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María Jesús Lamas, director and César Hernández García, head of medicines for human use at the Spanish Agency of Medicine and Health Products (AEMPS), discuss the challenges impacting the evaluation and analysis of products today. Furthermore, they give insights into why Spain is a leading global clinical trials destination and share their strategic plan for the next four years.

Could you introduce AEMPS to our international audience?

María J Lamas (MJL): AEMPS is the national authority responsible for the authorization of human medicines, veterinary medicines and medical devices and we control inspections, enforcement, and surveillance of the market while guaranteeing products safety and efficacy for the Spanish population. We work at the national level, while sitting and collaborating with the European Medicines Agency (EMA) and the rest of National Medicine's Agencies in a network-based model.

We take into account the entire life cycle of a therapy, so we are evaluating the process from the very beginning. This entails firstly providing scientific advice to researchers during the development phase on a national basis but also taking part in this advice at the EMA level. We then authorize and survey clinical trials, and then are the evaluators of the product after it has been

approved by the EMA and once it goes onto the market in Spain.

Our evaluations are then passed over to the Ministry of Health, who determine, firstly, if the medicine should be reimbursed using public funds and under which conditions, and secondly, the pricing of the product. This is done by the Ministry and the advice of various members of Spain's 17 autonomous communities. AEMPS takes part in this process by providing clinical assessments and assisting in the first four domains of the core model domains of the HTA process.

What are the main challenges you are facing today for the evaluation and analysis of medicinal products?

MJL: The main challenge for any evaluation operation is to guarantee the quality of the research we are managing as it must be reliable and accurate at all times. At AEMPS we are very good at using this information to identify the balance between the benefit of a therapy and the risks involved; however, now we must go beyond that and find a way of truly understanding which therapies are offering real value and innovation within the Spanish healthcare ecosystem.

Which processes have you got in place to identify this "real value"?

Cesár Hernández García (CHG): It is covered by the plan we have in place to identify innovation from the earliest stage possible, which allows us to better evaluate these products in the future. By providing information of the work being done throughout all stages of development to decision makers down the line – pricing authorities, regional governments, hospitals etc. – it allows for a smoother transition from the development and clinical phases, to the market access of treatments.

As mentioned previously, it is about assessing real value, and we believe by using concepts, such as big data, we can improve processes and address challenges, for example, finding new ways of developing clinical trials for quick market access. Our role at AEMPS is to use all the information provided to us effectively and then pass it on in an accurate and reliable manner to other authorities, so they can make in the end, the correct decisions for Spain.

MJL: Along with the EMA and the entire network, we are identifying innovation from the very early stages. From a scientific point of view, these are treatments that address clear issues in society or are directed towards a medical problem for which there is no current solution, such as in the case for many cancers and rare diseases.

Personalized medicine is a common trend in healthcare today. How well prepared are you for this new wave of treatment?

MJL: We have several challenges in this regard and they all are connected. Firstly, Spain has many excellent researchers in this personalized medicine field taking part in international studies. We must support them along this path as their scientific knowledge is a clear advantage to better understand these treatments and will help the entire healthcare system.

Secondly, personalized medicine is not only about a targeted treatment and it would be a mistake to look at it from this point of view. It involves many other aspects, such as genomic tools and preventative measures. Therefore, we must have a collaborative approach across the board, to best understand how to utilize personalized care throughout the healthcare system network.

Finally, there is the challenge of funding personalized care as in the end we must be able to pay for these therapies while maintaining the sustainability of the Spanish healthcare system in the future.

How has Real-World Evidence (RWE) impacted your processes?

MJL: Medicines must be continually evaluated in real-time, and the only way to do this is by using RWE. It should be a mandatory tool from early phases and market approval to pricing and post-reimbursement and this will help us to really understand the true value of a therapy. We are already utilizing big data, but this is mostly for pharmacovigilance and understanding the patterns of a medicine’s use in primary care to search for unknown adverse effects. Thus far this has generated some important findings and has led to some key changes in processes.

How has the Royal Decree of 2015 (Royal Decree 1090/2015) impacted the clinical trials ecosystem in Spain?

CHG: Europe put a regulation (Regulation (EU) No 536/2014) in place to increase the competitiveness of the EU in the landscape of clinical trials. While this Regulation is still waiting for a single clinical trials information system, we decided to take the lead and act proactively, and in 2015 the Royal decree was enacted with the aim of improving our relative position while fostering knowledge, facilitating transparency, and reinforcing a subjects’ safety.

This made Spain the first country to have this system, which in turn has created a smoother clinical trials process. All the actors are taking advantage of this, and although in terms of pure numbers clinical research has not grown, we are attracting quality trials that create a real impact on our healthcare.

What can be done to take the next step and become the clinical trials leader in Europe?

MJL: Increasing clinical trials numbers and attracting quality research is not only about the Royal Decree of 2015. This has been a long-term process built around a reliable healthcare system that has leading researchers, hospitals and universities amongst others. This infrastructure is crucial to making the nation attractive to companies looking to find a home for their clinical studies.

One thing we must remember is that clinical trials are developed by much more than clinical leaders, but incorporate professionals such as clinical pharmacists and radiologists for example. When drawing up clinical protocols we must recognize and include them, as otherwise they can be overwhelmed by their tasks.

Correct planning must take into account the entire infrastructure network. Although it is nice to grow the numbers of trials being undertaken in Spain, we must also ensure that what we can accommodate these trials, so they can be done to the highest standards possible. This, in turn, will make Spain an attractive site for the leading clinical trials in Europe.

What is AEMPS stance on biosimilars?

MJL: Firstly, we must ensure that biosimilars have the same quality as the original, and this links to AEMPS providing useful information to all levels of the healthcare system. The use of biosimilar is very much related to the pricing policy, an area we are not dealing with. Nevertheless, we must give guarantees to the people of Spain and ensure health professionals feel comfortable using these medicines.

How are you working to educate Spain that biosimilars are the same as the original?

MJL: We have two challenges; firstly, to educate the health professionals, and secondly, to gain the confidence of patients and citizens.

For biosimilars, the preclinical information is crucial to determine and prove the biosimilarity of a drug. Once this is the case, the clinical trials being done on biosimilars do not have to be of the same quantity as that of the original, as long as they clearly show that the biosimilar has the same results as the original.

Pharmacists have the training and technical knowledge to understand a drug's formulation at the pre-clinical stage. However, physicians who are more trained towards clinical trials, want the same level of clinical research on the biosimilar as the originator. We need these physicians to look more at the pre-clinical data, which already proves the biosimilarity, so they can then understand there is not such need for such large clinical studies.

Nevertheless, this is a challenge we face, and once we are able to overcome this, it will lead to building the confidence of biosimilars within the general Spanish population.

What are your objectives for AEMPS in the future?

MJL: Soon, we will launch our strategic plan for the next four years.

One of our goals is to increase our leadership presence in Europe as Spain has world-class clinical evaluators and Europe listens to us. Therefore, we must use this knowledge to be more influential on a continental level.

Secondly, within Spanish society, we must become closer to healthcare professionals and patients, as we are relied on as one of the leading voices in the nation. Being closer will only grow our knowledge and closeness to the issues everyday Spaniards are facing.

Thirdly, on a global level, the healthcare world is facing the threat of drug shortages. It is a large challenge to overcome, and Spain cannot do it alone due to the complexity of the problem. Therefore, we must work to coordinate at a European and global level to find answers as it is a situation which threatens the safety of patients across the globe.

Overall, we must work as a team at AEMPs and ensure people are proud to work here and deliver a key service to the country.

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