and the industry as a whole as it allows the government to promote savings faster. But that measure alone will not really make a significant difference. There are other burning issues like litigation with originator companies and arbitration courts, or price linkage, where generic medicines prices continue to be linked with originator prices regardless of the life cycle of the generic market. When entering a market, you would expect, and Mylan agrees, to a difference between generic and originator price. In Portugal, that threshold is at 50 percent. The continued linkage with originator prices, where the generic price difference is forced to be kept and subjected to the decrease of the price of the originator / reference product, is endangering the sustainability of the sector in Portugal. It does not make sense for generics needing to be 50 percent of the originator price several years after market entrance. This is because the originator price tends to change every year as per the basket of reference countries in which local health authorities calculate prices for pharmaceuticals in Portugal and, at the end of the day, creates a situation where one competitor permanently dictates the price of all other competitors in a given market. It also doesn't make sense that, when a generic market is created, not all generics can be marketed at the same price with all manufacturers being given the same opportunity, and that some generics that never entered the market or have a residual penetration rate dictate the price of later entrants.

What are the historical factors that lead to problems like unclear patent definitions?

The development of the generic market is directly related to how strong and important the companies that work on that market are, as well as their level of influence. Originator companies on value Mobile Annual Total (MAT) represent 83 percent and generics 17 percent in the market. This speaks to the number of people we employ, how we are perceived as a meaningful economic and social player on in the overall economy and, as such, how originator companies position the cost of innovation regardless of the Country's capability to support it. Without a strong and sustainable generics market, companies operating in this market have struggled to elevate the share of voice they would need to have to influence and be better heard by the authorities. The ability to communicate has not been levelled between innovators and generics, thus originator companies have succeeded in creating obstacles for generic entrance in Portugal, demonstrating how delayed the country is compared to other generic markets across Europe. For example, the Portuguese Association of Generic Companies (APOGEN) has often commented that approximately €63 million could have been made in savings in 2012-2013 from arbitration courts and blocked patents alone.

This trend is somewhat decreasing, and the government has created processes to demonstrate that more generic medicines can come faster to the marketplace. But current price levels do not allow companies in Portugal to be sustainable. For example, originators in Spain need a generic price in order to maintain reimbursement, and Portugal looks to Spain to calculate the price of the originators in Portugal. Then the Portuguese generic medicines market needs to be 50 percent below that price. When you have this model for calculating prices in a young generic market in Portugal, compared to other countries with older markets, you would identify that the price level on those markets will already be relatively low. When you look at those markets' established prices for Portugal, you can anticipate how this also contributes to creating price erosion that is systematic and why Apogen and generic companies, need to fight for the suspension of price linkage or the withdrawal of price linkage of the generic business in Portugal.

How is Mylan's portfolio represented in Portugal?

Mylan has one of the largest portfolios in Portugal among generic companies, with over 100 molecules and this will grow significantly over the next five years. It is not fully representative of the entire organization's more than 1,300 product portfolio, but it is significant and relevant to Portugal's generic market. The company's antiretroviral (ARVS) portfolio will be introduced in 2014. Mylan has 10 years expertise in HIV/AIDS and we are delighted to launch our first generic ARVS in Portugal.

OTC will also be more important here in the coming years. Essentially, Portugal's structure today is a generic business unit, but there will be many more opportunities within the Mylan universe that we will bring to Portugal.

How will Mylan's purchase of Agila in 2013 strengthen its injectable portfolio in Portugal?

With Agila, Mylan significantly expands its injectable product portfolio, pipeline and capabilities. Mylan expects to launch more than 800 injectable products through 2018.

Mylan Portugal will benefit from that acquisition over time. Agila already had a couple of products registered and submitted with the health authorities, but were not being marketed in Portugal. We will gain from this deal because we will be able to bring more products that will serve more patients and create more savings; that definitely leverages Mylan's position in the marketplace.

What is the strategic importance of Mylan Portugal to the organization?

Portugal is a significant market for Mylan Europe. It is actually ranked in Mylan's Top 9 countries in Europe. As in most Southern European countries, the generic market development has yet to reach its full-size capacity and continues to represent a significant business opportunity. We have an operational model that allows the company to design new strategies and implement innovative tactics to leverage our market performance and engagement levels with stakeholders and Portuguese authorities as well as benchmark some success stories to apply in Portugal. On the other hand, by operating in such a volatile market, Mylan can use the Portuguese experience to develop plans of action that can serve and anticipate the outcome of similar and surrogate markets. Therefore, this subsidiary can also play an important role in educating other markets and affiliates.

The market has shown strong double digit CAGR (Compounded Annual Growth Rate) over the past three years. Mylan is one of the fastest growing companies in the total and generic market in Portugal. We have effectively mixed talent management and employee engagement required to be successful in implementing those strategies and communicating our role to the government as a partner with added value for the market.

What will Mylan do to help alleviate the market in the future?

Over the next three years, Mylan will generate additional savings for public and private stakeholders of €117 million, demonstrating Mylan's commitment to Portugal and its market, sharing the burden of creating sustainability with all partners. Over the next five years, Mylan will invest $2.8 billion in R&D, including the development of the respiratory, biosimilar and ARV business.

How would you like the marketplace to evolve in the coming years?

Generic medicines' quality and value in the market need to be better well-known. I would like the market to be more transparent for registration, reimbursement submission and approval; there shouldn't be so many legal loopholes where originator companies tend to take advantage from. The market needs to be better structured at all levels so that companies come to Portugal to develop a predictable and sustainable business. 55 percent of Portuguese pharmacies have had product suspended by at least one supplier. Portuguese pharmacies experienced a decrease of about €350 million in sales in 2012, and the debt to wholesales that pharmacies owe amount to €330 million. There is no way that the Portuguese pharmaceutical market can be sustainable if pharmacies are not sustainable themselves.

The effort between retail and hospital needs to be equally balanced too. Retail market share of generics is at 17 percent MAT in value and 27 percent in volume and 15 percent in value and 55 percent in volume for the hospital market. Price linkage must disappear; the government should understand that competition is already sufficient to drive and promote savings that the government wants to achieve in terms of price reduction.

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