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16.11.2018

Tags: Spain, Dermatology, LEO Pharma, Digitalization

LEO Pharma's Paolo Cionini discusses recent structural changes in the dermatology specialist's Europe South operations, the importance of Spain to the regional group, and the nation's digital capabilities.

LEO Pharma has undergone a lot of structural changes in recent times; can you give us an insight into some of these changes?

The LEO journey started in 2009 with a clear long-term strategy to change the company and become a leader in dermatology; including fully dedicating R&D to this area and expanding the company worldwide.

In 2015 we acquired the dermatology arm of Astellas which gave us the opportunity to reinforce the basic part of our business and reach millions of patients worldwide. The strategy was to be stronger in dermatology, not only to reinforce where we were already in Europe and elsewhere, but also to expand our portfolio in countries where we previously did not have direct control of operations. The Astellas acquisition has helped us to gain a footprint in Italy, China, Japan and the US for example.

The second most important change was establishing agreements with AstraZeneca on two dermatological products – a global license for tralokinumab and a European license for brodalumab – giving us the possibility to enter the bioderma space. This is exciting for us not only in terms of diversification, but also in adding new competencies.

The biggest need in Europe and the US is around new products and technologies in advanced therapies. Pressure on prices and generic competition, among other issues, mean that it is not possible to drive expansion and achieve sustainable growth with only the established business.

Partnering with AstraZeneca made a lot of sense – they did not have any previous interest in the dermatology field and needed a partner with a lot of competencies there.

The third move we have made is a new organizational structure worldwide and especially in Europe. We have made some changes in the global leadership team – making it more international. We come from a somewhat traditional Danish culture and this cultural mix was much needed. Our leadership team now comes from an extremely diversified background.

How are the different markets served by LEO now split, globally and within Europe?

We have decided to split the world into three big areas: ‘Region International’ covering South America, Africa, the Middle East and the Far East; ‘EU+’ covering Europe plus Canada, Australia and New Zealand; and the US, which is a region in itself. We want to be even stronger in the US market while expanding in the Far East while restructuring in Europe in a sustainable way.

Most of the business today comes from Europe. We have decided to create four clusters within Europe: Cluster North, with the UK and the Nordic countries; Cluster CEE, which includes Germany and some countries in Eastern Europe as well as Switzerland and Austria; Cluster France combined with Canada, for cultural reasons, and the Benelux countries; and Cluster South, which is made up of Spain, Italy, Portugal and Greece.

This clusterization has brought three main benefits. Firstly, greater coordination across countries in order to leverage resources in a different way, especially in supporting functions such as HR, finance, IT and so on. Secondly, better optimization of resources and working more as clusters. We have decided to engage in many promotional initiatives using a ‘diamond model’, whereby instead of doing initiatives at country level and then replicating them elsewhere, a centralized team will decide upon initiatives at a cluster level. This allows us to cut costs on promotional activities and has thus far been extremely effective. Thirdly, collaboration across countries and clusters has been

heavily increased. At all levels, we have people in different functions talking to each other, being part of the same team, in order to create initiatives that are then replicated elsewhere.

Why has Spain been chosen as the focal point for the Cluster South?

Spain and Italy are similar sized markets, but LEO Pharma Italy is a much younger affiliate than its Spanish counterpart. LEO Pharma Spain is very strong in terms of competencies and experience and Barcelona is a very well-connected city, not only in terms of Europe but globally. LEO decided to focus purely on dermatology in 2009, but before that we were present in many different areas including thrombosis, which is still part of our Spanish portfolio.

How strategically significant is the Spanish market to LEO Pharma?

It is important for a number of reasons. Firstly, Spain is one of the fastest-growing markets in Europe, having come out of a deep financial crisis. This crisis has forced both politicians and business leaders to rethink their strategies and ways of working. Secondly, compared to other countries in Cluster South where most concerns are related to price pressures and generic penetration – here we have the same issues, but at least we have a dialogue with the institutions. One of the dialogues we have in place – that I hope will lead to a Royal Decree very soon – relates to products that are very low in price, such as topical antibiotics. The price of a pack of Fucidine® in Spain is less than a pack of chewing gum. That creates an issue as, in the past, there was not the correct perception of the value that we are creating. If the patients do not care about these kinds of therapies and the alternative is taking a systemic antibiotic, the system does not gain anything. This also creates problems in terms of resistance. The institution understands that this is a failure on all sides. Finding sustainable support for these kinds of therapies will help to optimize the consumption of and access to antibiotics.

In which ways is Spain a leader in new initiatives in the digital space?

It is one of the few countries in the world where we have an integrated system for our relationship with the doctors with web services dedicated to both patients and doctors. We are putting a lot of resources into keeping these services updated and we have received some recognition from institutions. One year ago, for example, we are asked to participate in a ceremony in Extremadura;

not one of the richest regions in Spain. One of the government's problems there was how to keep the doctors updated in what is a somewhat isolated region. We offered assistance on education and updates in dermatology to them, based on our digital platform. At the beginning, the regional government was sceptical, but after a year and a half they are extremely happy to have a partner like us updating and educating their doctors on dermatology.

This establishes a relationship between our company and the institution, but also the doctors and is an example of how accepting Spain is towards innovation.

eLEOmental is another service in our platform, which is a Sherlock Holmes-themed game based around difficult clinical cases in dermatology. This is a kind of academy for experienced doctors to challenge themselves and compete against others in a competition. At that level, it requires a lot of preparation and we have been recognized as an innovative company at various awards ceremonies because of this.

How do LEO's digital initiatives at the local level intersect with the LEO Innovation Lab?

I am a huge supporter of the LEO Lab and we are contributing to it from here. We have often discussed how to engage the patient in a more effective way, in terms of educating the patient about dermatology and using digital solutions to engage with their doctors much better. We are also trying to provide patients and doctors with the tools to track their improvements.

We are also working with the Lab on a diagnostic tool and have recently closed an agreement with a primarily oncology-focused pharma company. They have a problem with a couple of their drugs which are causing skin rashes. Combining their oncology treatments with our treatments for eczema, they can avoid stopping oncology treatments. There is also an app to monitor the situation and prevent further rashes from occurring. This is an example of a patient-centric initiative that combines the competencies of different companies.

LEO is also committed to open innovation. For example, our R&D department has opened an application to everyone which is evaluated seriously. In partnership, we start discussions because we believe that if we are partners, we need to make the lives of patients better.

Given your experience in the Italian market, how would you compare and describe the ease of market access in Spain?

The logic is not that different to Italy – there is a fragmented system with regional healthcare authorities playing different roles with different rules and regulations. The complexity is basically the same. However, centrally Spain is a little less complicated; there is more fluidity. We are now facing the prospect of a new government with new ministers, so a lot could change, but in general it is a lot easier to engage in dialogue with the authorities in Spain, which is very valuable. This allows us to better understand the needs of the central system and put ourselves in their shoes; working together to find common solutions.

At what stage is LEO Pharma Spain in launching its new biologic product – Kyntheum – to market?

We are have received the prices and reimbursement approval in July and we have already launched in the Market in September, as part of the second wave of market availability of the product in Europe. Kyntheum® is a significant product for the development of our company as it represents our first entry into the biologics space. A part of our company's management – including myself – has experience in biologics companies, but this still represents a massive shift for LEO in terms of resources, organization and investments.

To what extent does the changing of government stand as a threat to the current high levels of dialogue and engagement between industry and the authorities?

Political instability often goes hand in hand with changes, meaning that you have to start from scratch in building relationships and fearful of operating in a grey zone. As a company we are extremely trustworthy, and we like the super open approach of engaging in transparent dialogue with the authorities. I also like the idea that the institution can perceive the pharmaceutical companies as a partner. There is no sense for the company to just seek advantages for ourselves, because this will not work in the long-term. We are not a listed company – we are funded by a foundation – and our objective is to have patients that can live without skin problems. If we want to help our patients become free from skin disease, we *must* partner with institutions.

Patient-centricity is a large part of LEO's global 2025 Strategy; what initiatives do you have in place in that regard in Spain?

We have reinforced our patient-centricity moving ahead – including using the patients' individual names – to ensure that the right patient always receives the right treatment at the right time. This is why we entered the biologics space and why we have a pipeline fully dedicated to dermatology. Following this, our next generation of treatments will be in gene therapies and other personalized precision medicines.

Even the people working at the very first stage of the development of our products are truly dedicated to patient-centricity. When you think about the patients instead of a biologic target, your view is somewhat wider. In the future, companies will not succeed in dermatology if they only sell products; the whole ecosystem around the care continuum needs to be developed. This ecosystem also encompasses the development of products. This is why we partner with patient associations worldwide and why patients are part of our internal meetings.

At our 'LEO 100' meeting of the 100 most important people to the company, we have patients coming, talking with us and taking decisions because we want to keep that voice. This integration of the patient in the process is patient-centricity in action.

By 2023, where do you hope to have taken LEO Pharma in Spain and in Southern Europe?

In five years, we will have a much bigger Cluster South because we are going to launch two or three biologics into the market and acquire another business to strengthen. The objective by 2025 is to grow to be a EUR three billion company from 1.5 billion today. The company will also be busy in orphan drugs in dermatology, as if we want to be a truly patient-centric dermatology company we cannot only focus on the most prevalent diseases. We will also squeeze our R&D to understand the biologic mechanisms behind these rare diseases and if we already have potential treatment options within our portfolio or if we need to look to others on the market and potentially acquire them.

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