Javier Urzay – Subdirector General, Farmaindustria, Spain



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Javier Urzay, deputy director of Farmaindustria, the leading pharma industry association in Spain, discusses the main dynamics shaping the sector, including record levels of R&D investment and clinical trials, their collaboration with European organizations to develop digital capabilities, and the need for better access, investment in manufacturing and increased collaboration in preclinical research.



What is the role of Farmaindustria within the Spanish pharmaceutical industry, and in what state is the industry today as we emerge from the COVID-19 pandemic?

Farmaindustria is the association of the pharmaceutical industry in Spain with approximately 137 member companies representing 90 percent of the market share of branded medicines. The association's industrial and innovation footprint is very significant. Moreover, Farmaindustria reached its second-highest level of research and development (R&D) ever in 2020 and a record number of new clinical trial approvals (1027) despite the challenges of the pandemic.

The number of new clinical trial approvals rose again in 2021 and we expect the overall R&D figures to also be higher than in 2020. For example, there were 391 oncology trials in Spain last year, up from 355 in 2020, demonstrating that Spanish pharma is consolidating its position in clinical trials worldwide.

The pharmaceutical industry represents about five percent of total Spanish exports and approximately a quarter of all high-tech industry exports. The situation of the market in Spain is stable and the forecasts are positive, although further movement is needed in the areas of access to innovation and sustainability.

What are the main concerns of your members today?

The main concern is to increase the recognition of the socioeconomic value of the pharmaceutical industry and incorporate that recognition into the country's health, industrial, and economic policies.

Farmaindustria is working on a strategic plan for the pharmaceutical industry which is included in the recovery plan and scheduled for the first semester of 2022. The association will work with the government, the Ministry of Health, the Ministry of Finance, the Ministry of Industry and the Ministry of Science & Innovation to produce this strategic plan. The balance of policies will create an innovation-friendly environment for the development of the industry.

What can you tell us about this strategic plan?

The plan needs to have three pillars. The first is access to innovation and sustainability, which are two of the Spanish industry's key issues that need to be improved. The second is the industrial pillar to enhance competitive manufacturing in Spain. Lastly, the plan must have an R&D focus to

boost clinical trials, increase collaboration in preclinical research, digitalize the healthcare system, and find secondary uses for health data to provide better healthcare, foster research, and increase the reliability of information about the value of medicines.

The last time you spoke to PharmaBoardroom, you mentioned that reaching outcome-based agreements was relatively simple in theory but was practically complicated by the decentralized nature of Spanish healthcare. Is that still the case and how are you working around this issue?

Spain is underperforming in regard to the Patients Waiting to Access Innovative Therapies (WAIT) indicator with worse figures than previous years. Improving the access to innovation is a significant opportunity not only for the patients but for companies and the healthcare system itself.

The association is proposing specific ways to improve access to innovation such as new pricing mechanisms and individual agreements for companies to reach with the government to increase the industry's agility.

The decentralisation aspect complicates matters and is further muddied by additional, time-consuming barriers such as the Therapeutic Positioning Reports (Informes De Posicionamiento Terapéutico, IPT). This creates access problems with longer delays and makes the entire system more cumbersome.

Currently, Farmaindustria is producing proposals to streamline the system with specific views on orphan drugs for example.

In our last conversation, you spoke about Valtermed, a system to gather data and real-world evidence for evaluating the health outcomes of products that have a big impact on the budget. What is its status today?

Valtermed is a system managed by the Ministry of Health that is used for a few specific products and is not a universal, real-world evidence tool. It is complicated to use this system for many medicines due to the work required by the clinicians to enter data. The data needs to be integrated into normal clinical practice otherwise it is difficult to have full collaboration between clinicians, systems, and patients to collect this data.

One promising project is Data Lake, supported by European funds and completed by the Ministry of Economy and Digital Transformation and the Ministry of Health, aims to create a national strategy on health data. Farmaindustria hopes that the implementation of this project will enable collaboration with private companies to produce the real benefits of this data: access to new medicines, innovation, and better healthcare.

How do you guarantee that the data will be managed safely and efficiently?

This is a discussion at the European level with the European Health Data Space which guarantees that the data can be used while retaining its privacy, safety, and ownership.

Farmaindustria is participating in European projects such as EHDEN in this area which will bring results across the healthcare space. Data is required to have objective and rational discussions about issues and find solutions through the use of these databases.

How has COVID changed the perception of the healthcare system and the industry?

The perception of the industry has changed significantly with increased global recognition of pharmaceutical companies. The association is conducting projects to understand the changing social perception of the pharmaceutical industry to improve the situation.

There is a stronger reputation for the industry and a completely different perspective of pharma among society in general compared to a few years ago.

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In which areas are Farmaindustria’s members keenest to invest?

The clearest opportunities in Spain for all companies developing new medicines are in clinical trials. Decisions are taken on clinical trials every year and, if a firm is competitive, it is possible to bring new projects to Spain in a timely manner.

Spain has successfully implemented new European legislation around clinical trials. It was the first country in Europe to anticipate this legislation with a national regulation as a result of working together with AEMPS as well as the hospitals and clinicians to establish a good environment for clinical trials. There is an acceptance here that all aspects of the clinical trial process must function smoothly; from the initial protocol to the incorporation of the first patient, and the finishing of the projects, which can be highly complex and take several years.

Today, Spain is harvesting the results of decades of collaboration. The association hopes to improve this position in the future and is trying to bring clinical trials to medium-sized hospitals and different territories of the country. Approximately 45 percent of the clinical trials and patients are based in Madrid and Cataluña. However, Farmaindustria is now collaborating with regional governments in other parts of the country to offer these sources of investment and opportunities for patients and clinicians.

The Spanish healthcare system is one of our key assets. In Spain, the healthcare provision represents approximately 25 percent of the net income for 10 percent of the population with the lowest income. The healthcare system is a significant policy tool for equal opportunity and further investment in the system is one of the smarter policies any country should make.

Do you have any final comments to share with our readers?

Farmaindustria is working with the European Federation of Pharmaceutical Industries and Associations (EFPIA) to assist the Spanish government to envisage and produce an innovation-friendly framework for the pharmaceutical industry in Europe. This involves coordination to establish a single voice in Europe on this issue.

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