Aurora Berra – General Manager, Sobi Spain and Portugal

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Aurora Berra, general manager of Sobi Spain and Portugal, highlights her key priorities and the opportunities and challenges inherent in the fragmented Spanish healthcare system. Berra gives insight into the need for a bespoke rare disease focus and delivers advice to young women starting their journey in the healthcare industry.

How has the transition been from your previous roles to your position at Sobi?

I joined in November 2017 with a background in Big Pharma, at GSK and BMS. These companies were different in terms of culture, being English and American, and Sobi follows this trend, being Swedish at heart.

Nevertheless, the cultural differences although there, were not hugely significant. The biggest change for myself was the size. In my last role at BMS I managed 2000 people across 80 countries, and now I am focused on the Spanish and Portuguese markets, so the dimension is quite different in that regard.

Additionally, working now in the rare disease field is very interesting for me. It is exciting to work in a rare disease company, helping it to construct its own story and the next steps in its evolution. In 2018 we doubled in size in terms of staff and are on the way to doubling our revenue.

What interests you most about working in rare diseases?

It is a lot more complex in terms of market access as you are treating only a small number of patients and must show the relevant people the value you bring and how this relates to cost. Secondly, the impact on patients is a lot more rewarding as you are really making the difference between them living or not. Our treatments really change people's lives.

How have movements at global level trickled down to the affiliate?

Sobi has a business model based around acquisitions or partnership agreements for the commercialization of products, coupled with our in-house R&D department. For example, in haemophilia, we made an agreement with Bioverativ, now part of Sanofi, for the commercialization of Elocta and Alprolix in Europe. Sobi does have a vision to grow the operations in the US and abroad, with a strong focus on Europe, and in that regard, we are always looking for future opportunities and deals to grow.

Spain is an attractive nation for clinical trials. How is this reflected in Sobi?

We undertake phase II and IV clinical studies in Spain as part of the company's global program. It is a good opportunity for the company to capitalize on Spain's favourable regulations, and because most of the company's clinical studies are done in Europe, there is potential to grow this area in the future.

How is Sobi's global portfolio represented in Spain?

We have two business lines in Europe. Firstly, haemophilia, which is our main business line, and specialty care, with our main focus being Kineret®. We are looking to develop our immunology space further, and we have a partnership deal with a Swiss company to launch our first drug Emapalumab in 2019 in Europe.

Market access in Spain can be complex, with national and regional decision-making steps. How do these dynamics impact orphan drugs?

There is a centralized process for pricing and then we must negotiate with each of the 17 autonomous communities for access. This can bring challenges, but also opportunities, though with the changes in government that we are currently experiencing, it can be difficult as we must renegotiate with the new stakeholders each time. This is why Sobi, must do a special job in showing the drug evaluators and key decision makers the importance of rare disease treatments in the country.

I think the overall understanding of rare diseases is quite good, and it is about finding a balance between cost and the people suffering the diseases, but the question is, do orphan drugs receive market access at a faster rate than other innovative medicines? Probably not. In many countries, there are bespoke regulatory processes for orphan drugs, such as in Italy where there is a specific budget dedicated towards these treatments.

In Spain, we do have a national plan, but it is more a social strategic plan, rather than targeting the costs and market access side of the sector. The rare disease community must work together to catalyse these changes

Orphan drugs in many ways is personalized medicine. How ready is Spain for this new wave of care?

We are not the leading country in this regard, and we can do a better job as a pharmaceutical industry to better educate the national and regional administration in this area. The pharmaceutical companies know the steps that must be taken to identify patients and must be better at sharing this knowledge.

Additionally, a key part of this identification process is registers, which unfortunately Spain does not have, unlike the UK and Italy. Philosophically, people love the idea of personalized medicine, but steps like a registry processes must be put in place first.

What more can be done for the early identification of patients?

The current diagnosis period for rare diseases in Spain stands at a median of 5 years, so there issignificant room for improvement, and as a company, we can offer our specialized medicines

once we identify patients, so this step is crucial for us. We are working with patient groups, national associations and physicians to grow awareness in haemophilia, and most orphan drug companies are equally doing their part in this regard.

How well known is Sobi in the Spanish market?

Everybody working in the field of haemophilia knows who we are, and in terms of rare diseases we are working on growing our footprint. This was one of my first priorities when I took up the position, and we will continue to put Sobi into the light and be more present as a company.

Where is your competition coming from?

The oncology sector a few years ago was full of players, and now many big companies are joining the rare disease landscape. This can be seen with recent M&As, such as Takeda’s acquisition of Shire, and now possibly BMS purchasing Celgene. We are not playing with this size. Really anything can happen now if you look at the current pharmaceutical market dynamics

You are part of Foundation Twenty-Nine. What are the organization’s objectives?

As aforementioned, the diagnosis period for rare disease currently stands at around five years. We are working at the foundation to use IA to bring this number down and believe using this information is a key factor in designing diagnostic models. By analysing particular symptoms and phenotypes of certain diseases, we will help the physician to diagnose rare diseases earlier

What advice would you give women starting their careers in the healthcare industry?

Women at times can lack self-confidence, maybe due to the fact there are not as many reference examples compared to men. The self-belief in men is generally quite high as they have always had reference points and overall belief if they work hard enough, they can reach their goals. Nevertheless, times are improving, and some women are flying the flag as we can see in many examples especially in the pharma sector with few GMs in our country. This shows hard work does pay off and really, anything can happen if you are dedicated towards your goals. I encourage young women to truly believe that is possible to achieve what they want.

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