

Angel Fernandez â?? President and Managing Director, MSD Spain and Portugal



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Angel Fernandez, president and managing director of MSD Spain and Portugal, covers the company's current pipeline and portfolio strategy. He also explains how the company collaborate with a wide variety of stakeholders.

What is the history of MSD in the Spanish market?

Overall, MSD is a company with 127 years of history. Here in Spain, the legacy of MSD began in the early 50s with a technology transfer agreement that was signed with the Spanish Company of Penicillin and Antibiotics (CEPA), the basis of what would later be the Centre of Basic Research of Spain (CIBE), which would become a full-fledged R&D centre for MSD. 50 years ago in 1968 MSD S.A. started its operations directly. In terms of R+D+I commitment, one of our most recent developments in the Spanish market has been the birth of the MEDINA foundation. Ten years ago, all the knowledge and technology throughout MSD – part of it coming from the CIBE legacy was transferred to this public-private partnership centre of excellence in R+D+i whose mission is the discovery of biologically active molecules, drug candidates for unmet medical needs, and products of high biotechnological value for the industry.

What kind of performance has MSD experienced in Spain? What are some of the affiliates primary revenue drivers?

Here at MSD we are market leaders, with 5.5 percent market share, and a #2 ranking in 2017 in Human Health. I am happy to reveal that they now rank us as holding first position. We are also recognized as very important players in the animal health, veterinary industry, holding almost 20 percent of market share and ranked as #1. In the human health industry, IMS reported EUR one billion of sales. Our strategic areas for future development and most important sectors are vaccines, oncology, specifically immune-oncology, diabetes, acute care, along with – an emerging approach to the fight against cancer that represents a real ray of hope for many patients.

The highest value base in the company is placed on our vaccine portfolio as well as on oncology, the main MSD strategic priorities. We closed the partnership with Sanofi Pasteur last year in the nineteen EU countries where it was established, also here in Spain. This was an agreement that was concluded mutually and with one accord whatsoever. Both parties decided it was in the best interest to reassume direct responsibility over their own vaccine portfolios.

Vaccines are proven to be one of the most effective and cost efficient medical technologies ever invented, while immunization saves between 2 and 3 million children's lives per year so the case for investing in vaccines is both compelling and uncontested and an important plank of MSD's

offering.

The transition to bringing the responsibility of overseeing projects in-house has fortunately been very smooth and we have had many opportunities to find new local partners to join our team.

How has MSD fared in terms of creating a sustainable antibiotics business?

Firstly we should note that the biggest challenge we are faced is the antibiotic resistance that comes with widespread use. An equilibrium must be found between discovering something great and putting that same discovery in reserve to prevent and combat the antimicrobial resistances. However, knowing this, MSD is still committed to inventing and providing innovative antibiotics despite the challenges.

The solution to maintaining our mission and our business lies in having a strong pipeline. When looking at the company overall, we can see that the percentage of sales coming from antibiotics is not very significant. By having a large portfolio, we minimize risk exposure while staying true to MSD's legacy of responsibility. Discovery and innovation against diseases are embedded in the roots of the company, therefore we do our best to sustain ourselves while delivering top tier products.

What is the role of co-marketing agreements and collaboration with local Spanish organizations playing in the pipeline of MSD?

In terms of content, our manufacturing and marketing agreement with Rovi could be argued to be the most comprehensive. Just about a decade ago MSD transferred its manufacturing facility in Alcalá de Henares to Rovi, and since then we continue to be their primary partner. This, in some senses, reflects a trend towards outsourcing that can be seen right across big pharma. Nowadays they export our products, produce and supply products to us, and have added three MSD products to their portfolio. This is a very important partnership in terms of quality control, quality assurance, etc.. In that sense we have additional commercial collaboration agreements with Allmiral, Ferrer and Faes. Through co-marketing agreements such as this, we are better equipped to embed ourselves within the Spanish market and contribute through more than just the MSD organization alone. It is the genes of our operation in this country to play an active role within the community. We assume that the way to operate in the market is not to work singularly, but with other players to inject value back to the country.

There is also a tremendous relationship between MSD and patient associations. We have agreements to encourage the access to knowledge, support, and information. MSD has always had an on-going philosophy of patient importance – this is not just a recent trend for us. We believe if we operate under a patient focus first, corporate success will follow. For example, the concert for the MSD Salud program is to transition from just disease care to an emphasis on overall health, prevention, and awareness.

Another project we have completed in Spain is the creation of the MEDINA research centre of excellence, which has a collection of over 190,000 cultures of fungi and bacteria being used to test new antibiotics. We are proud to say that the foundation has the largest sample library in the world. Spain is a top-ranked worldwide clinical research market and 80 percent of trials throughout all of MSD have been executed here. All players are aligned to support innovation; the healthcare system, regulators, investigators, and of course our own team. They all are highly qualified and professional

researchers who operate to the highest level of standards.

How would you describe the ease of market access in Spain?

I do believe that Spain has a satisfactory level of market access. Looking at the percentage of drugs approved by the Ministry of Health and the time it takes to gain full market access, Spain falls in the more efficient side of the European markets – the situation here is not the worst nor the best, but overall still impressive. This being said, there continues to be room for improvement. Although the national approval time is relatively quick, practical access is hindered by the territory fragmentation in 17 regions. There are too many bodies – too many moving parts – that are making individual analyses throughout Spain. Hurdles created by national, regional, and hospital processes create demanding barriers to entry which then lose the benefits of offering all patients equal access to health innovations.

Despite these difficulties, MSD does have effective initiatives in place to better work alongside the healthcare system. We are moving away from the tradition of large-scale teams of sales representatives to instead having a souped-up market access division, which emphasizes communication and collaboration with industry players. These outcome-driven strategies we are harnessing aim to establish new agreements to aid in making the current healthcare system more sustainable. We have reconfigured the formula – there is not just one universal tool that can be used, we must keep a common denominator while still working on an individual basis with each region. Our strategy hinges upon being flexible and agile enough to be able to deliver bespoke solutions in different parts of the country. We have got to a stage where we are now comfortable with drawing up and implementing on-the-ground market access fixes in each of the different autonomous regions.

How optimistic is the industry about the new socialist government and what sorts of partnerships with the state apparatus do you envision in the short to mid-term?

Despite the inevitable feeling of uncertainty that comes with a change in government, I feel rather optimistic about the future.

The Collaboration Agreement pact signed at the beginning of 2018 is still in place, which is a very good sign, so, we remain partners. Statements by the new administration have been made about conducting co-payment reviews and a more enhanced system of public health care and universal coverage. In terms of public responsibility, these are all great things.

However, there remains a big question mark over where the money will come from to finance these proposed initiatives. We have to remember that the public healthcare system in Spain is still in deficit and remains improperly funded. As the country has transitioned out of recession, a delicate financial balance, in the form of the collaboration pact, has been struck that enables the industry introduce cutting edge innovation into the health system. We would certainly not want to see that balance upset.

What are the future ambitions and goals of MSD in the Spanish Market?

Looking towards the future, the goals we have at MSD are conservative yet committed. We hope to maintain our reputation, market position, and growth. We want to continue the current success we have seen in the company. There is a steady momentum to be industry leaders and the authorities in vaccine, antibiotics, and oncology so we may carry on benefiting both patients and society. We hope to continue making reality our mission and continue inventing for live

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