Ana Argelich Hesse, Managing Director Spain – Merck Sharp & Dohme

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Merck Sharp & Dohme (MSD) Spain's Ana Argelich Hesse comments on how the big changes experienced by the global organization in 2021, including a new CEO and the spinoff of Organon, have impacted the American giant's local strategy. Argelich Hesse also discusses regulatory changes in the Spanish market, Spain's importance to MSD as a clinical trials hub, product launches and Environmental, Social and Governance (ESG) initiatives.

Ana, recent reports in Spanish media put MSD as one of the country's top five pharma companies. Can you outline the company's footprint in the country and most recent developments?

MSD has around 1,200 employees in Spain, including the animal health business for which we operate a production site in Salamanca. The affiliate posted revenues of around EUR 1.043 million last year in human health alone, making it a top three company in the Spanish market, including both the retail and hospital markets.

One of the most important developments in the past year was the Organon spinoff, a project I had the chance to participate in globally and lead locally.

Touching on your move from a large telecom company to the pharmaceutical industry back in 2008, why did you decide to switch industries and make the jump to MSD?

I had moved from consulting to the telecom industry after becoming a mother. I joined the telecom sector at the advent of widespread mobile phone adoption, which was incredibly exciting and necessitated the creation of new business models. However, knowing the high capex needed in the telecom business, with significant infrastructure costs, I realised I needed new professionals motivations and expectations for my career.

Not long after my mother passed away from cancer, I interviewed at a pharmaceutical company and, with recent events at the forefront of my mind, was struck by the industry's impact. That interview also led me to realise that pharma is a great industry in terms of people management and – while it took me a year to make a final decision – I have never regretted switching industries.

My first role with MSD was to create the digital department, which fit well with my background, and I later moved around the management of various business units, learning about hospitals, primary care, immunology, vaccines, and so on. MSD is very good at exposing its people to different departments and experiences, allowing them to acquire broad knowledge in preparation for country manager positions.

MSD is coming out of a pivotal 2021 where it finalised the divestment of Organon, its women's health division. Can you comment on how those changes have impacted the strategy in Spain?

The company had a very broad portfolio and realised that there was great value in being able to focus. MSD spent about 25 percent of its revenue on R&D last year because of that need to focus. The investments are aimed at immuno-oncology, COVID-19 treatments, Alzheimer's and cardiovascular disease.

For the sake of patients, to have the right focus and manage supply and production correctly, the company chose to divest its women's health business as Organon. I had the privilege of working on the Organon project for nine months at a global level, which has resulted in a beneficial outcome for patients, MSD's portfolio, and employees. While Organon is taking off in women's health, we at MSD are now more focused on our priority areas such as oncology, vaccines, anti-infectives, and cardiovascular. Moreover, in Spain we also have a huge diabetes primary care business.

How would you characterise the impact of the change of global CEO with the departure of Kenneth Frazier and arrival of Robert Davis?

Kenneth Frazier is an incredibly smart person, charismatic and a superb communicator. Nevertheless, the succession planning has been natural, predictable, and orderly. Robert M. Davis, our CEO, knows the company very well. He is the driving force behind large strategic and business operations, such as the Organon spin-off. He is one of the clearest and easy to work with CEOs I have met in my life. He is also changing our way of working internally and has a personal commitment to diversity and inclusion as well as setting a special sensitivity by integrating the ESG (Environment, Social and Governance) strategic focus.

Robert Davis knows how to focus, manage financial markets, is clear about the investments made and employs a very direct style. MSD is a science-based company, and Robert has been capable of finding synergies between Merck Research Laboratories (MRL), Merck Manufacturing Division (MMD), and Global Human Health (GHH). He is positioning the company in a great way.

The third key development at a global level was the launch of molnupiravir, an oral antiviral treatment for COVID-19, which has not seen the same success in Europe as it has in other regions. What happened in your market, Spain?

Spain has one of the world's highest vaccination rates due to a successful effort from the government and autonomous communities. The successful campaign resulted in resilience against Omicron and other variants, with low hospitalisation rates. That means that the prioritisation of treatments against COVID-19 has been lower than other countries.

Antiviral treatments are in low demand at the moment, although demand does exist, and the Spanish government has started to distribute one such treatment from a competitor. MSD has an early-access program under AEMPS supervision and is being reviewed for approval by the European Medicines Agency. Our role as MSD in Spain, which we have played with diligence, has been to deliver access for patients.

Speaking about access and how MSD tries to bring the latest innovation to Spain, the affiliate is an international leader in clinical trials for the company. What can you tell us about that?

MSD in Spain is a little more than 50 years old and started with an agreement on research and development (R&D) for antibiotics. We had a huge research centre, oriented mainly towards antibiotics, and still have public-private collaborations in Andalusia.

On top of that, our R&D department, which is big and growing, participates in 80 percent of MSD's global clinical trials, making the affiliate number one in Europe by number of patients and number two worldwide after the United States. This reflects the excellence of the Spanish healthcare system, one of the best in the world, and its amazing physicians. We really enjoy working with researchers and Healthcare Professionals (HCPs) in Spain because they compete at a high level for clinical research projects. The reason why MSD in Spain is a global leader in clinical trials is because of the country's top-notch physicians, researchers, and hospital infrastructure. Naturally, public sector incentives need to be maintained to continue bringing that investment in. Nevertheless, it is important to highlight that Spain must improve access to health innovations to meet its objective of reaching those who really need them and, in that sense, to be at the same level as other EU countries such as Germany, France or Italy.

As for incentives from the public sector, what are some of the deficiencies of the system that you would like to see addressed?

The nature of the agreements should be reconsidered. Spain's decentralised healthcare system means that there are many duplications of processes and that quality of care across the country is not always homogeneous. The positive side to this, however, is that what does not work in one region can work in another, allowing better risk management and experimentation with new approaches. Every patient should have access to life-changing innovation, regardless of the region they live in.

We believe the closer to patients healthcare is, the better. Healthcare delivery is great because it is localised, but this carries a significant bureaucratic burden. I remain impartial on this, both models have pros and cons; Italy, the UK and Austria also use decentralised systems.

Fortunately, there are new regulations coming to make the system more efficient. The Spanish Medicines Agency (AEMPS) is helping on that front by tweaking the protocols that could position Spain as a European hub of clinical research; Spain has the right hospitals, patient population and medical expertise to have a leading position.

What else is at the top of your agenda? Do you have any product launches or local initiatives coming up?

There are two main items on our agenda: product launches and Environmental, Social and Governance (ESG).

In terms of products, we are focusing on oncology and making sure that these products get to patients in need. Today, only 52 percent of what is approved at a European level by the EMA is approved in Spain. Every country has lags to some extent, but Spain's access rates are particularly concerning. This challenge is made more complex by the fact that many of the medicines that have been approved come with many restrictions that limit the subsets of patients that can be treated. The Agency does a great job with comprehensive technical evaluations, but the issue is with the access process that follows. The European Federation of Pharmaceutical Industries and Associations (EFPIA) has a waiting indicator that reveals the situation in the country, showing Spain to be somewhat of a laggard in European terms. I hope that as an industry, together with public authorities, we can partner to ensure access for patients.

What is your approach to managing the Spanish affiliate's internal affairs?

We feel that offering flexibility to employees so they can enjoy a healthy balance between their private and professional lives is vital. In that sense, we have launched our flexibility framework, WELLFLEX to ensure the physical and mental wellbeing of our employees. Post-pandemic, our team is more united than ever before.

From a sustainability point of view, we must continue working on the environmental side with projects like those we have already completed around climate change and animal health. Having a human and animal health business helps us to focus on a One Health approach for the future. Working as one team cross-functionally including all divisions is our main goal to success.

What should we expect from MSD Spain over the next three to five years?

We will continue to be a leader in oncology, demonstrating our position as an innovative, research-based company that finds solutions for patients. Additionally, MSD has one of the strongest vaccine portfolios in the industry and will continue to invest in that area. Furthermore, we want to establish the most culturally diverse company possible, and one that leads digital transformation. The company is making huge investments into research, manufacturing and commercialisation and I

am proud to say that MSD Spain is one of the most developed companies on the omni-channel side.

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