

Marianna Konstantinidi - General Manager, CSL Behring Greece



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Compassion resonates through the voice of Marianna Konstantinidi, General Manager of CSL Behring Greece, Malta & Cyprus, as she speaks about the resilient and patient-centric operations of the Greek affiliate. She graciously shares her views regarding her first impressions of the plasma market, the challenging environment in Greece, as well as navigating the market of the future with agility and heart.

Ms. Konstantinidi, having only recently assumed the position of General Manager for Greece, Cyprus & Malta, what are your first impressions of the Greek plasma market in the last year and half (especially in comparison with the commercial roles you have held at big pharma)?

The plasma market differs significantly from the conventional pharma market. What is unique about the plasma market is that its raw material is finite, which impacts the capacity for the production worldwide. It is difficult to produce at a very high volume and rate at the global level – which vastly differs from conventional pharmaceuticals. A challenge in the plasma industry is that for certain products the global demand is greater than the global supply, which is universal challenge for the global markets as many countries are essentially competing to have sufficient supply for their patients.

How is the global CSL portfolio represented in Greece?

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In Greece, we offer the main plasma fractionation products. Many of the specialty products that we market are for rare diseases, like BERINERT[®] for patients with Hereditary Angioedema, a very rare but life threatening disease. We have also added recombinants for hemophilia in our portfolio, although they have yet to be launched and are expected to be in the market in the next years.

The first recombinant product of CSL registered in Greece is the orphan drug IDELVION[®], an albumin fused factor IX protein for hemophilia B that can be administered once every two weeks in some patients. We recently obtained marketing authorization for AFSTYLA[®], a recombinant factor VIII- the first and only single chain product for the treatment of hemophilia A, indicated both for children and adults

CSL Behring fractionates millions of liters of plasma every year and offers the broadest portfolio in the plasma derivative market. We are continuously improving our efficiency, both in production as well as in the research and development area by introducing new products every year.

What are the key growth drivers in Greece?

In regards to growth, the key drivers are intravenous immunoglobulin and the specialty products mainly for bleeding – such as factors for hemophilia and other bleeding disorders and rare diseases. We also have products that are unique for the Greek market such as the anti-tetanus immunoglobulin.

How has the Greek plasma market been affected by the economic crisis as a whole?

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The Greek economic crisis has been a major challenge. It has been more impactful to the plasma industry because it has higher production costs than conventional pharmaceuticals. Firstly, sourcing plasma is very difficult as it is very expensive to collect. These expensive source materials comprise a much higher portion of the therapy's cost than the chemicals used in pills and tablets. Biotherapies also undergo rigorous safety controls and inspections throughout every step of the year-long manufacturing process, from the [collection of plasma](#) to the final packaging of the finished product. Given that margins are already lower than conventional chemical pharmaceutical products, all the additional costs greatly impact the business operations and its profitability.

Working with the public sector in Greece means that you are subject to the volatility of the economic conditions. For example, in 2011, the PSI (Private Sector Involvement) was implemented,

wherein debt-restructuring programs profoundly implicated many pharmaceutical companies that were selling to the public sector, since the Greek government paid them in bonds. This impacted also the plasma industry where some products were withdrawn from the Greek market following the PSI. CSL Behring managed to continue to market the most important products in the Greek market to serve the Greek patients, despite the negative economic environment.

What are the key challenges in bringing innovation to Greece, especially for the plasma market?

Market access is a challenge for the blood derivatives in particular. Greece is not an attractive country for pharmaceutical companies due to the very low prices and all the mandatory discounts and rebates, as well as the continuously changing environment. It is especially challenging for the plasma industry where the production costs are high and the global supply is finite. Therefore, it is very important to find ways to secure access to treatments for Greek patients with serious and life threatening diseases. Imposing excessive mandatory rebates and discounts may hinder the access of new innovative blood derivatives to the Greek market.

Christos Dakas, General Manager of Shire, told us that drugs for rare diseases should be exempted from clawbacks and rebates as they typically have no available alternative. With a limited alternative option of plasma-based biotherapies for certain diseases, do you share this view?

It is certainly the stance of CSL Behring, as it is the stance for SFEE, to advocate for the exclusion of certain categories of highly-specialized medicines from the closed hospital budget by the government. We back the request to exclude plasma protein therapies (PPTs) also known as plasma derived medicinal products from the hospital claw-back mechanism. These are products for serious or life threatening rare diseases and the excessive clawbacks, rebates and discounts imposed may result in discontinuation of patient access to these products. For plasma derivatives, we cannot absorb both the rebates and the additional 32 percent hospital claw-back and sustain a margin to keep the business afloat. A 32 percent hospital clawback rate means that one in three products sold in Greek hospitals are given for free from the industry. This is not sustainable for plasma derivatives in general.

It is evident that there is a concerted intention by the industry and the government to move towards more structural reforms, yet the execution is lacking. Why do you believe this is so?

In my personal opinion, short term horizontal measures such as the hospital clawback were enacted as a means to reduce hospital spending and keep pharma companies accountable for the excess. However, patients in need of PPTs are clinically determined and the issue of induced demand cannot be applied to these patients and their treatments. It is astounding to believe that the hospital budget can decrease from approximately 730 million EUR to 570 million EUR in just one year, especially when the 730 million EUR were already 60 percent lower than in 2009. Hospitals are clearly struggling, as well as the pharmacies in them. This relays the issue back to the industry at large that is implementing solutions with a lack of a proper set of rules.

In order to have more balanced and sustainable legislation, there needs to be a rigorous multifaceted process which looks into factors such as the prevalence, incidence, population statistics, as well as prescriptions guidelines and protocols in place. There needs to be a more holistic approach to healthcare expenditure. As an example, regulators and the government need to account that a more expensive product might mean an opportunity cost of less hospital visits in the future, as well as having the patient as a contributing member of the economy by living longer and healthier. Policies that seek to achieve budgetary savings should thus take into consideration how their implementation impacts access to care for a small group of patients with rare diseases as well as the long-term capacity of the plasma protein therapeutics industry to innovate.

Despite the challenges in the Greek market and the bureaucracies it must navigate, CSL Behring stayed. What explains the level of commitment of CSL to this market?

We are committed to our patients first and foremost. Though the landscape is tough, CSL Behring has been present in Greece since 2003 as an affiliate, and our products were distributed in the country before that. We have products that are unique and we see the clear needs of our patients. CSL Behring was definitely impacted by the crisis, and we had to restructure our affiliate back in 2012. The reality was as hard for us as it was for many other companies in the market. However, this was a way to keep the affiliate running, while ensuring that we will remain here to service the needs of our patients with life-saving products.

How is the CSL Behring brand perceived in Greece?

Traditionally, we have been a company that kept a low profile in Greece. However, lately we are making efforts to increase the awareness of the company in the healthcare sector. Despite the fact that there is still low recognition of the name itself due to our specialization, the quality of our products speaks for itself and our patients and physicians know the company very well. Nonetheless, we are more cognizant of the need to become more extroverted and are gradually

implementing measures to do so.

In December, we had an excellent opportunity to celebrate our company's centenary in Athens under the auspices of the Australian Embassy in Greece.

For the future, where do you foresee the growth path for CSL Behring in Greece?

CSL has not attained its full potential in Greece and therefore it stands at a critical juncture to bolster its positioning in the market. I believe that by 2020 the Greek economy will have recovered, many of the new products in the pipeline would be realized and further investments would be made to foster its growth- provided that the Greek healthcare system would continue to support innovative therapies. I am confident that we will be in a much better position giving the resiliency that the company has already shown over the course of some very difficult years.

My ambition is to see our products reach more patients in need and to have one of the best and highly motivated workforces. Ultimately, I often like to say that CSL does not only stand for Commonwealth Serum Laboratories - it also stands for Committed to Saving Lives, which is what we do every day that we come to work.

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