Conference at the Senate

Opportunities and challenges in the regulation, evaluation and access to ATMPs

February 16, 2026

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Introduction

On February 16, 2026, Lasker and PORIB co-organized a conference at the Senate entitled: “Opportunities and Challenges in the Regulation, Evaluation, and Access to ATMPs”.

The conference was endorsed by the Platform of Patient Organizations (POP) and supported by Bristol Myers Squibb, Johnson & Johnson, and Vertex Pharmaceuticals.

The event was moderated by Ibán García del Blanco, Director of International Relations at Lasker and former Second Vice-President of the Senate Health Committee.

The meeting brought together 18 speakers and facilitated a shared reflection on the current state and future needs of Advanced Therapy Medicinal Products (hereinafter in the document, ATMPs) in Spain.

This document summarizes the presentations and presents the main conclusions of the discussion. Its purpose is to enable progress towards greater development and access to ATMPs from the perspective of patients, European, national and regional institutions, healthcare professionals, health economists and industry.

Endorsed by:

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Regulation and Health Policy

Conclusions

01	The main challenge is not the absence of legislation, but the need for greater **agility, predictability, coordination and reduction of duplications**.
02	The current framework already contemplates instruments such as **conditional financing**, the use of **real-life data** or **hospital exemption**, but their effective use is the main challenge.
03	It is necessary to maintain a strategic vision that balances **innovation**, **sustainability and equity**, providing certainty to professionals, patients and the industrial sector.
04	There is a European strategic concern to strengthen the **productive and industrial capacity** associated with innovation.

Evaluation and Funding

Conclusions

01 The decision-making system remains focused on the immediate budgetary impact. However, ATMPs require an approach based on their **efficiency and long-term value.**

02 These therapies represent a **paradigm shift** and need **specific evaluation models** that incorporate their curative potential, the reduction of future treatments and the complete clinical trajectory.

03 Re-evaluation with real-life data must have **direct operational consequences**, both in price and in access and extension of use.

04 Strengthening **information systems and interoperable clinical registries** is essential. Currently, tools such as VALTERMED are only partially integrated with the medical record, which limits their usefulness.

05 The evaluation should incorporate not only clinical efficacy, but also the **effectiveness of the care itinerary and the social and functional outcomes of treatment**, incorporating variables such as quality of life, social impact, caregiver burden, and value perceived by the patient.

06 Having **solid clinical records and periodic reviews of the value** would allow decisions and prices to be adjusted as evidence is generated in real practice.

07 The main challenge is not only the efficiency of the treatment, but also the ability to **assume its initial cost in the short term** within annual public budgets.

08 The **fragmentation of funding between regions** could lead to tensions and require the introduction of common mechanisms or compensation instruments for high-impact treatments.

09 The **re-evaluation of health outcomes** should be linked to dynamic financing mechanisms that allow access to be expanded when therapeutic value is confirmed.

10 **Duplication of evaluation or financing** processes delays the arrival of treatment to the patient.

Access, Equity and Organization of the System

Conclusions

01 There is a significant gap between the European **authorisation of therapies and their effective availability in Spain**.

02 Ensuring that any patient has access to the best treatment regardless of their **place of residence** remains a priority objective of the system.

03 Access is not solely dependent on the approval of the drug. Late **diagnosis**, lack of **continuity of care**, and delays in **administrative processes** are critical barriers.

04 The **evaluation and access times in Spain** show a structural problem of the process. **Territorial inequity** affects the entire care process, including neonatal screening, genetic diagnosis, evaluation, logistics, availability of centers and information systems.

05 ATMPs require **networked care models**, with effective coordination between reference centres and levels of care. Although there are relevant infrastructures (such as specialised centres, clinical networks, genetic bases), their use is not homogeneous between territories.

06 The **delay in diagnosis in rare diseases** shows that improving access to ATMPs requires first strengthening diagnostic capacities.

07 Genetic databases, shared information systems, and continuous monitoring are **critical infrastructures** for the development and efficient use of these therapies.

08 Shared **access to medical records and outcomes** across centres and levels of care would facilitate equity, assessment, and evidence-based decision-making.

Collaboration and Patients

Conclusions

01 **Patient participation** must be consolidated as a structural and active element in evaluation, financing and decision-making processes.

02 The social **visibility of rare diseases** has been shown to influence research, regulation and health priorities, evidencing the real impact of social participation.

03 **Public-private collaboration** is configured as a structural and inevitable element in the development, production and access to ATMPs. This collaboration should encompass research, manufacturing, clinical innovation, data systems, equipment and industrial development.

04 **Risk-sharing agreements** not only have a financial role but could also contribute to building trust among the actors in the system and facilitating the adoption of innovation.

05 Specific national programmes and other initiatives aimed at strengthening **productive capacity and competition** can enhance the affordability and sustainability of the system.

Institutional Opening of the Senate

Mr. **Pedro Rollán**, President of the Senate, has placed the meeting within the framework of the institutional commitment to health and innovation.

During his speech, he highlighted "the joint commitment of society and the European Union towards the continuous improvement of health services in our society".

He stressed that the conference would address **ATMPs from different approaches**, such as the **regional leve**l, given the Chamber's unique territorial representation, and from the **point of view of the regulatory framework**, considering that the Senate has its own legislative capacity.

In addition, he stressed that "**Spain is among the best health services in Europe and the world**. From the institutions we must guarantee that innovation reaches all citizens without generating inequalities and ensuring the sustainability of our health system".

He also stressed that "institutions must promote scientific research and the use of new therapies that allow a therapeutic benefit to patients". In this sense, he underlined the **transformative potential of ATMPs** in the treatment of diseases that "until very recently, unfortunately, were considered incurable or difficult to treat". These scientific advances, he emphasized, also pose a series of **ethical, regulatory, organizational and equity** challenges.

In his closing remarks, the President of the Senate reflected on the many years of work that **have enabled the Spanish health system to achieve a leading position globally**, particularly regarding **clinical trials**, some of which are associated with ATMPs". However, "we must not relax and we must continue to strengthen the pillars that have led us to this situation". He also concluded that "the true value of ATMPs lies not only in the sophistication of health technology, but also in their ability to restore hope to thousands of patients and their families".

Clinical and Comprehensive Definition of ATMPs

Ms. Sol Ruiz
Head of the Division of Biological Medicines, Biotechnology and ATMPs of the AEMPS

Sol Ruiz was the first speaker at this conference. She began her speech by explaining what are considered ATMPs, mentioning gene and cell therapy and highlighting their uniqueness.

She highlighted the procedure of the European Medicines Agency, which usually has a 210-day evaluation process that can be accelerated and, thus, reduced to 180. In addition, she stressed that **each country decides on the price and reimbursement**, so "even if a medicine has the positive opinion of the European Medicines Agency, it is not necessarily available in all countries of the European Union".

Speaking of **genome editing**, Sol Ruiz said that, in Spain, we already have several clinical trials with this type of technology. In this sense, she stressed that, although the number of patients may be low, "the results are really robust". Subsequently, she has used several examples of specific drugs and pathologies to illustrate the challenges and opportunities in ATMPs.

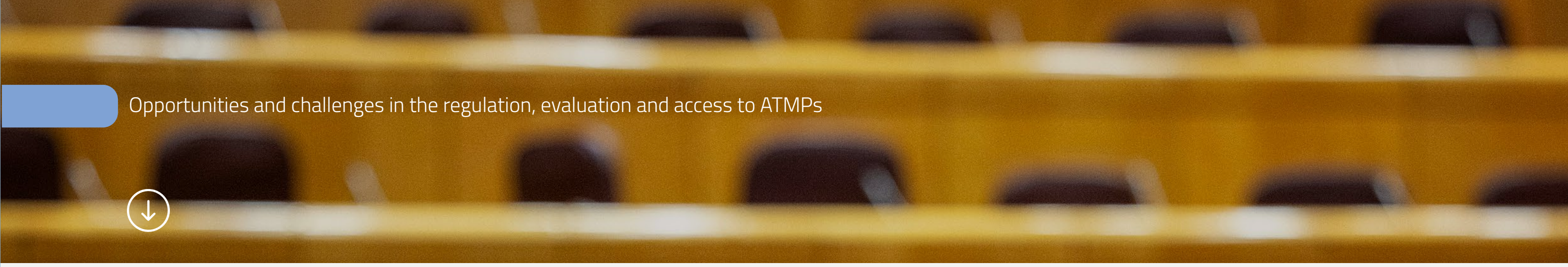
In this regard, she also mentioned the possibility of **authorisation for use** that allows Spain to use non-industrially manufactured medicines in hospitals without the need for a centralised marketing authorisation (**hospital exemption**). Sol Ruiz has highlighted the conditions for this use to be guaranteed, such as evidence of efficacy and safety.

Finally, she ended her presentation by highlighting **research and clinical** trials in Spain. She stated that **Spain has a leading role, above all, in "rare diseases, ATMPs, and innovative medicines",** not only in research but also in access.

Sustainability and Innovation

Regulatory framework, evaluation of its value and access to ATMPs

PANEL 1



Opportunities and challenges in the regulation, evaluation and access to ATMPs

Moderated by:
Mr. Pedro Carrascal
Director General of the Platform of Patient Organizations

Mr. Miguel Ángel Calleja
Hospital Pharmacist. Former president of the Spanish Society of Hospital Pharmacy (SEFH)

Mr. Daniel de Vicente
Member of the board of directors of the Spanish Federation of Rare Diseases (FEDER)

Mr. Valentín García Gutiérrez
2nd Vice-President of the Spanish Society of Hematology and Hemotherapy (SEHH) and hematologist at the Ramón y Cajal University Hospital

Ms. Isabel Pineros
Director of the access department at Farmaindustria

The panel was inaugurated with the intervention of **Daniel de Vicente**, who began by highlighting that, in recent years, there has been an increase in interest in rare diseases by society, both civil and clinical and scientific, and this is largely due to the role of patient associations. He also stated that “when **visibility** is given and also **a regulatory framework that favours this type of innovation**, research into this type of therapy is encouraged”. He stressed that only 6% of rare diseases have an effective treatment, and that in Spain there are about 3 million people affected. Additionally, he emphasised that, on average, you have to wait 24 months to access treatments in the country. “The fundamental thing is **to guarantee the voice of patients**” and that they can actively participate in the processes, from the evaluation of the drug to the financing processes.

The panel continued with the intervention of **Valentín García Gutiérrez**, who began by pointing out that, from the SEHH, “we are convinced that we already have an example of a **successful model**, such as the implementation of the CAR-T therapy model”. He emphasised the importance of considering equity when incorporating new therapies into the system, guaranteeing access that “is easy for patients”. These therapies, he stressed, **although they have a high initial cost, can “save a lot of resources**, such as treatments or subsequent lines and hospitalizations”. In addition, he stressed that the role of medical professionals is fundamental, and that “probably where everything is best centralized is in scientific societies”. He has expressed his concern regarding the “criteria for selecting experts in terms of funding and discussion” and “the enormous debate on the **conflict of interest** of experts” so that, with the current criteria, “no one who can be considered moderately an expert in these cell therapies will be able to be part of these committees and we will be excluded”. In this sense, he has concluded that these conflicts of interest (such as having participated in clinical trials) should not be considered as an exclusion criterion, highlighting the role of scientific societies in solving this situation.

Miguel Ángel Calleja highlighted, in his speech, the fundamental role of hospital pharmacy in the context of ATMPs. He stressed that we are talking about therapies that, “**apart from being effective and safe, are therapies that in many cases are a single administration**”, which is an enormous advantage for patients. He stressed the fact that, **although they are very expensive therapies**, the factor of producing a cure means that **the budgetary impact is being reduced**, in the long term. Regarding the challenges, the speaker focused on the re-evaluation of health outcomes and delays in the evaluation of innovation, comparing the situation with Germany, where it takes much fewer days than in Spain.

Isabel Pineros closed the first round of interventions at the panel, starting by highlighting the number of ATMPs that we currently have. However, regarding Sol Ruiz’s presentation, “when you review **how many of the 22 ATMPs authorized by the EMA are available in Spain, you can see that there are only 9, with a clear imbalance**. Therefore, it is necessary, on many occasions, a **change in the health organization**” and “our health system has to prepare to be able to incorporate these drugs, but this in no case has to be a brake to be able to have them in a much more agile time than we currently have”.

The director of the access department at Farmaindustria has also highlighted a recent work by the employers' association on neonatal screening; specifically, on equity in screening. She stressed that, without a doubt, the update of the Strategic Plan for ATMPs meant "a before and after" for the entry of the first CAR-T drugs in Spain.

In the second round of interventions of the first panel, **Daniel de Vicente** highlighted the importance of **genetic diagnosis**, stating that "50% of patients with rare [diseases] take an average of 5 years to be diagnosed, and 20% of these patients take more than 10 years. In addition to guaranteeing the diagnosis, Daniel de Vicente emphasised the need for diagnostic tests to be implemented with **equity**, highlighting the **difference between Regions**. He also defended the need to expand genetic screening equitably, especially for patients with rare diseases. In addition, he stressed that another problem we have is that **the process is not given continuity after the diagnosis of a patient**, to be able to access this type of medication. In this sense, **networking** is crucial, since many of these diagnoses are no longer carried out at the national level, but through European reference networks.

Valentín García Gutiérrez has defended that "**ATMPs force us to rethink how we measure the value of these treatments**", explaining that drugs used to be approved based on overall survival, and now this is no longer the case. Of course, he considers it necessary to evaluate the value they provide and what it really translates into, which explains why financing is more complex than approval.

He reinforced the idea that **these treatments save resources**, whether they are successive therapies, successive transplants or maintenance drugs, so "we have to **change the chip for these negotiations and have new indicators" and records.** For his part, **Miguel Ángel Calleja** believes that the key would be "to focus more on this **revaluation of health outcomes** and for this revaluation to have an impact", such as greater and accelerated access. In this sense, he considered that VALTERMED can be an interesting tool, although, right now, it is not focused in that way, as it is not connected to the medical record. He defended that Spain needs "that we do not work only because of the budgetary impact (...), that we act based on the **cost effectiveness**", reinforcing the idea that many of these therapies have high costs, but, if they are curative, this cost would effectively be lower.

To conclude the interventions, **Isabel Pineros** expressed her agreement with what was said by the other colleagues at the panel. She stressed that "we really like to label these medicines as medicines with uncertainty, but curiously they are medicines that have a **centralised authorisation**, which have gone through an evaluation of all European countries and in which their **quality, safety, efficacy have been assessed** and on top of that they have been rewarded with **a positive benefit-risk** balance". Because they have limited data, "they are given a conditional authorization, but not to **decide not to finance them in Spain**," but because additional information is lacking. Likewise, the director of Farmaindustria's access department stated that "**no law or Royal Decree must be changed to have conditional financing**". Finally, she stressed that we are focusing more on **economic agreements** and not **on payment for results**, which does not resolve any type of therapeutic uncertainty.

Financing and Public Procurement Models

Mr. Manuel García Goñi
Professor of Applied Economics at the Faculty of Economic and Business Sciences at the Complutense University of Madrid

Manuel García Goñi focused his presentation on public procurement and financing models.

The professor began his presentation by highlighting some data, such as the **66% increase in pharmaceutical spending**, adding hospital pharmacy, in the last 11 years (from 2014 to 2024). In this sense, he defended that "**we are spending more, but we are also greatly improving the quality of life of our patients and the quantity of life of our patients**". In addition, "we are tending towards a very individualised medicine", so this means high costs and **increases in research and innovation**.

Regarding expenses, Manuel García Goñi stressed that, as it is public money, we need **the national health system to be efficient and sustainable**. To these concepts, García Goñi adds that of solvency, because "it is not only about something being cost-effective, but it is also about us being able to pay for a treatment and, sometimes, we cannot afford it".

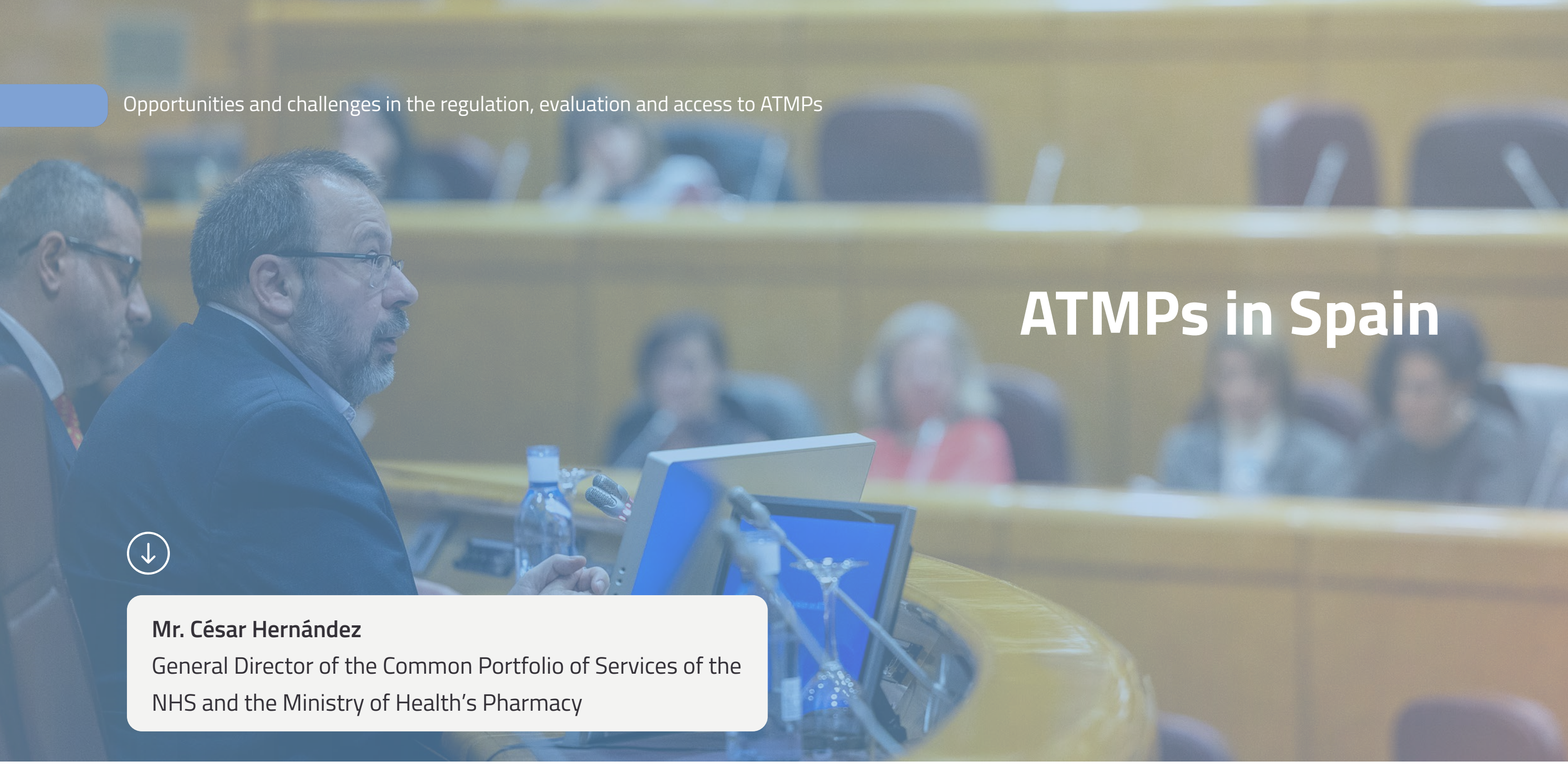
In his presentation, he also highlighted the **two types of markets** in which we have important innovations, especially in **pharmacological treatments and ATMPs**: those that have clear competition and those that do not, referring to the existence of **therapeutic alternatives** and the subsequent absence of monopoly.

García Goñi also explained the **usefulness of the *Horizon Scanning*** tool, which tells us approximately what "is going to reach the market in the coming months or years". In his opinion, it is an important tool for several reasons: firstly, "so that centres, hospitals, can **get used to and adapt** to solving the problem of how this type of advanced therapy drugs have to be provided to patients". On the other hand, it is also important to know "what we are dealing with when **setting prices**, and what value is added with respect to what already exists or will soon be available for negotiation".

In addition, the professor highlighted the **risk-sharing agreements**, in line with what Miguel Ángel Calleja mentioned in panel 1, which "smooth out the rough edges of the lack of trust that may exist between supply and demand".

From an economic point of view, the problem with ATMPs is that they are new and expensive products. In this way, on the one hand, **the supply needs to recover its investment and development**, so the price is going to be high and, on the other hand, the demand (the payer) has to bear these high costs and does not know how the market/patients susceptible to these therapies will act, so **the demand is short. This generates imbalance, which in turn generates a lack of access**.

Finally, he stressed the need to have a good **record of clinical data** to **improve the evaluation,** and that it is revisited with the generation of real-life data, as well as **the revision of prices**. The professor concluded that "ATMPs are **changing the balance of forces between the public and private systems**", with much stronger interaction on the public side and the need for incentives for both parties.



ATMPs in Spain

Mr. César Hernández
General Director of the Common Portfolio of Services of the NHS and the Ministry of Health's Pharmacy

César Hernández was the protagonist of the third and final individual presentation of the day. He began his speech by highlighting **Spain's leading role**, in Europe and in the world, **in the research and development of ATMPs**. In his opinion, this is due to three facts: 1) a very good academic structure at the time (around 2007); 2) the transformation of the exclusion clause of the Royal Decree on the manufacture of non-industrial therapy medicines for the manufacture of advanced therapy medicines; and 3) the 2018 plan of the General Directorate of Portfolio and Pharmacy to boost the arrival of CAR-T therapies.

There are going to be more ATMPs, so it is expected that these drugs "will serve to **significantly change the course of the disease and the quality of life of patients**". This is a major challenge, "not so much for the pieces of legislation that we have in place, but because of what this world of ATMPs means within them (...) also **overlapping with that of the world of rare diseases**". The legislation, he explained, tries to "have a broad and common framework where each of the issues find their accommodation", even if no explicit references are made to ATMPs or rare diseases.

"The challenge for the healthcare system is to **turn the extraordinary into the norm**," said César Hernández, reinforcing the idea that innovation must be encouraged.

The director general stressed the challenge of treating the 3.5 million rare disease patients in Spain with ATMPs costing 2 million euros per patient, which would result in an "**absolutely unaffordable**" **cost**. He also insisted that "the **budget base** cannot be extended according to the **population burden**", so it is necessary to continue to incentivise above the real clinical value of ATMPs, but also to generate "competition between the different actors that may arrive".

He also highlighted the **existence of specialised centres in the Autonomous Communities (the CSUR)**, giving the system the opportunity to evolve. This is important, among other factors, so that **patients do not have to travel** between communities during each of the phases of treatment.

From the Ministry, he commented that "the next report we make (...) it will include **all ATMPs.**" In addition, he mentioned the important **Pharmaceutical Industry Strategy,** published in 2024.

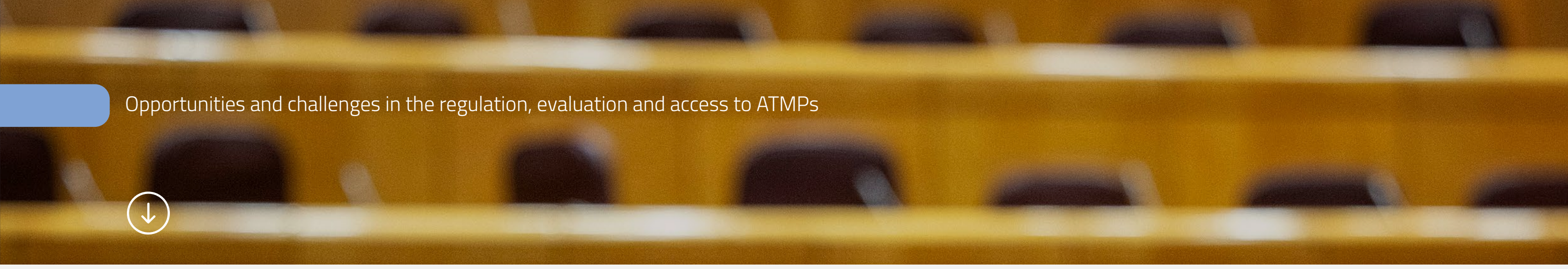
César Hernández also highlighted the importance of CERTERA and Terafront, which are the pieces that make it possible for everything that was launched with the Royal Decree on the manufacture of ATMPs medicines to serve to ensure that there are more products and more competition and, therefore, **more affordability and sustainability**.

Finally, he emphasised that **public-private collaboration** in the field of ATMPs is imperative. "Spain is in a good place to continue making a difference", and ATMPs are one of the focuses of the Pharmaceutical Industry Strategy.

Building the Regulatory Framework for ATMPs:

The pace of innovation fuels the debate from Europe to Spain

PANEL 2



Moderated by:
Mr. Manuel Delgado
Managing Partner of Lasker

Ms. Alba Soldevilla
Member of the PSOE in the Health Committee, Congress of Deputies

Mr. Rafael Belmonte
Second Secretary of the Health Committee, Congress of Deputies

Ms. Paschalia Koufokotsiou
Policy Officer, DG SANTE, European Commission

The second panel of the day focused on the European regulatory framework and national developments in ATMPs. The first speaker was **Paschalia Koufokotsiou**, Policy Officer of the European Commission's DG SANTE, who shared a presentation on the transformative part of ATMPs in the European Union. In her speech, she addressed the procedure required by these treatments, explaining the need for central **authorisation** and the role of the **European Medicines Agency** (EMA) **and its committees**. The policy officer highlighted the national competences of EU Member States, such as hospital exemptions, health technology assessment and issues related to price and reimbursement. She also explained that ATMPs have to be administered in specific treatment centers.

Alba Soldevilla began her speech by highlighting three principles that, in her opinion, the future medicines law must reflect in order to respond to ATMPs: 1) **agility**, avoiding delays, duplications or unnecessary rigidities; 2) **predictability and legal certainty**, since the system works best when the different actors know how it is evaluated, how it is decided and in what time the decisions are made; and 3) **transparency**, on the part of the Administration and on the part of the industry. To guarantee the stability of the legislative framework, the deputy stressed the importance of "**maintaining a vision of the system and the life cycle**", since "the decisions of this law not only affect the authorisation of the price, but the entire journey of the medicine within the system". In addition, she considered it relevant to achieve this stable framework for the **participation** of patients, Regions, professionals, industry and other actors.

In his speech, **Rafael Belmonte** highlighted two principles that he considers essential: 1) a risk, because "these are not easy times to legislate in Spain " and 2) ambition, which complements what Soldevilla said earlier, regarding agility. The deputy stressed that we should not let "innovation be permanently taken away by the United States and Chinese production" and that Europe should be left with the tasks of legislating and regulating. Coordination, he explained, is also fundamental, as well as **subsidiarity**. Likewise, the second secretary of the Health Comittee of the Congress of Deputies has stressed the importance of **tax incentives**, the clearest type of incentive for companies.

In the second round of interventions, focused on sustainability and evaluation systems, **Rafael Belmonte** highlighted the effectiveness of the clinical itinerary **as an element to be incorporated into the evaluation**. Secondly, he considered the issue of **incentivisation**, not only from the point of view of the Administration and financing, but also in terms of a "more agile regulatory framework, a more effective Administration or a little more efficient".

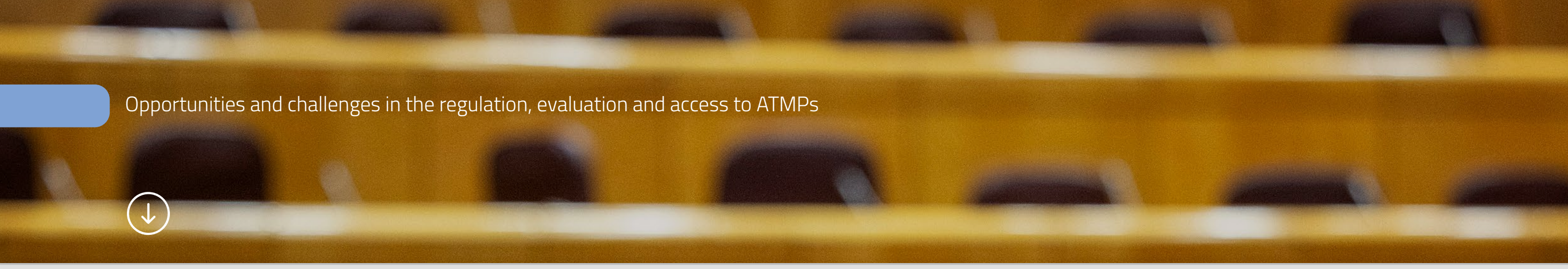
For her part, **Alba Soldevilla** pointed out that "ATMPs put us before the question of how to make decisions when **the initial budgetary impact is high and the evidence and benefits** are consolidated over time".

In this sense, she considered that "**clinical efficacy** is the central axis of the evaluation", but in the case of ATMPs "**focusing the analysis only to the clinical can provide an incomplete view**". Soldevilla also resorted to the Royal Decree on Health Technology Assessment to highlight the mechanisms it provides, such as the fact that "it allows subsequent decisions to be adjusted based on the value that the drug demonstrates in real life". Finally, she mentioned the specific characteristics of these therapies that "force public decision to be refined", such as clinical **uncertainty** and **budgetary impact**.

In the context of the **hospital exemption**, **Paschalia Koufokotsiou** mentioned the publication, last summer, of a study on its implementation in Europe. The representative of the European Commission highlighted the complexity of ATMPs, explaining that "the hospital exemption provides the **flexibility** for national authorities to approve the use of an advanced therapy", insisting that "there has to be a non-routine use".

A Comprehensive Vision of the Position and Access of ATMPs, from the Regional Perspective

PANEL 3



Moderated by:
Mr. Miguel Ángel Casado
Director of Pharmacoeconomics & Outcomes Research Iberia
and President of the PORIB Foundation

Ms. Nekane Murga
Coordinator of Personalised and Precision Medicine and ATMPs at Osakidetza

Mr. Gonzalo Balbontín
Managing Director of the Progress and Health Foundation of the Regional Government of Andalusia

Mr. Enrique Ruiz Escudero
Spokesman for the PP in the Health Committee, Senate

Ms. Concepción Andreu
Second vice-president of the Senate

The third and final panel of the day focused on the regional perspective, based on the approval, in July 2025, of the ATMPs Plan. **Concepción Andreu** has had the first intervention, in which she highlighted the main **challenges faced by the Regions** in the management and decision-making regarding ATMPs. The second vice-president began by mentioning **logistics management**, due to the particularities of each community, which can be addressed through the establishment of a solid network to be able to carry it out, including the **training of professionals**, highlighting the importance of training in the same way in all the Regions. **Financing and the evaluation** of the specific value is the second challenge that Andreu highlighted, insisting that they are common in all communities. Finally, **funding** for research and treatment, highlighting the importance of **public-private collaboration**. Concepción Andreu has defended that political options should not influence the Interterritorial Council, but that the focus should be "the clinical and health value".

Enrique Ruiz Escudero began by contextualizing the Regional Strategy for ATMPs of Madrid, launched in 2018. He stressed the **payment for results** and that "right now there is no legal support to carry out this type of financing of medicines", so we must **continue to move forward to avoid duplications**. He emphasized that "if there is a single evaluation, the Regions should not make another evaluation mechanism to duplicate, because all this is detrimental to the time it takes the patient to receive their treatment". In addition, Ruiz Escudero believes that the issue of **financing** in Spain must be analysed and that **equity** must be guaranteed, so that any Spaniard, "wherever they reside, has **access to the best treatment** in the circumstances that each one has".

For her part, **Nekane Murga** stressed that the Basque Country has an ecosystem that plays in its favour, as well as a **public health system with a "history of transversal work and very oriented towards equity"**, in which the medical history is shared with primary care in all hospitals. Murga mentioned, as an example, the fact that "we are working on a **genetic database**" that will be important when it comes to knowing variants. The speaker highlighted the importance of **equity** so that patients can access these new therapies, so **coordination is essentia**l.

Gonzalo Balbontín reflected on what was discussed throughout the day, such as equity, sustainability and financing, stating that all this brings together the role of the Progress and Health Foundation, which acts from various perspectives. "The first of these is that it acts as **coordinator of the network** of research management foundations that are in all the provinces" of Andalusia, a very large community that requires effective coordination, acting as a link between researchers, companies and health workers, as well as organizations such as universities. Balbontín also stressed the importance of **public-private collaboration and pay-for-success**, as well as "the need to invest in the activity to have **state-of-the-art equipment** and also in **information systems** that allow monitoring everything that is being done".

In the second round of interventions, **Gonzalo Balbontín** defended that the new drug law "should establish an **ideal framework for ATMPs to have their positioning, given that their production and administration is different from the most established processes**, they have a particularity that is worth taking into consideration". Finally, he stressed the importance of having regulatory coordination so that certain measures are applied in a homogeneous way.

Nekane Murga mentioned the existence of tools, such as the **common genetics portfolio** that was launched less than a year ago, or the **ÚNICO network** to coordinate rare diseases. In her speech, Murga defended synergies and the use of everything that the communities can achieve, such as the system of knowledge of results or the identification of reference centers.

Focusing on the barriers faced by the Regions, **Concepción Andreu** highlighted, firstly, the **bureaucratic complexity**. Secondly, she mentioned the **asymmetry of information and technical capacity**. Finally, she considered the **dispersion and lack of agility**. Likewise, the second vice-president has defended that the necessary adjustments to face these challenges are "**more agility, transparency and shortening evaluation** deadlines for the CAR-T". In addition, it is necessary to "**harmonise and simplify the criteria of the agreements**" and, finally, to have "**centralised financing** or a kind of common fund that delinks the treatments to these budgetary tensions of each Region".

Focusing on the assessment of the financing of ATMPs, **Enrique Ruiz Escudero** stated that "we must measure the impact of the investment made in pharmacy". He stressed that the agreement reached at the time was that it **was the community of origin that financed the treatment**, referring to the communities that did not have centers or units of specialization that could receive them. The senator once again highlighted **payment for results**, which greatly strengthens **public-private collaboration**. Within ATMPs, he concluded, it is necessary "to have a **dimension far beyond what has been done conventionally**".

Institutional Closure

Mr. Manuel Arellano
Vice-president of the Platform of Patient Organisations

Manuel Arellano closed this conference, starting his speech by reviewing what was discussed, such as the need to speed up **access**, guarantee **sustainability, communicate between systems or evaluate not only from a clinical perspective**.

The vice-president of the POP stressed that **ATMPs also deal with prevention**, to "prevent the disease from getting worse and so that people live". Although the initial investment is high, these therapies improve the quality of life of patients in the long term, so we should not focus so much on the short term.

ATMPs, he said, "are a **paradigm shift**", starting with health care. In this sense, the Platform of Patient Organizations highlights the importance of not analysing the value of ATMPs only from a clinical point of view, because there is a much broader vision that we must have, which encompasses the social part and aspects such as "**territorial equity**", "**real access times**", the "**burden on caregivers**" or "**quality of life**". He concluded, "innovations have to give a value, but a value perceived by the person".

Spain has a **very solid public health system, good public-private collaboration** and **professionals with a very high level of quality**. In the context of regulatory discussion and regulatory frameworks, "patient participation has to be understood as a structural element of the system."

We need a **strategic vision** in the medium and long term that is "**capable of balancing innovation, sustainability and equity**, and offering **certainty** to both professionals and people who are waiting for a therapeutic option that can sometimes be their salvation".

Manuel Arellano concluded his closing speech by defending that "ATMPs represent the best of medicine when they are **accessible**, rigorously evaluated, and applied with **equity**".

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About Lasker

Lasker is a **communications and public affairs consulting firm specializing in reputation management** and building trusting relationships between organizations and their stakeholders.

Using a strategic and integrated approach - *covering corporate, institutional, brand, and digital aspects* - the firm assists companies, associations, and organizations in designing results-oriented strategies for communications, public affairs, and crisis management.

With a senior, multidisciplinary team, Lasker combines analysis, creativity, and execution to manage public discourse, anticipate risks and opportunities, and align business objectives with the expectations of regulators, the media, investors, and society.

About PORIB

PORIB is a scientific and strategic consulting firm specializing in **Health Technology Assessment, Market Access, and *Real-World Evidence (RWE)*/Health Outcomes Research**, founded in 2004, serving the pharmaceutical and health technology industries, health authorities, universities, patient associations, and healthcare professionals. With over 20 years of experience, it is a leader in the number of publications in national and international journals, as well as presentations at conferences.

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