Interview: Denis Delval – Senior Vice President, Europe West and South, General Manager, France, ALK, France



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ALK's Denis Delval reveals how France is number one in terms of volumes for the group and number two in terms of revenues, just behind Germany; how the four Danes – Novo Nordisk, Leo, Lundbeck and ALK – are good examples of the best pupils in class when it comes to their business models and involvement in France; and why access to the French market is becoming increasingly difficult.

You have been general manager of ALK France since the company first established a presence here in 2006. What have been the key achievements and developments for the affiliate over recent years?

ALK has been present in France since 2006, when it acquired a small French pharmaceutical business. In 2006 ALK France was making a turnover of EUR 25 million (USD 27million), with 180 employees. At the end of 2015 we reached a turnover EUR 85 million including export (USD 93 million), with more than 300 employees. This is indicative of the continuous growth we have experienced over the years, in terms of sales as well as in terms of employees. Of our 300 employees in France, 240 are working in production. The number of people working in production has increased significantly, with almost 100 extra people over the last 10 years.

In 2014 we inaugurated ALK´s production site in France as our European hub for manufacturing all our sublingual drops products. Such a move was one of the largest product investments by ALK over the last years. ALK has three main lines of products focused on the treatment of allergies, each representing a significant part of our portfolio: our injectable range, our sublingual drops range and the tablets, and France is now our European center for all sublingual drop products.

In 2015, Europe accounted for 76 percent of ALK´s turnover, with France as the second most important market. What is the strategic importance of France to the group?

France is number one in terms of volume for the group and number two in terms of revenue, just behind Germany. When you have two countries that represent nearly half of total sales, France and Germany, our countries do have a clear leadership role both in our European results and in our ambitions to expand more globally. Having a high percentage of our sales in Europe is a challenge. We are going global and this is the whole rationale behind the group's decision to develop, register and market tablets which are suitable for market approval across the entire world, including the two largest pharmaceutical markets – the US and Japan. Nevertheless, for the time being, both France and Europe are key for the company; when something happens in France it inevitably has a knock-on effect on the entire group.

Since 2012, you have also been senior vice president for Southern Europe. Is this indicative of the strategic role that France plays within the group and what has this meant for your leadership of the French affiliate?

The rationale for expanding my responsibilities was the need to grow people within the organization. When you have a company that is consistently delivering good results, it is because you have a good team in place, because you are conducting business in the right way and also crucially because you allow your people to grow within the organization. By boosting the leadership role of the French affiliate, it not only strengthens my role as general manager, but it also strengthens the role of people in my team, providing them with further responsibilities and opportunities for personal development. France was a natural fit when it comes to responsibility for Southern Europe because culturally people tend to consider that we have much more in common with Spain and Italy. These two countries have been able to learn from the way we conduct business in France, and likewise we have been able to learn from these two countries – the key is that we all grow together. Just recently, on 1st October 2015, I was also made responsible for UK and Benelux as part of a reorganization of the group. ALK used to classify Europe into three regions, Northern, Central and Southern Europe, today we have two regions, one led by France and the other by Germany.

ALK is the world leader in the research and development, production and distribution of allergy immunotherapy. Allergy is a widespread disease, which is becoming increasingly common worldwide. Currently, more than 20 percent of the population suffers from respiratory allergies. What is the relevance of respiratory allergies in France and what is the approach that ALK takes in this area?

Epidemiological data indicates that across Europe and the western world around 20 percent of people suffer from respiratory allergies. The majority can be treated with symptomatic medication. 5 to 10 percent of the population cannot be successfully treated by symptomatic treatments, and in these cases doctors consider that the patient could benefit from a more radical treatment, one that treats the cause. This is where ALK comes in. We provide immunotherapy treatments, providing products that modify the patients' immune system in order to treat the cause of their allergy. We treat patients with severe allergic respiratory diseases, for both allergic rhinitis and allergic asthma.

ALK is a leading pharmaceutical company in terms of its contribution to science, with regards to both clinical trials and scientific publications. We have demonstrated the efficacy and safety of immunotherapy treatments in both allergic rhinitis and allergic asthma. A breakthrough was made in 2006 when the company launched Grazax – the first registered allergy tablet to address the underlying cause of grass pollen allergy. In September 2015 we were also the first to obtain a European market authorization for Acarizax, a Tablet of standardized house mite allergen extract to treat allergic rhinitis and allergic asthma.

What has been your experience when it comes to market access in France and how does the process compare to the other countries which you cover?

France is particularly difficult when it comes to market access. For our first product which received Europe-wide authorization, Grazax, the product was launched in most European markets by 2007. France was the last country in which we brought the product to market, not until the end of 2010. It took four years. France clearly has some of the most difficult market access procedures in Europe. Is this illustrative of the quality of evaluation in France? Or the difficulty for French patients to have access to new therapies ? The French administrative process is very long and based on three stages: local market authorization, scientific evaluation by the transparency committee, and finally the pricing committee CEPS (Comité Economique des Produits de Santé). France is unique in having these three steps. In a country such as Germany this process is considerably faster. Besides being based on three steps, the administrative timeframes are also long, and are not always respected by some bodies. The authorization process is stringent when it comes to the level of

satisfaction which is required, driven by an economic agenda. Major innovations do have access through the system of ATUs (early access to drugs not yet on the market), yet less than 10 percent of new products which reach the French market receive an innovation rating by the French authorities. France is a relatively fair environment for breakthrough innovation. But this is only 10 percent of the new products coming to market. For the remaining 90 percent, which are the vast majority of treatments and patients, the situation is extremely difficult

Tell us about your manufacturing and R&D footprint in France.

Over the last few years, ALK´s ambition has been to simplify our production capacities. Previously we had two sites in Europe responsible for our sublingual drops products, Spain and France. A strategic decision was taken to concentrate this business at our French site. At that time we believed that France was the best place to conduct such activities and that it would be looked upon favorably by the French authorities. If we had to take such a decision today, given the lack of visibility from the French government, I am not certain that the outcome would be the same.

Our R&D footprint in Vandeuil is based on supporting the extremely complex production set-up that we have in France. We are not working on chemical products, but biological proteins where every load must be tested with biological dosages. The people we have working on R&D in France are there to support the validation of our biological products. Our R&D for new products is based entirely in Denmark, due to the need for critical mass. Yet France has been very involved in our clinical development. From 2011 to 2014 we had over 30 centers conducting clinical trials in the country delivering high quality data for international phase III studies. We have been very active with KOLs, and with doctors when it comes to our global clinical studies.

Nicolas Giraud, general manager at Lundbeck France, was telling us how Novo Nordisk, Leo, ALK, and Lundbeck, as four Danish companies, represent close to two thousand manufacturing jobs in France, with 50 percent of these employees working in manufacturing. What is it that makes this country such an attractive place to be for Danish companies?

The four Danes are perfect examples of the best pupils in class when it comes to our business models. For three of us, Leo, ALK and Lundbeck, France is either the first or second most important affiliate. The four of us have long had significant production capabilities in France. Such sites are not only catering for the French market but are producing for the entire world, something which is very important for the French economy.

We do see increasing difficulties when it comes to having access to the French market. Danes are very pragmatic, straightforward people. In the past France was a friendlier environment for companies putting in place production sites. Danish companies have historically been particularly focused on Europe, and if you are focused on Europe then you need to be strong in France and Germany. France has always been a country where new treatments are welcomed by physicians. French physicians are more open to change than the likes of the British or the Germans, they are less conservative in their mind-set and more open to innovation and new treatments. The claim that France is a large market because of an overconsumption of drugs is wrong. France has always been an important affiliate in a European setting. Companies such as ALK have primarily been European companies, so inevitably France will be a key market. Yet today, with some of the lowest drug prices in Europe, where we are always one of the last to come to market, it is increasingly challenging to persuade our CEOs to continue investing in France. We will remain an important country in Europe due to the quality of our doctors and the high level of our clinical work. The country can remain attractive if we have better visibility, better access to the market and recognition of our industrial presence

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