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It is now once more an attractive proposition to invest in Greek manufacturing and regain some of the momentum lost in the previous decade

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Speaking shortly after the unveiling of a

EUR 55 million investment in a new factory in Keratea as part of a wider EUR 155 million spend up to 2025, ELPEN's Theodore Tryfon outlines the company's ambitious expansion and diversification plans; his hopes for the future of essential medicine manufacturing in Europe post-COVID; and what Greek pharma champions like ELPEN can offer the continent.

Can you walk us through the scale and logic of ELPEN's recent investments and your hopes for their impact on the company's business?

We took a strategic decision for a new major investment, with implementation beginning in 2019, based on the goal of remaining competitive in the European and Greek markets. Like all major companies in our sector, we need to continually upgrade our production and research and development (R&D) capacities to maintain our competitive edge.

Although this plan was laid out before the COVID-19 pandemic, it aligns closely with Europe's post-pandemic institutional priorities. A new agenda is emerging across the continent with a focus on reshoring and repatriating pharmaceutical manufacturing and R&D capacity, both of active pharmaceutical ingredients (APIs) and finished products, to secure supply for European citizens.

This is clearly a long-term process that will take several years, but we are pleased to see that Europe and the Member States are recognising the significance of having a strong manufacturing base within Europe. Nevertheless, setting priorities is only a first step, policies need to be adopted to follow this logic and provide incentives and guidelines that will bring this goal to fruition. Post-COVID, there is clearly an increased demand for ensured pharmaceutical production in order to mitigate the shortages issues that the pandemic highlighted. This needs to be addressed by a more robust and competitive European pharmaceutical manufacturing sector.

ELPEN specifically is adding value to Europe's Manufacturing Base by contributing to Europe's strategic autonomy and ensuring patients' access to high-quality, affordable medicines by increasing and upscaling its existing medicine manufacturing capacities with the new manufacturing facilities in Keratea and Tripoli.

ELPEN has upgraded production capacity and capabilities in its three existing manufacturing plants in Attica and has initiated an additional new plant in Keratea, Attica, near Athens airport. Our new plant focuses on the production and development of inhalable products (for asthma and chronic obstructive pulmonary disease) and solid forms (for cardiac, antihypertensive, respiratory and CNS diseases, antibiotics) that can serve up to seven million patients. It is the only factory in Greece, and one of the few in Europe, that has been specifically intended to manufacture using the most modern eco-friendly propellant gases with a low environmental footprint, in accordance with the newly legislated European directives that will soon come into force.

Additionally, our company is also going to invest in a new production facility for highly potent oral solids in Tripoli. Moreover, ELPEN is working to create in the next years a biotech startup incubator at the Athens LifeTech Park; also providing preclinical trial contract research organisation (CRO) services to large companies; and is focusing heavily on research and education activities.

This plan sounds transformational for a company primarily known as a generics manufacturer. How do you define ELPEN's positioning today?

Becoming more competitive involves diversification, specialisation and transformation. The company has already transformed from a primarily Greece-focused generics manufacturer to an international player with a significant export footprint both in Europe and across the world.

This diversification covers the types of products we develop and produce as well. ELPEN has an increasing focus on combination/hybrid products in the respiratory and cardiometabolic fields

which have a different legal basis for marketing authorisation and can shorten time-to-market, which in our business is crucial. Additionally, our new oncology plant will allow us to enter the highly potent active pharmaceutical ingredients (HPAPIs) formulated into oral solid dosages.

On top of that, through the Athens LifeTech Park ELPEN wants to be a major part of the Greek research ecosystem, collaborating with academia, research institutions, and highly qualified professionals, both in Greece and abroad. There is a strong network of high-calibre pharma and biotech leaders of Greek origin in the US, many of whom want to contribute to their home country through research collaborations.

ELPEN aims to maintain its positioning as a leader in the Greek market while bolstering its footprint internationally, building on the business-to-business (B2B) model that has proved so successful in recent years and has secured some of the largest generics companies as partners in many European markets. The firm now has a direct presence in Germany and is also exploring the possibility of establishing itself more directly in the Middle East and North Africa (MENA) region.

Just how challenging were the financial crisis years for Greek manufacturers like ELPEN, and how much has changed since 2019?

A few others and I could write a book about what happened in the Greek pharma sector between 2010 and 2019! It was an exceedingly difficult period, across all sectors

However especially for the family-owned Greek companies which are major employers of the healthcare sector, supporting our staff was always a priority and one which I am proud to say we were able to maintain, even during these tricky times. While many other businesses downsized, we managed to keep our personnel and even increased personnel funds in areas like production, with the aim of becoming more sustainable and competitive in the long term. However, the larger impact of this period was observed significantly in the decrease of investment capital we had available, due to the low fixed pharmaceutical budget and the high level of clawback returned to the state. Discounts soared to very high levels with many net prices between EUR 2.00 to EUR 3.00 per pack. For local companies, this proved hugely challenging.

Following the economic crises, the pandemic was a second subsequent shock to the healthcare systems and all its stakeholders with significant economic uncertainty for what the next day would look like. However, from 2019, some positive investment incentives were put in place for the first time in many years, due to the increased awareness of the value of our sector and the significance

of fortifying European healthcare systems. Additionally, there has been an increased demand for pharma products and the general economic and political system has become more stable and predictable.

Although clawback predictability remains an issue in our sector, some improvements to the tax system, tax breaks for people coming from abroad, and tax incentives for R&D and production have been welcome. A significant turning point for the Greek pharmaceutical sector has been the recognition by the Greek State of the capabilities of the manufacturing footprint in Greece and its inclusion of the offsetting clawback reform in the national Recovery and Resilience Facility Plan. This policy has initiated a big investment boom from our sector amounting to EUR 1.2Bn.

It is now once more an attractive proposition to invest in Greek manufacturing and regain some of the momentum lost in the previous decade. Greece has a strong manufacturing base with 45 production units – one of the largest per capita in Europe – as well as qualified personnel.

In our 2017 interview you highlighted some of the key challenges in the Greek generics market, including a lack of trust in and awareness of generics, insufficient incentives for doctors and patients to switch to cheaper products, and unsustainably low prices. How has the situation shifted since then?

The situation remains constant with minor improvements. There are still several extremely expensive products entering the market with high volumes, which the still low pharmaceutical budget cannot sustain. Therefore, a strong health technology assessment (HTA) system and negotiating committee needs further progress to determine which products truly add value for which specific patient subgroups. Greece lags behind in this field but has made some progress in recent years.

Additionally, 70 percent of all prescriptions should be older generic and off-patent products with low prices. There should be clear prescription guidelines for doctors on this and incentives for pharmacists. We have seen some progress from the government, in collaboration with our industry association PEF, but more needs to be done. No country, especially one with as large a debt as Greece, can pay for all these new products without creating space by switching to older ones.

Given the challenges of the Greek market can it be a revenue driver for ELPEN? Or is the company simply maintaining a presence out of a sense of social and national

responsibility?

ELPEN has been operating in the Greek market for over 55 years, since our establishment in 1965. We have a long-lasting tradition as a family-owned business to support the community we are in, just as much as the community and our people have supported our growth all these years.

Moreover, our company's core values are intertwined with our social responsibility. Our identity is strongly rooted in our local presence and we are very proud to represent and be ambassadors of Greek pharmaceutical manufacturing not only in Greece but abroad as well. Local companies, and large companies generally, are part of the social ecosystem and foster social cohesion, both by providing employment opportunities and investing in our local research and development ecosystem.

Despite the challenges, ELPEN is a Greek market leader in cardiovascular generics, an area in which we have a long tradition. Being a leader creates opportunities, so yes, Greece has great potential to be financially viable. However, our commitment is not solely based on profit.

Companies that produce medicines like ELPEN have a particular responsibility to fortify patients' access to medicines and we have been committed and will remain always committed to this goal. Most recently, the whole of the Greek pharmaceutical industry worked together to cover the shortages created during the COVID-19 pandemic when imports of antibiotics and APIs from India and China dried up. Despite the extremely low margins this generated, we were willing and able to fill the gaps and produce in Greece for Greece and other EU countries.

What are your hopes and expectations around reform at a European level, especially given the strong role local manufacturers like ELPEN played in avoiding essential medicine shortages?

Pre-pandemic, Europe went to an extreme focus on driving cost containment solely by driving down prices. Currently, ELPEN, is actively participating in EU discussions regarding the new pharma policy expected to be adopted by the Commission this year, not only as a leader in the Greek market but also as a member of the European association representing generic and value-added medicines, Medicines for Europe. I am currently both President of the Panhellenic Union of Pharmaceutical Industry and an Executive member of the Board of Medicines for Europe.

There are currently several ongoing discussions between Medicines for Europe and the EU about reforming the procurement, pricing, and reimbursement systems to ensure that price is not the

only criterion in discussions. We hope that Member States will recognise the necessity to reform systems to take into consideration other factors other than only price such as security of supply in their procurement practices and ensure companies in Europe can continue providing medicines, ensuring resilience and security of supply.

Greece is set to receive EUR 30.5 billion from the EU Recovery & Resilience Facility (RRF) as part of its pandemic recovery, with healthcare funding being channelled into digitalisation, primary care reform, and a clawback offset for manufacturing and R&D. From your perspective, how well is this new income stream being allocated and are there potentially areas it could better serve?

Greece has achieved great steps forward in digitalising many aspects of its public sector in recent years and, as part of an industry that is rapidly seeing the benefits of digitalisation, automation, and artificial intelligence (AI) adoption, even more investment in digital tools makes perfect sense.

The tax deduction reform for R&D investment adopted in the national RRF plan is a good example of how industry and State can collaborate to launch new investment capacities. In fact, the pharmaceutical sector has been the first successful sector to absorb funds from the Greek national plan, with 53 investment projects being approved in the first year. However, current incentives do not go far enough given the monumental clawbacks we have to give to the state. Thus more needs to be done. Moreover, given the ten-year crisis and subsequent loss of investment capital we suffered, there is a need for fast-track policies. Without radical and rapid reform, the critical mass of investments that Greece needs to solve the long-term issues in its economy will never come to pass

With general elections approaching, in Greece, are you confident that whichever government is in power will have an open ear to the pharmaceutical industry’s concerns?

I strongly believe that the proposals by the Greek pharmaceutical industry create significant local added value for the economy and ensure patients’ access to uninterrupted access to their therapeutic treatments. We create employment opportunities, exports to decrease the deficit, supply pharmaceutical products to patients, and collaborate with academia through research projects.

I believe that our industry’s local added value is supported by all political parties that want to encourage growth and competitiveness.

How difficult is it to find and retain the talent you need in Greece in order to support ELPEN’s future investment plans for growth?

Brain drain has been a problem in the Greek community for many years, as many talented young university graduates left Greece during the crisis. However, opportunities in the pharmaceutical sector have opened the road for many talents to return and we are proud that we are contributing to our national brain gain once again. As President of PEF, I can ensure that one of our highest priorities is establishing opportunities for young scientists to find jobs in our local industry. We established PEF’S Professional Development Programme in 2022 with Greek universities on quality assurance, regulatory issues, and R&D, which is helping us develop talent for our industry. This is a cornerstone of our policy and strategy and will allow Greek pharma to retain more of its young people.

What is your final message to our international audience about where Greece stands today?

I strongly believe that Greece has all the potential to become a hub of pharmaceutical R&D and production for its region. This is why Greek companies such as ELPEN, have launched significant investment plans. For companies that want to invest, there is a stable tax system, tax incentives, qualified personnel, and a large manufacturing footprint. Greece is also a secure country with great weather and culture and an increasingly attractive destination for remote professionals. For all these reasons, I urge international companies to invest more in clinical trials in Greece, engage in more contract manufacturing with Greek companies, and also engage in some joint ventures with them.

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