Pablo De Mora â?? VP and General Manager, Sobi Spain & Portugal

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Sobiâ??s VP and general manager for Spain and Portugal, Pablo De Mora, comments on his experience during the pandemic, the Swedish companyâ??s haematology and immunology portfolio, including its EMA-approved COVID-19 treatment, and the reimbursement challenges faced by rare disease players in Spain. Moreover, De Mora highlights Sobiâ??s vast clinical trials operations in the country and how the organization is trying to â??Humanize Rare Diseases.â?•

Just four months into your time as Sobiâ??s VP and general manager for Spain and Portugal, the WHO officially declared a pandemic. What can you share about your experience during the crisis and the ways in which it changed an organization you were just getting to know?

COVID-19 had a significant impact on all of us, bringing radical change to our lives and forcing us to act differently. Even though Sobiâ??s mission did not change, the pandemic presented a challenging situation for rare disease patients since they require personalized treatment and were unable to get face-to-face encounters with physicians.

I joined the company in November 2019, four months before the World Health Organization declared the novel coronavirus outbreak a global pandemic. Reflecting on that period, I feel that Sobiâ??s initial reaction exemplifies the companyâ??s boldness; I remember the organization taking a

proactive role, moving meetings online way before the authorities took official action. This was a big undertaking since nobody was ready to organize such a transformation in such a short period of time. Physicians were impressed by the companyâ??s stance because they saw it coming, understanding that Sobi strives to do the right thing. Our belief was that we did not cancel things, we transformed them.

Almost two years later, we live in a different world, one where we are getting used to living with the threat of COVID-19. Patients are going back to hospitals and booking appointments with doctors, but there was a period of time when the key issue was delivering medicines to patients. We organized a home delivery system to guarantee just that by partnering with different stakeholders, including the Spanish Federation of Haemophilia (Fedhemo).

With over two decades of experience in the pharmaceutical industry, including many years with MSD and Novo Nordisk, what attracted you to Sobi and the rare disease space?

Sobi attracted me because of its mission to take care of patients with rare diseases. I found Sobi Iberia to be a very appealing project from the start and became excited after seeing first-hand the passion of the team and their sense of purpose, that is, doing the right things to help improve the quality of life of rare disease patients. Of course, as a long-time industry executive, it helped that Sobi is a fast-growing biotech player in a unique position to fulfil that mission.

Sobi has positioned itself as a global innovator in rare diseases with over USD 1.6 billion in annual revenue, offices in over 30 countries and commercial operations in more than 70. Can you explain the companyâ??s footprint in Iberia and its product portfolio?

First of all, I want to stress that Sobi is a great company full of great individuals. Their passion makes it a privilege to work alongside them. After years of experience with other companies in different geographies, I have realized that, often, you are attracted to large companies with huge capabilities without really understanding what they do, but in Sobi it is the opposite, talented people want to join because they know that it will be an opportunity to do something special, to have a big impact that will be noticed not only by patients but the entire community.

Sobi Iberia has a team of about 50-75 people, depending on whether you count its valuable interns, making it a mid-sized company. We have two main structures, one based in Madrid and the other in Lisbon to cover both Spain and Portugal efficiently; both organizations are growing nicely. Furthermore, we are organized into two business units, one is haematology, which is a very competitive environment, and the other is immunology and specialty care; these are two highly coveted areas, making it an attractive destination for people with an interest in rare diseases. Within haematology, Sobi has products for Haemophilia A and B, both with high quality and safety, plus a leading position in their categories. In immunology and specialty care, we have a number of products for different diseases, some for autoinflammatory conditions, one of which has been recently approved to treat COVID-19, and many more for extremely rare diseases like Amyloidosis, Chylomicronemia and Tyrosinemia.

At a global level, last year, haematology accounted for 57 percent of Sobiâ??s revenue, while immunology stood at 35 percent and specialty care at 8 percent. Is the revenue split similar in Spain?

The situation is similar in Spain, where haematology leads the way and immunology keeps growing. Looking to the near future, on the haematology side, we are getting ready to launch a product for Immune thrombocytopenia, a bleeding disorder, and further down the road we have a product for an ultra-rare disease called Paroxysmal Nocturnal Hemoglobinuria (PNH). We also have new products coming in the immunology space; both franchises are growing.

According to data from the Spanish Association of Orphan and Ultra Orphan Medicinal Products Laboratories (AELMHU), about 60 percent of orphan drugs with a commercial authorisation are not reimbursed in Spain. Can you comment on the situation and the role Sobi is taking to close the gap?

I do not yet see a big change; we need to do more. The Spanish ecosystem knows the recipe and understands that there must be a permanent dialogue between the administration, patients, HCPs, academia, regulatory authorities, and industry.

It is particularly difficult to obtain funding in Spain and, when you do get it, it is an unnecessarily long process. The country must be able to fund more drugs for patients in need, it is an area to improve, and the way to do it is by hiring a good team of professionals that can improve market and patient access. For its part, Sobi has a dedicated team that makes sure that we connect with stakeholders so that they understand that rare diseases are a challenge that affects everyone, not only a small number of patients but the whole system.

We started an initiative called Humanizing Rare Diseases with the objective of putting a spotlight on them, conveying that it is not just a number but rather people and families. Society should ensure that they receive equal treatment by approving products as fast as any others. This project involves patients and their associations, health professionals, administrations and other institutions. We are already at the end of the process and in 2022 we want to present its conclusions.

Since rare diseases never have enough funding, there are many patients that remain, unfortunately, untreated. In part, this is due to a lack of understanding; when I speak to people about what my job entails, people in Spain relate to haemophilia because it is well known in the country but most other rare diseases are unknown, even by doctors precisely because they are infrequent.

In order to raise awareness among doctors and authorities, companies often look at clinical trials as a solution, exposing HCPs to the disease, stimulating the ecosystem and offering patients a novel treatment. How is Sobi Iberia approaching the question of clinical trials in a country with one of the highest number of studies worldwide?

We have a number of clinical trials for haemophilia in Spain, including some phase IV for products that have been approved and were launched many years ago, which are additional studies that produce real world evidence to measure how the treatment is performing in terms of efficacy and safety; we do them for both Hemophilia A and B. In addition, we currently have Phase IV clinical trials for our upcoming Thrombocytopenia product which is an important one in Spain.

In immunology, we have been funding studies to evaluate our anti-inflammatory drug anakinraâ??s effect on COVID-19 patients. It has been found that, since the virus leads to an auto inflammatory process that can lead to ICU and death, if you stop the process, you significantly reduce mortality rates. The main study, conducted Greece, helped Sobi secure approval from the European Commission and we have carried out similar clinical trials in Spain.

Our paroxysmal nocturnal hemoglobinuria treatment has just been approved in Europe and is going through Spainâ??s reimbursement process.

The companyâ??s leadership has publicly spoken about the strategic importance of real-world data. Of course, its home country, Sweden, is well known for its health registries and data collection. How difficult is it for Spain to be part of that effort considering that it has a decentralized healthcare system?

Spain and Portugal do not have the Scandinavian system where they report everything and keep good track of clinical histories, allowing those countries to be clinical trials machines. Nevertheless, Spain excels at the rolling out of clinical trials, although there are difficulties at the beginning because they must go through ethical committees in each of the 17 regions that have a different approach; there is a high level of administrative complexity.

However, once you clear those barriers, which Sobi is very good at, the quality of the research is great; the centres have good experience in enrolling patients and collecting data. Spain has become the second-best region in terms of recruiting patients for one of our Hemophilia A studies, only behind Scandinavia and recruiting almost as many patients as Germany despite having around half of its population. The country is good at executing but not as much in the administrative part of setting up the trials. The situation in Portugal is similar.

The health sector has made headlines in Spain in recent months after the announcement of a project that will inject hundreds of millions of euros coming from the European Union into the sector, mostly on research. Do you expect them to have a particular impact?

I certainly hope so and we are looking into it. I am not an expert on that topic, but the belief is that the projects will have a greater effect on basic research than real world evidence research. The funding coming from the European Union are targeting basic research, often helping start-ups, rather than late-stage clinical trials. I hope that more funding is given to improve reimbursement and help more rare disease treatments get to the market.

In Europe, diagnosis of rare diseases takes an average of five years and only 6 percent of those diagnosed have a treatment option. What is the situation in Spain?

The situation varies from one disease to the other. Taking Chylomicronemia or Amyloidosis as an example, you encounter ultra-rare diseases that are complicated to diagnose, where patients are sent from one doctor to another for around five years before being diagnosed. That is something that needs to be taken care of by educating HCPs and performing more research.

On the other side, there is a group of diseases like haemophilia that are easy to diagnose but have a low prevalence. The second group is easier to deal with but, for the first group, we must put the right basic research and academic funding to allow the community to better understand them.

Are there any projects that you would like to highlight that you believe will have a profound impact on Sobiâ??s activities in Spain and Portugal?

There are two things that we are proud of and excited about, one is the Immune Thrombocytopenia product because it will make the life of the patient easier by providing a treatment that is easy to take regardless of diet; Sobi is offering real innovation through an oral treatment. The second project we are excited about is the Paroxysmal Nocturnal Hemoglobinuria (PNH) treatment, which is an important disease with high unmet medical needs and only one product that has really worked in the last decade. The latter is a good example of the overall situation in rare diseases, where either there are no treatments or just one.

Sobi is working on a new generation of treatments that will address those unmet medical needs that will improve quality at all levels, from efficacy and safety to patient adherence.

To conclude, is there any advice you would like to send to young professionals looking to make a career in the pharmaceutical industry?

Perhaps they should be giving me advice instead of the other way around! What I like about new generations is that they attach a special value to helping and doing the right thing, they are slightly more altruistic, it is not all about the package and compensation.

My advice for them is to be willing to grow and to be open to international opportunities and different experiences. At the end of the day, if they keep their passion, curiosity, and willingness to help patients, they will go as high as they want. Sobi Iberia has an incredibly talented and well-trained workforce, which is especially important in rare diseases because even doctors often lack the knowledge; you cannot go in there without having profound knowledge about the disease if you are to engage in deep discussions with HCPs and patients. Sobi will always provide limitless development opportunities to young professionals that train hard and are flexible.

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