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Michael Himonas of SFEE, the umbrella pharmaceutical association of 40 global innovative biopharma companies and 20 local companies in Greece, explains how the country's pharmaceutical clawback and rebate system is restricting the growth of the industry and ultimately limiting and delaying patient access to medicines. However, Himonas is also keen to note the advantages of Greece as an investment destination, citing big projects from Pfizer and Boehringer Ingelheim as case studies, noting the country's world-class healthcare personnel, and adding that funding from the EU Recovery & Resilience Facility (RRF) is set to boost the digitalisation of Greek healthcare.

Following a severe recession in the 2008-2018 period, Greece seems to be on surer economic footing these days, with nine percent GDP growth in 2021, unemployment down to under 15 percent, and an administration rolling out several business-friendly measures. What are the prospects for global life sciences companies in Greece today?

Greece finally exited its decade of government-debt crisis in 2019, but the positivity that this brought was short-lived, given that the COVID-19 pandemic hit the country in early 2020, and the fact that Greece is now facing an energy crisis brought about by the war in Ukraine. As such, GDP is now growing at eight percent for 2022, but this is heavily linked to inflation growth of 12 percent driven by the energy crisis. The economic outlook for 2023 is of a much more modest 2.3 percent GDP growth. In essence, Greece has been on the tarmac and ready for a nice take-off since 2019, but this has not yet happened.

In terms of the pharmaceutical industry, public investment in health and pharmaceuticals has largely remained flat in recent years, with expected spending for 2023 in line with the country's overall GDP growth. The crisis years saw public spending cut dramatically, and this remains at very low levels. In 2022, there was a 6.3 percent increase in spending on pharmaceuticals from pharmacies, and a 12.3 percent increase in hospital spending. Despite this overall eight percent increase of the market, the spending in real terms has not grown and the mandatory returns have increased.

These 'mandatory returns' are a serious concern for the industry and *the* key topic in our discussions with government. The Greek clawback and rebate system is the highest in Europe by far, taking up over 47 percent of sales, and it hits all pharma companies – whether local or international, big or small – who must pay back a significant proportion of their revenues to the state. Unlike other European countries which have capped their clawback system (Portugal) or replaced it with a discount scheme (Romania), the Greek clawback mechanism is out of control and unsustainable.

Do you feel that the current government is amenable to the arguments being put forward by the pharmaceutical industry regarding the need for reform of this system?

The current government *is* business-friendly and has proposed several positive measures. However, public spending on pharma is still considered an expense rather than an investment in public health; an unfortunate residual effect of the crisis years.

The State is focusing on introducing new clawback calculation methods that create anxiety and dilute predictability.

Pharma companies in Greece are very concerned and are already cutting back on personnel. As of now, very few products have been withdrawn from the market, but this increased pressure *will* hurt innovation, lead to fewer investments, and the delayed introduction of life-saving new drugs to the Greek market.

What proposals are you making to the Greek government to reform this system?

We are asking the government to take a two-pronged approach. The first prong is to increase spending gradually from its very low levels to cover the needs of the population. The second prong is to manage spending and reduce wastage within the system. Greater efficiency can be created by utilising already-available digital tools, registries, protocols, and enforcing greater control overall by the authorities.

Greater generic penetration – at the right price – will also be important within this second prong. There are 80,000 doctors in Greece – one of the highest numbers per capita in the world – who are competing for clientele and are often willing to prescribe the most expensive medicines available to keep the same patients or gain new ones. The same results could often be achieved with a cheaper generic equivalent, but there is no incentive for doctors to prescribe such medicines. In other words, the mix is wrong, not the volume.

How well digitalised are patient records in Greece today?

The country boasts an excellent e-prescription system – one of the best in Europe – but beyond that there are issues.. For example, our hospitals are not digitalised and there are no national standards or protocols around the digitalisation of patient records and registries.

However, the government has now appointed a top-class minister of digital affairs who is working on putting patient registries in place and connecting them with e-prescriptions as a top priority. Moreover, EUR 278 million of the EU Recovery & Resilience Facility (RRF) that Greece is set to receive from the EU has been budgeted for digital upgrades to the system. Rightly, this is also a priority for our MoH.

What are your hopes on how the EUR 30.5 billion RRF will be spent and its potential impact on pharma and healthcare in Greece?

The RRF is composed of both grants and loans, which must be paid back, as well as specific areas that must be invested in. In terms of healthcare, there is approximately EUR 1.5 billion on the table, EUR 278 million of which has been earmarked for digital upgrades, EUR 317 million for hospital upgrades, and EUR 271 million for primary care.

This funding injection has the potential to make the biggest difference in primary care. A more efficient primary system would see patients visit hospitals far less, thereby significantly reducing the expenses incurred by the state.

Does Greece have sufficient human capital to build up its primary care infrastructure, especially given the high numbers of Greeks that left the country during the crisis years?

This is a challenge. There are approximately 15,000 Greek doctors residing and working abroad and a high-level key opinion leader (KOL) recently told me that 80 percent of nursing school graduates leave Greece for employment opportunities elsewhere. The fact that these nurses and doctors can quadruple the salary they would have got in Greece in a Western European company like Germany makes this a simple decision for many.

The Greek government recently launched an ambitious program in primary care based on establishing personal doctors that act as a first port of call for patients in a similar vein to the general practitioner (GP) system in the UK. This is part of making the overall system more efficient and boosting the country's primary care capabilities and while it is just a first step, it is a clear sign that the country is moving in a positive direction on this issue.

How would you characterise the general market access scenario in Greece and how soon after European Medicines Agency (EMA) approval do new medicines make their way into the Greek market?

Greece performs well on the European Federation of Pharmaceutical Industries and Associations (EFPIA)'s WAIT Indicator and is generally quite good in terms of access to new medicines. This is because we have a government which accepts the introduction of new medicines and is willing to, at least partially, pay for innovation. Secondly, a government owned organisation known as IFET has been established which imports and distributes pharmaceutical products not available on the market either because they are new medicinal products which have not yet obtained state approval or products which have been approved, but their distribution has been discontinued.

However, the good momentum that has been established in the last two or three years will not continue unless the way that mandatory returns are calculated and how the negotiation committee uses those mandatory returns changes. There needs to be a more pragmatic and realistic approach. The negotiation committee demanded a 47 percent discount on average in 2022, which is unworkable for pharmaceutical companies, especially those bringing forward highly innovative medicines. Additionally, Greece is not yet utilising tools seen in more modern reimbursement systems such as pay-for-results, outcome-based arrangements, and managed entry agreements.

The EFPIA's proposal around equity-based tiered pricing (EBTP) whereby all centrally approved innovative products are introduced based on the GDP per capita of each country could also be a good and fair solution to improve access not only for Greece but also for other markets.

Greece has a solid pharma manufacturing footprint, with EUR 1.688 billion in production value in 2020, over 23,000 employees, and recent expansion announcements from both local firms and multinationals. Is this an area that can be developed even further, especially given the rhetoric about the nearshoring of supply chains post-COVID?

There are two sides to this coin. In terms of conventional manufacturing, Greece has at least 42 factories, but only one – that of Boehringer Ingelheim – belongs to a multinational. Many of the facilities owned by Greek companies are expanding and investing in their facilities, both to increase existing production or to create biologics manufacturing capabilities in Greece for the first time. During the height of the COVID-19 pandemic, this strong manufacturing base helped ensure that the country never ran out of medicines. Outside of this manufacturing spending, there have been other important investments, such as Pfizer's data hub in Thessaloniki which has generated over 750 jobs.

However, following the COVID-19 pandemic and the energy crisis coupled with overtaxation, many multinationals are merging business units, laying off staff, and downsizing in Greece.

While the nearshoring of production in Europe to secure supply chains against future health crises is a reality and a great opportunity, this applies more to firms working with generics. Innovative medicines, for now, continue to come from abroad in Greece.

Looking forward, if you take the 47 percent clawback and rebate and add the corporate tax of 20 percent, there is a tax of almost 70 percent, which puts future investments in jeopardy. The government must reduce these mandatory returns, and maybe eventually look to give more incentives to stimulate collaborations of the local factories with the multinational players.

What work is ongoing in terms of bringing more clinical trials to Greece?

SFEE has a working team with the Ministry of Health on how to attract more clinical trials to Greece. Together with PwC, we even conducted a study on this topic, taking lessons learned from other markets and trying to bring them to Greece. Creating more homogeneity of practices between hospitals and reducing bureaucracy is a key barrier that we are working on as we look to leverage the 30-40 of Greece’s 128 public hospitals that are capable of conducting clinical trials.

Will the game-changing progressions in Greek healthcare come from the private or public sector?

In Greece, like all markets, pharmaceuticals is a highly regulated market with heavy state control. There is significant bureaucracy with prices, reimbursement, and hospitalisation managed by a publicly controlled system. Therefore, the government needs to give full authority to the Ministry of Health and the Ministry of Development to press on with the changes that are needed.

However, as in other markets, collaboration between the public and private sectors has already proved to be fruitful. For example, we had success in digitalisation due to the Minister of Digital Governance giving the green light to collaborate with private companies. The Ministry of Health is now also creating a framework for private hospitals to work for the public sector; if a patient needs to receive treatment that cannot be given at a public hospital, they will receive it at a private facility with the public sector bearing the cost. Taking ideas from other countries, Denmark has moved to set up a private company in charge of all the networking for clinical trials [Trial Nation – Ed.]. This is something we could also emulate.

We are communicating to the government this need for greater collaboration, and while we understand the seriousness of the decision for a public entity to begin working with a private sector actor, these partnerships will be vital to future productivity and progression.

What makes you optimistic about the future of your industry in Greece?

Clawbacks remain the hurdle, but under the RRF there is a clawback offset mechanism of EUR 250 million for two years and a cap on the amount that can be clawed back, which is positive. Other sources of optimism include the expansion of digitalisation to increase efficiency, and the evolution of health technology assessment (HTA) committee. This should be expanded from a committee of part-timers to a fully-fledged independent organisation.

Elsewhere, Greece has a strong tourism sector which could eventually create a silver economy, with all the investments that come with it. Additionally, our scientific personnel, doctors, and nurses are world-class, which we could be capitalising more on. Finally, as the Pfizer investment in Thessaloniki, the large factory of Boehringer Ingelheim in Athens and the recent manufacturing investment plans of Greek companies show, Greece has a lot of potential as a hub for Southern Europe and the Balkans in information technology as well as healthcare.

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