Pascal Apostolides – President, SFEE; General Manager, Abbvie, Greece



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With a dual role as the president of SFEE (Hellenic Association of Pharmaceutical Companies) and the General Manager of one of the most innovative biopharmaceutical companies in the world, Abbvie, Pascal Apostolides candidly discusses the milestones of Abbvie as an independent company, the impact of clawbacks and rebates in the Greek pharmaceutical landscape, as well as the importance of opening a dialogue with ministries and all stakeholders.

Mr. Apostolides, you boast an impressive 30-year career history with Abbott, and have been the one responsible for spearheading its transition to an independent Abbvie. What has been your leadership approach in maneuvering this change?

AbbVie was launched in 2013 but our story begins in 1888. AbbVie is a global biopharmaceutical company, leveraging its 125 years of heritage with Abbott, vast presence, and strong core values to have a remarkable impact on patients. Our goal is to address highly unmet medical needs resulting from complex and serious health issues. AbbVie is a biopharmaceutical company that is delivering a consistent stream of innovative medicines.

I have been fortunate enough to lead the Greek affiliate through a smooth transition from Abbott to AbbVie after the split of the two companies in 2013 by combining expertise, financial stability and resources to effectively commercialize advanced therapies (pharma company mindset) and at the same time stay focused on our culture and innovation spirit in order to achieve breakthrough

science (biotech company mindset). AbbVie’s medicines are available in 170 countries. We have a strong workforce with 28,000 employees worldwide and 7,200 in Europe with 15 R&D and manufacturing facilities worldwide including of which 135 are based in Greece.

2017 will mark the fifth year of Abbvie as an independent company. How is it performing in the Greek market? What have been some key milestones?

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Greece is a country that has been in recession for nine consecutive years. We are facing tremendous challenges in terms of ageing population, unemployment, refugees, an unsustainable health budget, secondary care inefficiencies, and lack of a solid primary care structure. Within this turbulent environment, AbbVie, as a biopharmaceutical company with a leading position in immunology and emblematic biologic product (Humira®), offers treatment solutions to 13 serious autoimmune diseases. Moreover, AbbVie also has a leading position in the Greek market with its breakthrough oral regimen (Viekirax®/Exviera®) for the hepatitis C virus. We are also very excited to launch another proprietary breakthrough oral product, Venclyxto® that has been approved by the EMA under an orphan drug designation for chronic lymphocytic leukemia. We certainly have a very promising pipeline, which includes products that could potentially target therapeutic areas of great unmet medical need such as glioblastoma, solid tumors, hepatitis C therapy for all genotypes, autoimmune diseases, and neurodegenerative diseases.

From our interview with Fabrizio Greco in January 2016 in Italy, he spoke about the revolutionary treatment to eradicate Hepatitis C. Is this also a therapeutic area of concern for Greece?

Greece is a country of high prevalence in Hepatitis C (~1.2 percent). Greek health authorities, despite the tight financial situation, have provided restricted access to the new innovative hepatitis C oral treatments that lead to virus clearance in up to almost 96-97 percent of cases. Additionally, the Greek Government has joined the WHO action plan for Hepatitis C eradication by 2030 and has engaged for the generation of a national action plan. However, there is no screening program in Greece. Only 19 percent of cases are diagnosed and a large population remains undiagnosed since the disease is asymptomatic. The Greek Government has engaged to proceed with negotiations with pharmaceutical companies in order to lift current access restrictions and allow therapy for earlier fibrosis stages.

Market access for innovative treatments is a major concern for many of our interviewees as the process is increasingly becoming more long-winded and expensive.

How is Abbvie navigating this challenge?

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Looking into this issue necessitates analyzing two core issues, namely that of new medicines and restricted budgets, and the relationship of these two variables. Part of the value proposition refers to looking into other markets, where there is a dedicated negotiating committee designing schemes with the respective Ministries of Health to provide access to more patients. There is no previous experience on the negotiation process in Greece. There are many well-known schemes in other countries that could be emulated in Greece that have the potential to eliminate an entire disease, such as Hepatitis C, for example, once it is implemented properly. Understanding the variables at play and promoting strong collaboration amongst all stakeholders are crucial ingredients in mitigating today's challenges. Therefore there is great room for learning from other countries, by looking at systems that deliver the best results in the most cost effective way. Although proposals have been put forward in this direction we have not managed to move forward with the negotiations in the last six months. However, the latest news indicates that the state is determined to move ahead and most likely these negotiations will be a pilot for negotiations for other new innovative medicines in the future.

Clawbacks and rebates are also challenges and a concrete goal has been set to reduce clawbacks to 30 percent year by year. Is this feasible? Additionally, how has this impacted Abbvie's operation here in Greece?

By definition, a clawback is a measure put in place when a target is exceeded and there needs to be contributions by the pharmaceutical industry in order to share the burden. Ideally, the state should put targets that are realistic and clawbacks to be paid by the industry should cover a reasonable excess, ranging from two to five percent. Equally the imposition of a rebate mechanism by the state to pharmaceutical industry mandates that pharmaceutical medicines are providing discounts based on their volume of sales. However, in the case of Greece, both mechanisms have ended up as a perfect excuse to avoid structural reforms as close to one billion euros will be paid by the industry in rebates and clawbacks in both retail and inpatient segments at the end of 2016 (which is more than 30 percent higher than 2015). This essentially means that one in four medicines are provided for free by pharmaceutical companies in outpatient expenditure, and that one in three medicines are also given for free in the inpatient setting. The imposition of an open-ended clawback mechanism means that there is no incentive for structural reforms by the state as any excess expenditure is obliged to be paid by the pharmaceutical industry. This lack of predictability jeopardizes investments and job opportunities and threatens the survival of

companies; ultimately leading to an unstable healthcare environment.

How do you evaluate the government's response and openness to dialogue with the industry? Do you find that the channels of communication are open?

Over time we have managed to establish an open-ended dialogue with the Ministry of Health and in the second half of 2016, the Minister of Health formed a committee to control pharma expenditure, which includes representatives of all key stakeholders and both pharmaceutical associations, at the multinational and local levels, namely SFEE (Hellenic Association of Pharmaceutical Companies) and PEF (Panhellenic Union of Pharmaceutical Industry). The objective of this committee is to propose measures and structural reforms that could have short- and medium-term effects in controlling expenditure. However, in the midst of these discussions, the Minister announced that they are planning to impose higher rebates without commitment that these rebates would replace the clawback reduction by 30 percent – as committed in the latest MoU – and an additional 25 percent rebate on new innovative medicines, which would mean that these medicines would have to provide further discounts of up to 55 percent on a price basis that is among the three lowest prices of the 27 countries of Europe (per Greek pricing decree legislation). We hope that the Ministry of Health will listen to our objections and counter proposals and will work out a legislative framework which will protect patient access to new therapies by expediting the evaluation of these therapies through Health Technology Assessment (HTA) – per MoU requirement – and will then enter into the most optimum reimbursement schemes based on EU experience from other countries like managed entry, price / volume, risk sharing or negotiating agreements with the industry.

Despite the harsh conditions of the market, all multinationals have stayed. How do you explain this apparent paradox?

Many multinationals have stayed as a testament to their commitment to the Greek market and patients. After all, medicine is also a social good. As part of the pharmaceutical industry at large, there is an embedded responsibility, which we all have to live up to – however, there is a limit. The snap decisions on pharmaceutical policy under pressure from Greece's lenders show that the government so far has continued along the beaten track of horizontal measures mainly through pharmaceutical price cuts and imposition of rebates and clawbacks instead of structural reforms. The continued imposition of horizontal measures would lead to decreased investments like clinical trials and will most likely have an adverse impact on the ability of multinational companies to increase manufacturing in Greek factories from present levels There is an incentive for all to find a winning solution for all parties as medicines could be part of the solution in the healthcare system

by adopting the appropriate policies. Our plea for a call to action is largely driven by the desire to remain viable in the flailing Greek economy, for the ultimate benefit of Greek patients.

What recent updates have there been on the ongoing discussions regarding the challenges in the pharmaceutical industry?

Hit by the financial crisis and with an already ailing public health budget in the background – public pharmaceutical expenditure in Greece is 50 percent of the European average. The Greek healthcare sector is struggling to cope with the various cost containment measures adopted in the past years and to adequately respond to the healthcare needs of its population. It is clear that the challenges we face need a new way of thinking about how we manage healthcare by focusing on things that really make a difference to patients and allocating appropriate resources accordingly to primary and inpatient care.

Patients' access to necessary treatments and innovative lifesaving medicines should be a top priority for all stakeholders and therefore unduly penalizing the entrance of new therapies is not the proper mechanism. As mentioned previously, a localized HTA evaluation that caters specifically to the epidemiological profile of Greek patients and evaluates the needs of medicines according to the gaps in the Greek healthcare market.

What are your strategic priorities in the upcoming three to five years? Do you foresee a "light at the end of the tunnel"?

The fact that interactions have intensified with the participation of all key stakeholders is a sign that there is light at the end of the tunnel. However, there needs to be stronger commitment to finding win-win solutions by prioritizing key areas for improvement and areas for present and future investment. The key objectives of decision-makers in Greece remain the structural adjustments, the improvement of social cohesion and ameliorating the operational conditions for a sustainable economic recovery. However any prospect for an economic recovery remain slim without a fundamental shift in policy-making and implementation of structural reforms.

What is your final message to our global executive readers, who are perhaps evaluating whether Greece is still a viable global market?

Greece has a high caliber of educated youth, healthcare professionals and a scientific community which can do excellent research, when proper incentives, infrastructure and streamlined procedures are in place (on par with European standards). In the healthcare sector, R&D and clinical trials are areas of opportunities for growth if the above conditions are met; in particular investment in clinical trials by pharmaceutical companies in Greece can triple or quadruple in the

next three to four years as the pharmaceutical industry in Europe is investing in countries where the right conditions are in place; therefore if the right conditions are in place, Greece can be seen as competitive vis-à-vis other European markets. Greece also has the potential to increase manufacturing and export of pharmaceuticals from its existing 28 factories as pharmaceuticals already hold the number two position in Greek exports with EUR 1 billion in revenue. Equally, other areas of the economy can be opportunities for growth and investment as now is the time for the Greek economy to bounce back.

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