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*Ram3n Villamar3n Valdenebro, general manager of Shionogi Spain, highlights the key steps that needed to be taken to establish the affiliate over the last 18 months and his plans to grow its portfolio, both in the pharmacy and hospital sector. Furthermore, he gives an overview of how the company has adapted to the fragmented Spanish ecosystem and the perception he is looking to build as a new entrant in the market.*

**You founded the affiliate for Shionogi here in Spain in April 2017. How have the first 18 months been for yourself and what has been the process to set up the operations?**

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In the past, I have had experience setting up operations up from scratch, from my time at TEVA, and most recently working with Samsung Biologics, to set up Biogen's biosimilar range in the Iberian Peninsula. Therefore, when I started the Shionogi Spain affiliate in April 2017, I already had a good idea of what to focus on – the people. During the early stages, a majority of my time was spent on finding the best employees to hire.

We had to build the correct Shionogi Spain structure, and make sure the people understood what we were doing here. Globally, Shionogi has had some blockbuster products, though historically outside Japan they have been commercialized by third parties. Therefore, when hiring new staff, it was a process of explaining our projects, and above all, exactly who is Shionogi and what do we do.

Once we got this first step of finding the correct people up and running, the next step was to bring in commercial products. In July 2017, a record time of three months after opening the Spanish offices, we launched our first drug, Ospemifene, which benefits women during menopause. Shortly after, we began looking at how we can continue to grow our women's health line. As Shionogi is a company that historically is very comfortable working with partners, we engaged with other companies that have similar interests in women's health so we could create a full offering. This has involved a great deal of business development to build these partnerships, and we are planning to launch a few more products in the upcoming months.

In parallel, we are also preparing other launches of hospital products coming from our pipeline over the coming months, focusing on infectious diseases for resistant organisms, liver disease and opioid-induced constipation. These will be entering the hospital system, which has little synergies with the pharmacy/retail sector which we have been involved in with our women's health portfolio. We now will be dealing more directly with the 17 Spanish autonomous communities, so we must build up our market access and government affairs competencies.

To give an overview; we will be growing our women's health portfolio through partnerships as well as launching products in the hospital sector.

### **The Spanish healthcare market is fragmented, with some 20 odd thousand pharmacies and 17 autonomous communities. How do you manage this situation?**

Market access for a country like Spain is complex, and first involves talking to the Ministry of Health about pricing. If you wish to have your product delivered to the correct patients, the key is working hand-in-hand with the different layers of the healthcare system so the professionals in the decision-making process are informed about your drug.

Because the autonomous communities in most cases control their own decisions, we must adapt our strategy to their local needs. This is great for a company like Shionogi as we have innovative drugs that benefit the patients and system immensely. Now we must demonstrate to local level governments what exactly is the benefit we bring, so our drugs can be reimbursed, and ultimately be given to patients to improve their lives.

### **Do you feel that Spain properly rewards innovation?**

I think that the country is becoming a lot more professional in rewarding innovation. We are looking a lot more towards technical assessments, rather than just purely comparing new treatments to what is on the market. Innovation is really being seen on an individual basis, which is excellent for

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companies who are investing a lot of time and money into products as if we can provide the correct information, our innovation is being given the right value. Nevertheless, improving this system is an ongoing process, though it is definitely on the way up.

### **How important is Spain for Shionogi?**

Spain is one of the EU-5, so just purely from the market size, it is an attractive nation commercially. Shionogi has many products that match the unmet medical needs of the country, such as therapies for anti-microbial resistance (AMR), crucial for a country that has a large number of cases.

Furthermore, despite the obvious positives of being a large market, Spain is one of the best public healthcare systems in the world, with many top hospitals and European KOLs. This is great for Shionogi as we are a company that is on a learning curve. We already have a 140-year history, though a majority of this is solely in Japan. We understand that the entire global market is changing, and this is happening now; therefore, we must adapt to these shifts first-hand, so we can learn throughout the journey. Having a direct presence in Spain allows us to do this by building relationships to we understand the needs of patients.

### **A way of engaging and building a name in the medical community is through clinical studies. Is Shionogi Spain undertaking these R&D operations?**

Absolutely. We began investing in clinical studies even before opening up the offices of Shionogi Spain, and this follows the companies clear R&D focus that places us as a purely innovative company. Additionally, I believe Spain is one of the top nations to conduct high-quality clinical studies, with a European leading public healthcare system, world-class hospitals, and amazing medical staff. Really it is a win-win situation for the company and country. They are exposed to our products, and patients receive innovative therapies.

Overall, this also highlights Shionogi's long-term commitment to Europe and Spain. We are here for the long haul and we are now setting our foundations to build for the future.

### **Shionogi is really the new kid on the block. What is the perception you are looking to build?**

A trustful reliable partner for healthcare professionals that helps treats patients by providing solutions to unmet medical needs.

### **What are your priorities moving forward?**

Firstly, to complete the structure for the commercialization of our hospital medicine launches, so this will involve dealing with the market access for the 3 drugs to be released. This process is a long journey, so better to start sooner rather than later.

Secondly, we will close business development opportunities in the women's health franchise and soon construct and close a complete portfolio.

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## **What attracted you to move to Shionogi and set up the offices in Spain?**

Firstly, it is not the typical business, and we are very much looking to do things in a different way. We see patients as the basis for everything we do, and then build the structure around this.

Secondly, from a business perspective to work for a company that is looking to build its name, but already has a long-standing 140-year history that consists of many blockbusters, is very appealing and an extremely unique opportunity. I was able to merge the innovation of Shionogi with the design structure I believed would work, and I can say it has been an amazing experience thus far and I am positive will continue to be in the future.

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