

Interview: Javier Ellena Aramburu, President & CEO Spain, Portugal and Greece, Lilly Spain

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After serving as President of Lilly Spain between 2001 and 2009, Javier Ellena spent three years running Lilly's middle-sized European markets (EMS). In 2012, he returned to his previous role and added Portugal and Greece to his responsibilities. Ellena speaks about the definitive role of Spain in the Lilly organization and outlines the key investment opportunities that are present in the country today.

How did your experience as head of Lilly EMS change the way you approach the Spanish market?

In my previous position, I had the opportunity to manage 28 countries, which combined markets belonging to mature and developing geographies. This required flexibility in terms of approaching and understanding the different realities of each country, particularly when GDP per capita or health expenditure in GDP can vary significantly. It was a wonderful and rich learning experience in that I saw how some local teams reacted, adapted or operated under difficult circumstances, and how others maximized opportunities of a very well organized healthcare system.

Much of this variety has been applicable in Spain since 2008.

As such, we need to adjust everything we do as a company in order to face this reality. In the case of the pharmaceutical industry, the size of the market was reduced by 28 percent between May 2010 and December 2013, and this has mainly affected innovative medicines. Parallel to this crisis, the pharmaceutical industry has experienced an internal patent cliff. Thus, Lilly and other innovative companies in Spain have been operating under very complex circumstances.

Lilly has been subject to a number of patent expiries in recent years for drugs like olanzapine and duloxetine, and 2013 was certainly a difficult year. What role will Lilly Spain play in getting back on the offensive side?

In the European context, Spain will play a key role in helping Lilly return to times of growth. The entire Lilly organization experienced difficulties after the loss of olanzapine in 2011. Furthermore, duloxetine expired in December 2013 in the US while data protection exclusivity will expire by the end of 2014. While sales of olanzapine were split 50-50 between the US and the rest of the world, duloxetine's ratio is closer to 80-20. I believe that 2014 will be the worst year for Europe because of the absorption of the impact of duloxetine's patent expiration. That being said, we are preparing the launch of some new and promising molecules in oncology and diabetes in 2015. In 2016 and beyond we will see the commercialization of several other new molecules in different

therapeutic areas for autoimmune diseases like psoriasis, lupus, rheumatoid arthritis, and Alzheimer's. In a few quarters, Lilly will have a constant flow of very attractive, innovative brands in different therapeutic areas. Spain will have outstanding opportunities to help or benefit from the launch of these brands, and every therapeutic area I mentioned is growing. While they are also highly competitive, given the degree of innovation in Lilly's medicines we remain confident that Spain will be one of the growth engines in Europe that helps the organization as a top-ten subsidiary.

The affiliate also runs an important manufacturing facility that exports to 123 countries worldwide. How much does this plant represent in terms of global exports?

Our facilities in Alcobendas only manufacture and package oral dry products, but as of June 2014, we will start packaging a totally different line of products that were formally part of an operation conducted in Germany. This decision will help the plant to replace some of the volume lost as well as maintain volume for the next few years. More importantly, we will start operating differently. Lilly has already brought new technology to Spain that is very well aligned with the profile of the majority of molecules in our pipeline, where we will focus less on traditional compounds and more on biologics.

What do you perceive to be the real outcomes of the recent protocol between Farmaindustria and the Ministry of Health? Can we expect to see concrete changes in the near future?

The pharmaceutical sector is strongly dependent on our institutions; eighty percent of its sales are ultimately for the public healthcare system. We want to continue being a good partner for the Ministry, and formalizing the way we work together can help.

When the reference price system was approved last month through a Royal Decree, the government announced that the criteria for pricing and reimbursement would be ready by late 2014 or early 2015. This is incredibly important, because this decree will determine how new brands or molecules will be assessed in terms of usefulness, how they will be funded, and how this innovation will be made accessible. This decree will set the framework for the next decade, and it is a top priority for innovative pharmaceutical companies. I am convinced that the only way this will happen is through frank and formal dialogue, productive collaboration, and a common objective that ultimately serves patients. This will not happen overnight, but if we do not build these foundations now, it will never happen.

As head of Spain, Portugal and Greece, what are some of the organizational changes that you are employing to navigate these harsh times?

We have a twofold strategy of delivery and transformation. Doing both simultaneously is not easy; it's like trying to fix a pipe with running water. Delivery has involved introducing several measures to adjust the organization according to the reality we are facing in all three countries. We needed to change the business substantially through the introduction of many measures while still being able to deliver on our commitments and to achieve our goals. This is critical because the funds we are receiving today are being used to clinically develop more than 60 molecules. As success is vital, Lilly has devoted about 24 percent of sales to R&D in 2013, probably the highest among the top 30 companies worldwide in relative terms. About ten molecules are in Phase III and several are in regulatory processes both in the US and Europe.

In terms of transformation, regardless of whether Europe or the world recovers previous growth rates, the paradigm is completely new. What the market expects from the industry is more

demanding and complex today, and thus we cannot continue operating as we did in the old days. To succeed and create this transformation, we need to define key elements and capabilities and then create more efficiency. It is not just about having more molecules; it is about playing a game, where winning involves healthier patients. This game requires more and different work to launch a drug successfully compared to launching a drug a decade ago. Today, the focus is on clinical evidence and demonstrating meaningful and concrete value propositions. This means truly proving the value of how new medicines can help patients and our public system to maintain its quality with greater sustainability. That is why this recent protocol is so important. When I talk about increased complexity, it is due to having many more stakeholders in this country. The industry needs to understand what is needed and expected not just from the Ministry of Health, but also the Ministries of Economy and Industry. We need to be able to provide, fulfill and satisfy their expectations.

With one of the worst unemployment rates in Europe and a significant contraction in pharmaceutical expenditure, how do you make a convincing argument to invest in Spain?

Unemployment at such a level is indeed a social drama, but it is also an opportunity. This unemployment is massively affecting the best educated generation in Spain's history. Consequently, many qualified people who want to join corporations are leaving because they cannot find jobs according to their studies and capabilities. I am convinced that people would come back if they found good professional opportunities according to their education. This is very frustrating, and it is hard to explain to Spain's youth about what we are doing to solve this as a responsible society. Thankfully, the worst days are behind us; looking at the future, Spain has incredible human talent, financial reforms in place and a very competitive labor market. In our particular sector, Spain has a very strong scientific community. The productivity of some of the country's R&D centers is huge, and we have a solid public hospital network for conducting very high quality clinical trials. Lilly actually has more patients enrolled in different trials in different phases in Spain than in Germany, which has twice the population. It is not just about lower prices; quality is fundamental as well, and Spain can provide both.

The country's laboratories interact with many universities and private and public R&D institutions, which has offered outstanding opportunities to produce real innovation.

The transition from the past to the present has been difficult and painful. The industry has had to implement many unpleasant procedures. However, the sector has maintained solid levels of employment, which is remarkable in today's environment. When you look at today's key indicators in Spain's healthcare system, I believe that all measures implemented put Spain in a competitive and healthy position. For instance, Spain has aligned itself with the goals set by the troika without intervention in terms of GDP expenditure in medicine, and pharmaceutical expenditure compared to total healthcare expenditure is below 15 percent. While the process has been agonizing, we can be optimistic in that a new cycle is starting from a very healthy base as a consequence of all the measures implemented. Establishing parameters for handling potential innovation will be critical to ensure that the pharmaceutical sector will have a brilliant future in Spain.

What role will the pharmaceutical industry play in the reconstruction of Spain's economy, and how will Lilly contribute?

I am convinced that Spain will recreate a good macroeconomic environment in which to operate. This must require more activity in something other than tourism or construction. Spain needs to be much more intense in the use of technology and creating the right environment to attract investment related to knowledge, and specifically biomedicine or bioindustries in the health sector. The number of biotech companies that have been established and have succeeded in Spain has skyrocketed in recent years. If Spain can create this environment for bio-investments in different fields, the country clearly has a huge opportunity to attract European talent. Generally speaking, the country needs to define what it wants and to identify the key growth engines to accelerate the recovery of the economy.

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