

# Guillermo Castillo - Managing Director, Ipsen Iberia, Spain

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31.07.2018

Tags: [Spain](#), [Iberia](#), [Ipsen](#), [oncology](#), [biotech](#)

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*The managing director of the Spanish affiliate of one of France's most exciting and ambitious mid-caps speaks out about crafting a commercial powerhouse and efficient launch machine in oncology, and shares the secrets of deftly managing organizational change.*

## **How would you describe Ipsen's legacy and footprint within the Spanish market?**

The story of Ipsen's engagement with Spain commenced some 30 years ago with the acquisition of a small company in Barcelona called Lasa that possessed both a production facility and an R&D centre. Since then, many changes have occurred as we have continuously adapted to the maturing industry environment. While both of these assets have subsequently been relinquished, this is not a negative step, but rather reflect part of the natural evolutionary path of the company.

The adjustments happened when Ipsen took the strategic step, at global management board level, of rationalizing production. Nowadays Ipsen's R&D activities are focused in Europe (France, UK, Ireland and Germany), the USA and China. Our three main R&D hubs are located in Paris-Saclay, France; Oxford in the UK and Cambridge in the USA and we have five other R&D sites located in China, France, Germany, Ireland and the UK.

One of the Spanish affiliate's main claims to fame has actually been its part in the creation of star product, Somatuline, used for the treatment of neuroendocrine (NET) tumours and the hormonal disorder Acromegaly. Somatuline, which was launched in the US three years ago and continues to undergo sequential innovation, was originally developed here at the local site.

Today Ipsen constitutes a very robust entity in Spain. We are a market leader for our two principal products and are consciously deploying an agile, biotech-style mindset in a face-paced world that is becoming ever more competitive. The way in which we proved able to launch an oncological product for renal cancer, Cabometyx, in Spain in under a year - nine months to be exact - is testament to fast reaction speeds and willingness to adapt to respond quickly to emergent needs.

**How strategically relevant is the Spanish affiliate to Ipsen right now, especially considering the general pivot more towards the American market and away from Europe?**

While it is true that North America is a highly strategic marketplace - last year accounting for a quarter of total sales revenues, 24,5% specifically - Ipsen still derives the lion's share of its sales (34%) from the European operations. Within that, Spain accounts for a healthy 11% of sales by geographical area (Europe) contribution. In terms of revenue generation, this is a key market, especially considering that we are focusing on innovation and specialty care which very much represent the future of medicine. When it comes to maintaining our relevance, in the eyes of the global management board, our superior ability to contribute to R&D via clinical trials and our rapid introductions of new products into the market are both absolutely fundamental. Those are the two characteristics that ensure that the Spanish affiliate participates right at the vanguard of Ipsen's worldwide transformation.

Drug developers often bemoan the complexities of bringing portfolios to stagnating European markets, but we buck this trend by proving that it is, indeed possible to speedily and efficiently execute product launches. I personally believe that the secret is about properly understanding the operational environment, the needs of European health systems, and how a company can contribute to a system while simultaneously introducing innovation. We very much hope that our experience in launching Cabometyx can serve as a showcase example of the possibilities within Europe to introduce innovation despite the inherently complex business environment, when many public health systems are experiencing severe financial constraints.

**Ipsen has a new CEO in David Meek and a fresh strategy aimed at transforming the company into both an efficient launch machine in oncology and a commercial powerhouse. How are these changes trickling down to the local level?**

For the past two and a half years we have been undergoing a wholesale transformation. Our role as a local affiliate was to align with the structural changes and fresh vision while all the time protecting portfolio performance and minimizing any kind of operational disruption. On one hand, we are a solid outfit, with high-performance products still in the growth phase and expanding year on year. For example, we have certain established products have been on the market for 3 decades, yet every year we still witness an increase in market share.

At the same time, we are launching cutting-edge products in oncology, which represents a completely different ball game to be participating in. The challenge is to keep performance high and maintain the results-orientated mindset of our local staff whilst simultaneously assembling an entirely new team for our brand new oncology unit. Remember that we are building the oncology arm up right from scratch so that entails sourcing new sets of capabilities that with, hitherto, never had in-house. Our goal is to bring in new, fresh air and to inject that biotech mentality that will be so critical to our future success.

One of my priorities has been to manage change and expectations in a harmonious manner and to accomplish the integration of these two distinct sides of the business in a smooth and seamless fashion. We are very proud to, in a sense, possess these two different business sides, but to have been able to integrate the different characteristics into a single, coherent, high-performance offering, we are now One Ipsen. So far the oncology business has been a huge success accounting for as much as 62% of global revenues, and 83% of current revenues in Spain 83%, which demonstrates just how deep the transformation has been.

**If we deconstruct your local offering, what are the main components and revenue drivers?**

The three key areas of specialty care in which Ipsen operates are oncology, rare diseases, and neuroscience. Oncology accounts for the largest portion of Ipsen's local revenue at 83%. The remaining 17% of revenue is divided with neuroscience accounting for 10% and rare diseases at 7%. In Spain, there is no consumer health care. The company decided two years ago license all its products in primary care. The consumer health segment is not deemed sufficiently attractive to us in Spain so the introduction of that OTx model that you will have heard is being rolled out in some

other markets has not affected us over here in Spain.

### **What are Ipsen's lead products?**

I would say that Ipsen, in Spain, has two standout products. The first is Decapeptyl, which is used for the treatment prostate cancer. We are actively promoting this product and continue to conduct clinical studies with the drug. We have been a market leader in the treatment of prostate cancer and a leading brand for one and a half years. By harnessing bone therapy for prostate cancer, we have been gaining market share every month.

Our second main product in terms of market share and revenue is, of course, Somatuline. It is an incredible drug that was developed here in Spain. Initially, the indication was for symptom control of neuroendocrine tumours, then, in 2016, we attained the indication for tumour control as well. Somatuline is the best product in terms of data from trials and reachability for patients, which is why we are market leaders.

Additionally, we have indications for the hormonal disorder, acromegaly, where we also play a very important role. It is a rare disease and for pathologists it's a very difficult disease to diagnose. This often results in a very late diagnosis so the patients are not in good condition when they start to receive treatment. Out of a strong sense of responsibility to increase awareness of the importance of early diagnosis, we have been conducting campaigns to raise awareness across the medical community.

### **How did you manage the launch of Cabometyx within only 9 months?**

This eye-catching success was a combination of several factors. First and fundamentally, we have an extremely good product. Cabometyx is a new generation of TKI drugs used for the treatment solid tumors. When I joined the company, Cabometyx had already been acquired by Ipsen. Then we obtained the EMA approval in September. At that particular moment, Ipsen didn't have the complete oncology team it has today - we were still building up the capabilities and only has the business unit head in place so we has to be quick off the mark to catch up.

After 3 months we had prepared the price and management brochure. We decided to approach health authorities by showing the data, the clinical value of product, and its value to the health system. Being very transparent in terms of pharma macroeconomics, we started the negotiations.

We submitted to dossier in December and received approval in March. This is a good example that a very complicated process in a country like Spain could be long or not at all. In this case, a combination of factors, but most importantly a product that can contribute to improving patient life, is a product that is easier to achieve access for.

It was the first time in my professional life that I had a process surpass the infrastructure needed for a project. We then decided to implement the managed access programme, which after the approval, made the drug available for free for all patients with indication. This program was open until the end of the project, so when we finally released the new product into the market we kept this program for all patients for free. Finally, in September we launched the product officially in Spain by meeting with the 17 different regional authorities.

**Spain is notorious for having the equivalent of 17 different health systems as a result of the devolution of powers. How do you practically deal with this complexity?**

The key to success lies in understanding. Before saying something is complex it is imperative to fully comprehend the process. It is true that in Spain there are 17 autonomous regions, each with its own processes. Irrespective of decisions over pricing and reimbursement, in the end, the regions are the one paying. This situation must be accepted and we have to establish individual mechanisms in order to get our products to the patients in each of the regions.

It all starts with mapping out and establishing a standard profile for each region. For example, we know that in some regions the average time for access is roughly nine months. We can speak of a minimum and a maximum bandwidth. While some regions might usually take nine months, we might manage it in three, and contrastingly in some regions we still do not have access. Regions have massive discrepancies and a local solution is needed to solve a local problem.

What is important is to have a clear reality of what is happening in each region; centralized or decentralized. We firmly appreciate the importance of maintaining presence in the regions alongside the value and access players. Therefore, we have decided to go for a complete different model in terms of organizations.

One local fix that we have come up with- some companies of our size are doing the same - is to combine the positions of the access and key account manager into a single job under which the holder accountable for everything that is happening in these areas of responsibility. Sourcing talent for such a position is, of course, challenging, as you need to identify someone with the full array of

skill sets.

At the end of the day, for both hospitals and private oncology, what we needed are people who are able to understand the environment. Individuals who understand the needs of the players, what's happening in the hospital, and who are able to talk to the oncologist at the level of their knowledge. The profiles of the managers that we have for oncology are very high. It was difficult to find individuals who could cover a lot of area simultaneously within the same position.

**Spain is highly competitive for clinical trials in terms of approval and time frames, what is Ipsen doing as a company to react to this?**

Referring back to two and a half years ago, we had some clinical operations in Spain, mainly phase IV trials. One of my priorities from the beginning was to increase the number of clinical trials in Spain and to do more in phase II and III. In the end it is crucial for a business to contribute to the innovation within any country in which it operates. There is a massive difference between standing in front of the Ministry of Health when you want to launch a product and saying 'I have no research', rather than saying 'we have done clinical trials, we have collaborated with academies and possess the real world evidence to demonstrate that this product delivers the intended impact in a way that offers value for money.

From the beginning, this has been our priority. We have increased, and will continue to increase, the innovation of clinical trials in the next years. For example, at the time when I started, we were not in the Profarma program. However, last year we submitted the proposal, attained the approval. This further demonstrates how invested we are in our R&D development. From 2016 to 2017, Ipsen has grown its investment of R&D in Spain by almost 4 percentage points.

Although this is an area where we have improved, there continues to be more that can be done. We want to demonstrate within the company, to the global management board, that Spain is an excellent place for clinical trials.

**What is Ipsen doing to be a true partner to the government in order to find ways to make healthcare more financially sustainable?**

Having empathy is essential. We have to understand that the other side is taking care of the costs – considering how our health system is universal and the costs of oncology are rising exponentially.

The introduction of innovation and maintenance of the financial viability of the system are both essential. Our patients are the central focus of both aspects, and their life quality of life is key. We are very open in the respect of reaching agreements as long as the focus is on results and performance related outcomes. If the drug works, the system pays and if the drug doesn't work, the system doesn't pay.

Regarding the different realities of the autonomous regions, we have to be flexible. Some are very advanced in what they are doing and others are laggards and we have to adjust to their capabilities and the infrastructure on the ground. We have signed risk-sharing agreements and in reality, we are open to any kind of agreement that will ensure innovation, the sustainability of the system, and of course the profitability of the company. I would say that we are very receptive and always collaborating at the hospital, regional, and national level. It is important to be creative, versatile and open to trying out new arrangements.

### **Where does Ipsen want to find itself in the upcoming years?**

In two years, Ipsen Spain will be one of the leading companies of oncology in terms of true innovation as opposed to volume. We have two new indications for cabometyx including for pancreatic cancer where there are currently very few treatments and also some combinations for immunotherapy coming on-stream. In two and a half years Ipsen will be a company that will be able to consistently and systematically roll out products for its patients in less than a year.

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