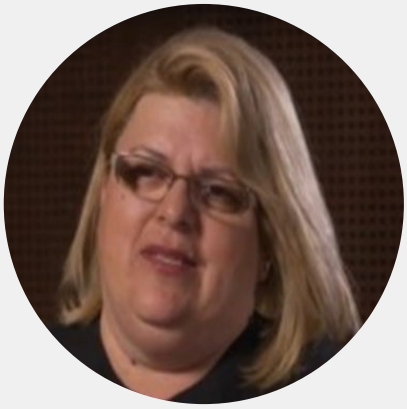
Arina Gholmieh – General Manager, Egis Romania



We are passing through difficult times for generics companies in Romania

03.04.2020

Tags: Romania, Egis, Generics, Biosimilars, Market Access, Strategy, CEE, Coronavirus

Arina Gholmieh introduces the Romanian affiliate of Egis, a leading pharma manufacturer in the Central and Eastern Europe (CEE) region. Gholmieh highlights the difficulties that pharma companies, and especially generic producers, face in Romania: clawback tax, pricing methodology, and a low penetration rate of biosimilar medicines.

You have an impressive and long-standing career in the pharma industry – most of it at Egis. Please introduce your background and leadership to our international readers.

I am a physician by training, specialized in paediatrics. I joined the pharma industry in 1997 and started working at Hemofarm, now part of STADA. To be honest, I didn't plan to stay in the pharmaceutical industry for long, but one year later, I joined Egis and it has been over 20 years since then. I started as product manager, before becoming marketing manager, and then general manager starting 2013. After so many years, not only can I say that I am deeply devoted to the company, although it can be hard sometimes to find the right work-life balance, but I can say that Egis Romania grew under my watch.

What have been the main challenges that you have faced while leading the affiliate?

Unfortunately, in 2013 the former GM of Egis Romania passed away and I took on the responsibilities of leading the affiliate without being fully prepared to manage the whole business. I had to learn on my own and on the go, which was definitely a challenge.

After a short period of time, we had to face the pricing correction in 2015, which, corroborated with an increasing claw-back, had a strong impact on the profitability of several products. Like most pharmaceutical companies, Egis had to go through a restructuring process and had no choice but to let go a significant percentage of its people. This was the toughest period of my career as GM. It was not easy to regain the trust of the people after such a big restructuring.

Since then, my focus has shifted towards maintaining a sustainable growth and capitalizing on the opportunities occurred. Now, I see that this was the right way to go in order to ensure the stability of the company, of our employees, and of our results. We have managed to set and fulfil ambitious yet realistic goals year after year; as well as establishing a sustainable portfolio as a solid base on which we are building the growth of the affiliate.

In our conversation with Valentina Băicuianu and Adrian Grecu on behalf of APMGR, they mentioned that the characteristics of the Romanian market put generic medicine producers under great pressure and risk. What are the main challenges faced by generic pharma companies in Romania?

We are passing through difficult times for generics companies in Romania. There are three main challenges that the industry faces nowadays.

The first is the clawback tax – the main burden for the pharmaceutical industry – and its growth over the past few years. It appeared in 2009 as a temporary measure in the context of the economic crisis. For more than 11 years, the pharmaceutical industry has supported this “temporary” measure, as a gesture of solidarity with the government. Meanwhile, the clawback tax has become permanent and a stable and predictable revenue for governments, as well as a safety net for lack of effective drug budget management. However, 11 years have passed, and not only that clawback is still here, but it has increased significantly.

It is not fair that generic players are obliged to support innovation to the same extent as the innovators. By their very nature, generic drugs offer increased access, but they also facilitate budget optimization.

Generic medicines usually have more affordable prices, and the fact that we pay the same percentage of clawback tax and the computation is made on the consumption including the margins of wholesalers and pharmacies, means that our products are more affected. The lower the prices are, the higher corresponding margins of WS and pharmacies, which means that the higher % of clawback is applied on cheaper products. Consequently, we have had to review our portfolio and withdraw some valuable products or sometimes, even keeping certain medicines with negative contribution on the market just because they were the only alternatives for the Romanian patients. But from the business perspective these products eroded the profitability of the overall portfolio.

Secondly, we face a pricing methodology that sets the lowest price among 12 reference countries. In combination with the clawback tax, this creates a painful situation in which the Romanian patients do not have full access to medicines. I think this policy should be reconsidered.

Thirdly, there are several barriers to biosimilars penetration in Romania. Egis promoted and distributed the first biosimilar monoclonal antibody approved by the European Medicines Agency (EMA), a product containing infliximab as active substance, which was followed by the launch of other biosimilar medicines Rituximab, Trastuzumab, and Pegfilgrastim. Unfortunately, although biosimilars are of crucial importance to the patients – they have more affordable prices than innovative medicines, which allows that a higher number of patients could be treated with the same budget, still, their penetration rate is only four percent in Romania Here is the paradox! Because in rich countries, such as Norway, where the government is interested in the potential budget savings and the potential higher number of patients treated, the biosimilar penetration rate is over 90 percent. In this context, it would make sense for the Romanian government to support and increase the penetration rate of biosimilar products, which could help the Authorities in the process of budgetary optimization they have to proceed to and treat with the same budget a significantly higher number of patients.

How is Egis contributing to overcoming these issues?

Due to the fact that lately the situation became unbearable, there has been a historical alignment between generics companies, innovators and local medicine manufacturers to tackle the clawback situation. Egis is a board member of the Association of Producers of Generic Medicines in Romania (APMGR), which, together with the other industry associations has proposed a scenario with a differentiated and capped clawback tax: 25 percent for the innovative products and 20 percent for generics. Let’s hope that there is a real will to find a solution. Otherwise, for sure that all the

companies will be obliged to withdraw from their portfolio and from the market a significant number of products, in which in fact will negatively impact in the end the Romanian patients.

Another topic under discussion between APMGR and the government is the penetration rate of biosimilar products. The association is part of a working group established together with the authorities that allow us to communicate and present our proposals in our endeavour to solve the existing situation. But several times we passed the message to the authorities that it is the moment to make decisions and to do real things – measures should be implemented for the benefit of the patients.

Egis is one of the leading generic pharmaceutical companies in CEE. What is the scope of the therapeutic areas covered by Egis in Romania?

Cardiovascular area is a traditional presence of Egis in this field where the company developed value-added products – fixed-dose combinations which from the point of view of increased compliance and adherence are serving better patients' needs.

We entered the biosimilar field at a very early stage, and we hope to develop it in the near future. This year we have launched Pelmeg (Pegfilgrastim) in Romania. Unfortunately, the current barriers affecting the retail and tender products will challenge the intention of continuing to launch new biosimilar products in Romania.

There is a growing interest in the over-the-counter (OTC) & food supplements segment, where there is no clawback tax. In this category, I have to mention the brand Betadine, which is among the few disinfectants registered as medicines in Romania and belonging to OTC category – a reliable product which proved its efficacy and gained its notoriety in more than 20 years of safe usage. In the coming years, we have several product launches planned, which will strengthen our presence in the biosimilar segment, as well as in the fields of cardiology, diabetology and oncology. We would also like to enter new areas.

What is the strategic significance of Egis Romania to the organisation?

Egis Romania is an important entity for the mother company. We are the fifth-largest affiliate globally and the fourth when looking at the CEE region. The importance of the Romanian affiliate consists of a well-balanced portfolio, a wide range of products and, continuous sustainable growth.

In 2019 Egis Romania grew by nine percent. Of course, our potential growth opportunities are linked not only to our products but also to the business environment. On the short term basis, I expect that Egis Romania will preserve its position globally and within the CEE region.

After holding the position of GM for almost seven years, how would you describe your leadership style?

I believe in the value of a participative leadership. I am not the kind of leader that imposes his own beliefs and opinions; on the contrary, I expect people to be committed to the company and to our results. In order to achieve this, they need to be part of the decision-making process. Therefore, I encourage them to share their ideas so that they can be more involved, but in the end of the day, everyone must implement the decisions that we make as a team.

What are your future expectations for Egis in Romania?

In the short-term, I wish for all of us to overpass the crisis generated by the coronavirus pandemic and to be able to restart our activity with full power as soon as possible. Of course, on a medium- to long-term basis, I look forward to strengthening our presence in the traditional therapeutic areas but also to be able to penetrate new areas, serving a wider group of patient’s needs.

With regard to the business environment, I have some wishes as well. As a board member of APMGR, I look forward to the implementation of the measures needed to ensure the viability of generics on the Romanian market. These measures include the introduction of a differentiated and capped clawback, growing penetration of biosimilars allowing budgetary optimisation, and new pricing policy to ensures wider and preferential access to treatment for Romanian patients.

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