Interview: Regina Múzquiz – Director General, BioSim, Spain

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Regina Múzquiz, director general of the Spanish Biosimilar Medicines Association (BioSim), discusses the importance of biosimilars as a tool to alleviate costs to the healthcare system and save EUR two billion in three years. Additionally, she points out the recent legal proposals on public procurement and reference pricing system that the association has put forward and the challenge of convincing physicians that biosimilars constitute a great opportunity for both patients and healthcare system.

Can you tell us the rationale behind the creation of BioSim?

BioSim was born under the umbrella of the Spanish generic producers' association, AESEG, but the member companies that were researching, developing and producing biosimilars deemed it necessary to differentiate themselves and come up with a different and independent association. Furthermore, healthcare authorities in Spain regard biosimilars in a different way from an economic and an administrative point of view and, therefore, some of Farmaindustria's members also felt the need to be part of a different entity representing the interests of biosimilars.

As a result, BioSim is today a young institution, independent from other business associations in the sector, and whose fundamental mission is to integrate and work for the benefit of its members, the pharmaceutical sector, and society as a whole. For me, the most important feature of BioSim is the effort to achieve common goals of the different perceptions – because at the end of the day,

while innovative and generics companies have different business cultures, they also share many similarities. In addition, I would like to highlight that our Board of Directors is composed of nine companies representing all these different areas (innovative, generics and biosimilars), which, in my opinion, guides the Association in the best way.

In 2016, the BioSim Advisory Council was constituted to ensure a fluent communication between representatives of the entire biosimilar landscape. Who are its members and its main goals?

Certainly, the Advisory Council was constituted with the aim of bringing together the representatives of all stakeholders involved in the management and use of biosimilar medicines. Therefore, patient organizations, scientific societies, professionals' associations and other experts, were called to join the Council. In its advisory capacity, the Council is consulted before some major decisions such as the publication of the Guide on Biosimilar Medicines for Physicians.

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What are the most important lines about the specific legislation for biosimilars you propose?

I think the most salient line is the law on public procurement that we put forward. We advocated for the acquisition of biological drugs through the modality of framework agreement. If we want to enhance market access of biosimilars in Spain, it is fundamental to have a public procurement plan implemented at regional level. Currently, 90 percent of biosimilars are to be found in the hospital segment – only insulin and follicle stimulating hormone (FH) can be purchased in pharmacies and shortly Rovi's enoxaparin will also be allowed.

However, another significant barrier, making it challenging for biosimilars to penetrate the market are the healthcare practitioners. On the one hand, if doctors are aligned, this represents an opportunity for the segment, but on the other hand it is fundamental that we respect the freedom of prescription, which I have in high regard. In addition to this, optimizing management in hospital pharmacies also contributes to patient access to biological medicines including biosimilars and it further allows the healthcare service to come up with policies in favor of a rational use of medicines. I think this agreement represents a hub of opportunities.

In addition to this, we are also calling for price differentiation with respect to the biological reference. Generics have a very clear reference price system and within the same scope the government included biosimilars. However, as mentioned above, we are very different in nature.

Firstly, the costs of developing biosimilars can by no means be compared to that of generics; they need to be prescribed by brand, and they cannot be substituted by pharmacists. We have recently submitted our proposal to the project of Royal Decree that modifies the Royal Decree (RD)177/2014 about reference prizes currently ongoing.

What is the timeline of the implementation of this proposal?

Regarding the framework agreement, it is still in process. It is our job and responsibility to convince the health authority of the 17 autonomous communities the importance of this proposition.

The reference price system for biosimilars is still a proposal to the ongoing project and we have to wait for the Ministry of Health to take a forward step in this sense.

The situation is very different for biosimilars, a booming sector in 2017, with more than 30 products approved in Europe, of which almost half have reached the authorization in 2017. Can you give us the full picture of the importance and the uptake of biosimilars in Spain?

I believe that the Biosimilar segment has incredible growth potential, not only in Spain but in every single European country. Many originators of biological drugs will lose their patents shortly, which ultimately results in a steep increase of the business. Unfortunately, all the numbers and statistics that we have at our disposal is the outcome of our own data collection as getting figures and numbers of uptake of biosimilars in Spain either by molecule or by region from a public source of information is quite difficult at the moment. I strongly hope that moving forward we will have more information and data on the subject to showcase the incredible benefits biosimilars are bringing to the whole healthcare system. Based on our in-depth analysis, the biosimilars will be able to produce EUR two billion savings within the next three years in Spain.

What is the stance towards biosimilars on behalf of the central government?

In Spain, we do not have special market access issues regarding biosimilars. For the time being, the blockbusters of most renowned pharmaceutical players are approved in Spain. All biotechnology-derived biosimilars must be approved under centralized authorization procedure, via the European Commission after evaluation by EMA and only the biologicals, such as low molecular weight heparins, can be approved in each country. At the moment, we have 39 approved biosimilars in the EU belonging to 15 molecules, while in Spain we have 26, which is mainly due to the time lapse between the EU authorization and the confirmation of the Spanish Agency approval, patent expiry dates or the particular interests of each marketing authorization holder.

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BioSim and the Federation of Spanish Medical Scientific Association (Facme) signed an agreement and set up a working group aimed at disseminating knowledge and resolve any doubts that may arise in clinical practices. What are you concretely doing to disseminate knowledge of biosimilar medicines to clinicals, administrators and patients in Spain?

We are currently involved in a campaign on the dissemination of knowledge and we are conducting scientific sessions in hospitals with the frequent help of clinicians and pharmacologists with high expertise in the regulatory processes behind biosimilars. We work with hematologists, rheumatologists, gastroenterologists, oncologist and many other experts. This is fundamental because these experts can impart lessons to their colleagues in hospitals from both a doctor's and regulatory point of view. We are very proud of it, because these sessions are attended not only by the heads of every department, but also by every single doctor and aspiring physician in the unit.

What are some of the most pressing remaining issues your members face?

I believe that one of the main problems is the containment on behalf of the government mainly focused on increasing downward price pressures. It makes it very difficult for the vast majority of biosimilar companies to regain the investment and therefore increase their business activities in these areas. If the government keeps on having this mindset it can be very risky for the biosimilar industry.

From your experience, where do you see biosimilars in the next five years?

I believe biosimilars will significantly expand their presence over the next few years. With the same quality, safety and efficacy of originator biologicals, biosimilars strongly increase the efficiency of the healthcare system, which ultimately results in better, faster and more affordable access for patients. Biosimilars can no longer be ignored.

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