

**Stefanie Granado â?? Director General Iberia,
Takeda**



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Stefanie Granado, director general of Takeda Iberia recounts the opportunities available for Takeda in Spain following its acquisition of Shire. She also discusses Takeda's local acquisition of TiGenix, handing Takeda stem cell production capabilities, and how this makes Spain a key market and hub for the company.

Takeda has recently completed the acquisition of Shire for USD 62 billion. How has this impacted your operations here in Spain?

Spain was previously not part of the top five EU countries but was in the Southern Europe cluster. However, following the acquisition of Shire, Spain's position was changed, and it now reports directly to the head of Europe and Canada.

The acquisition immediately puts Takeda within the top ten companies both globally and in the Iberian region, creating a completely different footprint and visibility in Spain. This is a very exciting moment for us, offering greater opportunities that would have been unavailable without the acquisition. We continue to be the leader in rare diseases and aspire to be the top company in the gastrointestinal and oncology areas wherever we are present. We are one of the leading players in Spain and are looking forward to partner with the local authorities and healthcare providers.

Together with an external focus on our customers and partners, integration remains my leading priority. The objective is to accelerate integration. We try to be as fast as possible to maintain the focus on the delivery of our services to our patients. Until the integration is completed, it means uncertainty for our people which is something that is not sustainable long term. Moreover, as long as our focus is internal, we cannot capitalize on the new opportunities at our expanded capabilities bring with them.

What is your local portfolio?

We do not simply try and land the whole international portfolio here. Instead, we adapt it to the local Spanish environment. Nonetheless, we have a broad representation of the international portfolio and here in Spain, we have achieved four best launches worldwide. We do not have the vaccines component, but lead in rare disease, as is the case globally. We are going full speed in our GI portfolio and are determined to fulfil the global ambition of becoming the leader in this therapeutic area. This is also where two portfolios (legacy Shire and legacy Takeda) are combined and are proving very complimentary, providing a larger footprint and more opportunities for the patient.

Furthermore, we now have a complete portfolio to offer to the patient along the IBD disease journey.

Moreover, neuroscience is something that maybe is more important in Spain compared with other European countries. The current focus is on ADHD, with a very strong pipeline globally. We have interesting projects in the pipeline that Spain is ready to capitalize on.

Finally, oncology is an area where we have recently created a separate oncology business unit. This is a sign that we are committed to oncology and that for us it is a strategic pillar where we want to ensure that the team stays nimble and as agile as possible. This is the rationale behind the establishment of a separate oncology profit and loss statement here in Spain.

How prepared is Spain to embrace and adopt innovation?

Spain is a key market for Takeda's R&D footprint as it has well prepared and highly skilled healthcare providers. Spain is more than ready to embrace innovation. The main issue we encounter relates to the recurring changes in the government, creating uncertainty around the processes and future policies. Still, the current policymakers are endeavouring to professionalise this, which is what I believe is needed - more rigid processes.

Market fragmentation is also a key challenge in ensuring that Spanish patients can receive the top tier of innovation. It is key to understand the 17 autonomous regions, as each has a different reality. This requires more resources than other stakeholders. You must also have the right teams who know how to interact and partner with the autonomous communities, which is what Takeda strives to do. This is not always easy as we want patients to have equivalent access over Spain. We cannot solve market fragmentation in Spain, but we do look at other countries and try to adopt best practices on specific topics, for example, market access and innovation.

Some CAR-T therapies have been priced at EUR 300,000. Catalonia has been one of the first autonomous communities to accept this, putting in place a risk-sharing agreement. How well placed is Spain to put in place solutions that require real-world evidence?

We are learning. I am not sure that many other countries are really prepared either. Nonetheless, Spain is definitely trying to catch up. Now the Ministry of Health has put in place a platform, *valtermed*, which strives to achieve this. At Takeda, we have several risk-sharing agreements, although the process is slowed due to the bureaucracy involved in trying to collect and submit this data. Nonetheless, the mindset to embark on these agreements is there and compared with my other colleagues in Europe, we have the tools needed to adapt to these much better than we do in any other country.

Spain is a very strong clinical trial hub. What is your footprint for clinical trials?

The scientific and operational level is very high, and the KOLs have a high degree of knowledge which makes Spain an attractive location for clinical trials. We conduct trials from phase I all the way to phase IV in Spain, and the number is increasing annually. Commensurately, we have a team that also focuses on real-world evidence in addition to a centre of excellence for this in Spain serving other countries within Takeda which is unique. This demonstrates that Spain is the place where you can do things related to outcomes and value-based approaches. The first patients globally in a

clinical trial globally for a gene therapy treatment of haemophilia is also taking place in Spain.

TiGenix was acquired for EUR 500 million (USD 560 million), providing Takeda with its first stem cell factory globally. What does this mean for Takeda in terms of moving into regenerative medicine?

This is something which makes us really proud because it is at the forefront of innovation and is a major achievement. This is the largest stem cell plant in Europe and one of the top three globally. The level of sophistication operationally is also especially high. Almost 80 percent of the around 100 employees possess some form of postgraduate qualification, so it requires a highly educated and highly skilled workforce. We will invest an additional 10 million euros this year as this plant is taking Takeda from a manufacturing perspective to a new level.

Logistically it is really a masterpiece given the turnaround times we can achieve. Once entering a new jurisdiction, you have to certify the centre because they need to know how to handle the products and ensure that it is well administered to the patient. We have a number of partnerships with logistics suppliers, including Spanish logistics suppliers. Most of the supply chain all the way from R&D to supply is Spanish based. The logistics is run globally so that we can track where every single dose is going in order to coordinate more effectively.

In the long term, we expect to have more production sites around the world, with Spain maintaining its position as the hub and where the rest of the world will be trained.

What advice would you give to a young woman starting in the healthcare industry?

It is critical to have more backbone than wishbone. A young woman must ask and request to get the positions she wants that will aid her in developing her career. Finding a company that is really supportive of this also remains critical. For example, here in Takeda, out of the six general managers for the five European regions plus Canada, the roles are occupied by five women, leading: Canada, Italy, France, Germany and Iberia. This is Takeda's commitment to maintaining a diverse team.

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