Mihalis Himonas – General Manager, SFEE (Hellenic Association of Pharmaceutical Companies), Greece

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General Manager of the Hellenic Association of Pharmaceutical Companies (SFEE), Mihalis Himonas speaks about his role spearheading Greece's main pharma association, the contribution of the pharma industry to GDP, market access challenges, and solutions for creating a sustainable healthcare environment.

As the organization representing the united voice of the pharmaceutical industry in Greece, please give us an overview of the Hellenic Association of Pharmaceutical Companies (SFEE)?

At SFEE, we believe that health should be at the heart of economic and social welfare in Greece. Our priority is to ensure unhindered access of all patients to both innovative and long-established medicines, reducing inequalities in healthcare provision and improving health outcomes. SFEE represents the large majority of the pharmaceutical industry, which plays a tremendous role for the national economy. The pharmaceutical industry is the second largest sector of the Greek economy, providing 26,100 jobs directly, and overall totalling 87,000 jobs indirectly and through induced impact. The industry's direct impact on GDP is estimated at 1.52 billion EUR, including its indirect effects and the increase in consumption, with a total impact that comes to 7.55 billion EUR. The pharmaceutical industry is undeniably one of the key pillars of growth in the Greek economy, especially given its strong competitive activity, as well as its potential for record growth rates in

the near future.

The organization was established in 1982, and is directed by the General Assembly, which elects a Board of Directors every three years. Our main objective is to mitigate the challenges of the current crisis environment and stand as a solidified voice representing our member companies to the different influential stakeholders. As the current Greek government has insisted on opening dialogue with the Association as a whole, as opposed to each member individually, we have a deep responsibility to be a key communication platform and bridge the different interests of the parties involved. Today, our main goal is to be a true ally in the effort to remedy the health system and develop a national strategy focused on patients.

The protection of patients' rights to unimpeded access to necessary treatments is of utmost priority for SFEE. Anchored on this philosophy, we also aim to ensure a well-functioning healthcare system, achieved through a National Health Plan which alludes to a modern strategy that understands the functioning of the pharmaceutical market. We create a strong rapport with the government and the relevant departments in the likes EOPYY (Social Security Organization) and EOF (National Organization for Medicines), in order to be able to liaise the pertinent topics of the industry on behalf of our members. We also engage with EFPIA (European Federation of Pharmaceutical Industries and Associations) to ensure that we remain on par with the EU standards and keep abreast with the changes.

As an organization representing both large multinationals and local Greek companies, how do you foster coherence within the pharmaceutical industry as a whole?

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The footprint of the industry has been vital to the domestic Greek economy. In Greece, the tendency has been that many Greek companies have strong manufacturing activities, with 27 plants currently under Greek ownership. Capitalizing on this strength, many multinational companies partner with local Greek companies for their manufacturing needs, not only for the Greek market but for exporting internationally. As it stands, 55 percent of the products in Greece are imported, whereas the rest are manufactured here in Greece. For the latter,16 percent are manufactured by local Greek companies and approximately 29 percent are manufactured domestically for foreign multinational companies. We see tremendous growth potential in fostering further collaboration with global and local companies, thus capitalizing on a strong domestic manufacturing economy while increasing our global visibility and viability in the international stage.

Another main area of concern in healthcare is market access. What are the main challenges that you identify in this regard, especially against the backdrop of an economic crisis?

The major issue of concern is in regards to new drugs. In an effort to maintain the budget set by the fiscal measures, a constraint has been put in place for the introduction of new drugs in the Greek market, as new drugs are believed to be the root cause of excess in pharma expenditure. Regulators in Brussels are currently discussing this issue, and the proposed solution, as it stands today, is to create regulations that will make the process more time-consuming and expensive for the innovators. Though no final decision has been reached, some of the tentative discussions have revolved around some new proposed measures by the Minister of Health, including a measure stating that in order for a new drug to be launched in Greece, it must already be available in 14 other countries in Europe, seven of which should have HTA systems. These measures are unacceptable for SFEE as they harm patients' access to new lifesaving medicines, for example by creating a two to five years delay for market entry. Additionally, these measures harm our member companies' sustainability, for example the proposed measure to impose an additional rebate of 25 percent to each new drug, bringing the total burden to more than 60 percent (volume rebate 20 percent, plus extra rebate 25 percent for new medicines, in addition to claw-back 17 percent on average). However, it is also recognized that innovation must have a way to come to Greece and that it does not entirely lag behind the standards of the EU. There is a concerted effort to counter these directives, but we are also cognizant of the importance of staying within budget. I expect that the final measures will be a compromise of different extremes to accommodate the different interests at stake.

Another strong area of contention is clawbacks, for which SFEE has shown solidarity with PEF (Panhellenic Union of Pharmaceutical Industry) for contending this issue. What are the measures undertaken today to tackle this concern?

Public pharmaceutical expenditure, which has undergone continuous cuts in recent years, is now subject to a ceiling of EUR 1,945 million plus EUR 570 million for hospitals; this amount is insufficient, hence expenditure keeps spiraling out of control. This is because it was determined arbitrarily, without taking into consideration the real needs of Greek patients, the burden on tertiary healthcare and the soaring numbers of uninsured people. The gap is covered, on one hand, by patients themselves (out-of-pocket patient costs almost tripled from nine percent in 2009 to 26 percent on average in 2015) and, on the other, by the industry which finances 25 percent of pharmaceutical expenditure through rebates and claw-backs. That is, one in four medicines used is

paid for by the pharmaceutical industry.

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As if that were not enough, the government is now acting to squeeze more and more money out of pharmaceutical companies: on top of the already stifling claw-backs and rebates, it tries to exact more revenues from the industry. To illustrate the situation that companies are expected to deal with, the claw-back to EOPYY increased by 42.3 percent in the first half of 2016 year-on-year, whereas the newly introduced hospital claw-back came to EUR 140 million (41% of expenditure) and is likely to double by the end of this year. In a budget of EUR 570 million, this is far more that the industry's fair share of the burden.

A positive note in this matter has been the Memorandum signed last year, which states that clawbacks need to be reduced by 30 percent for 2017 and another 30 percent for 2018. Creating a cap on the percentage would provide optimism for many companies for 2017 and the upcoming years. However, the government, instead of taking measures to reduce the unreasonable and unfair claw-back by 30 percent in 2017 – as required under a MoU commitment – in fact is trying to substitute a reduced claw-back with a higher rebate. This threatens the survival of pharmaceutical companies, jeopardizes thousands of jobs, and creates disinvestment conditions in the industry. This uncertainty was even addressed at the EU level, yet it remains to be undetermined for the time being. Anxiety is widespread for many companies, both Greek and multinationals, who are trying to plan their budgets for the upcoming fiscal year.

In an era of "big data", information is of utmost importance. What are some of the opportunities and challenges faced by the pharmaceutical industry at large in this regard?

SFEE and its member companies adhere and strictly comply with the national legislation of the Disclosure Code, which refers to the requirement for all pharmaceutical companies to disclose all the transfers of value, direct and indirect, monetary and in kind made to healthcare professionals (HCPs) and healthcare organizations (HCOs) relating to the development and promotion of prescription medicines for human use. As an association, we strong support the values of transparency and disclosure as promoted by the EFPIA across Europe and we have been pushing as an industry to push for its enforcement. On December 2014, a law has been passed regarding the Disclosure code wherein companies have to disclose their financial activities with doctor in 2015 by June 2016, which is six months later of the end of the fiscal year.

This law today has not been enforced because it has been blocked by the Data Protection Authority, following an appeal by the doctor's association, claiming privacy breach. The National Drug Association (EOF) appealed this decision, which has been heard in court on December 20th for the second time. As it stands today, we are awaiting the final decision of the court due to be made this month. Nonetheless, we would like to stress that SFEE and its member companies are strongly behind the enforcement of the Disclosure Code to promote transparency across the industry.

It is evident that the current Greek market is laden with challenges. What are some of the proposed solutions to create a more sustainable healthcare system moving forward?

Profound structural challenges are necessary to revamp the current state of healthcare, and it requires political willingness, proper discipline, as well as coherent design and implementation with all stakeholders as to have a sense of social consensus. The most realistic first line of defense is to capitalize on underutilized strengths of the system such as the e-prescription system, which is deemed to be one of the most sophisticated in Europe. Collecting and analyzing "big data" would be crucial to setting national health priorities, budget forecasting and anticipating budgets. Moreover, key aspects such as the introduction of registries, therapeutic guidelines and proper generics policy should be of high importance in the healthcare agenda.

Another area of untapped potential that has been identified is clinical trials. How do you believe this can benefit the overall state of the pharmaceutical industry as a whole?

Clinical trials are directly related to the development of new therapies. Our long-term vision in this respect is to promote Greece as a clinical trial hub in Europe and globally, as one of the means for pharmaceutical development, and indirectly for the growth of pharmaceutical manufacturing as well through a network effect. Greece's strategic geo-positioning as well as its current research infrastructure has a wealth of potential to attract more foreign direct investment if this area is developed more.

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Last year, the amount invested into clinical trials in Greece amounted to 80 million EUR. In context, Cyprus, which is a much smaller geography, invested 85 million EUR, whereas Belgium, a country of similar population size, invested 2.5 billion EUR. It is evident that more can be done to nourish

the same level of activity here. Multinationals are yet to be enticed by the prospect of Greece in this area given the layered and slow bureaucracy, as well as a lack of incentives. Clinical trials are a competitive product. We face tough competition from neighboring markets with similar profiles such as Romania and Hungary who have enforced a far greater incentive mechanism than Greece. For example, there is only a 100 percent tax break incentive in place in Greece, which shies in comparison for economies like Hungary and Czech Republic with 200 percent and Turkey with 250 percent. Thus, there need to be a legislative support in the upcoming years that can help improve the state of clinical trials and help develop its potential.

In sum, what is your overarching final message to our global executive readers on behalf of your members about the state of the pharmaceutical industry in Greece, and what is to be expected in the foreseeable future?

If the reforms take place, and Greece is released from its tight financial policies, I am optimistic that the market will flourish. Greece has the potential to become a central hub for the Balkans and the surrounding areas. We currently have great companies, excellent scientific personnel, highly educated doctors in hospitals, a potential for health tourism, as well as strong export orientation. Therefore, there is a plethora of elements that will propel Greece to excellence, but we must remain patient and proactive in changing market conditions for the better.

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