

Sanofi Pasteur MSD - Ricardo Brage, Vice President

Spain



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Ricardo Brage serves as Vice President Spain for Sanofi Pasteur MSD. He discusses how he sought to change the subsidiary in response to pricing reforms as well as the challenges surrounding regional tenders for vaccines.

How did the joint venture of Sanofi Pasteur and MSD come to life?

In 1994, Sanofi Pasteur and Merck and Co. Inc decided to create a joint business together, an unusual decision between two big corporations, taking into account the high specialization required and potential of vaccines. The average survival time for a joint venture is between 11 and 13 years, and as SPMSD is celebrating 20 years in 2014, there must be a strong business reason that makes our shareholders continue being together in a vaccines market.

What makes vaccine companies different from typical pharmaceutical companies?

Vaccines are noticeably different from pharmaceuticals in that you give vaccines to healthy people, and usually only once. Thus, success on one side is losing business on another. Products for healthy people also mean much heavier and more rigorous manufacturing, clinical trials and quality control. Clinical trials for vaccines can involve up to 50,000 individuals over many years to ensure a high range of effectiveness and safety. There are actually very few key players in the

vaccine market, especially considering companies like Baxter, Crucell and Novartis are moving away from this area. This means that barriers of entry are very strong. Vaccines require a high level of investment, and a real understanding and specialization in the business to succeed with a wide portfolio. Manufacturing is complex, takes a lot of time and money, and its process has all sorts of legislation in terms of safety.

Vaccines also have a strong political component, as they are considered very powerful public health tools. Across the world, governments deal with infectious diseases through third-parties. This equilibrium is sometimes hard to achieve, and in Spain the government does not have the capability to develop its own vaccines and thus relies on private companies. Therefore, vaccines are a highly sensitive public health topic.

What were your initial objectives when you first came to this organization in 2011?

One of my key objectives was to improve profitability and sustainability of the organization knowing that the outlook was not bright, given that the country had experienced almost 13 consecutive quarters of GDP reduction. I had to ensure that our business model was in line with market trends by analyzing our fixed-cost business structure. Vaccines are a risky business, because supply is often uncertain, chemical synthesis is not easy or predictable, sometimes resulting in different outputs, and there are no alternatives like there are in pharma. Furthermore, because of the configuration of Spain's public health business, almost all purchases go through tenders. Tender business is risky in itself, in that you might lose a contract by one cent. You cannot plan your resources in this situation, so I have to structure this organization with a sustainable cost structure if things go wrong with production, launches or tenders while maintaining market leadership.

Therefore, my plan was to change the way Sanofi Pasteur MSD operated in Spain. Many cost bases had to be reshuffled, which in turn forces the organization to work very differently while adapting to a new business situation. The public market had decreased almost 40 percent, which had not even happened with construction companies in Spain, who were some of the hardest hit by the crisis. This was not because of units or doses, but because of price. Government started to introduce a centralized procedure to aggregate purchases, starting with flu vaccines, significantly pushing down prices. You then have to decide if you will fight for new markets where you can sell fast with higher margin and get your money back, because prices not only go down but payments are often late in Spain. This is not a good business, but given the political component there are certain decisions you have to make; we cannot let Spanish children be unvaccinated. This shows commitment by companies to the Spanish population and government. We are still here and we

will provide vaccines to the population. But we also need to reassess our business model and adapt it in terms of size and position, and this means we can no longer rely heavily on our public business, which used to represent 70 percent of business and today represents 55 percent. Sanofi Pasteur MSD Spain has therefore developed its private business and as a result we have become much more profitable. The company has shrunk and rebuilt but has become more competitive and the culture is different. But it certainly seems to be working. We have been able to look at different markets while maintaining the same level of sales in the last three years. The affiliate was also credited as one of 50 best places to work in Spain by Great Place To Work, which is important considering we reduced our workforce by 30 percent about 18 months ago.

Does the vaccine industry have to reevaluate in terms of adapting to the rules and regulations of each autonomous community?

The government has said that vaccine services must be the same across Spain. This is handled by the public health department for pharmacies within the Ministry of Health. While there is general agreement regarding which vaccines need to be covered across all regions, there are some regional differences in terms of how vaccine programs are implemented. The list of vaccines is based on a national recommendation committee for vaccines, and this is driven by Agencia Española del Medicamento y Productos Sanitarios. The Ministry of Health issues a first round of tenders for every vaccine, sets up a maximum tender price and invites suppliers to participate. With the maximum price set and technical criteria established for each region to issue regional tenders that impact pricing, regions then consider the most appropriate tender for each vaccine. This means that private companies have to evaluate the technical criteria in each region to determine whether or not the price in every region is sustainable. Generally speaking, every company plays in the first round, but due to all of these specificities regarding centralized procedures and regional tender processes, some companies may not choose to participate for particular products. These differences exist for vaccines of all sorts.

Besides these regional differences within the calendar, there are some regions that want to follow a specific or slightly different public health policy within the specific region. Sometimes the Ministry or the vaccine committee agrees on changes here, and some regions will not change. The same principle applies when you try to implement a new vaccine within the national schedule. Access can take a long time because you should inform everyone about the specifications of new vaccines to everyone, and then get the product approved and funded. In the meantime, some regions might go for certain products alone without considering processes at the national level.

This must imply that your sales force has really evolved over the last few years!

The regional access team deals with all of this work, which involves dealing with technicians and lawyers within the public health department in the regional governments. When you speak about tenders and contracts, there is always interpretation and the chance to appeal against how the tender is issued. The government often allows budgets to go for a specific tender, and then companies like Sanofi Pasteur MSD have to chase payments as a result. Purely scientific arguments used to be the main focus, and now the focus is more about management of the whole account. It is important to remember that everything here is 100 percent funded, which is a critical configuration of the market. If a vaccine is in the national calendar, citizens do not pay regardless of price or conditions. Most vaccines in the national schedule are doing a good job across all regions. This interest is good at least in terms of insurance of volume, but 100 percent coverage is a hurdle for new vaccines. Companies have to either put new products into the system completely, or not at all. Sanofi Pasteur MSD Spain is working with Spanish authorities to look at other European countries for ideas as well. Spain is a market in which you will sell more if you gain more share, at a price as close as possible to the maximum tender price. Many tenders come at the same time, usually within a period of six weeks, so sometimes you do not know the result of one when you propose the offer for the next. It is a bit like being at a casino; maybe I win a lot or nothing at all!

What is SPMSD's competitive advantage in Spain?

SPMSD has the widest portfolio possible because we are the only European company solely dedicated to vaccines. It is a structural component of being a joint venture, and we should make good use of it. Sanofi Pasteur MSD is a very important company because it has vaccines to cover 20 of the World Health Organization's priority infectious diseases across all age groups, which provides many possibilities. Pharma companies can live with one blockbuster in one area for many years. Vaccine companies require specialization and a wide portfolio for a strong and continuous presence. Sanofi Pasteur MSD is also privileged to have two pipelines, which ensures strong continuity of innovation and business.

What is your vision for the next few years?

My vision for Sanofi Pasteur MSD is to find new markets and new prevention services. The more you speak with customers, the more you realize that vaccines might become a tool but not necessarily an aim itself. I am not only in the vaccine business; I want to keep people healthy through preventative measures. That has opened up potential partnerships we are exploring in Spain and they will materialize in the coming years. In terms of access, sooner or later things will change. As new vaccines evolve, there will not be a clear distinction between pharmacy

departments with pharmaceuticals and public health. There will probably be some copayments and tailor-made vaccines for individuals. That will of course affect how Sanofi Pasteur MSD evolves as well. Insurance companies will probably play a strong role as well; as the population ages, the number of citizens with private insurance paid by themselves will increase. We know that government programs will cover a specific part of the population for a specific range of diseases. There are many people who will probably benefit from preventative measures, which in turn will have private insurance already with them. We have also seen more labor regulations or social benefits for corporations, who are linking these plans for their employees to ensure their health and productiveness. Pharmacies in Spain will have a stronger role in the future in terms of providing access, opening up a new channel. There might even become small vaccination centers, given the widespread pharmacy structure in Spain, which consists of 25,000 pharmacies. This would be particularly useful in rural areas. Overall, access through pharmacies, co-payments, the role of insurance companies and new vaccines will probably reshape the market again in the coming years.

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