Interview with Ludwig Everaert, Founder & CEO, Archemin

11.01.2013

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Historically, Belgium is widely recognized as a major regional hub for clinical development. How would you compare the current environment to 1999, when Archemin was first established, and how has Archemin developed in the ensuing period?

I began my career in the pharmaceutical industry as a Clinical Research Associate at Roussel Uclaf 23 years ago. After five years working as a CRA I switched to Faulding Pharmaceuticals where I became responsible for the regulatory affairs of the Benelux countries. When I joined this company we were in the process of setting up a regulatory affairs department. I was offered the opportunity to make headway in regulatory affairs, medical & technical writing, pricing & reimbursement and drug registrations.

In 1999, I founded MPI – Medical and Pharmaceutical Information, which eventually transformed into Archemin. The company is specialized in regulatory services and clinical research activities. As I was the only employee in the company, I did not have the capacity to offer the broad range of services that I am qualified in.

I concluded that pricing & reimbursement and medical & technical writing were services that I could provide from my home office. After having gained significant experience in five or six years as an entrepreneur, I brought on-board a first employee to assist me with the workload. As the saying goes, a reputation is difficult to make and easy to lose. Hence, at that time our main

objective was to establish a solid reputation on the market.

Today, we have 11 collaborators at Archemin and focus on a range of services including: pricing & reimbursement, pharmacovigilance, medical writing, development of quality systems as well as regulatory affairs. The clinical research activities on the other hand are limited.

Do you plan on expanding your portfolio in the future?

What we see today is that the era of the blockbuster drugs is nearing an end. Instead, we see a new generation of drugs targeted at specific groups of patients. There have been advances in molecular biology that are improving our understanding of how cells work.

At the same time, the development of targeted drugs is carried out worldwide. However, pharmaceutical companies that aim to launch their innovative new products in the Belgium market, requiring pricing and reimbursement from the local authorities, will often only obtain reimbursement rights based on a pharmacoeconomic model.

Having this said, pharmacoeconomic models designed for international use need to be validated in the Belgian context because healthcare in this country is of course financed differently compared to other nations. Validation of these models involves surveys, which may imply that non-interventional trials will have to be conducted. It is in this niche where Archemin’s strength lies; small scale non interventional clinical studies. We have written and followed-up on reimbursement applications for many companies and therefore know exactly what the issues are in pharmacoeconomic models as well as the questions that need to be addressed. Furthermore, we have experience in clinical trials and know how to organize these.

Having said that, I do not expect Archemin to grow into a large company within five to ten years’ time, but we will be very strong in this particular niche.

The Belgium market is well saturated with local and international CRO’s. What makes Archemin unique in this competitive landscape?

What makes us unique is our strength in pricing and reimbursement matters as well as our focus on class I drugs and niche populations combined with our knowledge of conducting clinical research projects.

There is a logical synergy between regulatory affairs, pricing and reimbursement, clinical research and pharmacovigilance. Naturally, these activities go hand in hand and we are therefore a highly specialized company focused on a small market niche.

In July of this year new EU legislation concerning pharmacovigilance has come into effect, pharmaceutical companies no longer need to rely on a recognised doctor or pharmacist concerning their pharmacovigilance obligations in Belgium. Does this provide opportunities for Archemin?

Generally, we offer these services to medium and small sized pharmaceutical companies that may not have a regulatory department and have insufficient experience to conduct pharmacovigilance activities. Therefore, we will fortunately be unaffected by these developments.

In terms of EU regulations, there is the harmonization law on clinical approvals delay where Belgium used to have the competitive advantage over all European countries. How do you think this will change the landscape for research companies in Belgium?

Obviously, Belgium’s fast drug approval of clinical projects is something of a relative nature. I believe that what is more important is the accessibility to hospitals and top level universities in this country.

We have been fortunate in the sense that the authorities have seen the importance of granting rapid approval times for clinical trials. Moreover, Belgium’s favourable business environment includes high-quality universities and research institutions which greatly enhance the local industries appeal. However, we are indeed limited by our small population and a corporate tax rate that is higher than the EU average.

Therefore, if the government wants to take action I suggest they offer increased tax reliefs for research based activities which will help to stimulate investments in research. Another disadvantage is Belgium’s fragmented nature in terms of its highly competitive regions that have varying attitudes towards research and development.

The new regulations will certainly have a positive effect on small scale operations, such as our own, in a sense that European law is explicit. The changes will enable us to interact with companies located in other Member States, creating a level playing field. In this respect, Archemin looks forward to become a partner on the European market.

In addition to this, I would say that Belgium has a very particular reimbursement system. The RIZIV/INAMI (Belgium’s reimbursement authority) requires companies that aim to launch products in the Belgium market to validate the drug within its new environment. It goes without saying that companies may be obliged to validate pharmacoeconomic models within the typical Belgium context. In other words, companies have to be able to cover the market with local market knowledge within the cultural context of the country; i.e. the local flavours have to be respected.

Archemin has handled 13 class I reimbursement dossiers for global pharmaceutical companies over the last eight years.

In 2004, we were successfully able to obtain Class I reimbursement rights for a number of our clients in the context of the legal environment that existed at the time. Three years later however, the regulations and overall attitude of the reimbursement authorities shifted considerably. This had the effect of making the knowledge we had gathered during our first reimbursement dossier obsolete, complicating the more recent applications. Two years later after that, the rules of the game had changed again.

Hence, the continued fluctuations in laws have been rather frustrating for the pharmaceutical industry. In my opinion, only small and highly specialized companies such as Archemin were flexible enough to keep up with these changes. This gives us a unique position in the market because even large pharmaceutical companies do not always have the experience with these relentless changes.

As a company to whom clients outsource clinical research, you must prove that you can do the job better than the client can do themselves. For this, high quality staff is key. How do you attract and retain the best talent?

When we first began our pricing and reimbursement operations, the first person I hired six years ago held a PhD in ecotoxicology; not exactly the most fitting profile for pricing and reimbursement matters. However, through sheer dedication, we were able to create a strong and specialized team for pricing and reimbursement services.

At Archemin I have always invested in my personnel. I believe it is essential to create experts in certain fields and therefore I am not fearful of hiring junior profiles. We have managed to create an environment where young professionals have been able to blossom within their professional field.

How would you describe Archemin’s culture and atmosphere?

Archemin’s focus is on human capital because without its personnel we do not exist. People are Archemin’s main asset.

Due to the terrific opportunities I was exposed to during my entire carreer, I feel an obligation towards my collaborators to give them exactly the same opportunities to make them feel the thrill of being able to create something from scratch.

In August this year Archemin has been accredited as advisor for “Strategic Entrepreneurship” by the Enterprise Flanders implying that Small and Mid-Size Enterprises making use of your services to develop their certifiable management systems may be eligible for financial support. Could you elaborate on this?

At Archemin we try to attract people with accurate qualifications. We invest in training to make sure our employees keep updated and have the right accreditations. This has made Archemin a service provider which has been recognized by the Belgium authorities.

Where would you like to take Archemin in to following 2 to 3 years and what goals would you like to realize?

I do not expect Archemin to become a significantly large company. We will remain a relatively small company with a focus on pricing and reimbursement, medical writing, regulatory affairs, clinical research and pharmacovigilance. Within this domain, our aim is to become among the top three players in Belgium with a professional and efficient team, operating in accordance with well-established procedures. In this respect, we intend to shape Archemin into a reliable and trustworthy partner.

In addition to this, we are also expanding our service offerings into other complementary and logical fields; namely, the development of quality systems for the pharmaceutical, medical device and biotech industries.

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