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Laboratorios Elea's General Manager tells the story of the laboratories outstanding growth over the previous five years, the his firms upcoming launch of the first Argentinian developed biosimilar product.

To begin, would you please introduce yourself and Elea to our readers?

I joined Elea four years ago as general manager, after working for Gador and Sanofi in a similar position, had previously worked with GSK as a marketing manager. The first pharmaceutical company I ever worked with was Schering AG, which has since been acquired by Bayer.

Elea is currently roughly tied with Gador for third place in the Argentinian pharmaceutical market, with Roemmers and Bayer taking the first and second positions respectively. Argentina is one of the few nations worldwide that has a domestic pharma industry that dominates the international pharma sector in terms of revenue; seven out of the top ten firms are Argentinian, and 60% of the market value is sold by Argentinian laboratories. This market is primarily a branded generic market, and many of these top Argentinian firms have a strong presence across Latin America, and in some parts of the Middle East and Africa. We have a very strong healthcare system that usually covers 100 percent of the cost of medications.

I believe that Argentinian companies will continue to dominate the market, especially those that have made significant investments in biotech in recent years. Furthermore, I expect these firms to

grow and solidify their positions across the rest of Latin America, and in their other markets, as they start to launch new biosimilar products. Elea is one of these players, and we are going to launch the first Argentinian developed biosimilar product (Rituximab) in the coming year, with another two or three in our pipeline that will be launched the following year.

Since 2009, Elea has advanced from fifth to third place in the Argentinian pharmaceutical market. What have been the key tactics that have lead to this success?

The first important event was the acquisition of a product line from Merck, as the deal included 140 sales reps and more than 20 brands, covering approximately 190 products. Once the deal was signed, there was the challenge of integrating the two businesses, as well as the two work forces, as the Merck and Elea business cultures varied significantly. With respect to our portfolio, some of these products helped us to build and strengthen our position as the first ranked company in gynaecology, and helped us to establish a strong presence in the diabetes market. Since diabetes is the fastest growing disease in Argentina, at 35% per annum, acquiring some of these global brands from Merck was very significant because now several of them are some of our best selling products out of our 400 different brands, with Glucophage ranking in our top 20 brands.

Since 2009, we have substantially increased the size of our sales force and now we have the largest sales force in the country with nearly 300 reps. We have also had several very successful product launches in our OTC line, and built a strong ophthalmologic line through acquisition and we are now the third largest player in the Argentinian ophthalmology market. In fact, Elea is currently ranked number one in the ‘new products’ category by IMS.

Why is Elea the partner of choice for multinational pharmaceutical firms, and how successful has this business area been for Elea in the last five years?

Multinational companies often want to launch products in countries like Argentina, but lack the sales force to properly market the products. Since only the top five or six firms have sufficiently large sales teams, there are only a few competitors for this business that we must contend with overall, across all therapeutic areas. As I mentioned before, we have the largest sales force in the country with 300 reps covering every region in Argentina, from Tierra del Fuego to the Bolivian border, and are also 50 percent owners of Disprofarma, the largest pharmaceutical distributor in Argentina.

Most of the business we get is in areas that we already have a strong portfolio in, and as such we have partnership agreements with Pfizer for some gynaecology products, Novartis for a few vaccines, and others; in total, we have licenses from six of the top ten global pharma companies,

and we are always looking for more such opportunities. We recently were in negotiations with Menarini to acquire their Argentinian portfolio as they have closed their local office, and while these brands went to Roemmers in the end, Menarini has told us that they would like to license some other products to us in the near future.

What role have export markets played for Elea's growth in recent years?

Since 2009 to now, the Argentinian market has had double-digit growth in volume and at this point we are producing at full capacity; 24 hours per day, seven days a week. Given this constraint, while we have had some minimal growth in the exports of certain products such as hormone products such as oral contraceptives, overall we have not had enough excess volume to supply any additional markets outside of Argentina. Before we can start to resume this export growth in earnest, we must first make some significant investments in new productive capacity.

What does your current pipeline look like overall, and what direction would you like to take with new projects?

Overall, we are managing to invest about 10 percent of our revenue in R&D, which is being mostly focused biosimilar drugs, in the oncology, rheumatoid arthritis and ophthalmology areas. The other big category is OTC products, as we are currently the second largest OTC manufacturer in Argentina.

Another field that holds a lot of potential is the insulin market, as currently there are only a few big insulin producers worldwide, and in Argentina the only players are Novo Nordisk, Sanofi, and Eli Lilly. We are currently investing in developing a new plant for insulin production in Argentina, and we hope that in a year and a half we will be starting to build a strong position in Argentina, and the rest of Latin America.

Have public institutions played a role in building this pipeline?

Elea has worked with public research institutions on a variety of projects in the past, and public sector in general plays vital role in R&D in Argentina. First of all, public hospitals are very important because they have the patients, the physicians, and public universities and research institutions have a lot of scientific and research expertise. However, these organizations lack experience developing commercially viable strategies, and commercializing product, so there are a lot of potential synergies between the public and private sectors in Argentina. Two of our recent successes from such partnerships are Abarax, which is a treatment for Chagas disease that we are now exporting to Latin America, the US and parts of Europe, and Vaxira, which is an oncology

product developed in conjunction with the University of Quilmes. We also have two more oncology brands that will be launched in the year and some others in earlier stages of development that will target colon, lung and breast cancer.

Do you see any room for improvement in the public-private R&D model in Argentina?

Investment is of course always an issue and thus far the majority of the investment in these projects has come from the private partners. However, with the rising costs of developing new pharma and biopharma treatments and then funding clinical trials, particularly in oncology, it is becoming more critical that the government also takes a financial stake in the projects. With the strong track record of success in public-private-partnerships, I think it is very likely that the government will be willing to take such a financial position.

What do you see as the greatest challenge facing the Argentinian biotech sector over the next few years?

Learning to navigate the regulatory environment for biosimilars is our biggest challenge at the moment, primarily because these regulations are quite new and still somewhat in flux. Developing the expertise and relationships necessary to be able to efficiently register and launch a biosimilar product is a top priority.

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