

# Sean Connor - General Manager Benelux and UK/ROI, ALK, The Netherlands

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*Sean Connor, General Manager Benelux and UK/ROI for ALK, details the company's strategy both in terms of products and therapeutic areas and provides us with his assessment of Netherlands regulatory environment and market access.*

**You have been General Manager for the UK and ROI since 2013, and, in January 2015, you were also given responsibility for the Benelux region. Why does it make sense to group these diverse locations?**

First of all, the Dutch and British cultures and management styles are quite similar, even if the markets themselves are relatively diverse. Since I took over, the working relationship between our teams in the UK and in the Netherlands has been extremely productive and already produced interesting synergies in several areas we cover. Furthermore, the language barrier is not really an issue, as almost everyone in the Netherlands speaks English very well.

**What are your current priorities for the Dutch market?**

In the past, ALK offered to customers almost everything they wanted, whereas most of people who suffer from allergies are affected by only five allergens. This means that we can rationalize our production and offering, while still addressing the concerns of a vast majority of patients. ALK is thus in the process of transforming into a company specialized in licensed medicines for allergy,

moving away from our previous product portfolio built extensively on unlicensed products. We are becoming, both at national and global levels, a company that supplies highly evidence-based medicines, fully licensed, fully regulated, and that really change the lives of patients. In the Netherlands, we have been moving forward on this transition for several years, but it is only this year that we started to really see the effects on our business. Furthermore, as from 2015, there is no reimbursement widely available for unlicensed products in the Netherlands, which fits well with our move towards licensed products.

ALK has a number of production plants all around Europe, and, taking into account these elements, we have decided to simplify and streamline our manufacturing process as a part of our transformation process. One of the production facilities we are currently divesting of is located in the Netherlands that produced mainly unlicensed products, as well as of the animal health business linked to this facility.

**It is fair to say that the Netherlands is seen by its peers as one of the most challenging EU markets. Given your own unique insight into not just the Dutch but also the UK and ROI markets, what is your assessment of the Dutch market?**

The Netherlands is becoming more in line with other European countries, and austerity has hit healthcare like everywhere else in Europe. The public authorities have been forced to respond to budgetary pressures and healthcare budgets have been impacted. Nevertheless, the unique situation I see in this market is how importantly health insurance companies are involved in the reimbursement process and how they have a much more active role in the Netherlands that I have ever seen elsewhere in Europe. Nevertheless, I regret that insurance companies have become stricter regarding the use of unlicensed medicines where there is no licensed alternative. The challenge is that if a company has a licensed medicine, where is the incentive to get the licensed medicines used in place of an unlicensed product? This is clearly a contextual challenge that we are facing now, and some help from public authorities on this side would be warmly welcomed.

Another challenge lies in the fact that a large portion of the most innovative and expensive medicines have been transferred from the GVS system to the hospital budget, while the hospital budget only increases by one percent annually even with the addition of these therapies. Hospitals and clinicians subsequently feel much more pressure in their prescribing of medicines given the strained hospital budget.

**Has the transfer of certain medicines to the hospital budget impacted patient access to ALK's treatments?**

Yes, as up to 60% of our product portfolio's reimbursements are now within the hands of hospitals boards. The hospitals must now consider the drugs costs outside of total patient tariff, while in the past they were sometimes able to pass costs onto primary care. With this new system, there are a lot more negotiations, account by account, in order to ensure that there is a clear patient pathway, and that we precisely agree on who will be paying for which part of the pathway. This situation represented an important challenge for us at the beginning of 2015, and we have managed in most cases to secure funding for the relevant patients. I think that the pressure on reimbursements will nevertheless continue to increase in the upcoming months and years.

**The Netherlands is sometimes seen as a test bed for new initiatives. In terms of market access, do you think that the new strategies that you are employing in the Netherlands can be interesting for the other ALK affiliates?**

We will probably follow a relatively traditional approach for the registration of our new products, as we have a good value offering that fits the current ways of assessing market access. Being innovative may help patients get access to our medicines more quickly, and this is an approach we are actively exploring in this region. In the UK, I had to work with the National Institute for Health and Care Excellence (NICE) for many years on launching products. This experience really allowed me to understand what value really means and how complex these arguments can become.

The Netherlands is a tough market, but I want to highlight that efforts have been made from the various stakeholders in the system to enable us to provide our patients with our new evidence-based medicines more quickly. We are for instance about to launch a new product, and I am already speaking with public authorities at an informal level. They are quite open about using different methods to evaluate this product, even if we have not agreed on anything yet. I think there is a strong willingness to look at different methods for reimbursing products from the Dutch authorities. In this vein, the Netherlands can very well be a forerunner in innovating around patient access to innovative medicines, all the while allowing pharmaceutical companies to still make reasonable profits in a reasonable timeframe.

**Allergy is a widespread disease, which is becoming increasingly common worldwide, and more than 20 percent of the population suffer from respiratory allergies. What is the relevance of respiratory allergies in the Netherlands, and what is the approach that ALK takes in this area?**

The prevalence of these allergies is absolutely huge: everybody knows somebody who has some kind of pollen or animal allergies for example. The question for ALK is how much value we can add

by offering our allergy immunotherapies to people, and current measures don't necessarily reflect the impact that respiratory allergens have on the quality of life of the sufferers.

Most allergic people want to avoid allergic symptoms; the first thing to do is to keep exposure to allergens at a minimum. If this doesn't work, patients can take medicines like antihistamines and corticosteroids to help manage symptoms. There is nonetheless a group of patients for whom basic avoidance and medicines targeting symptoms do not work. We concentrate our efforts on this patient population. Immunotherapies will deeply change the core of the disease, but many of our treatments last several years requiring regular visits to the hospital, so a strong patient commitment to the treatment is absolutely mandatory. Patients following immunotherapies represent less than 1% of the total patient population suffering from respiratory allergies. We should be able to reach a larger number of patients, but to do so we have to balance the value argument and enable clinicians to access our therapies and pass the benefits onto the patients.

The Dutch system is heavily reliant on general practitioners, who are more willing to directly offer immunotherapies to patients, rather than automatically referring to a specialist.

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

Talking specifically about the Netherlands and allergy, we are the market leader with approximately 77 percent market share. We are very dominant, and ALK is obviously the partner of choice when it comes to collaborating in the allergy field. The challenge we face in the Netherlands is that the market for allergy medicines is becoming smaller because it was dominated until recently by unlicensed products that are no longer eligible for reimbursement! We are thus working towards increasing usage of our licensed products.

**ALK's lead product candidate, the HDM SLIT-tablet, was approved by the authorities in both Europe and Japan. How much progress have you made to get this to Dutch patients?**

The HDM SLIT is licensed in 11 countries and is due to be launched in 2016. The Netherlands will be part of the next phase of the launch, undergoing a mutual recognition procedure that will be in process in 2016. Otherwise, the next eighteen months will see no other big launches. We are also moving quite fast on asthma prevention for children, and we should receive some important results from this research in 2016. Regarding a current drug in this field, we are still at the early stages but this product will be extremely important for the company and will clearly embody a strategic shift toward asthma prevention. The company can unlock many synergies via this pairing of

asthma prevention and allergy therapies.

**The Netherlands will hold the Presidency of the EU in 2016. If there were one idea that you could express to the Minister of Health at this pivotal moment, what would it be?**

The Netherlands, and Europe more widely, absolutely needs to find a way to ensure innovative medicines are not restrained by market access and reimbursement policies, whilst respecting the necessary budget constraints.

**Looking forward, where would you like to see ALK in the Netherlands in five years?**

I would like to be able to say that ALK products will be the ones displaying the most numerous therapeutic evidence and offering the best value to the Dutch healthcare system. I also hope we will be able to ensure that the restrictions around market access in the country are appropriate and allow the patients that need innovative drugs to easily and quickly access these medicines.

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