Evangelos Zekkas – President & Managing Director, Help Pharmaceuticals

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Evangelos Zekkas outlines Help Pharma's internationalisation journey in recent years, with the Greek firm's exports now accounting for 60 percent of production and 50 percent of turnover. Zekkas, the company's long-serving president and managing director, also gives his thoughts on Greek pharma's role in Europe post-COVID more broadly, the challenges of the domestic generics market, and the policy reforms needed to ensure sustainable access to pharmaceuticals for all.

Can you start by giving our audience a brief introduction to Help Pharma and an overview of its business performance and development in recent years?

Help S.A. was established in 1971 and has been an important Greek pharmaceutical company for more than 50 years. The company has since come a long way, as its activities currently include the development, production and distribution of pharmaceuticals, medical devices, food supplements and cosmetics, for both Help and currently some 45 other companies, thus having obtained significant know-how in these areas. One of the strong points of the company is that its para-pharmaceutical production can benefit from the same EU-GMP standards of the pharmaceutical products in the factory.

Help has its own 8500 m^2 manufacturing facilities in Pedini, Ioannina, a location that facilitates the transportation of products to the Balkans, Western Europe and Asia *via* Turkey. The company has been investing in the current facility since 1984, continuously improving its manufacturing capabilities. The last investment programme of EUR 4.0 million was completed in 2022, with an emphasis on creating a new modern QC laboratory capable of supporting both manufacturing activities and any research and development projects undertaken.

Regarding pharmaceutical forms, the company manufactures sterile solutions (injectables in vials and ampoules), nasal sprays, oral solutions (syrups, suspensions and oral drops), solid forms (tablets, capsules, sachets, pellets) and semisolid forms (creams, gels, ointments and suppositories).

For product development, the company utilizes its own staff, however, it also has close cooperation with local institutions. In particular, Help is enjoying a very close cooperation with the University of Ioannina, also located in Pedini, with a large portion of the scientific personnel of the company being its graduates and with collaboration in a number of research projects. In parallel, Help is in a position to readily utilise the considerable university infrastructure to support demanding projects.

Help also has substantial know-how on exports, as it has been one of the first pharmaceutical companies in Greece with export activities, for more than 35 years now. Due to the 2008 crisis and its effects on the local pharmaceutical market, the company has given an increased focus to exports over the last few years. As a result, today it holds 170 MAs in 53 countries, with 2022 exports reaching 60 percent of production and 50 percent of its total turnover.

In Greece, the company has more than 150 MAs but also has significant agreements with some multinationals for the promotion and distribution of their products in Greece. The company’s network of sales representatives covers the whole country and is focused on the areas of

pulmonology, GP, cardiology, diabetes, and gynaecology.

Given Help's increasingly strong manufacturing footprint and the rhetoric about the nearshoring of essential medicine and ingredient supply chains in Europe post-COVID, what role do you foresee for Help (and for other PEF member companies) in Europe moving forward?

I believe Help, as many PEF member companies that maintained and increased manufacturing capabilities for FDFs all these years are well-placed to cope with increased demand, which we are already observing.

In order to cope with this, Help is undertaking a number of actions, including:

- Strengthening our infrastructure in order to enhance our capabilities for the supply of contract development/manufacturing services.
- Investments in selected production lines, such as currently in injectable products (ampoules and vials)
- Interventions in supply chain management, in order to minimise risks from lack of materials or increased supply times.

With regards to manufacturing, there is a need to re-evaluate policies regarding the stock of critical materials, selection criteria of suppliers and alternative approved suppliers to mitigate potential issues stemming from a problematic supply chain. Price alone should not be the only criterion for the selection of a supplier, as we are now feeling the long-term results of such a model.

In parallel, it is much more important for Europe to finally learn from this, ensuring the uninterrupted supply of essential medicines to the local population by following similar criteria in its supplier selection.

With 60 percent of Help's production exported to more than 35 countries worldwide, how are you looking to further develop operations beyond Greece's borders?

One of the key advantages of the company, which has facilitated our export activities has been the suitability of our factory's location. The location of the factory favours road transportation to the Balkans, Italy and Asia, since it is located an hour away from the northern border of Albania and Igoumenitsa port, but is also located next to Egnatia Odos, the main highway to Turkey.

Furthermore, there are several more infrastructure investments underway in the Region, including the modernization of the airport in Ioannina and the port in Igoumenitsa. With an expanding infrastructure in the region, cargo transportation costs are expected to be reduced, thus permitting further development of our export activities.

At the same time, our factory is the only pharmaceutical manufacturing facility in the Epirus Region, the region with the lowest percentage of employees in Greece and among the lowest in the EU. This allows us to tap into several funding opportunities for upgrading our manufacturing capabilities to accommodate increased demand, improve competitiveness and further support our export activities.

Having significant experience with several companies and countries over the years has enabled us to offer customised cooperation models to our partners, taking into account their specific needs. Our current cooperation models mostly include contract developments with or without tech transfer, co-developments, contract manufacturing, and out-licensing services (with our own MA or private label), however, we have a lot of flexibility in our partnership models and are always open to discussing new types of cooperation.

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?

As Greece maintains a pretty healthy generics industry, with significant exports to many parts of the world, we can certainly claim that the reasons for the small generics penetration in the country have nothing to do with the quality of its products or the size of Greece’s industry in the sector.

For Help in particular, in the past 5 years, a number of factors have affected the company. The COVID-19 pandemic and resulting disruptions in production and mainly in the supply chain, followed by considerable price increases in energy costs were added to an already troubled Greek pharmaceutical market, already stretched by low prices and clawback that currently exceeds 40 percent on average. The combination of low prices and high clawback has made several generic products non-profitable, which had to be withdrawn from the market.

On the other hand, our presence in the Greek pharmaceutical market over the past 50 years offers us a significant recognisability and specialisation in certain therapeutic categories, elements that have enabled us to sign promotion and distribution agreements with large European generics companies. In this way, we have managed to maintain our position in the Greek market despite the

withdrawal of a number of such products.

How challenging is it to remain competitive and profitable in such an environment?

Unfortunately, the conditions that have shaped the landscape of the pharmaceutical market in Greece over the last decade are particularly difficult for a generics company and our ability to intervene is limited. We believe that very careful choices must be made with regard to investments in the development of new generic FDFs. In general, a very cautious design of the product portfolio is required, which should contain a healthy mix of Rx and OTC products, reducing as much as possible the dependence on sales of Rx products.

Our current turnover does not rely on generics sales in Greece to the extent it did in the past, while there is also a significant distribution of our turnover to several regions in the world, which is an important parameter due to the geopolitical instability experienced in recent years.

Greece seems to be on a 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 your views on this positive economic upturn and what do you see as the challenges and opportunities of an uncertain political situation with elections looming later this year?

It is certain that the business environment is much more secure under the financial and political conditions that have been developed over the past few years in Greece. We hope that the stability that has been achieved is maintained over the following years and especially after the upcoming elections.

In any case, it is necessary to drastically re-evaluate the pharmaceutical legislation and in particular the rebate/claw-back regulations, thanks to which there is no pressure on the system to rationalise prescribing, as all waste is directly charged to the pharmaceutical companies. This should go hand in hand with measures to increase the prescription of generic products, ideally also ensuring near-sourcing of essential medicines. Maintaining the current system is undermining the foundations of the pharmaceutical industry in Greece and poses a serious threat to its development, but also to the sustainability of the health sector in general.

Greece is set to receive EUR 30.5 billion from the EU Recovery & Resilience Facility (RRF) as part of its economic recovery from the COVID-19 pandemic. Funds have been earmarked for the green transition; digital transformation; employment, skills and social cohesion; and private investment and economic transformation. What are your hopes on how this funding will be spent, and its impact on pharma/healthcare in Greece?

We are very hopeful that the funds from RRF that will be directed to the Healthcare sector will be addressing long-overdue needs in primary care and the digitalisation of hospitals. Both will address significant inefficiencies of the system.

However, at least some of the funds from RRF should be used to reorganise pharmaceutical expenditures. No particular care has been given to the pharmaceutical budget over the past years to accommodate for the significant introduction of new medicines, increased prescription needs due to the ageing population, or rising costs. Consequently, the budget has remained at approximately EUR two billion, a fraction of what it was 15 years ago. In parallel, we can observe a geometric increase in clawback, from EUR 78 million when introduced ten years ago to 1.36 billion, as clawback essentially compensates for the inadequate budget. As cheaper drugs are displaced from the market due to non-profitability from a combination of low prices and high clawback, they are replaced by more expensive alternatives, thus having an even greater increase of clawback. With clawback already accounting for more than 40 percent of total pharmaceutical expenditure it is clear that immediate measures need to be taken in order for the system to remain viable.

Do you have a closing statement for PharmaBoardroom's international audience?

Pharmaceutical coverage of the population is essential for social welfare and cannot be overemphasised, particularly after what we have been observing with an increasing frequency over the last few years. There are significant lessons to be learned by everyone, on a company, national and EU level and I hope specific steps are taken in a timely manner.

The need of patients to access essential medicines and the change in European pharmaceutical policy should guarantee the resilience and competitiveness of the pharmaceutical industry, in order for it to be able to cover the needs of patients and healthcare systems.

In light of the upcoming relevant regulation on the European pharmaceutical policy, it is important to provide incentives to the pharmaceutical industry to invest in the manufacturing of its products

within Europe, ensuring a sufficient supply of medicines to the European population.

In this direction, it is necessary to enhance the production of FDFs and APIs in Europe, as during the pandemic several drug shortages were observed in essential medicines. During that time, Greece did not encounter similar issues, in spite of its more precarious financial position, as its strong manufacturing base allowed it to compensate for any shortages.

It is also important to recognise the strategic importance of the pharmaceutical sector in any European emergency plans and to ensure that measures are taken to minimise impart in the cost of goods, but also to reform the models of supply and pricing of pharmaceutical products.

In this direction, there is still a need to balance the EU’s environmental targets and European drug policies with the aim of avoiding the creation of obstacles to patients’ access to essential medicines and treatments.

In the end, with regards to the company, the differentiation of its sources of income, the significant experience obtained over the years in the whole chain of development, manufacturing and distribution but also the spirit of cooperation with the other Greek and foreign partners allows Help to persevere through these challenging times, setting the groundwork for bigger growth in the future.

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