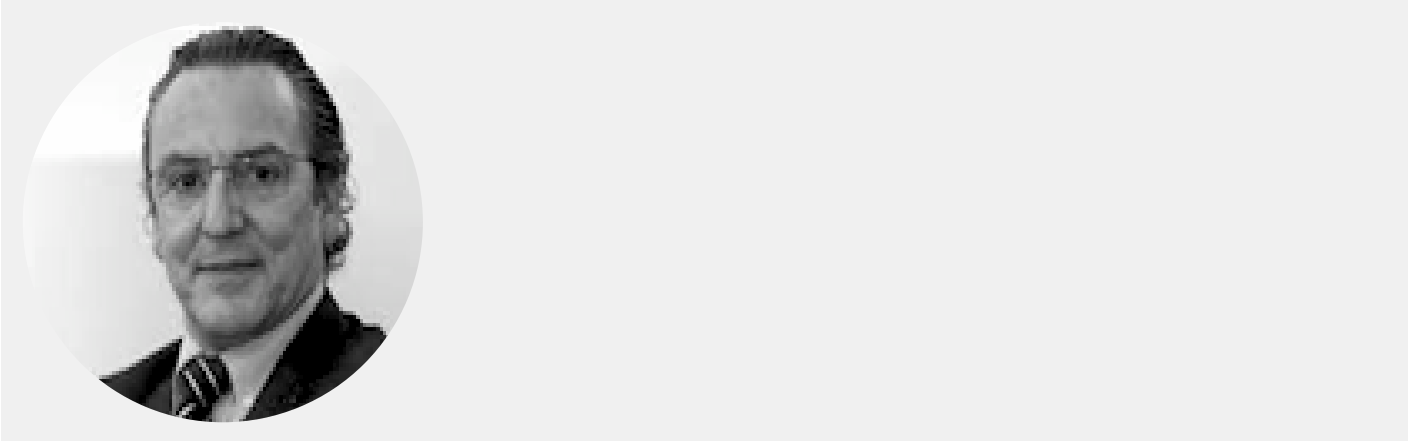
Interview: Luis Cruz, General Manager Spain & Portugal, CSL Behring



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Tags: plasma market

In a market dogged by price cuts and changes in regulations, the challenges for blood plasma companies have become graver than ever. In spite of these challenges, CSL Behring remains one of the most important players in Europe's highly competitive plasma-derived product market. Luis Cruz, general manager of CSL Behring Spain & Portugal, discusses how CSL Behring has prevailed and the company's commitment to science and innovation.

How has the plasma market been affected by the Spanish recession?

As it has happened for all pharmaceutical products in this country, the cost-containment policies implemented by the Spanish Government have reduced the bill for plasma-derived products. This has prompted us to place an even greater focus on innovation. In turn, we have been able bring several new products to the Spanish market in recent years, which has been a real positive for patients with the types of rare disorders that CSL Behring therapies are intended to address.

How difficult is the national tender process for plasma-derived products in Spain?

The approach is quite similar to traditional pharmaceuticals. Nevertheless, Spain has 17 Autonomous Communities, and everyone has transferred responsibility for healthcare. Today, we see each Autonomous Community taking a unique approach to this situation. It is often the smaller communities that follow centralized initiatives put together by the Ministry of Health.

Manufacturing of plasma products takes longer than most pharmaceutical products, which can lead to supply instability. How do you deal with these issues in Spain?

You are right, the manufacturing process can take anywhere between six and nine months, involving up to 400 quality control tests. That represents a substantial amount of work performed by large and highly qualified teams and also an important investment to ensure that products have the appropriate quality. Because of the efficacy and safety of these therapies, the demand for plasma derived products has been increasing constantly in the past years. Consequently, we have been increasing our manufacturing capacity in the different facilities that we have at a global level. This allows us to ensure that we have the right amount of product available when it is needed. We are extremely proud of our reputation for reliably delivering safe, high quality products to patients who need them. Underpinning all of that is our company's commitment to operating with the highest ethical standards, around the globe.

The plasma industry has experienced some decline due to more modern products being developed in recent years. How has CSL Behring adapted to this evolution?

Our adaptation is based on investing smartly in areas where we have unmatched expertise and knowledge. Because we are committed to provide the best products to patients with certain rare and serious we have been increasing every year our investment in R&D. In fact, we have doubled that investment in the past four years. This year, CSL Behring will spend approximately $500 million (USD) in R&D, in a very focused and strategic manner.

What examples can we find of CSL Behring's latest R&D developments being marketed in Spain?

One of my favorite products is our subcutaneous immunoglobulin, Hizentra. Patients with Primary Immunodeficiencies must visit the hospital on a regular basis and spend hours receiving their immunoglobulins' i.v. infusion. The subcutaneous administration allows for home treatment and also allows for some activity during administration. For younger children this option is especially valuable as it offers patients a great deal of control in managing the condition. Looking ahead, we are working on several very exciting new products for use in treating people who have hemophilia. These will be recombinant.

Do you participate in clinical trials in Spain?

Yes. I am especially proud of this because in the past five years we have changed substantially our situation in the Spanish market and now we contribute with Spanish centers for the clinical

development of some of our main projects. One of our projects involves coagulation factors with extended half-life so that patients do not need to infuse as often.

How appreciative is the Spanish government of CSL Behring's R&D investments?

The hospitals have recognized and appreciated CSL Behring's efforts to bring research to our country. There are a number of rare diseases where Spain's know-how coming from important reference centers makes this market an important contributor to the development of new drugs.

In terms of the reimbursement process for orphan drugs, what is CSL Behring's value proposition to the government given your products' high costs?

The National Healthcare System provides full reimbursement for hospital therapies. Most of CSL Behring's products are being used for congenital deficiencies exclusively via hospital prescription. Once you replace the missing protein, usually symptoms get under control. It is clear that these are products that bring true value to our Healthcare System.

CSL Behring produces treatments for bleeding disorders, fluid replacement, immunoglobulin therapies, and wound healing to name a few. How is the product portfolio represented here in Spain?

Actually, in Spain in the past five years we have been launching a new product almost every year. Today we have available in Spain practically all products that the company markets today and we are in the process of licensing the few missing products.

While CSL Behring is the number one plasma company worldwide, in Spain it is ranked third due to the presence of Grifols. What strategies would you like to take to ensure CSL Behring's number one positioning in Spain?

It is true that CSL Behring is a global leader in the plasma protein biotherapeutics industry. In Spain we will continue with a commitment to our global mission, which is to research, develop and market biotherapies that are used to treat serious and rare conditions.

More than thinking on what our position will be in the Spanish market place, we want to show that our commitment to saving lives and improving the quality of life for people with serious and rare conditions is evident in everything we do. Our position will come as a consequence of the good work we do and we will continue to do.

You are also head of Spain's association for companies specializing in rare diseases (AELMHU). What synergies are you able to extract from being involved with both

organizations?

The most important synergy is the shared mission to help people with rare and severe diseases to get the products they need to live better lives. I also believe that the old Spanish Healthcare System has disappeared as it had proven to be unviable and unsustainable. Now we are in the process of switching to a new system that has yet to be formalized. We are trying to keep up with everything, but the process of defining this new system is not an easy one. Of course, as a companies' association, we are trying to ensure that rare diseases get the reasonable support when the new system is defined. We know that in the future we will not be able to spend in healthcare as much as we have been spending until now. We have heard this many times recently: public spending must be contained. But, by definition, when new treatments for rare diseases are discovered preventing patients from dying and suffering, we have to generate "new expenses". The Ministry of Health must make new resources available for these patients who will not only survive, but who will often need these treatments for life. From where should we get these "new resources"? I believe that this is the most important challenge that the Ministry of Health and the Autonomous Communities face today. They will need to make decisions on what to finance and what not to finance.

What would you recommend the Ministry to do differently?

My recommendation is for the authorities to think longer term and to start helping the Spanish population to realize that Healthcare is very expensive and that we all need to be conscious that resources for Healthcare are not unlimited. Every Autonomous Community will have to have specific budgets for rare diseases to make available information networks, diagnostic and treatment. Today, hospitals have serious difficulties in financing the diagnostic and treatment of new patients with rare diseases when financial resources were not budgeted. The system does not have an automatic mechanism to solve this problem in these centers. A specific budget for rare diseases should definitely be created.

How have you adapted the way you handle your sales staff or way you approach the market?

We do not have a specific culture for Spain. In Spain we apply the same culture that CSL Behring has at a global level. I consider myself very fortunate to be part of an excellent Spanish team. I feel very comfortable working for a company with such an excellent reputation for excellence in all that it does, and one that supports its employees to grow and to develop not only from the professional perspective, but also on the personal side. In our company we value positive attitudes, both in

terms of working as a team and also of assuming the social responsibility of doing a good job. When talking to the members of the Spanish team, it makes me proud to realize that they believe in what they do. They have all accepted and interiorized our company's mission.

How did you find the evolution of Spain, given your extensive international experience?

There have indeed been some noticeable differences in the Spanish market. For many years the clinical people working in the Spanish Healthcare System had available all the resources that they asked for based on their clinical know-how. This is no longer the situation and now they need to demonstrate and convince hospital management that what they ask for is really needed. Now getting the simplest of items can be very complicated. We have to thank the Healthcare Professionals and their vocation because in these difficult times their commitment and hard work is preventing the system from collapsing.

What is your medium-term vision for the future?

It is an optimistic vision as CSL Behring will be maintaining in Spain a broad portfolio of high quality products, will contribute to the development of the new and improved products generated by the company, and will continue to market products in Spain based on patients' needs.

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