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Javier Urzay, deputy director of Farmaindustria, gives an overview of the growth of the pharmaceutical sector in Spain and the challenges to find a balance between rewarding innovation and sustainability. Moreover, he talks about the development of clinical trials in Spain and the currently discussed new collaboration agreement with the government.

How did the Spanish pharmaceutical industry perform in 2018?

We are still waiting for the final figures, but the growth of the health public sector was roughly 5 percent, including both hospitals and retail.

Although it has been a complicated year because of all the changes in the government, we have managed to achieve good results. The Spanish healthcare system is considered a sign of the country, of how people care about each other. It serves as an example of social cohesion and equality of access opportunities to living long and healthy lives. As well, since the health sector is one of the main drivers of economic growth all over the world, it is considered one of Spain’s economic assets. We need to exploit and profit from this opportunity, not only for social welfare but for the nation’s economic growth.

What are the advances in new collaboration agreement that you are renegotiating with the government?

It is still soon to say anything. We have begun discussing making some amendments on the current agreement, but we will continue our talks during the first quarter of the year. However, we don't know whether the new political situation, being the calling of a national election in April this year, will allow us to renew it as quickly as we would have liked.

Do governmental changes have an impact on the pharmaceutical industry as a whole?

Of course, instability is always a source of concern for the industry. There is a big part of our operations that depend on the government; we have to reach an agreement from a macroeconomic point of view and address our usual business, such as how to ease the approval of new medicines. This must happen regardless of what happens at the highest level of politics.

Nevertheless, we always go by the saying; business as usual. We will continue working at a more technical level with the Ministry of Health and the Ministry of Finance as part of the pricing commission. It is important that political instability doesn't affect the market, and in the end we will still be delivering treatments to patients.

Historically, have political changes impacted the regulatory and technical level when it comes to patients' access?

Although we have had political instability in the past, I don't think these changes have had an effect during the past years. Even though we did not have a government during 2015, we performed our business as usual. Therefore, if it did not happen in the past, I don't see why we would let it happen in the future. People have to understand that even if there are problems at a high level, we have to go on and keep working. We will keep on moving and facilitating the environment for our companies.

What differentiates Spain and makes it so open to embracing innovative therapies?

Here in Spain, the role of the Minister of Health is to coordinate the healthcare system and decide the prices and reimbursements of pharmaceuticals. Then, we have to take into consideration the

autonomous regions, which manage their own budgets, healthcare and market access. The regional governments are committed to bringing innovation to their patients, but they also need to take into consideration their budgetary constraints.

It is a challenge for the National Healthcare System to find a balance between market access and sustainability, but we are definitely committed to collaborating with them in the search of solutions which may entail thinking outside the box. I think that is one of the keys in the Spanish system.

Which do you think is the best way of financing the new drugs?

This is something that will be hard to manage. From a theoretical point of view, reaching agreements based on positive outcomes is relatively simple; while, from the practical point of view, it is rather complicated due to the decentralization of healthcare management.

One of the approaches the Ministry is taking to tackle this issue is the recently announced Valtermed, a system to gather data and real-world-evidence for evaluating the health outcomes of products which have a big impact on the budget. We are committed to working along with the Ministry of Health. Though we must make sure the system does not delay price reimbursement, one of our main concerns.

Since 2013, the government also put in place its own initiative, the IPTs -reports on therapeutic positioning- which offer evaluations of the clinical value of new products and their positioning in the market based on clinical differentiation. These reports are constructed by the Agency together with the regions, which is a good starting point for the reimbursement procedure, but it is still key to turn it into a high-speed system.

Do you see many differences between the communities on how open they are to innovation?

There are some differences between regions, but I think that internal differences within the regions are sometimes more important. I wouldn’t say that Catalonia or Madrid are more open to innovation than other regions, as each distinct autonomous community and even each hospital evaluate which products they want to use in clinical practice.

Do you think it is time to have a more centralized approach to the healthcare system in Spain?

Honestly, I don't think there is a chance for things to go in that direction. Even though Spain has very different regions, such as Andalusia with its 8 million people or La Rioja with 300,000, each autonomous community has its own voice. It happens similarly in the UK and in Germany. I think there is no going back on the distribution of power between the regions. However, there is a lot more to do in the areas of coordination, common policies and national plans.

People don't want to have the exact same facilities in every region, but to be able to access good quality healthcare that meet their needs. In places like Castilla y León that are decreasing in population and have a big territory, offering all treatments in every town and city becomes too expensive. Therefore, we need to have more specialized and coordinated centres.

Could you give us an overview of the clinical trials ecosystem in Spain?

Spain is a very good place to perform clinical trials in comparison to other countries as it has a great healthcare system with an integrated primary and hospital care. We have been working towards this for the last 12 years.

In 2006 we began a project called "The Best", as companies were worried that the Royal Decree of 2004 would make them lose their positioning in the field of clinical trials. We decided to start measuring the timelines for approval and patient recruitments and many companies agreed to share their databases and combine them with ours to have all the information available for companies, hospitals, regions and associations. At the beginning, there were 25 companies collaborating with us, and now there are more than 50.

We measure the time that passes from the moment the study protocol is sent until it gets approved by the ethics committees and the Spanish Medicines Agency and the patients recruited. This whole process back in 2006 used to take 190 days and now it is down 120. One of the reasons we started this project was to have a more productive communication with the stakeholders, who realised that the key to attracting clinical trials to Spain was the speed. Moreover, we began measuring the time it took to recruit patients in Spain within Europe for the same international projects. In 2005 we used to take three more months to recruit the first patient in comparison to the first patient-in anywhere in Europe, while now it takes 18 days average, which means that we are close to being the first recruiter in almost all projects.

What steps can Spain take to be the number one country in clinical trials in Europe?

Speed is a key factor in order to show other countries that we are ready to fight for the timelines, which are critical in this area. Now that the legislation allows us to sign contracts with a suspension clause with hospitals before having the Agency's approval, the process goes faster. We also have to keep monitoring everything to keep things objective and have healthy competition.

Also, we have to keep fostering early-stage clinical trials, that is phases I and II. To do so, we are producing now the fourth edition of our directory of phase I centres with a lot of information about the healthcare system and the characteristics of the current ecosystem.

What is the percentage of phases I and II?

In 2018 it was 48 percent, which is good in comparison to the 38 percent of 2005. In 2017, the Agency approved 605 clinical trials, a big growth against the 473 that were approved in 2004. Clinical trials in the field of oncology have also grown, reaching 51 percent and positioning Spain as a European leader in this sense.

It is also important to build an ecosystem of collaborations and to keep all stakeholders proud of the results and their participation, as well as to align their interests. This includes patient associations, which are happy to offer their patients new options of treatment that appear and a source of savings to the system. We win by bringing investment to the country and the industry is happy to find new solutions. Nevertheless, it is still an ongoing process that doesn't have an ending.

Women in healthcare is an area Spain sets itself apart. What initiatives has Farmaindustria in place for this?

I think that companies are aware that the Spanish health sector, in general, has a lot of women. We are proud to say that above 40 percent of the decision-makers in the pharmaceutical industry are women, which is high compared to the 12.1 percent that you can see in the IBEX35. There are also many companies that have their own internal policies to ensure that women have the same career opportunities in the pharmaceutical sector.

What are the strengths of the Spanish pharmaceutical sector that make you optimistic for the future?

From my point of view, we face the same challenges that the rest of the global industry; that is, how we need to bring new disruptive medicines to our patients. I am thrilled about the changes that these medicines will bring, though our main concern is how to implement them in a sustainable way. We are very optimistic we can as this concern about sustainability has been the same for 30 years, yet we always find a solution.

Furthermore, Spain must increase its investment in healthcare. Even if we have an efficient system, 6 percent GDP dedicated towards public healthcare expenditure is very low and unless it goes up in the coming years, it will be even more challenging to sustain the healthcare system we want. In order to achieve this, we have to change the mind of the decision-makers by bringing solutions, and those companies unable to keep up with the quick development of disruptive medicines are specializing and investing in niche markets to survive the process. There is a place for everyone and we need them all.

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