Christos Dakas – Managing Director, Shire Greece & Cyprus



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A strong proponent of the value of orphan drugs, Shire Greece's Managing Director, Christos Dakas, shares his insights on the recent merger with Baxalta, the necessity of exempting orphan and haemophilia drugs from clawbacks to circumvent market challenges for critical treatments, as well as his vision for the bright future of the newly-redefined company.

Shire's 32 billion merger with Baxalta in June 2016 marks the creation of Shire as the largest biotech company focused solely on rare diseases. How has this significant change manifested itself in Greece?

The impact of this merger is strongly evident, as it delineates the beginning of Shire being the biggest player in rare diseases globally. The combined revenue of the "new" Shire in Greece reached about 50 million EUR in 2016 and taking into account our resources, there is strong optimism that we will launch many promising products from our combined pipeline in the upcoming years. The current goal today is to generate 20 products by 2020, which is highly realistic given Shire's stance today in the global market and hopefully we will be able to emulate this in Greece.

As the Managing Director of Shire Greece & Cyprus, how would you characterize Shire's presence and portfolio in Greece and how it has evolved since its inception?

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Shire began in Greece in two different ways. Shire used to be one company with two distinct business units, namely, Human Genetic Therapies and Specialty Pharma. The latter was introduced in Greece through a distributor who launched our internal medicine and gastrointestinal treatments. The rare disease and orphan drug part of the portfolio was introduced at the onset of direct presence of Shire in Greece. We began in 2007 with the launch of Elaprase, which is a treatment for Hunter's disease, and shortly followed by the launch of Replagal, a treatment for Fabry disease, in 2008. These two products therefore became the basis of the creation of the representative office which has now grown and evolved into a fully operating company. I am proud to say that in 2009, we were one of the first countries to introduce Firazyr, which was our first treatment for hereditary angioedema. In fact, Firazyr was so well-received in Greece that in 2015 we had the fifth highest per capita sales globally. Overall, the portfolio here in Greece is a good translation of the global Shire portfolio.

Given that you manage Greece & Cyprus together as a region, how would you distinctly characterize Greece as a market?

It is important to distinguish the Greek market before and after the financial crisis when characterizing it, although it has remained a good market in both circumstances. Before the crisis, Greece was the sixth largest market in Europe, on par and even higher than other small yet sophisticated markets such as the likes of Belgium, Switzerland and Austria. However, it was clear even then that market behavior and economic conditions were not sustainable, especially given the lack of controls. In implementing austerity measures, the Greek market had gone from one extreme to another, as evidenced by the shift from an almost 5.2 billion EUR pharmaceutical market in 2009 to a 1.945 billion EUR today. This figure also indicates the strict budget conditions for the industry today and in the upcoming years, as it also covers the uninsured, which means that the burden is currently placed on the shoulders of the pharmaceutical industry. The imposed rebates and clawbacks that the pharma industry is called to return, are estimated to reach 1 billion in 2016. This is a clear sign that the budget for pharmaceuticals is not enough.

Having a closed hospital budget also carries a significant impact, not just for the industry at large, but more specifically for a company like ours that is dedicated to rare diseases. From 2013 to 2015, the hospital budget stood at approximately 730 million EUR per year but thereafter, a budget of 570 million EUR was introduced. Given the nature of Shire's business, many of our products for rare diseases are reserved for hospital use only and therefore the limited budget has had an impact on the pathway of treatment for the patients that need them. As a company, we have strongly expressed that orphan drugs should be exempted from the clawbacks, especially given

that these treatments typically have no alternatives. We have also sought to exempt our product portfolio acquired from Baxalta from clawback, which is strongly anchored on plasma and blood derivatives for hemophilia and immunodeficiencies and are also limited to hospital usage. Even though hemophilia and some immunology products are typically used at home, Greek authorities have mandated their purchase solely through hospitals. Hospital clawbacks for Shire in 2016 are estimated to reach 32% of our hospital sales which practically means that one in three medicines have been provided for free. The situation is similar to other pharma companies in Greece with a hospital portfolio.

How would you describe your relationship with the Greek authorities and the regulatory nuances in this environment to gain market access?

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By and large, the Greek healthcare system is laden with challenges and authorities have not taken adequate measures to reform the system holistically, but only focused on short-term horizontal measures like price reductions, delays in introduction of new products and the imposition of ever increasing rebates and clawbacks. These concerns are exacerbated by the large volume of prescriptions, as well as high generic prices that are contributing to low penetration rates in the market. It is evident to many of us, that we currently have the wrong model and that reforms need to be made. What I believe to be most under threat is the sustainability of the level of investments in the country, especially given the rumors coming from the Ministry of Health that for the introduction of new products, it will be a requirement to have pre-approval in 14 countries including seven with HTA decisions and an additional 25 percent increase in rebates. In general, if these measures which are currently under discussion come into fruition, it would make the introduction of our new products in the Greek market extremely difficult. This is particularly alarming for our patients and us as the introduction of new orphan drugs and other rare diseases treatments for hemophilia and immunodeficiencies might become a most difficult task. Given the impact of our treatments which literally save and improve the lives of our patients, it will be sad to be faced with such a dilemma.

How would you assess the Greek authorities' attitudes towards orphan drugs given the country's pressing healthcare spending sustainability concerns?

It is absolutely imperative for us that regulators begin to understand there needs to be an exception for orphan drugs from hospital clawbacks. Not enough is being done to differentiate the characteristics of rare diseases and orphan drugs that merits them with a stronger sense of

urgency, as opposed to other ‘normal’ pharmaceutical products. Hospital budget constraints also limit access to orphan drugs both for existing and new patients. In theory, it is understood that orphan drugs are distinct, but in practice, there needs to be a shift in the mindset of regulators to reflect and implement the differentiation of orphan drugs.

Given the aforementioned uncertainty and challenges in the market, do you believe that the goal to introduce 20 products by 2020 is feasible in Greece?

Given the current challenging scenario, I am apprehensive about how pragmatic this goal is when seen in the lens of reality. Nonetheless, I remain optimistic given that I truly believe in the impact of our products, and therefore, I am not only concerned about the business objectives, but also that we retain the same high value and significance in our patients’ lives. As Shire, we are cognizant that we are ultimately a business and therefore must concern ourselves with the profit levels – however, being in a business of rare diseases with only a few thousand patients suffering a certain disease worldwide, which translates to only a small number of patients in a certain country, a stronger, more compassionate relationship is automatically instilled with our patients, which places them at the focus of our efforts.

Given this caring relationship with our patients, it is also important for us to build a robust relationship with the government and shift the discussion from cost to value. The emphasis is not only on the sentimental value, but also on the cost-saving value of being able to treat a patient efficiently with the proper drug, in order to avoid taking more drugs and longer hospitalization days in their treatment trajectory. Inefficient treatment also means a loss of human capital that could potentially contribute to society and the economy at large. Having a holistic discussion, instead of a singular cost-based analysis is important in understanding the real value of Shire’s products and their necessity in the market.

Patient care is at the crux of relevant topics in terms of rare diseases. How does Shire build a rapport with patients and patients’ associations?

As Shire is the leading company in rare disease with life-saving and life-altering treatments, I feel fortunate to we are able to contribute by creating service programs for our patients. Given the small number of people being treated by our therapies, we have built a nexus of support system wherein we are strongly engaged with offering services to our patients helping them and making easier their everyday lives. The fact that we can take part in the joy of learning that our patients and their families have a better quality of life is driving our efforts and makes our job even more rewarding. We believe that we are contributing to the improvement of our patients lives and having

the opportunity to see the clear and direct impact that our therapies have, is a meaningful and unforgettable experience for us that motivates us to keep fighting for improving access to our therapies.

What are the main priorities in your agenda today and what is ahead for Shire Greece?

The full integration of Baxalta into Shire stands at the crux of our priorities today. There are many synergies between the two companies that has made us strongly compatible and complementary for each other, yet there is still work to be done in ensuring that operations are consolidated. The growth and expansion of the company is also a priority this year with two new product launches and the preparation of three more. Our focus is to work with the Greek authorities and enable easier access to our therapies both for our existing patients and new patients – taking into consideration the budget constraints. We are also implementing improvements to the services that we offer to our patients. With the help of all relevant governmental stakeholders as well as physician and patient associations, we will work in creating an environment that will enable a faster and easier uptake of orphan and other rare diseases products.

From a more personal standpoint, you have been with Shire for eight years. Can you foresee another eight years in this company and in this role?

Combining with another formidable company like Baxalta reaffirms Shire’s commitment to orphan drugs and rare diseases. I am confident that under the global leadership of our CEO, Flemming Ørnskov, we are transforming into a company that is stronger, bigger and more focused, with a much larger portfolio of life-saving and life-altering products. As Shire, we have also increased our global footprint which means that we are able to provide our innovative products to more and more people around the world. The fact that I know that our efforts, as Shire, is making an impact on patient’s lives has been the burning flame that drives me. Knowing the difference that our therapies make for patients and their caregivers keeps me highly motivated and makes my role most rewarding.

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