'The evolution of value in Health Care': Post-ISPOR meeting
Madrid - 7th February 2018
Organized by the ISPOR Spain Regional Chapter

About 200 professionals from pharmaceutical companies, healthcare managers and other experts in the healthcare sector attended the First Post-ISPOR meeting: 'The evolution of value in healthcare' on February 7. The event was held in Madrid and organized by the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) Spain Chapter and Diariofarma. The objective was to present to the Spanish attendants the most relevant outcomes from the debates that took place in the last ISPOR Annual European Congress held in Glasgow, November 2017 and discuss the implications of presentations into the Spanish context.

This meeting was the first of a series of meetings aimed to summarize and translate to the Spanish audience, who either did not attend the ISPOR Congress or did not have the opportunity to participate in all sessions, the main topics that were covered during the event.

New potential funding models for medicines and health products

Discussant: Isabel Pineros, member of the Ministry of Health. Moderator: Carme Pinyol, president of ISPOR Spain Regional Chapter

As a member of the Committee, that sets prices and funding conditions of medicines in Spain, Isabel was presenting the current pricing and reimbursement model.

The policy for setting the price of medicines in Spain was discussed as less conditioned by the price in other countries in the European Union (EU). Although the prices in other states serve Spain as a supporting information when establishing prices, the Ministry of Health prefers national comparators. In the same way, in the evaluation of the price revision for new indications, the existence of lower prices in the EU may have an influence, although it is not a main criterion.

Novel approaches to facilitate access to innovative medicines: prices for combos
Caridad

Panelists: Pontes, Manager of the Pharmacotherapeutic Harmonization of the Catalan Health Service (CatSalut), and María José Calvo, Deputy General Director of Pharmacy of the Madrid Health Service (Sermas). Moderator: Natividad Calvente, vice-president of ISPOR Spain Regional Chapter

The event was opened with a round table to address the alternatives of pricing and the novel approaches to facilitate access to innovative medicines, with special emphasis on new cancer treatments. Both speakers agreed on the need to have registries and a systematization of the information to measure the health outcomes of the therapeutic novelties and, additionally, to study the costs.

Although comparative efficacy is what guides the evaluation, it is also necessary to consider the severity of the disease, the medical need and the perception of the patient's benefit. In their opinion, it is necessary to analyze the product contribution in alignment with health priorities.

The introduction of new indications, especially in oncological medicines, requires consideration of new funding and pricing systems according to the value of the drug. In their opinion, one should take into account the value of each drug to pay and give the population what they need; however, the reality is that the value lies in the theoretical setting and it is unknown how it works in clinical practice.

Another topic addressed that, currently, the pharmaceutical industry is rewarded with a focus on return on its investment, rather than on the benefit provided by the innovations.

,The round table discussed that it would be necessary to change the focus towards how much the society is willing to pay for the health results obtained and then set the

They suggest that the price of drugs should be set in relation to the maximum value that is expected to be obtained. In those cases where the results are not as expected, the price might be lowered for those alternatives with no additional benefit.

Other options such as spending ceiling or payment by results, in which there is already some experience in Spain were also mentioned.

As a sum up, a wide range of options for pricing and reimbursement of medicines were discussed. The major concern from the representatives of Regional Governments is how to deal with limited budgets where the cost of treating a disease does not have to be more burdensome for the system due to the fact that more modern medicines are used. "By adding more treatments we cannot assume that the resources required by a disease need to be increased, it is an unlimited growth system that could put sustainability at risk," explained Pontes.

The round table closed with a series of suggestions for the future. The autonomic representatives marked as a challenge to advance registries and information systems, as well as to consider the payment by process and link it to the outcomes. In relation to the industry, they demanded innovative proposals that respond to the challenges and offer solutions that make the system sustainable.

<u>The challenge in front of the new cancer drugs</u>

Panelists: César Hernández, head of the Department of Medicines for Human Use of the Spanish Agency of Medicines (AEMPS) and Jorge Mestre, health economist. Moderator: Lluis Bohigas, economist.

The second round table discussed new paradigm in the treatments against cancer. The difficulty to define what is innovation was emphasized. Regarding this aspect, it would be interesting to have a tool that would confirm "unequivocally" that something is innovation, although in the decisions making process there are other items to be considered.

There is also the need to have more evidence to facilitate decision making. Results should reflect clinical practice and although payment by result is mentioned as an option, in Spain the budget impact is driving most of the decisions. This fact is also related, according to Mestre, to the reduction of drugs prices when new indications are incorporated.

In any case, one of the major challenges for the future will be the management of uncertainty and, therefore, address solutions to reduce it, if possible, before authorization, as explained by the representative of the AEMPS. In relation to the tools that can be used to reduce this uncertainty, Hernandez explained that one of them is the conditional authorization, which must be conditional throughout the process, including pricing, and should serve to increase the evidence.

Real World Evidence: Challenges

Discussant: Pablo Rebollo, principal HEOR, IQVIA. Moderator: Cristina Espinosa, Secretary of ISPOR Regional Spain Chapter

The conference was dedicated to Real World Evidence (RWE), that is, the collection of a n a l y z e d data from patients to provide knowledge about how they are diagnosed and treated under conditions of usual clinical practice, as expressed by Pablo Rebollo, which highlighted the difficulty of accessing existing databases and their limitations.

Having a large amount of patient information is an important revolution in the health sector, which helps decision-making. However, in order to use all its potential, it is fundamental to have adequate access to data, to know how to organize and analyze it with adequate methods to be able to interpret it in order to use it in an optimal way. In this regard, there is a consideration to move forward with a new type of data that incorporates those of real life with the veracity provided by the Big Data. Rebollo spoke of Real World Big Data as the field to which to move forward.

Rebollo highlighted the barriers in the use of computerized health data, the protection of privacy for ethical, technical and cultural reasons. However, he claimed that there are studies which indicate that citizens are willing to share their health data, if they remain anonymous and the data is used only for research purposes.

Have the QALYs died?

Panelists: Antoni Gilabert, Director of the Pharmacy and Medicine Area of the Health Catalan Consortium and Álvaro Hidalgo, professor and Director of the Seminar on Research in Economics and Health of the University of Castilla-La Mancha. Moderator: José María López, Director, Diariofarma.

Both speakers agreed that QALYs continue to be a tool to be used in the pharmacoeconomic evaluation of drugs.

For Gilabert, it is a useful methodology for decision making, with special emphasis in the clinical part in relation to the economic aspect; it is standardized and allows the evaluation of the cost versus the results. He considers that, although there are objections and reluctance for its use, QALYs and economic

evaluations in general continue to be extremely useful, providing support to enter an analysis, debate and prioritization in a transparent manner.

Hidalgo also believes that this method provides transparency, incorporates the perception of the patient and, as another advantage, it is an instrument of comparability among medicines and different diseases. As mentioned in a previous round table, the tendency is to move towards a methodology that classifies innovations with more transparent and objective criteria, as a support for taking reimbursement decisions.

As limitations, he stressed that other aspects related to the value of the drug, quality of life, advantages of the route of administration etc. are not considered in the purely economic evaluation. Further on, Gilabert pointed out that there is a lack of in-depth training in the payer's field to assume the use of this technique in an ordinary way.

In relation to the need of a more holistic evaluation of innovations, the multi-criteria decision analysis (MCDA) emerged in the debate, which provides elements such as the subjectivity of the patient. Also for Gilabert, this method, which is being tested by CatSalut, is an alternative, because it incorporates aspects that traditional evaluation does not take into account, although it does not allow for macro-level decision-making. For this expert, the most important of the pilot project that has been launched in CatSalut for the introduction of the MCDA "has been more important the learning process in the first experiences than the final results by themselves". It represented a change of mentality in the way of reaching agreements and it was unanimously assumed in the launch of the project.

At the end of the meeting attendants were invited to join the II Post-ISPOR meeting that will be held after the ISPOR Congress in Barcelona in November 2018.