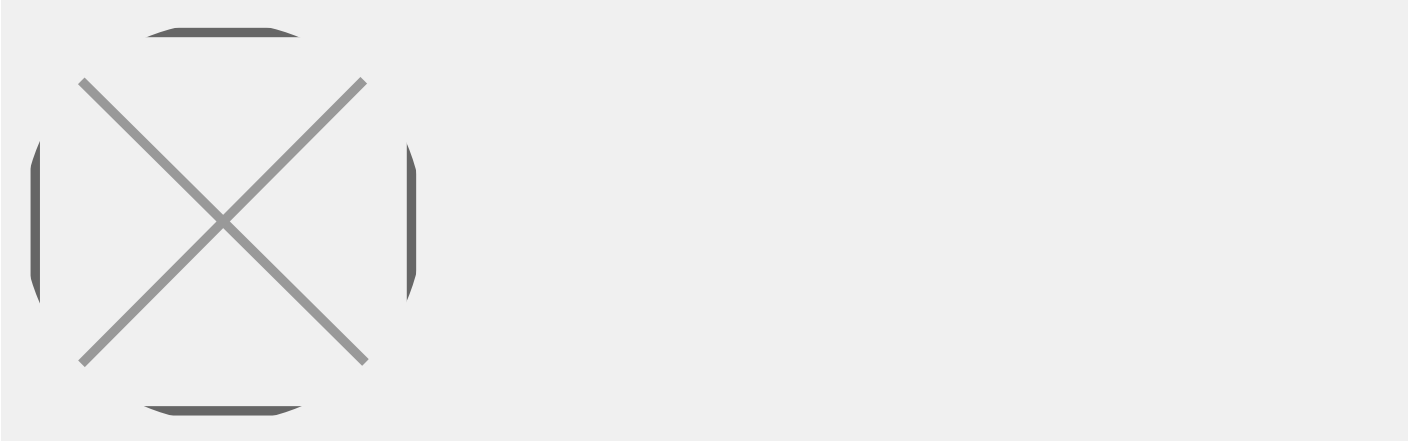
Interview with Carlos Gallardo, General Manager UK & Ireland, Almirall UK



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The UK is leading the biotech turn, and is recognized as the largest biotech market in Europe. Why did Almirall only decide to enter this market until late 2007?

Almirall was founded in 1943 in Barcelona (Spain) and in 1944 it started its industrial and commercial activity. In the 60s it began its research and development activity. Almirall has evolved to become one of the most committed European pharmaceutical companies, an important milestone from when it was floated on the stock market in June 2007.

Almirall's growth is currently based on the following strategic objectives:

• Leveraging our research and development.

• Growing internationally.

• Maintaining leadership in the Spanish market .

When, in the late 90s -this was before my days at the company- Almirall management took the decision to expand internationally, and create an infrastructure to commercialize our medicines in Europe, we had mainly three R&D products: a migraine reliever, an antihistamine, and an anti-inflammatory drug. These were the assets that we had to disembark in the countries. In most of them, just launching these products -or recovering the rights from distributing partners- was sufficient enough to create a self-sustaining and robust affiliate. In the UK it was different. A number of factors, internal and external, contributed to not making it attractive enough for Almirall to create an affiliate at that time, or not as attractive as other markets that were prioritised by management.

In 2007, we acquired a company in Germany, Hermal- the leading dermatology company in Germany. The intention was to diversify our business into dermatology. Hermal, at that time, was already distributing seven or eight brands in the UK; so, on the back of this, we already had a few products with enough critical mass in the UK. And then, very close to the time when we acquired Hermal, we had the opportunity to acquire a portfolio of products from Shire. It was a very good fit, because the key Shire products were also dermatology brands. The Shire products, together with the Hermal products, provided an attractive turnover with growth prospects, so the UK affiliate was created soon after.

Around this time, we also recovered the distribution rights of two proprietary Almirall brands Almogran (for the treatment of migraine) and Preservex (a non-steroid anti-inflammatory). We then undertook a strategic review and decided to prioritize the dermatology portfolio, so most of our commercial efforts and resources went behind supporting those brands. We are already a top-10 company in dermatology, because we have very good products, and because of our efforts to increase the patient awareness of certain dermatological disorders.

In addition, we have a very interesting late-stage pipeline in development. We plan to launch another dermatology drug in 2011 (Actikerall) , and we are progressing in other therapeutic areas such as Chronic Obstructive Pulmonary Disease (COPD) and Irritable Bowel Syndrome with Constipation (IBS-C). The derma product has already been filed in the UK, and we are awaiting approval, to hopefully launch in 2011. The IBS-C product has finalized phase III trials and is aimed to be filed next year while the COPD product phase III is underway and, provided positive results, we aim to file it in mid-2011.

We are in the midst of an exciting opportunity, because not only do we have new products to expand our dermatology franchise, but we also have the transforming opportunity to launch two products that have a very attractive profile, in therapeutic areas that have a large unmet need. So again, very exciting times for us! We will be moving from a comparatively small, specialty dermatology company, to a larger, general practitioner-based company—Therefore, we will have to expand dramatically to be able to reach all the prescriber base and compete efficiently and effectively against big pharma players, who have very big interests in that space.

It is a significant challenge for us to grow in this way and to take on the big companies, but it is a challenge that we look forward to. One of my key objectives since I joined the UK was to build a top-performing team that could support Almirall in achieving these goals, and the company’s ambitions in the UK market.

I am very pleased with the quality and the talent that we have been able to attract here. We are now around 50 people. Since our launch, we have had a relatively stable number of employees, but we have built up the skill set of our staff. Now, I believe that the company is very strong in its

human resources and that this will become a source of sustainable competitive advantage.

Looking at performance: last quarter, Spain sales dropped approximately 4.6%; in other countries, sales went up 1.9%. How has Almirall UK faired, in the two years that you have been here? What is your outlook for 2011?

We have experienced double-digit growth as an affiliate both in 2008 and 2009. Last year was a fantastic year for us, because we had a growth of 26% in the UK -in a market that is growing in the low single digits. This year, our level of growth will probably be a bit less, but we will still be growing, at a rate significantly higher than the market at large.

The UK is contributing quite well to the European Almirall business. The majority of company business is still in Spain: about 55%. But by definition, we develop products to be commercialized worldwide -either by us in Europe (where we have fully-owned affiliates in Austria, Belgium, France, Germany, Italy, Nordic Countries, Switzerland, Poland, Portugal, Spain, United Kingdom/Ireland,) and Mexico as well, or through partners elsewhere. This is our business model. We are aiming for global registrations, and our ambition is to launch in every country. Therefore, the turnover has to eventually evolve from being that of a domestic Spanish company -as we were in the mid-90s- to that of a very geographically-diversified player. For the UK's part in that globalization, we plan to grow to the very limits of the market potential -to represent the same % of company sales, as the UK represents of total pharmaceutical sales in Europe. If we manage to account for more than that percentage, this will then mean that the UK affiliate has done a very good job!

When you look for partners, what do you look for?

We look for partners on a product-by product basis. In the latest example, for our COPD product that is completing phase III development , we looked for regional partners. We signed an agreement in 2006 with Forest Laboratories in the U.S. We are looking for regional partners in Asia as well.

What can we offer to a potential partner? Our commercial expertise, our track record with previous collaborations, and the flexibility we have in deal making. We try to adapt uniquely to a partner's needs, and flexibly structure deals, in order to be more attractive than some of our competitors.

You are involved in clinical trials in the UK. At the ABPI/BIA conference on October 25th, it was mentioned that productivity from clinical trials has been low of late, while costs are rising. How do you convince the headquarters to continue investing in clinical trials in the UK?

A significant part of our R&D efforts are now in respiratory, and I hear from my colleagues in R&D that the quality of the clinicians and investigators in clinical development in the UK is second to

none in the respiratory arena. So I believe that it is in our best interests as a company, from an innovation perspective, to continue to invest in the UK.

Most of your R&D takes place in Reinbek, Germany—for dermatology—and Barcelona for other therapeutic areas, now largely respiratory. How can the UK contribute to the global company's R&D? For example, in terms of conveying market feedback regarding unmet needs here?

I think that we have a very experienced global marketing team in Barcelona, and this team has a significant input in early stage development, including the discovery stage. All of the marketing input, in terms of unmet needs, etc., must be looked at from the perspective of what your competitors are developing, and how our products will profile against those competitors' developments and existing products.

Marketing is a contributor, and has a big say, in what programs are prioritized, and in what we call the target product profiles. There is a team -a joint R&D and marketing team- that works on putting together the desired profile that we want to meet in our development programs. This profile is presented to the R&D team, and marketing says to them, "ok, this is what you need to deliver". Of course, the R&D team then has input regarding what is and is not technically doable, based on available science and company capabilities. So we see what the market requires, and then decide whether we have the capacity to produce it.

I think that the challenge, not just for Almirall, but for the industry, is to have input not just from what patients need -because this is very well known- but also from what the payers need. Because the information that you develop to get your product approved is not the same information that payers want to see, for example, in pricing discussions in different countries. If you look at respiratory drugs: the regulatory endpoint is FEV1(Forced Expiratory Volume after 1 second), how much your expiration capacity increases after taking the drug. And if you go a significant X percent beyond baseline, and it is safe, the regulatory authorities will be pleased to approve it. But then, if you go to a payer -for example a medicine manager in a Primary Care Trust (PCT)- with the FEV1, sure, it is interesting for them, but they want to see budget impact in the localities, the outcome in other health-related endpoints such as the rate of hospital admissions and whether this product can reduce it, and how the product compares to previous standard treatments at the local level, etc. So: what are the endpoints, how many patients, what are the secondary endpoints and what do you measure?

You actively developed your team to be able to approach these PCTs. Now with the latest NHS reforms, PCTs will disappear. How will you now prepare your team to continue to perform at a top level in the UK?

I think that a key need for a company like us is to be very close to our customers. To be very close to the different pharmaceutical stake holders -global, national, and local. For example, today in a PCT you have the clinicians, the different administrators such as the medicines managers, some key nurses, etc. Even when the NHS does away with formal PCTs, these kind of people will continue to be influential within GP consortia. It is important for us to be close to the changes, be close to how stakeholders networks evolve, and then understand from them what the local needs are, what they want from us, and how to align our value proposition to their needs. Once you have this information, then you know what you will have to do to provide value. Do I have the right skill set to do it? If no, then I have to skill up my human resources, or to acquire the expertise that I do not have.

With these reforms, we will have to wait and see how the new GP consortia will form, how many will be there, how they are going to take decisions -all these questions are still very unclear.

If we look at your own skills: we see that many Spanish companies are using the UK as a learning school. Is this what drove you to leave Pfizer? To get some experience in the UK and then move up within the family company?

I think of the UK not as a learning school, but as an important and challenging market, where the company wants to send good managers. Of course, if managers are operating in a difficult environment, they will learn from these challenges, and that will put them into a good position to tackle challenges elsewhere.

What makes you a good manager?

It is fundamental, when you come to a new function, in a new country, where you are not an expert, to find the right support and expertise.. So for me, a key priority was to find the right people to support me in making the right decisions. My style is very support-driven, in that I always want to find people that are better than me in their functions. I want to have experts next to me that can take part in joint decision-making. I see my role as making sure we have a common vision and roadmap to achieve our goals, that I provide them with the right challenges and motivation, and with the right tools and resources. So it is more having the right people, and making sure they have the right environment to do the job effectively.

What attracts people to work at Almirall UK, and what keeps them motivated?

I think it is the project and the culture. We are a new company in the UK, and the people that come here have the opportunity to be a pivotal member of creating something: to be a contributor in shaping the Almirall of the future in the UK. In the office in Stockley Park, we are now 12 people, so each of these 12 people are very influential in defining what we are -and they have a say in how we move forward, because we have a very inclusive culture. This, together with the vision of a quick

growth, and going from a small company to something much bigger in the coming years. The products that we have now are enabling us to grow double digit, much faster than the market. We also have transforming assets in our pipeline, so we are planning that our growth will actually accelerate in the coming years.

So our employees have the ability to shape something from its infancy to a fully grown up stage. For a lot of people, that is a very attractive opportunity. And our culture is not very restraining, or hierarchical -so that is attractive as well. Finally, we feel a bit like a start-up, and we have a very entrepreneurial ethos. A lot of people with big pharma experience are a bit tired of being constrained, and of being in a company where they do not really understand the vision, the full picture, or how decisions are made. For these people, an opportunity to come to an environment where they can personally participate, in a transparent decision process, is very appealing.

If we see the company in two years, what will we find?

I hope you find a company that has gone from being a not yet very well-known specialty dermatology company -even though we are top ten in that market in terms of sales- to a company that is well-known, respected and seen as a partner by the NHS and our customers, innovative and agile, with good solutions for patient and doctor's needs. And we wish to be present not only in dermatology, but also in respiratory, and IBS. So much bigger and more diversified.

Almirall is an R&D-based company and we are really betting on our innovations. That is the way that we want to be seen: as a company that is developing strong innovations and good products, and -in line with our values- we want to be seen as a company that is based on trust, and walking the talk, delivering on our commitments to partners, and developing a long-term strategy with healthcare providers and patients.

What is your final message to the international readers of Pharmaceutical Executive?

I think that we are now in times of pessimism in the industry. It has become increasingly challenging to deliver new products that deliver value to patients and society and where, at the same time, this value is rewarded by the health care systems. The amount of effort and investment required to meet the technical, regulatory and market access requirements for new products has grown dramatically at a time where R&D productivity is decreasing and patent expirations are reducing the ability to fund these needs. This is a pretty gloomy picture. However the responsibility to deliver innovative medicines is still largely ours, and I am convinced that the industry will create a new paradigm in drug development that makes the risk reward equation attractive again. However this is not only responsibility of the industry but also of governments and healthcare providers. . There is light at the end of the tunnel—and maybe we will get there sooner than we think!

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