Humberto Arnés – Director General, Farmaindustria, Spain

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17.05.2018

Tags: Spain, Farmaindustria, Association, Pharma, Regulatory Reform

Humberto Arnés, director general at Farmaindustria, Spain's leading pharmaceutical industry association, discusses the dynamics of the Spanish pharmaceutical industry showcasing a growth of 2.7 percent of the total public pharmaceutical expenditure while highlighting the association's strategic plan, revolving around sustainability and access, transparency with healthcare professionals, an increase in industrial activities and focus towards the patient.

Spain has currently one of the most robust economic revivals among EU member states. Has the pharmaceutical industry benefited from this economic growth?

We have been through difficult times from 2010 to 2015, as Spain was severely hit by the Eurozone economic crisis. However, the Spanish economy has been expanding at a faster rate than European member states such as France, Germany and the UK since 2015. This is fantastic news for the pharmaceutical industry since, as a regulated sector and one depending on state budget and funding, we directly depend on the economy's good health. In fact, we have been constantly growing for the last three years leading to a growth rate of 2.7 percent of the total public pharmaceutical expenditure. In the two segments of the pharmaceutical industry – the hospitals and retail market – growth varied to a certain extent. In the hospitals segment, growth was 3.3 percent, while retail sales grew by 2.2 percent. I cannot think of any other European

pharmaceutical market in Europe with the same growth trajectory.

Two other important indicators reflect this positive change: the availability rate and the waiting time. The availability rate reflects the amount of products approved by the EMA that are actually available in Spain, and the waiting time reveals how long it takes for a product approved by the EMA to reach the Spanish market. We had dramatically dropped behind for both indicators during the crisis, and we are now back in line with Italy, France or Germany.

What are some of the latest regulatory changes worth highlighting within the Spanish pharmaceutical market?

An important milestone in the Spanish pharmaceutical industry was the Collaboration Agreement we signed with the government in order to establish a predictable and steady framework for the pharma sector. The agreement sets out to match the growth of public expenditure on medicines to that of GDP, as to enable the government to meet its budgetary adjustment objectives while ensuring patients have access to the necessary medicines.

If the expected expenditure threshold were to be exceeded due to the therapeutic needs of the society exceeding the development of the economy, the government and Farmaindustria are committed to come up with suitable solutions that will make it compatible, including compensation from the industry. We are renewing this agreement every year.

Globally the industry is looking for new models to promote innovation while also accommodating the structural budgetary constraints that most social security systems encounter. Which models is Farmaindustria advocating for in the context of the Spanish system?

The challenge is how to reconcile the sustainability of the healthcare systems in Europe and the introduction of innovation into the market. We believe that in Spain it is necessary to contemplate this challenge in a holistic way. Firstly, by preserving the current pharmaceutical model based on IP rights. When patents expire, national health systems can benefit from the entry of generic medicines, which ultimately alleviate the state’s purse. Secondly, to maintain the competitive model of the market. Thirdly, smart pricing and new payment models such as discounts, risk sharing, etc. are already in place or explored.

But ultimately the priority and the efforts should be put on improving the efficiency of the healthcare system – I am thinking of duplications of diagnostic tests, for instance. One way to improve the various inefficiencies of the healthcare system is by measuring health outcomes and the costs associated to each intervention to decide the most efficient intervention for every single case or patient.

At the moment we are working on a challenging project with the International Consortium of Health Outcome Measurement (ICHOM) with three pilot projects in three Spanish regions – Madrid, the Basque Country and Galicia – to convey the importance of the value to measure healthcare outcomes and its associated costs. Even state-of-the-art technologies provide savings to the system and are beneficial for the patients, the health system, the industry and ultimately for medical professionals because they have better tools to provide solutions to their patients.

What would you say are the priorities of the association and the major challenges facing the industry for the year to come?

As an organization we represent most of the pharma industry in Spain with 167 members. We currently have 22 working groups, which help the association shape, establish and strengthen priorities and the positioning of the pharmaceutical industry bringing together one single common objective.

We have rotating presidencies and at the beginning of each we come up with a strategic plan, establishing the new priorities, while also taking into account the previous priorities. For us it is very important to have a strong understanding of this plan and a clear idea on where to focus our activity on every term.

What we are currently prioritizing is, first and foremost, sustainability and access. Another important aspect is transparency in our relationship with the healthcare professionals. Thirdly, to strengthen two fundamental levers of the pharmaceutical sector: industrial activity and innovation. Lastly, the alignment of Farmaindustria’s agenda with that of our international federations’ (Brexit, HTA, IP incentives, etc.).

Can you elaborate more on the initiative on transparency?

The pharmaceutical industry in Europe is involved in an initiative on transparency. Every year, at the end of June, the pharmaceutical industry is disclosing the transfers of value provided to the healthcare professionals. The European initiative led by the sector was initiated in 2013 within the context of the European pharmaceutical industry gathered around the European Federation of Pharmaceutical Industries and Associations (EFPIA).

In 2016, the board of Farmaindustria gave the green light to an amendment of our Code of Practice of the pharmaceutical industry by which all companies that adhered to it will have to inform healthcare professionals that transfers of value derived from their collaboration as far as education, scientific-professional meetings and services provision will be disclosed in an individual manner.

This evolution from the Code is endorsed by a report released in April by the Spanish Data Protection Agency which stated the legitimacy of the disclosure on an individual basis is supported by the current European legal framework (Directive 95/46/EC), so that it will only be necessary to inform healthcare professionals that each transfer of value will be disclosed without being mandatory for the professional to sign a previous individual consent. This makes Spain a pioneering country in this field.

Both Stephen Ubl of Phrma and Nathalie Moll of EFPIA stretched the importance of communicating directly to the general public, and that the industry has failed to do so in many years, partly explaining the rather negative image it sometimes suffers from. Do you share their views?

One of what we call ‘transversal’ priorities is communication. We definitely feel the need to not only communicate the value of the pharmaceutical industry in terms of contribution to the health of the people but also in terms of the positive impact that it has on the economy.

The pharmaceutical sector in Spain is very strategic. The sector directly employs over 40,000 people with more than 50 percent of our jobs going to post-graduates. Another striking point is that 20 percent of the entire industrial R&D investments is undertaken by the pharmaceutical industry, and it also constitutes a source of qualified, stable and diverse employments.

One differential factor is also the fact that we are the main driving force in public R&D in biomedical research. More than 40 percent of our R&D efforts are in collaborative projects with R&D public centres in our country. As a result, Spain has a very strong and important network of public R&D centres in bioscience. On a side note, Spain enjoys an important network of public

hospitals and one peculiarity is the integration of primary and specialized care within the network which facilitates clinical trials.

It is safe to say that there is no other sector providing the same value to society, because we provide health solutions to patients, secondly, we strongly contribute to the country’s R&D and economy and we are generating savings to the health system through innovations.

However, the reception of such contribution is not perceived as we think it should. We are working with mass media and social networks to improve this image. We listen to society and we offer solid and verifiable information based on facts and figures about our valuable contribution.

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