Antonio Pusole – General Manager, ALK Switzerland



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Recently arrived from Germany, ALK's new general manager for Switzerland highlights some of the unique features of the Swiss allergology field, and some of the opportunities for ALK to positively impact patients' lives in the future.

ALK says roughly one in five people suffer from some degree of allergy around the world, with only one percent treated with immunotherapy. How do treatment rates compare in Switzerland, a country known to have an innovative and very high quality healthcare system?

Regarding rates of allergy immunotherapy, I would highlight that for patients with allergies to insect venoms the treatment rates in Switzerland are higher than in Germany for instance. If we consider an allergy to bee venom, a patient with a severe and potentially deadly allergy to bees can be treated with an immunotherapy developed by ALK and reduce the severity of their allergy to the point that they are very close to 100 percent safe if accidentally stung. This is something not known by many physicians, yet in Switzerland ALK has had a successful history engaging with specialists regarding the capabilities of immunotherapies for insect venoms and today the treatment rates for patients with such allergies are at a very good level.

However, this is not the case in more widespread indications to pollen allergens such as grass pollen and birch. And the supply of house dust mite sufferers is even worse. In spite of similar prevalence to pollen allergy the rate of treated patients is much lower. We don't have such significantly differences in treatment rates in other European countries.

Is there a particular prevalence of patients with sensitivity to a particular allergen in Switzerland?

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Allergies to ash trees are significantly more prevalent in Switzerland and parts of Austria than many other countries, and so it is quite an important allergen from the perspective of Swiss allergologists, yet it doesn't receive significant attention internationally. It can be challenging to develop an immunotherapy for such niche allergens as Swissmedic requires efficacy to be demonstrated in a double blind placebo controlled studies to be able to register the product, and given limited patient populations, it can be hard to recruit for and justify funding such trials.

Luckily, it is possible to import unregistered products on a named patient basis from a market where it is registered. As ALK has registered our ash pollen immunotherapy in Austria, a medical doctor or a pharmacist (with a cantonal retail license) is able to import these products on behalf of Swiss patients using this mechanism. However, while our immunotherapies for the most common allergens are reimbursed in Switzerland, it has been challenging to get reimbursement for this ash immunotherapy since, as it is not registered in Switzerland, it is not listed on the positive reimbursement list. It is an ongoing priority for ALK to communicate with the insurance companies and authorities that given the small size of the market in Switzerland, it isn't really feasible to make the investment needed to register them here, and thus the only possibility to treat ash allergies is using the named-patient import mechanism.

How is the field of allergology managed in the Swiss healthcare system, and who would you highlight as the most important organizations and KOLs in the country?

Allergology is a specialty in Switzerland, with about 150 specialists and additionally ENTs, dermatologists, pediatricians and pneumologists active in this field across the country. The physicians specialized in allergology all know each-other quite well of course which creates some "small town" type dynamics which are very different from those seen in Germany where the market is much larger. Within this group, we have identified 15 to 18 regional KOLs. However, it is important to remember that the language divisions are important – so the largest number of these KOLs are Swiss German, followed by the French, and then a smaller number of Swiss Italian allergologists.

In terms of organizations, there are a few important societies, the most important of which is the European Academy of Allergy and Clinical Immunology (EAACI) which is headquartered in Zurich. Peter Schmid-Grendelmeier is a very well respected Swiss allergologist who is a VP of EAACI, and

also heads the Swiss Society for Allergology and Immunology (SSAI) which is the officially recognized specialist association for allergology, and thus has indirect input on issues regarding pricing and reimbursement.

Considering that the field of allergy immunotherapy is quite competitive, how would you assess ALK's current positioning in the Swiss market?

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ALK is one of the few companies which covers the full range of allergens in Switzerland with both sub-cutaneous immunotherapies (SCIT), and we also offer our innovative sub-lingual immunotherapy tablets (SLIT), however due to the registration hurdles discussed earlier, we have not brought our sublingual-drops to Switzerland yet. While the newer SLIT options are appreciated by many patients and physicians, some patients prefer a few injections instead of reminding to take a tablet every day for several months. Thus, ALK is fully committed to maintaining our portfolio of SCIT products for patients who prefer this option, while continuing to expand our SLIT offerings.

Another aspect of our positioning to consider is that the Swiss authorities and payers, like those across Europe, are continuously looking for greater standards of evidence in terms of "evidence based medicine", and this can be challenging for companies operating in a field based on technologies first developed nearly 100 years ago! Despite the challenges, ALK is committed to making the investments needed for the future. In fact, over the last year, we have made significant investments to our production facilities for our SCIT products and as a result have unfortunately experienced some slight delays in terms of product delivery. Timing wise, some physicians who have noticed such delays may associate them the production stoppage and mass recalls made by one of our competitors in 2015 and 2016. However, this is certainly not the case as any minor delays have been due to investments and upgrades being made.

Looking ahead, what do you see as the biggest opportunities for ALK to impact patient's lives?

Considering that by our best estimate, one percent of patients with allergies receive immunotherapy, this is clearly a market with significant potential. However, the challenge remains diagnosis and awareness – many common allergies are difficult to properly diagnose, and most patients and many physicians are unaware of how far allergy immunotherapies have come in recent years and how effective they are today. Additionally, since many patient's symptoms are not dangerously severe, they are often overlooked or misinterpreted. The truth is that they can

become far worse if left untreated.

This is where I see the greatest opportunity for ALK to have a real impact on people's lives. For instance, this could be for patients suffering from an allergy to household dust mites, because the allergens are so small they can easily enter the lungs. Thus, while the usual symptom seen with this allergy is rhinitis, this can develop into asthma if left untreated. ALK has shown in a double-blind, placebo controlled trial program with over 6000 patients that if patients with household dust mite allergies are treated with our immunotherapy Acarizax in early stages, then the asthma symptoms can be significantly reduced.

As such, it is incredibly important that those in the field of allergology work together to change societal mindsets towards treating allergies. If left untreated, allergies can progress and even become life threatening, yet this fate can be avoided through proper treatment. Seeing as only one percent of potential patients are treated, there is no reason companies in the allergy immunotherapy field should not work together – the immense potential for us to impact many lives positively, and plenty of growth potential for companies to share.

More generally, having just moved from Germany to Switzerland in the last three months, what would you highlight as the key differences between the two markets?

On the surface, Switzerland and Germany are in many ways similar, as we share far more than that which could sets us apart. For ALK, the Swiss affiliate is managed as part of our Central Europe North region, and in general these markets fit together well, particularly the German speaking DACH countries are 90 percent similar in my view.

However, the 10 percent of issues where Switzerland does differ are critical. Switzerland is not Europe in the EU sense. For the pharma industry, this is most significantly represented by the fact that Swissmedic does not recognize EMA approvals and is fully independent, and although the regulations are often similar you must comply with different requirements. This means that even small changes at a product have to be approved separately by Swissmedic, an approval by European regulatory authorities is not enough.

Another significant difference is Switzerland multi-lingual and multi-cultural makeup. The Swiss affiliate is quite small, so we are supported by the larger organization in Germany – this works well in the sense that a marketing campaign which works well in Germany will probably work largely well in Switzerland, too. However, such materials must be adapted and translated into both French and Italian, of course. Moreover, there are many situations where you are expected to be able to switch easily between the languages; moving between conversations in French, Italian, German,

Swiss German and even English at a conference or symposium is really challenging even if you have the language skills in each individual language.

Finally, very much to the credit of the Swiss people, this country is quite special. Yes, the environment does play a part – looking out the window from an office or hotel and seeing the majestic Alps is a real privilege – but the country is very open-minded to different cultures, really invests in education, and is a really fantastic place to live and raise a family.

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