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Managing Director of MSD Greece, Cyprus & Malta Agata Jakoncic, who also serves as president of Greece's PhRMA Innovation Forum (PIF), draws on her three decades of industry experience to outline some of the key challenges in the Greek pharma market today which threaten its sustainability and the ability of Greek patients to access lifesaving medicines. Jakoncic also highlights how inter-stakeholder collaboration and better data utilisation could bolster sustainability in Greek healthcare and provide win-win solutions across the board.

You have been at MSD for almost thirty years. Talk us through your career path. What has brought you to this point?

I am a pharmacist by profession but quickly shifted to the pharmaceutical industry. I started in Slovenia, where I am from, and soon after had an assignment in the US. Most of my experience is in the markets of Central Eastern Europe, the Baltics, Romania, and Southeast Europe. Primarily, I have worked in commercial, marketing and supply optimisations across different countries and regions. I have learned a lot through my career journey, and I am still enjoying it.

You took over as Managing Director at MSD Greece in 2017, in the midst of a financial crisis. What state was the affiliate in when you took over, and what has been achieved since? Where does MSD stand in the Greek market today?

There were many challenges in the market in 2017 and 2018. The pharma environment was frequently changing. Various austerity measures were introduced, frequently changing clawback mechanisms, discounts and mandatory rebates. It was a volatile time. From an organisational perspective, MSD Greece has focused on therapies that offer the greatest therapeutic benefit and cover unmet needs, such as oncology and vaccines. When I look back over the last five or six years, I am proud of what we have achieved in the Greek market. That was the year when we repatriated vaccines and MSD has since established itself as the leading vaccine company in Greece. We worked hard to achieve sustainable national funding for vaccines in collaboration with all relevant national stakeholders.

Also, we have become the leading company in oncology, which started with the launch of Keytruda, and the number one company in infectious diseases. To get there, we had to decide where to prioritise our investments and pursue win-win solutions to achieve sustainable growth during the crisis year.

The organisation has definitely changed over the years. We are stronger in three main areas: digitalisation, policy and access, and communication to our stakeholders. To do this, we have attracted fresh talent, formed new teams equipped with digital knowledge and capability, and established a strong digital & data analytics department. This has led to the integration of digital tools in our marketing department and the implementation of omnichannel marketing.

In terms of policy and access, we have hired young talent with strong analytical skills, strategic focus and a good understanding of the market and the value of medicine. Overall, we are redefining our communication channels with our customers.

Finally, we improved our work culture and defined our vision and mission as a company not only globally but also locally. We have developed an inclusive approach towards our employees, and we have been able to attract talent from the market. Many of our employees have grown internally and moved to roles with regional responsibilities.

To what extent is the instability and unpredictability of the market today similar to that of the crisis years? What progress has been made in terms of the stability of the

market?

Unpredictability, transparency, and sustainability have continued to be challenging. During my six years as MD for MSD Greece, the way austerity measures are calculated has changed yearly. Although we are in April 2023, we still do not have the final bill for 2022. We do not know what the bill will be for 2023, and soon, we will start planning for 2024. We have been operating for three years not knowing what our final numbers will look like.

Is this something you see in other CE countries, or is it a challenge unique to Greece?

There is a particularity to Greece, which is a result of 10 years of economic crisis. Historically, healthcare expenditure in Greece is lower than the EU average (see Figure 1). There were many cost containment and efficacy measures introduced in the aftermath of the 2009 crisis. To take control of the financial crisis, austerity measure mechanisms have been established such as the introduction of rebates and clawback mechanism, which has gradually become the main financing mechanism of pharmaceutical care in Greece

Other countries, even in Western Europe, have similar mechanisms but in Greece, there is a public funding cap, and expenditure can go as high as it is needed based on market demand. Most of the difference is paid by pharmaceutical companies.

Back in the early 2010s that gap was relatively manageable, but today pharma is substituting whatever gaps and needs are there. That is unsustainable. For example, in 2021, seven out of 10 medicines needs to be given for free in the hospital segment, because the budget is EUR 500 million, and the consumption is well over EUR one billion (see Figure 2). Based on what we know, 2023 will be even worse. Therefore, the headroom for innovative medicines in the hospital sector today is almost non-existent since an innovative treatment can rarely be funded sustainably through this mechanism, or in other words is paid only for one-third of the cost.

Despite the challenges of sustainability over recent years, MSD has become the number one player in vaccines and has established a leadership position in infectious diseases and oncology. How have you managed to achieve success in this context?

Firstly, early on, we determined where to invest, what to focus on, and what not to focus on. Secondly, we carefully assess the access possibilities. This has become a critical factor in deciding whether to launch a product or not, because of the high austerity measures. So, while we have had success with some products, there are four products we have not launched. Of course, we strive to get the products and innovations to the Greek patients, and we know the patients appreciate that. As I mentioned before, we have established high-level, cross-functional teams of medical, digital, commercial, marketing, analytics, and value & patient access expertise, to assess where we can provide a unique customer experience and highlight our clinical value.

Although we are number one for vaccines, we also work with institutions to find sustainable funding solutions. For example, back in 2020 vaccines were removed from the clawback mechanisms. Furthermore, there are also governmental efforts to rationalise financial agreements through the system. There are now financial agreements between the authorities and pharma companies which give patients access to new therapies through sustainable reimbursement schemes. Instead of waiting for the bill, the state has introduced certain therapeutic areas for which we can negotiate with an option of closed budgets.

But beyond all these, I would like to stretch out that we as MSD globally and locally have remained true in our legacy and commitment to inventing for life and working on providing patient access to innovative treatments. Innovation is at the core of what we do both globally and locally. We use the power of leading-edge science to save and improve lives around the world in areas such as oncology, vaccines, infectious diseases, and cardiology. Therefore, MSD will continue investing in R&D in order to meet patients' unmet needs and tackle some of the world's greatest health threats.

And let us not forget that biopharmaceutical innovation redefined expectations in once-incurable diseases. According to a recent study, medicines are responsible for more than a third of the improvement in life expectancy from 1990 to 2015 in the US. This highlights the crucial role of biopharmaceutical innovation, as life expectancy increased by 3.3 years during that period[1]. And if we talk about HIV, improvements in treatment accounted for 76 percent of improvements in mortality for patients with HIV.

Moving on to the access question and inter-stakeholder collaboration and clinical trials. If a product is tested in a country first, doctors get exposure to it and patients receive it early, establishing the company as a partner. To what extent is that something MSD is engaging in in Greece?

We are absolutely engaging in clinical trials. In 2020, the Greek government introduced initiatives to invest in clinical trials and offset part of the clawback. In the first year, it was a great initiative that motivated us to invest in more clinical trials. We advocated for that because it was a unique system in Europe. The initiative looked good in 2020, and we all embarked on and promoted it. Currently, MSD has 42 clinical trials, of which about 10 are phase I or phase II studies, that is very scientifically demanding studies. However, it has significantly deteriorated and the offset for investment in innovative R&D and clinical trials has been minuscule. But we still invest in clinical trials in the country because we trust in the high competencies of the Greek scientific and medical community, and we want Greek patients to have access to innovation as early as possible.

The Greek government emphasises attracting innovation, and there is investment from companies like Microsoft, Google, and Amazon. The Greek economy looks good. In fact, the International Monetary Fund (IMF) has upgraded Greece from a projected 2.4 percent to 2.6 percent GDP growth, while most countries have been downgraded. There is a good story there, but it needs to be sustainable. As the example of incentives for clinical trials shows the unpredictability in the Greek economy is disappointing. You cannot trust that what succeeds one year will succeed the next.

As part of a multinational organisation, you have to advocate for investment to headquarters that may be more inclined to invest in similar-sized European countries, with more predictable set-ups.

Yes, exactly. Due to the perception of the Greek market after the financial crisis, we really advocated for Greece and worked to communicate that to our companies. But there was a strong plea to maintain a sustainable and predictable environment. I am sure you can imagine how difficult that is when we do not know at which level our final bill of returns will end up.

You have a dual role as president of Greece’s PhRMA Innovation Forum (PIF). What does that role entail, and what key issues are you advocating for?

One of the main problems in Greece's current market is the gap between the public pharma budget and the expenditure. There is an unsustainable level of pharmaceutical expenditure, and that is the most important efficiency challenge in financing pharmaceutical care. Here I want to emphasise the hospital sector. We wanted to look at it broadly and find more institutional and sustainable solutions. So, in 2020, we put our heads together to establish a roadmap for sustainable and effective pharmaceutical care in Greece. That is presented as a proposal for dialogue with the government and industry. This roadmap has been broadly presented to the embassies, stakeholders, and the government. It contains five elements. The first is a stable and predictable pricing and reimbursement system. There are many discrepancies in the way the pricing and reimbursement system works. The second is to establish a more transparent and efficient Health Technology Assessment (HTA) system. Third: the empowerment of clinical and biomedical research and funding for innovation. Fourth: transparency and monitoring prescribing, implementing clinical protocols and registry implementation. That point is important because, in Greece, we are not monitoring prescriptions.

Does that play into digital patient records and the digitalisation of the system on a broader scale?

Yes, exactly. The fifth is sustainable and predictable financing. With this ambitious five-step roadmap, we want to remove all the protectionism away and start from scratch. We are advocating for a good monitoring system, good registries, good digital patient records, and to monitor what we do. Then we can better understand how much pharma financing is needed in the Greek market.

How does the PIF interact with the SFEE, and how do its aims differ?

SFEE is an association which represents the entire industry, so its positions must naturally strike a balance between all their aims. PIF represents 26 leading Research and Development companies and therefore is responsible for supplying 60 percent of the total pharma market value.

All those companies share one vision: to discover, develop and provide innovative treatments to the patient, and cover unmet needs. We are committed to providing the most advanced treatment, access to innovation, and investment in scientific research. We aim for preventative treatments, and we invest in human resources. Our organisation invests a lot in our people to provide high-level, added-value trainings in healthcare, policy, access, and digitalisation. We aim to keep and

develop the capabilities of the people. We support different policies for timely, equitable and sustainable access to our innovative products.

We got out of the COVID-19 crisis because of innovative companies, vaccines, and therapies. Just recently, the end of COVID-19 emergency measures was announced in the US. Therefore, I think there is a need for a group that focuses solely on those elements.

As part of Greece's own recovery from the COVID-19 pandemic, the country is set to receive substantial EU funding. What are your hopes for how the funding will be spent?

EUR 1.2 billion will go into healthcare reform and investment for specific areas, such as the primary care health system, to achieve higher quality healthcare, digital transformation to implement patient e-records, national health, and hospital infrastructure. We have a large number of hospitals, each with its own system. There is no convergence of the systems, and therefore, no interoperability. There will also be public screening programs for breast, cervical and colorectal cancers, and cardiology along with mental health reforms.

An important part of the RRF was a commitment from the government to gradually reduce the clawback mechanisms. Another part was that the offset to R&D was very small. The government commitment was as follows: with 2020 as the baseline, the clawback must be EUR 50 million less than 2020. In 2023, it must be EUR 150 million less than 2020. In 2024, it must be EUR 300 million less, and in 2025, it must be EUR 400 million less.

This is a commitment from the government and is on our agenda for discussions with the Minister of Health. The government has decided to inject EUR 150 million from 2023 into the pharma budget. irrespective of whether the clawback reduction targets are achieved. I think it is problematic to inject money with no cost control measures that will not be as effective as they should be. If you have no control of prescription, or following therapeutical protocols, and no elimination of special protectionism, the desired effect may not be achieved. We as PIF and MSD as a company are working on a practical roadmap for efficiency improvement in pharma spending that will lead to lower costs for patients, savings in public spending and better market conditions for the pharma industry. The way our system has developed means that either we all win together, or we all lose together. Collaboration, therefore, is the key to future success.

You have painted a picture of a challenging scenario, but also one in which you are very engaged, both as MSD and as part of these industry groups. What do you hope to achieve in the short to medium term?

There is a lack of sustainability in the market, given the yearly changes in how the clawback is repaid. There is a recently published legal legislative action, which states that low-cost products will not be required to repay the clawback. However, the clawback from low-cost products will be given to innovative industry. In every country in the world, old products create savings so that innovation can be introduced to the market. Whereas here it is the opposite, innovation is made a burden, which is why seven out of 10 medicines will need to be given for free. We do not know if we will be asked to pay for eight out of 10. I do not think that can continue. Therefore, I am hopeful that the Greek market needs innovation. As things are currently, it is impossible to introduce, so something will need to change.

I see the potential in the Greek market because Greece is in a fantastic position geo-strategically. It is close to the Middle East, Europe, and Southeast Europe. Today, data is oil to a machine. Europe is developing a European Health Data Space. Post-crisis, the Greek market has had a good data collection system, but this data is not being utilised. I do see a lot of potential, and Greece, with its geo-strategic location, is at the forefront and can become a hub for secondary data usage. We at MSD Greece have been advocating since 2015 that Greece has the potential to become a centre of excellence in RWD/RWE due to the wealth of data that remains unharnessed.

Is the data not being utilised in that it is not made available to third parties?

Exactly. Through research by the Foundation of Economic and Industrial Research that was supported by MSD Greece, we have found that every million euros invested in creating that data ecosystem contributes approx. another million euros to GDP growth (Figure 3) and creates 24 high-end paid jobs (Figure 4). I am hopeful that if the Greek system starts using the data and makes decisions based on the data, this will lead to a sustainable, transparent, and predictable pharma market.

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Is there anything else you would like to mention?

I would like to emphasise that the unpredictability, frequent changes, and non-data-based decisions cause many problems for the pharma industry. We need to sit down and carefully decide what we introduce to the market and what we do not. We cannot optimise the function in our organisations anymore. All organisations have streamlined their functions. I think working together on a good policy and access environment and utilising the data is the key to future success.

Sources

[1] https://catalyst.phrma.org/study-finds-biopharmaceutical-innovation-is-responsible-for-35-of-the-increase-in-life-expectancy-from-1990-to-2015

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