José Manuel Rigueiro – General Manager, Actelion Spain



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Jose Manuel Rigueiro, general manager of the Spanish affiliate of Actelion, discusses the lack of trust between health authorities and the industry and the challenges of launching new orphan drugs in such a fragmented healthcare system. He highlights the successful launch of Uptravi

® and his commitment to avoid business disruption during the complex integration process following J&J's USD 30 billion acquisition of the Swiss company.

These are exciting times for Actelion. Last year the company was acquired by Johnson and Johnson. How is this integration process going in Spain?

We are operating as distinct, but not separate companies, which means that we maintained our corporate office and our strong footprint in Switzerland regardless of the recent acquisition. We also operate independently from a commercial point of view. Overall, given the similarities that the two companies share, we did not find any major procedural difficulties – for instance, the patient centric approach that is typical of Actelion is also an integral part of Janssen's corporate culture. The integration in Spain is going smoothly, especially from a cultural point of view.

While it is clear the extent to which J&J benefits from Actelion's innovative nature, what does J&J bring to Actelion?

Following the acquisition, Actelion is now becoming a new therapeutic unit of Janssen. The competitive advantage for Actelion is J&J's ground-breaking expertise in market access, governmental affairs and within the legal sphere. The idea is to leverage all these assets and

continue building our presence in the market based on these capabilities.

You have been the general manager of the Spanish affiliate since 2012. What is the scope of Actelion in the country and what is its legacy?

Actelion had an 85 percent market share and we aim at remaining the preferred partners for the future. Actelion has a strong pipeline and has recently launched Uptravi®. Together with the new resources from Janssen we are aiming at closing the gaps in the field of diagnostics and I can foresee that the scope will be broader.

Can you depict the challenges of the recent Uptravi® launch?

The challenge of bringing orphan drugs to the market in Spain is mostly around pricing as these are expensive drugs and reaching a very small number of patients. The goal was to achieve the right price at the right time, which is something that we succeeded in. This is a drug that can significantly add to the quality of life of the patients from five to eight years after a given patient catches a disease.

The European Commission approved 53 orphan drugs, but only 18 are securely reimbursed here in Spain. Why does such a discrepancy exist?

It is a mix of causes. Firstly, the health authorities do not have the financial means to cover all the approved drugs at EU level. Secondly, there is lack of trust between authorities and industry. It is crucial that they understand that survival of patients is higher through clinicians and hospitals but also through the work of the industry and the drugs that we bring to the market. Specifically, in the case of rare diseases, some companies dealing with the segment purposely decided not to be present in Spain as it is much more convenient for some of them.

Big hurdles in the reimbursement process are also the 17 autonomous health systems as well as the hospitals. Even if the regions approve the drug and agree on the reimbursement, the hospitals may think differently. This is why Spain is essentially an ‘access’ market, meaning that companies typically devote more resources to market access than in other countries, even with a similar size. Due to this fact, drugs uptake in Spain is very slow and it has negative repercussions on patients, for the forecasts and for companies.

Comparatively, where does Spain stand in terms of market access of orphan drugs next to other Western European countries?

When compared to France or the UK, where the first step is much tougher, these countries have no regional hurdles. In Spain, it is the other way around, where market access at central level is quite manageable but at regional level is thoroughly unpredictable.

What is the secret of success for doing a good launch in Spain?

Uptravi®, for instance, covers unmet needs and this is something that we were able to explain to the health authorities. As I previously mentioned, on one hand there is a lot of work that needs to be done between health authorities and the industry in terms of trust, and on the other hand Actelion aims at remaining the partner of choice for the medical community.

How would you describe the state of play of rare diseases in Spain?

We do not have all the drugs approved in Spain we reckon we deserve a better treatment as we cover real unmet needs. In Spain, rare diseases account for less than 8 percent of the total drugs expenditure at national level, meaning that normally it would not be a problem to have them reimbursed given the small number of drugs that we would launch. I believe that right now, it is a matter of understanding what are the priorities of the country. Again, we noticed over the years that some companies do not have a presence in Spain and sell their drugs through distributors. This is why Actelion is different, as in a way it has a real commitment to Spain.

For instance, in the case of pulmonary arterial hypertension (PAH), we have a diagnostic rate of 65 per million inhabitants. In other countries, it would be around 120 per million inhabitants. It means that we still have a way to go to achieve the same diagnostic rate. Reference centers for rare diseases play in this context a crucial role. In order for them to function efficiently, they need to be connected, which is not yet the case in Spain. If a patient from Seville needs to be treated in a reference center in Madrid, it represents a significant struggle.

Actelion is a leader in PAH. What is the company doing to raise awareness and educate physicians about the disease?

This is probably the foundation of our investments – help physicians increase the knowledge of the pathology. Patient centricity is very important and not necessarily easy – we strive to adapt the process of the company by having the patient at the center of the decisions. For example, when conducting local clinical trials, we consult patient associations before making any decision.

Looking ahead, what are your priorities?

From a business point of view, my priority is now to succeed in our launches, to retain the talent of the people in this challenging period of integration and to avoid the disruption of the business.

However, from a patient perspective point of view, we aim at increasing their life expectancy by at least eight to ten years and improving their quality of life.

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