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The deputy director of the Spanish Biosimilar Medicines Association (BioSim), Isabel del RiÌ•o, comments on the current status of biosimilars in Spain â?? including the nearly EUR one billion in savings they bring to the system â?? the most important elements included in the upcoming national plan to promote the use of biosimilars, and explains how gainsharing agreements could further improve the uptake of these medicines.

Can you briefly introduce your background and current role with BioSim?

Prior to joining the Spanish Biosimilar Medicines Association (BioSim) in 2016 as project manager, I was focused on research and education; I have a PhD in agricultural engineering and a masterâ??s in biotechnology. I also did an MBA after moving to the pharma industry through BioSim, plus a masterâ??s in Pharmacoeconomics. Today, I serve as deputy director for the association.

Spain is considered one of the most advanced countries in Europe when it comes to biosimilars as it was one of the first nations to create its own legislation, following the EUâ??s directive. According to recent reports, biosimilars have been gaining market share steadily for the last three years. Can you comment on the situation?

According to the latest numbers provided by the Ministry of Health, the penetration of biosimilars stands at 31 percent on average (adding the hospital and retail settings). In hospitals, the uptake during the first quarter of 2021 was 64 percent, compared to 17 percent in the retail setting. These numbers are low compared to other European countries.

Today, there are 56 approved biosimilar products (brand names) in Spain, only 2 of which were introduced in 2021, and 17 active substances exposed to biosimilar competition; the last active substance approved was Bevacizumab in 2019.

Jacqueline Corrigan-Curay, the Deputy Center Director for the US FDAâ??s Center for Drug Evaluation and Research, recently said that biosimilars are experiencing great uptake in the US, pointing to oncology products that have reached nearly 60 percent market share after only two years. How does that compare to the situation in Spain?

Oncology molecules have experienced a similar situation in Spain. For example, trastuzumab products gained a 68 percent market share in only two years; rituximab reached 77 percent; and bevacizumab biosimilars reached 47 percent in only one year. These are good figures, however, the 31 percent average across all molecules remains low.

We can only hypothesize about the reasons. Oncology molecules, for example, have been well adopted by oncologists because they have previous experience with biosimilars of more simple molecules (filgrastim for instance), which is not the same case for rheumatologists or gastroenterologists. Another hypothesis is that these medicines are normally administered to acute patients (a switch strategy is not necessary as in the case of immune-mediated diseases) and therefore gaining penetration is easier.

On the other hand, some products with low uptake levels such as insulin, teripartide, follitropin or enoxaparin sodium, are mostly dispensed at retail pharmacies where the price is the same for originator and biosimilar medicines.

Products that are dispensed in the hospital setting, such as those for oncology or for chronic diseases like rheumatoid arthritis, are purchased through tenders, where companies bid and give commercial discounts. Biosimilars can compete in terms of price but the new procurement law mandates that other criteria besides price should be considered, technical criteria based on value.

As Spain lags behind other European countries in biosimilar adoption, do you think it is a question of trust from doctors or patients?

We have observed big improvements in terms of trust from both healthcare professionals and patients in the last few years. There is still work to be done, but BioSim has been working hard to address the challenge, publishing different guidelines for prescribers and patients that explain the advantages of biosimilars for the healthcare system and how these products contribute to more access for patients. The association also conducts educational training sessions for prescribers and pharmacists, and organizes events with patient associations, which is not easy because they have been misled about the safety, quality and efficacy of biosimilars in the past.

Another item on our agenda is the continuous collaboration with universities to include biosimilars in academic curricula for medicine doctors, pharmacists and biotechnology graduates.

How aligned is the association with the European Unionâ??s upcoming ambitious blueprint for improving affordability and access to medicine, including biosimilars?

The strategy will have significant consequences as it addresses relevant issues such as increasing volume in order for patients to get faster access to biologic drugs, a rule on interchangeability. We call for a clear rule on interchangeability so that switching, always at medical decision, can be done with greater confidence by doctors and patients. Our expectation is that the strategy will encourage

member states to implement better policies.

For its part, the Spanish Ministry of Health (MoH) is currently working on its Generic and Biosimilar Medicines Plan. What should our audience know about the plan and its effects on the market?

After reading the first draft, BioSim has welcomed the plan, considering the MoHâ??s effort to create a better framework for the promotion of biosimilars something positive. The plan includes many measures that we have been advocating for in recent years, such as incentives, objectives and clearer interchangeability rules. We are advocating for two things: that the plan takes different considerations for generics and biosimilar medicines because, although both are off-patent medicines that contribute to a sustainable healthcare system, they are very different from a regulatory standpoint. Some measures are focused on the regulation of prices, and we have the risk of price erosion; there must be a balance if the market is to remain attractive for companies.

France, for example, included biosimilars in its national health plan in 2019 with the objective of increasing uptake to 80 percent by 2022. Spain has a good opportunity to set positive and ambitious objectives, too; the targets should be set for each particular molecule.

The MoH should encourage autonomous communities to establish their own objectives because the uptake in each region varies significantly, from 5 percent to 46 percent.

BioSim also advocates for the inclusion of gainsharing programs in the plan since, while it speaks about linking financial incentives to prescriptions, it does not specify how. Moreover, the plan should introduce a sustainable procurement system that does not only focus on price.

Can you explain how the gainsharing schemes you just mentioned work?

After conducting a very comprehensive review of gainsharing models in other countries, we have identified that the British model has the best chance of succeeding in Spain. Gainsharing schemes have a long tradition in the United Kingdom; Southampton Hospital published a work about its experience, explaining that a multidisciplinary team organized a program to switch from originator to biosimilar that was coordinated by a medical team, which makes perfect sense because prescribers must be involved in the process. Since biosimilar drugs are less expensive, the money saved was shared between the teams involved in the program, helping them hire more staff, invest in innovation or buy new equipment.

It is a good model since every party gets involved in the project and savings are redirected within the system to address different issues. In Spain, due to the decentralization of the healthcare system, stakeholders must include regional health and finance authorities.

BioSim has estimated that the public system will save up to EUR 930 million in 2021 thanks to the use of biosimilar medicines. Can you comment on that figure and how you came to that conclusion?

The EUR 930 million number is the result of a budget impact analysis we commissioned, made by an independent consulting firm in collaboration with a professor from the Complutense University of Madrid. The results pointed to almost one billion euros in savings each year from 2020-2022, and

revealed that, if the goal of having 80 percent uptake is met, we could get an additional EUR 400 million in savings.

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