Faye Kosmopolou – General Manager, Panhellenic Union of Pharmaceutical Industry (PEF), Greece

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Faye Kosmopolou of Greek generic industry association PEF discusses Greece's potential as a pharma manufacturing hub for Southeast Europe post-COVID, the challenges of overcoming low generic penetration rates in the domestic market, and why she is optimistic for the future of Greek pharma moving forward.

What is PEF, who does it represent, and what is its mission?

The Panhellenic Union of Pharmaceutical Industries, known as PEF, is an association representing 49 Greek pharmaceutical companies. 32 of these companies have manufacturing operations spread across 45 factories, while the other 17 have commercial operations only. Our association was first established in 1935 and since then we have actively engaged in public dialogue regarding pharmaceutical care, healthcare policy, and patient access.

PEF's mission is to ensure the supply of top-quality affordable pharmaceutical products while promoting the growth of the local manufacturing base, both in the Greek market and internationally. Our member companies are recognized as leading manufacturers and service providers in Europe and beyond, exporting to over 140 countries worldwide. This is also one of the reasons why the pharmaceutical industry has been identified as a key economic sector within Greece, generating significant added value for the healthcare system and economy through its highly skilled workforce, intensive investment activity, and ever-increasing export potential.

We contribute EUR 2.8 billion to Greece’s GDP every year, have 11,000 direct employees and generate an additional 53,000 jobs. Additionally, a EUR 1.2 billion investment plan in research and development (R&D) and production projects has been launched for the 2021 to 2026 period.

PEF’s members primarily sit in the generics space, but how important are value-added medicines and biosimilars in Greece?

Our members produce both standard generics and added-value medicines, creating incremental innovations in areas like novel production methods, alternative formulations, new delivery systems and dosage regimes, and new indications of existing molecules. Added-value medicines are one of our sector’s main growth drivers and strong points. While PEF’s members do take a strong interest in biosimilar medicines, the country is still at the early stages of researching and developing these products. Nevertheless, our members are strongly engaged in – and investing in – R&D. We are recognized around the world as leading developers and contract manufacturers and are proud to employ over 800 highly skilled research scientists within our members’ R&D facilities, working in collaboration with academia in Greece and Europe.

Manufacturing in Greece is in full compliance with the rigorous good laboratory practice (GLP) and good manufacturing practice (GMP) regulations set by the European Medicines Agency (EMA). Our research departments are well organized with meticulous quality control systems and products manufactured in Greece have been approved for their quality and effectiveness by numerous national health organizations worldwide.

Generics penetration in Greece is far lower than the EU18 average at 24.5 percent; to what do you attribute this and what measures have been taken to remedy it?

Various initiatives have been enacted by past governments to increase the market penetration of generics. The penetration targets set by the memorandums of understanding (MoUs) in place since 2012 were initially 60 percent before being revised down to 40 percent and have unfortunately still yet to be achieved.

Over the past decade, the Greek government has tried to control pharmaceutical expenditure by setting annual closed budget ceilings. Since 2014, the outpatient pharmaceutical budget has practically been fixed at about EUR two billion, a reduction of 62 percent compared to 2009, when the pharmaceutical budget was EUR 5.2 billion. This was mainly achieved through extensive price cuts, compulsory rebates, and the country's unique clawback system.

After a decade of pharmaceutical policy reforms, it was finally realized that focusing on pricing alone to increase generic penetration is a rather poor choice. The absence of economic incentives for both the patient and the pharmaceutical supply chain, as well as insufficient administrative capacity to control the unjustified switching towards more expensive alternatives, explains the stagnant generic penetration levels. PEF has always engaged in open dialogue with policymakers about the significant savings that generics can produce, releasing financial pressure from constrained public budgets.

All stakeholders have a responsibility in this, just as the State has a responsibility to enact effective policy measures that can create a functioning market with win-win relationships for all stakeholders.

In addition to PEF's advocacy efforts towards the national government and institutional stakeholders, to what extent does the association engage in patient education initiatives?

PEF has consistently engaged in dialogue with all stakeholders involved in the prescribing, consumption, and reimbursement of pharmaceutical products. Our aim is to share the benefits of generic products with patients, payers, and society at large.

To this end, we have launched two major public awareness campaigns since 2013, disseminating critical information around generics and focusing on the safety and quality of the generic products produced by the Greek manufacturing industry. We aim to let the Greek people know that Hellenic (Greek) medicine is safe, effective, and affordable, and is a good solution for the health system, for people and for the economy.

These two campaigns have had a particular impact in terms of changing the public perception of our industry. Previously, the fact that Greece has a robust manufacturing base was not widely known even within Greece, with many assuming that most pharmaceutical products are imported. This has improved but most importantly the trust of Greek patients and national payers in domestically produced medicines and their added value to ensuring access for all has been ever-growing.

Is Greek pharma manufacturing an area that can be developed even further, especially given the rhetoric about the reshoring of essential medicine and active pharmaceutical ingredient (API) supply chains in Europe post-COVID?

We believe that Greece can become the hub for Southeast Europe in pharmaceutical R&D and production. This potential was clearly displayed in Greece's response to the COVID-19 pandemic, when all our pharmaceutical manufacturers embraced a collective spirit of solidarity. Our sector was able to ensure uninterrupted coverage for more than three million patients, which underlines the advantages of having a strong pharmaceutical manufacturing industry. Unlike other EU member states of the EU, Greece did not face medicine shortages but was able to safeguard supply and even export to larger countries like the UK and Germany, which were heavily reliant on imports from low-cost suppliers in China and India.

One of the major lessons learned from the pandemic was that the EU had a fragile supply chain and that there was a clear need to re-shore pharmaceutical and API production within Europe. That is why the EU and its government recognise the need to establish incentives to increase investments in the sector.

In Greece, policy reform around the clawback offset adopted under the Recovery and Resilience Facility (RRF) has allowed our industry to unlock an investment plan amounting to EUR 1.2 billion. This investment will update the capacity of the Greek manufacturing industry, ensuring patient access to affordable and high-quality medicines and also contribute to Europe's strategic autonomy in pharmaceuticals.

Moreover, Greece is the only European country to have included the pharmaceutical industry within its RRF plan, which will allow the inflow of new funds into the country and lead to the opening of 12 new manufacturing sites, 16 new R&D facilities, and 32 new manufacturing units.

Under the clawback rules—which are designed to control public spending on drugs—pharmaceutical companies are required to return funds to the Greek government when public spending on drugs exceeds the amount the government budgeted for this expense. What impact has this clawback mechanism had on the willingness and ability of pharma to invest in Greece?

The clawback mechanism was enacted in 2012, under the first MoU between the Greek government and the EU, initially as a temporary measure. However, since then it has been reinstated three times and this cost containment policy has become a permanent measure that makes the landscape very difficult for all pharmaceutical companies operating in Greece.

In 2012 the clawback amounted to EUR 78 million while just ten years later it has surpassed EUR 1.36 billion. This is an enormous amount and makes life unbearable for all companies, especially Greek ones. The dramatic and consistent increase of the clawback has proven to be unsustainable, a hindrance to local investment capacities, and a significant drawback for foreign direct investment in Greece.

Do you feel optimistic about the future development of the Greek pharmaceutical industry?

I do! The pharmaceutical industry has been one of the leading economic sectors in Greece for over 90 years. When PEF was established in 1935 its aim was to create and maintain a sustainable environment for the pharmaceutical industry in Greece in order to ensure patient access to safe, affordable, and high-quality medicines. Our goal remains the same and our role in the Greek and European market will become even more significant over the next decade. The lessons learned from the economic crisis, the COVID pandemic, and the current geopolitical instability has demonstrated how important it is for any society to have a robust pharmaceutical production base.

Additionally, we have excellent talent in Greece and many of the scientists that went abroad during the height of the economic crisis are now returning home. Moreover, the new investment plans that Greek pharmaceutical companies have launched mean that our sector will be able to generate an additional 2,000 new jobs in the next five years, providing our young scientists with opportunities within Greece. I am proud that as a sector we are contributing to reversing Brain Drain.

The Greek pharmaceutical industry is intertwined with Greek society and adds true value to the economy and to the healthcare sector. We remain a trusted partner of both public and private bodies that are working towards building a healthy society and we aspire to invest in R&D that directly contributes to bettering the quality of life of patients in supporting a more sustainable and healthy society.

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