Interview: Ksenija Pavletic – CEO PregLem & President Gedeon Richter, France



05.11.2015

Tags: France, pharma, pharmaceuticals, exclusive insights, R&D, Gedeon Richter PregLem, womens' health, Esmya, uterine fibroids, Innovation, manufacturing

The president of Gedeon Richter France and CEO of PregLem, a Swiss-based biotech company acquired by Gedeon Richter in 2010, discusses the exciting synergies that have emerged from this partnership in the past few years, her perspective on market access in France and the challenges and opportunities she has faced in her international career with both big pharma and start-ups.

In announcing the acquisition of PregLem in 2010, Erik Bogsch, group CEO, said the deal represented a tremendous strategic opportunity to strengthen Gedeon Richter's core women's health business in the main European markets. What is PregLem's strategic importance to the group?

PregLem was set up as a small, innovative start-up dedicated to women's health. We currently have several compounds in development, one of which one has been commercialized, Esmya. This product is first-in-class treatment for uterine fibroids, which represents a true innovation because prior to Esmya, the only treatment was surgery, which was often quite drastic (hysterectomy). Uterine fibroids is an extremely common condition, something that over 50 percent of women over the age of forty have. Apart from methods that relieved the symptoms, like surgery, painkillers and some forms of contraceptives, there was no medication developed for this condition.

Initially, Gedeon Richter had a focus on generics and was particularly strong in Central and Eastern Europe. In the generics business, however, one competes primarily on cost and Europe is definitely not the best place for this; one has to move to developing countries such as China and India to remain competitive. For Gedeon Richter to stay in Hungary, they needed to reorganise their portfolio. Thus, over a decade ago, they made a strategic decision to enlarge their portfolio to include biosimilars and specialty pharma, in order to become a true European company. We currently derive a third of our sales from gynaecology. The acquisition of PregLem offered Gedeon Richter an innovative portfolio of products in this area.

In turn, what did Gedeon Richter bring to PregLem?

The partnership is mutually beneficial. Most directly, as a mid-sized pharma company, Gedeon Ricther offered PregLem the financial resources and infrastructure to further develop.

The most attractive element of our partnership, however, was their interest in not just our technology but also our know-how and expertise. For us, this was an assurance that they will not simply acquire the company and fire everyone in PregLem, but rather, would assist the PregLem team to achieve their full potential. Most notably, they have helped us develop Esmya for long-term use, which was approved in May 2015. Esmya was initially developed for short-term use, because the process is simpler and as a small company, we decided a more prudent approach was warranted. But the real potential in Esmya was in long term treatment, and with Gedeon Richter's support, we achieved this.

What was also excellent for PregLem was the fact that Gedeon Richter acquired the Grünenthal oral contraceptives portfolio shortly after the acquisition of PregLem. This was an already commercialized portfolio, which meant that it helped consolidate Gedeon Richter's presence in women's health. Given that PregLem did not have any compound on the market, the acquisition of a mature portfolio generated the revenues to sustainably support PregLem's development.

What has been the challenges in creating synergies between the two companies?

Any transition of this scale is never straightforward. Gedeon Richter and PregLem had very different cultures, which meant that there was a lot of adjustment to be made on both sides. For PregLem, we had 22 employees, with a real start-up mentality that differs significantly from a company of 10,000 employees. Gedeon Richter recognized the need for innovation and sincerely wanted to innovate, but there is some adjustment to be made with the adoption of an entrepreneurial mentality.

For instance, they needed to adjust to the increased length of time and effort it requires to see concrete results from innovation products. This applies particularly to pricing and reimbursement decisions. For Gedeon Richter, product launch has never been an issue because they are producing cost-effective generics; obtaining regulatory approval was very quick. As a result, they were launching products consistently and on products where the return on investment (ROI) materializes in two years. With innovative products, the ROI is usually three to five years, or even longer. This is part and parcel of the innovation process, and it had to be taken into account.

Gedeon Richter is a relative late player in the fields of gynaecology and reproductive health, where many other pharmaceutical companies are present. Why did Gedeon Richter decide to enter this field and how successful have you been, particularly given the possible negative perception surrounding the 'Eastern Europe stamp'?

Undoubtedly, Gedeon Richter is starting to be a real player in women's health, particularly in France and more broadly, in Europe, despite its youth. In France, the affiliate was only set up in 2012. We launched Esmya in August 2013. Doctors have only heard about Gedeon Richter for just over two years. We conducted a recall study six months ago, and we are perceived as the third-best company in terms of science, ethics and innovation, behind Bayer and MSD, which is an amazing achievement and testament to our successful entrance.

Gedeon Richter is establishing itself in the gap left in the aftermath of the departure of big pharma after the 'Million Women Study' in the late 1990s and early 2000s, where a key finding was that women currently using hormone replacement therapy (HRT) are more likely to develop breast cancer than those who are not. This had a huge impact on HRT and women's health as a field more generally, and many pharma players fled this market. The decline of investment was keenly felt. Before Esmya, the last product launch in fibroids treatment was twenty years ago. There are still existing big pharma companies in these fields, but the critical fact is that they are simply capitalizing on their existing production and portfolios, they are not investing in innovation. Thus, the dominant strategy for Gedeon Richter is to establish their brand as an innovator in this field, a long-term partner of choice for doctors and an expert in women's health.

It is a bit of a myth that there is still a significant negative public perception surrounding pharmaceutical production in Central and Eastern Europe. The image of Central and Eastern Europe has improved significantly. Gedeon Richter has also dealt with this issue very shrewdly in the acquisition of PregLem, by allowing PregLem to retain its brand within the group. As a Swiss-based biotech company, our brand lends Gedeon Richter its name and reputation. The image of Gedeon Richter in Western Europe is currently built on the ex-Grunenthal portfolio and Esmya

brands, so we have also managed to sidestep this issue in this way.

France is often considered one of the most difficult markets to launch new products in. Gedeon Richter notably has a very strong pipeline of innovative products. What has been your experience of market access in France?

France is one of the most challenging markets for market access. The authorisation process in France is lengthy and there is also a lack of transparency that makes it very difficult for companies. With the European Medicines Agency (EMA), the company is entitled to ask for clarifications regarding EMA's decisions, and a meeting will be set up between the company and the key personnel (*rapporteur*) in charge of the particular dossier. We can ask for a clarification if we do not understand their concern and we can meet them to discuss. This interaction between the agency and the company is not allowed in France, due to fears of a conflict of interest. While this is understandable and any conflict of interest is damaging and should be prevented, there needs to be more transparency in the regulatory process.

Our main problem now is with the French authorities' assessment of the patient population which will require Esmya. Currently, there is a cap in our reimbursement contract, which is tied to the estimation of the patient population size. The authorities estimate the number of patients affected by the relevant condition and set a cap for the amount of prescriptions. If we exceed this cap, the company has to pay for the excess drugs. Currently, their estimated population size does not align with our figures, and this is problematic. The lack of transparency makes it even more difficult, as we cannot understand the process by which their figures were produced or resolve the discrepancy. Finally, in terms of a European comparison, Esmya was approved by EMA in February 2012, and we launched our product in Germany and UK in March 2012. The product was launched in Spain, which is also known for its lengthy negotiation and approval process, and is typically one of the last markets, in December 2012. In France, we had to wait until August 2013.

You have worked with both big pharma, when you were at Merck Serono, and a biotech start-up, which is PregLem. What do you feel are the advantages of working for a mid-size multinational like Gedeon Richter?

In a start-up, there is a very strong 'do-it-yourself' mentality, which is a fantastic learning experience. My time with PregLem as a start-up was one of the best experiences of my life. But it is extremely stressful and I had to juggle a myriad of different responsibilities and tasks, both big and small. With a big company, there is a lot of relief because there are different departments to share the burden and the workload. The difficulty is then to adjust to a more structured, more

bureaucratic way of working. Now, it is also a challenge to balance my work between Switzerland, as the CEO of PregLem, which I was appointed to in July 2015, and my work in France, as the Manager of Gedeon Richter France. A mid-sized company combines the best of both situations. Gedeon Richter is mid-sized, which allows it to maintain some personal communication amidst the company organization.

You have had a very international career. You are Croatian, you work for a Hungarian company, which acquired a Swiss biotech and are managing the French affiliate from Switzerland. How has this multiculturalism contributed to your management style?

I firmly believe that experience is the best teacher. I have taken a lot of management courses but nothing can prepare you for the company culture shock that was my transition from PreGlem to Gedeon Richter, setting up the affiliates all over Western Europe, and then establishing it in France. In addition, it is also very important to adapt to the local way of conducting business. Erik Bogsch wanted to have someone who is French-speaking and familiar with France to serve as the French general manager for Gedeon Richter.

Currently, our operations in France are still very new as we only have thirty-four employees. I however believe an affiliate should always have a local leader, because there are local ways of doing business everywhere, and it is not for a foreigner to come in and teach the locals how to do business. After Gedeon Richter France is established, I will gladly step aside for a French General Manager to take place.

What is your final message about Gedeon Richter France?

Given that Gedeon Richter specializes in women's health, France is one of our most important markets. The latest innovation, know-how and inspiration is coming from France, more than anywhere else. France has always had one of the best healthcare systems in terms of quality of care and access for women, so if we want to establish ourselves in the field of women's health, we need to be present and successful in the French market.

Click here to read more articles and interviews from France, and to download the latest free pharma report on the country.

See more interviews