# ALK Abelló Spain – Graham Skarnvad, General Manager



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*Graham Skarnvad arrived to Spain as country manager of ALK's Spanish affiliate at the end of 2009, right when the crisis was in full swing. Later on he took the full legal responsibility – also as: General Manager for Spain, and Portugal. He discusses his mandate and increased in investment in R&D and production in Spain as well as exciting new products in the pipeline, including tablet and venom immunotherapy.*

**In your first role as country manager, what initial challenges did you face as they relate to ALK, and what measures did you take to adapt?**

We faced a declining market due to unemployment and crisis. ALK's products have relatively high copayment, so the crisis is more immediate in allergy vaccines than the rest of the business. Our own internal restructuring was a way of adapting the organization to the crisis. Additionally, the affiliate changed its portfolio to target more profitable products. We also continued our policy of going for registered, quality products. In that sense there has been no drastic change in our strategy.

**How does Spain's division of autonomous communities work with the distribution and prescription of your products?**

We only have two traditionally registered products, our grass tablet immunotherapy product and an adrenaline autoinjector. These go through the traditional channels for distribution. We distribute

our other products directly ourselves because they are made individually for each patient. In that sense, these two products have been impacted by the autonomous communities. There are indeed differences in each region, and ALK has experienced some challenges with a few communities in terms of trying to limit the possibility to prescribe our products. We dealt with it like any other pharma company by convincing the relevant people with scientific data. The regions' limiting of prescribing our products is not material at the moment, and it is partly because of the limited budget impact of ALK-products.

**So these regions were more willing to take similar products from a competitor like LETI?**

Our big challenge is that we have registered normal pharmaceuticals competing with "name-patient" products. The authorities do not seem to push registered quality products, but they do keep allowing old-fashioned products to be prescribed on equal terms. Physicians can prescribe these products equally to registered alternatives, which is a problem for a company like us that has been investing in registering our products. This is starting to change however; new regulations will give us a more level playing field.

**What is the value proposition that ALK offers to Spain?**

We do evidence-based medicine. There is a lot of hearsay in the area of immunotherapy or allergy vaccines because of the lack of proof in double-blind placebo controlled trials. That is where we are taking allergy vaccines. ALK is creating a paradigm shift in the sense that we are the company that invested the most in developing real registered products such as our tablets for grass, house dust mites, ragweed or birch allergies. We are not just proving that they work in the first season. If you have allergies, you would like the medicine to work. But vaccines need to have a continuous effect. We are the only company that has demonstrated this effect two years after stopping medication, and this is due to our continual investment in this area. We are also the only company that is investing in proving that our product prevents asthma. In 2015, we will have the results of the grass study in asthma prevention in children. We are treating more than 600 children for three years, and we will obtain data after five years to see if the group in action develops less asthma than in the placebo group. This will be the first time in history to prove the preventability of asthma.

**That would indeed be a huge advancement in medicine. What does the ALK group hope to achieve if this study succeeds?**

I think we would go for a label change so that we do not just treat the allergy with a sustained effect, but also prevent asthma. This is one of the reasons why so many big pharma companies are

interested in us. We are partnered with Merck in the US, Abbott in Eastern Europe, and Torii in Japan. These partnerships have been established because of our investment in evidence-based medicine.

**How much does ALK's facilities in Spain represent for global sales?**

Spain represents just under ten percent of global turnover. ALK is a very European-based company, but outside Europe we have affiliates in US, Canada and China. The rest of the countries we sell to are through distributors in partnerships.

ALK Spain has normal affiliate functions including sales, marketing, medical and clinical development, finance and HR. Then we have about 30 scientists working in basic research about 110 people working on our production site.

**Many multinationals in Spain are not only committed to this country through R&D or manufacturing facilities, but they are also increasing their investments. Can we expect to see something similar with ALK?**

We have proven this; we will be producing our adrenaline autoinjector for the entire world from Spain. The facilities here are indeed world-class and we are in the process of validation. Because of the adrenaline auto injector Jext, we also intend to increase the number of people working in production. ALK Spain will also be doing all distribution for Europe for vaccines in the future. We will be the hub for all of ALK's shipping. This process has started as we have already taken over all subcutaneous vaccines, but the whole project should take between three and five years. Lastly, ALK Spain produces all diagnostics for Europe. Consequently I hope our image with the health authorities increases because of this. They say they want to recognize our R&D and production efforts but in reality they do not. We actually just had the price of our adrenalin pen lowered by the authorities, which we do not understand because we already have the lowest prices in Europe.

ALK is not a grassroots company. We established production of the adrenalin pen in Spain not to support the Spanish market but because we can get the same quality at a great price. We also have factories in France, and the cost of labor is not much higher there. We could have put our autoinjector production there, but we chose Spain. ALK also has a global business team for SAP, and more than half of the employees in this group are in Spain. We work hard to support the Spanish economy because it makes sense for us.

**Vaccines as a product have a strong political component to them, often a sensitive topic for public health. How does that affect the way you do business, or does it influence the**

**government relationship?**

The field of allergy vaccines has been perceived by the authorities like magic, until now. They are unsure about the long-term effects of an allergy vaccine that can prevent asthma. There is not much evidence out there and that is what we are trying to create. In that sense, I think that the authorities do not see our vaccines as flu vaccines. Essentially we are trying to create that influence with the authorities that previously did not exist.

**ALK's global market share of allergy immunotherapy is about 33 percent. How does Spain compare?**

It is lower in Spain but we do not have exact market figures, precisely because our products are name-patient products. IMS does not have data on us. We do our own estimates about our positioning. It is lower than 33 percent, but we are still either number one or two. Our problem in Spain is that there are 12 local companies in our niche in an unregulated market. There are just a couple of such companies in northern European countries, those markets are highly regulated in terms of quality.

**How will you implement the Focus 2016 strategy of "Simplify, Innovate, Grow" in Spain?**

We will only distribute from one place, which means that all distribution will be done from Spain. The adrenaline pen is a big part of the "innovate" and "grow" areas. We see huge potential for this pen not just in Europe but worldwide. We have also determined our most profitable areas in ALK's product portfolio. We are focusing much more on the most profitable products, which has to do with evidence-based medicine. We are proving that allergists' perceptions are real. I think that trying to prove that you can prevent asthma is very courageous and innovative and has enormous potential. Moreover, our House Dust Mite tablet has shown that it can lower Asthma exacerbations, apart from working in Allergy. Hopefully this tablet will be registered in EU in 2015.

**What is left for you to achieve here?**

There is still much left to achieve. Because of the copayment situation the entire allergy vaccine market has been in decline for the last five years. Thus we need to first get back to a period of growth. We have many new products to launch, in particular our house dust mite tablet which will hopefully be launched in Spain in 2016. This is another example of our innovation. We call these products allergy vaccines; we talked about the fact that we can possibly prevent asthma but with our house dust mite tablet we have proven for the first time ever that we can actually treat asthma. We enrolled 900 patients in a well-designed clinical trial, and we have shown that we can

lower the number of exacerbations. I hope the authorities work with us in that, especially considering that proportionally we run more clinical trials in Spain than any other ALK market due to the quality being the same here as it is in Germany or many other more expensive European markets.

We also work with vaccines for venom allergies like bees and wasps. This treatment has a 95 percent success rate. In Spain, between 20 and 30 people die annually from bee or wasp stings, many of whom could have survived if they had a vaccine treatment. This means they must receive an injection every month for three years. Some physicians do a retest with an actual sting, to convince the patient of the efficacy. We would like to do much more on spreading the news about the benefits of venom immunotherapy. Not too many people know about the huge potential behind this life-saving niche.

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