Annual *REPORT* 2023

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*Spanish Association of Orphan and Ultra-Orphan Drug Laboratories (AELHMU by its Spanish Acronym)

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1. Letter *from the* President

This Report is an invitation for us to reflect together on what we have achieved in 2023 and the challenges we face if we are to provide patients with the best treatment options when they are needed. Although the past year has been marked by the political election calendar and a complex context of global conflicts and economic tensions, we are proud to continue to advance AELMHU's fundamental lines of action.

In this annual report, we would like to highlight the past year in a positive way, focusing on the progress made, the increase in and continuity of our activities and our tireless commitment to cooperation and understanding with the health administrations and the rest of the health and social partners on the issues that concern us, at a time, in addition, when a new regulatory framework for the sector is being decided.

At the national level, the various elections held in 2023, both at regional level and the general elections on 23 July, largely conditioned the political and health agenda. On the part of all those involved in the sector, the renewal of the teams that make up the different administrations has required an effort to adapt, always based on the commitment to reinforced collaboration, the continuity of the projects and the joint search for effective solutions. Our working groups have played a key role in this process. Thanks to member involvement, we have broadened our scope to ensure our participation in important debates on key issues, such as the review of the Union's general pharmaceutical legislation or the new national model for health technology assessment.

Not only have we taken part in the various public consultations at regional, national and European level, but **we have also participated in key meetings and training sessions that have given us the opportunity to contribute our experience** and maintain a fluid and constructive dialogue with experts and authorities to work together to improve a legal and economic framework that promotes investment in research and development of new treatments and facilitates access and availability of a more complete range of new types of therapies for patients.

Efforts to reduce access times to medicines to treat rare diseases and increase the number of funded treatments are reflected in data from AELMHU's Report on Access to Orphan Drugs in Spain 2022 and the 2023 quarterly reports. This progress is a direct result of the commitment and cooperation of all actors involved and marks the beginning of what we hope will be a positive trend in the approval of orphan drugs.

As a result of this action, the Association has strengthened **our position as a reference interlocutor in the various political, economic and social spheres.**

This representative work has also been strengthened by the incorporation of five new members, which allows us to join forces and consolidate our own sectoral voice within the healthcare sector to continue working for the benefit of patients.

In conclusion, 2023 has been a demanding but rewarding exercise for all. At all times, we have moved forward with the conviction that our efforts are well supported by a wide range of partners who contribute on a daily basis to expanding knowledge about rare diseases in our country.

Therefore, on behalf of all AELMHU member companies, **we would like to express our sincere thanks to patient associations, the scientific community, institutions, experts and the media** for their full willingness to contribute to the achievement of our shared goals.

Finally, as president, I would like to express my deepest thanks to each and every AELMHU members. Your dedication and enthusiasm in joining forces to promote the different initiatives launched have been fundamental to achieve this year's goals and to continue moving forward in our objectives.

As we look to the future, we reaffirm our commitment to contributing to improving the health and quality of life of people affected by rare diseases, giving visibility to the pathologies and highlighting the research carried out by the sector to discover and develop new treatments.

María José Sánchez Losada
President of AELMHU

2. Governing *and* Representative Bodies

2.1 GOVERNING BODY

The General Assembly is the governing body of the Association, made up of members in their own right and in total equality, which adopts its resolutions by the majority principle or internal democracy.

Governing Body *Meetings*

The Assembly held **two update meetings** and **two assemblies** throughout 2023, to address issues of interest to the sector and stakeholders, to follow up on the action plan and the activity of the working groups, as well as to address all issues that could affect the organisation and its partners.

DAY	MONTH	CALL FOR PROPOSALS	TOPICS DISCUSSED	FORMAT
14	March	Meeting update	Quarterly update of the Association's work	Online
30	May	General Assembly	· Activity Report 2022 · Approval of accounts 2022 · Budget update 2023 · Activity update · Dues 2024	Hybrid
26	September	Meeting update	Quarterly update of the Association's work	Online
30	November	General Assembly	· Work update · Strategic Reflection Project	Hybrid

New *members*

During 2023, AELMHU welcomed 5 new members, bringing the total number of members to 26, an **increase of 22.7% compared to the previous year.**

The following companies were incorporated during the year, in alphabetical order:

- **ARGENX**, a global immunology company developing antibody-based medicines for patients suffering from severe autoimmune diseases and cancer.
- **BIOGEN**, a leading global biotechnology company dedicated to the research and development of products to treat complex and devastating diseases. Their focus encompasses areas such as neurology, neuropsychiatry, specialised immunology and rare diseases.
- **HORIZON THERAPEUTICS**, a biotechnology company that strives to bring innovative medicines to patients by understanding the challenges they face. Their focus is on researching, developing and commercialising medicines that address critical needs for people affected by rare and rheumatic diseases.
- **IMMUNOCORE**, a global commercial biotechnology company based in Oxfordshire, researches and develops biologic medicines using soluble T-cell receptor technology.
- **ITALFARMACO**, an international pharmaceutical company founded in Milan in 1938. Their objective is to meet the need for health-enhancing medicines as efficiently as possible. Through innovation and pharmaceutical talent, Italfarmaco strives to provide efficient medical solutions and improve people's quality of life.

2.2 REPRESENTATIVE BODY: BOARD OF DIRECTORS

The representative body of the Association is the Board of Directors, a collegiate body formed during 2023 by the following persons:

Mª José Sánchez Losada

PRESIDENT

General Manager of CSL Behring in Spain and Portugal

José Luis Moreno Sánchez

VICE-PRESIDENT

General Manager of Ultragenyx in Spain and Portugal

Beatriz Perales Zamorano

SECRETARY AND VOWEL

Director of Market Access, Institutional Relations and Communication for **Sobi Iberia***

Sergio Bullón Avendaño

TREASURER AND VOWEL

General Manager of Alnylam Pharmaceuticals in Spain

* Beatriz Perales serves as AELMHU secretary.

During this financial year, the AELMHU Board of Directors, led by María José Sánchez, has focused on contributing to **improving the health** and **quality of life** de of **people affected by rare** diseases. To achieve this, they have focused their action plan on **making these pathologies visible**, promoting **research** and **making it easier to access** new treatments.

The Association **works with patient associations,** public administrations and other agents in the sector with the aim of transferring its knowledge and experience on these minority diseases. One of its aims is **to educate and inform** about the value of orphan drugs, **raising awareness** about these diseases and **bringing visibility** to the impact that new treatments have on improving health outcomes. Together we are contributing to improving the health and quality of life of patients.

3. Activities

3.1 REPORTS

AELMHU's **mission** is to contribute to improving **the health and quality of life** of **people affected by rare diseases** giving social visibility to these pathologies and promoting **research** and rapid access to new treatments. To this end, the Association promotes the **creation and distribution** of accurate, truthful and objective information, which allows for **regular monitoring of the advances made** in research into new therapeutic alternatives, as well as analysing the barriers that exist to improve patient access to more effective medicines.

In 2023, the Association had a prominent and extensive reporting activity by promoting **four reports**: the Annual Report on Access to Orphan Drugs 2022, the 2023 first and second quarter reports and the Clinical Trials Report 2022.

These sources of information have become **fundamental documents** to understand the evolution of rare diseases and the situation of orphan drugs in our country.

Reports on Access

AELMHU regularly presents the **Report on Access to Orphan Drugs in Spain**. This analysis is now a benchmark in the pharmaceutical sector and in the field of rare diseases.

The report on orphan therapies in Spain focuses on the **number of treatments**, the **approval times** and their **funding** in our country, as the main objective of the study. The data for this analysis are drawn from public sources from the European Union and the Spanish Ministry of Health.

These updates on the status of orphan drugs provide a detailed overview of access to orphan treatments in the country. While there are improvements at EU level, such as the notable increase in the number of orphan designations and marketing authorisations in the European Union, there are significant challenges at national level, as evidenced by the decrease in registered National Code applications and in the number of new treatments funded.

ACCESS
Report
MAY-AUGUST
2022
of orphan
medicines in Spain

Analysis of all trade-name ODs with European orphan designation in force as of August 31, 2022

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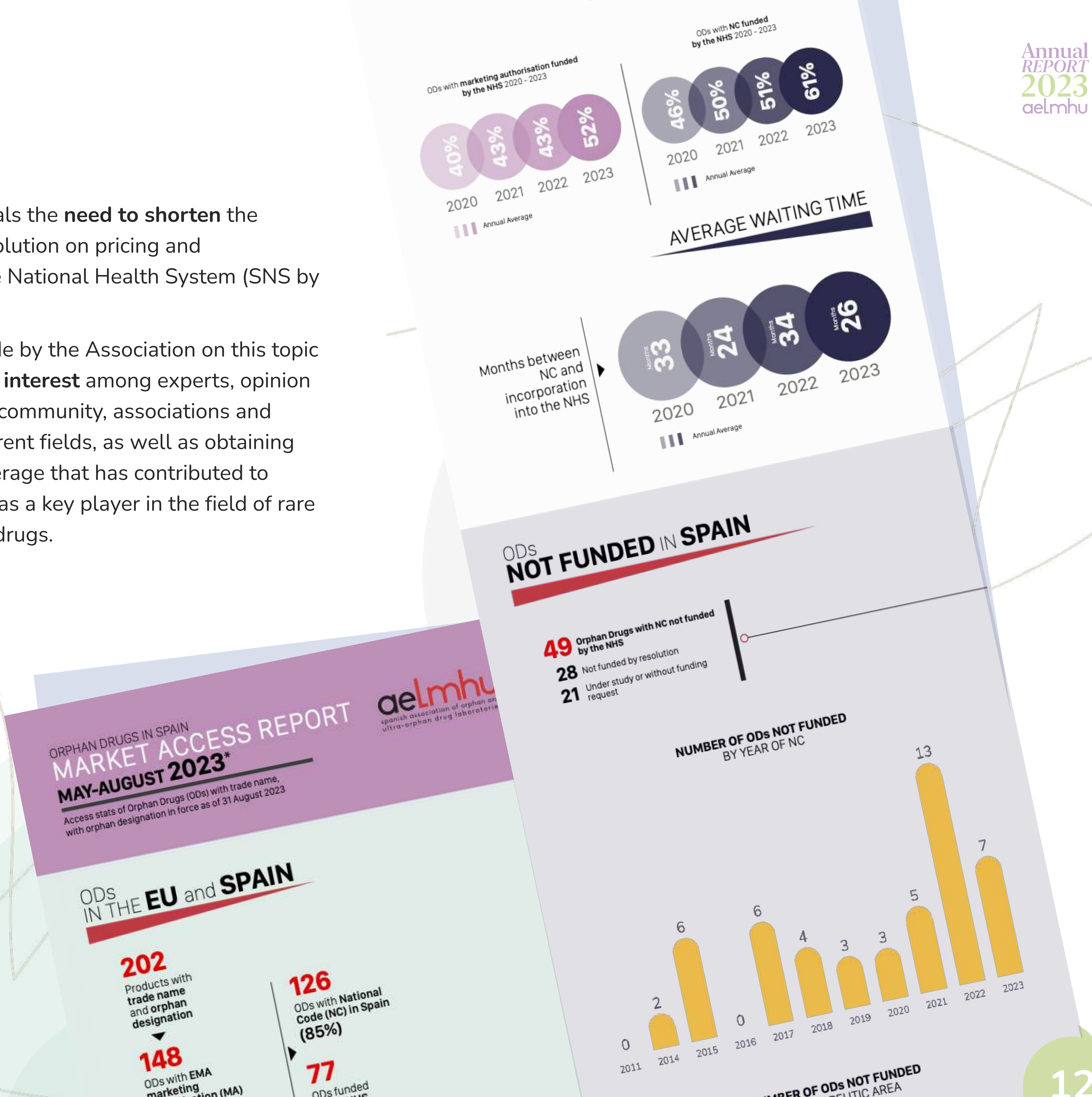
This information reveals the **need to shorten** the **waiting times** for resolution on pricing and reimbursement by the National Health System (SNS by its Spanish acronym).

The **publications** made by the Association on this topic have generated **great interest** among experts, opinion leaders, the scientific community, associations and institutions from different fields, as well as obtaining significant media coverage that has contributed to positioning AELMHU as a key player in the field of rare diseases and orphan drugs.



ORPHAN DRUGS IN SPAIN

MARKET ACCESS REPORT

MAY-AUGUST 2023*

Access stats of Orphan Drugs (ODs) with trade name, with orphan designation in force as of 31 August 2023

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ODs IN THE **EU** and **SPAIN**

202 Products with **trade name and orphan designation**

148 ODs with **EMA marketing authorisation (MA)**

126 ODs with **National Code (NC) in Spain (85%)**

77 ODs funded

ODs with **marketing authorisation funded by the NHS** 2020 - 2023

ODs with **NC funded by the NHS** 2020 - 2023

AVERAGE WAITING TIME

Months between NC and incorporation into the NHS

ODs **NOT FUNDED** IN **SPAIN**

49 **Orphan Drugs with NC not funded by the NHS**

28 Not funded by resolution

21 Under study or without funding request

NUMBER OF ODs NOT FUNDED BY YEAR OF NC

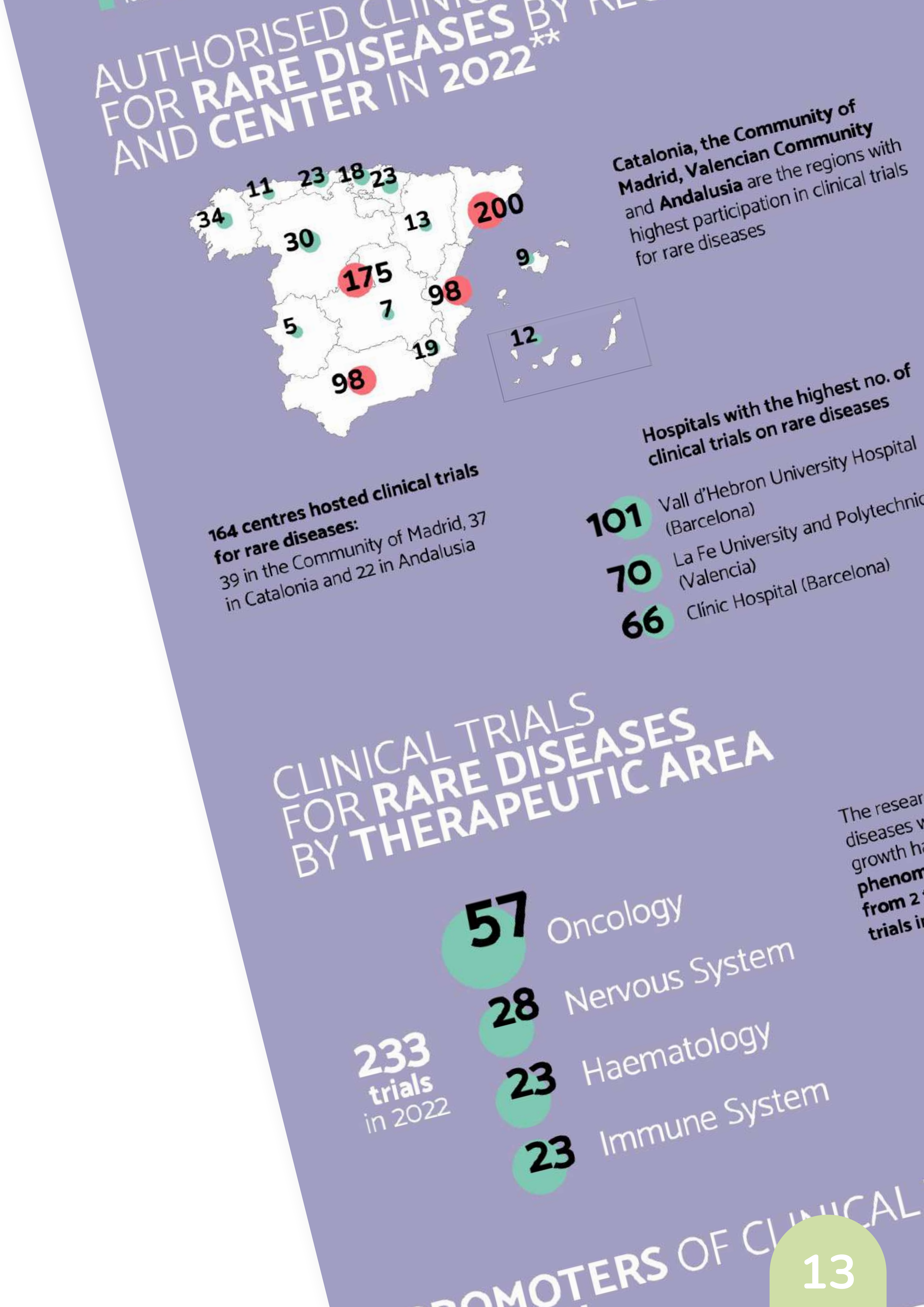
Clinical Trials Report (CTR)

The Clinical Trials Report on Rare Diseases in Spain reflects a **strong** and **continuous** commitment **by the pharmaceutical industry to research on rare diseases**, showing a clear drive towards innovation, knowledge and the search for therapeutic solutions in this field.

One in four clinical trials authorised in Spain in 2022 focused on rare diseases. According to the report presented by the Association, a total of 233 trials on these rare diseases reached an all-time high.

Although there has been an 8% decrease in the number of total clinical trials authorised in Spain, research in the field of rare diseases experienced a 3% rebound.

In contrast, patient participation in RD-focused trials decreased by 5% to 9% of the total number of participants.



AUTHORISED CLIN
FOR **RARE DISEASES** BY RE
AND **CENTER** IN 2022**

Catalonia, the Community of Madrid, Valencian Community and **Andalusia** are the regions with highest participation in clinical trials for rare diseases

164 centres hosted clinical trials for rare diseases:
39 in the Community of Madrid, 37 in Catalonia and 22 in Andalusia

Hospitals with the highest no. of clinical trials on rare diseases

101	Vall d'Hebron University Hospital (Barcelona)
70	La Fe University and Polytechnic (Valencia)
66	Clinic Hospital (Barcelona)

CLINICAL TRIALS
FOR **RARE DISEASES**
BY **THERAPEUTIC AREA**

233 trials in 2022

57	Oncology
28	Nervous System
23	Haematology
23	Immune System

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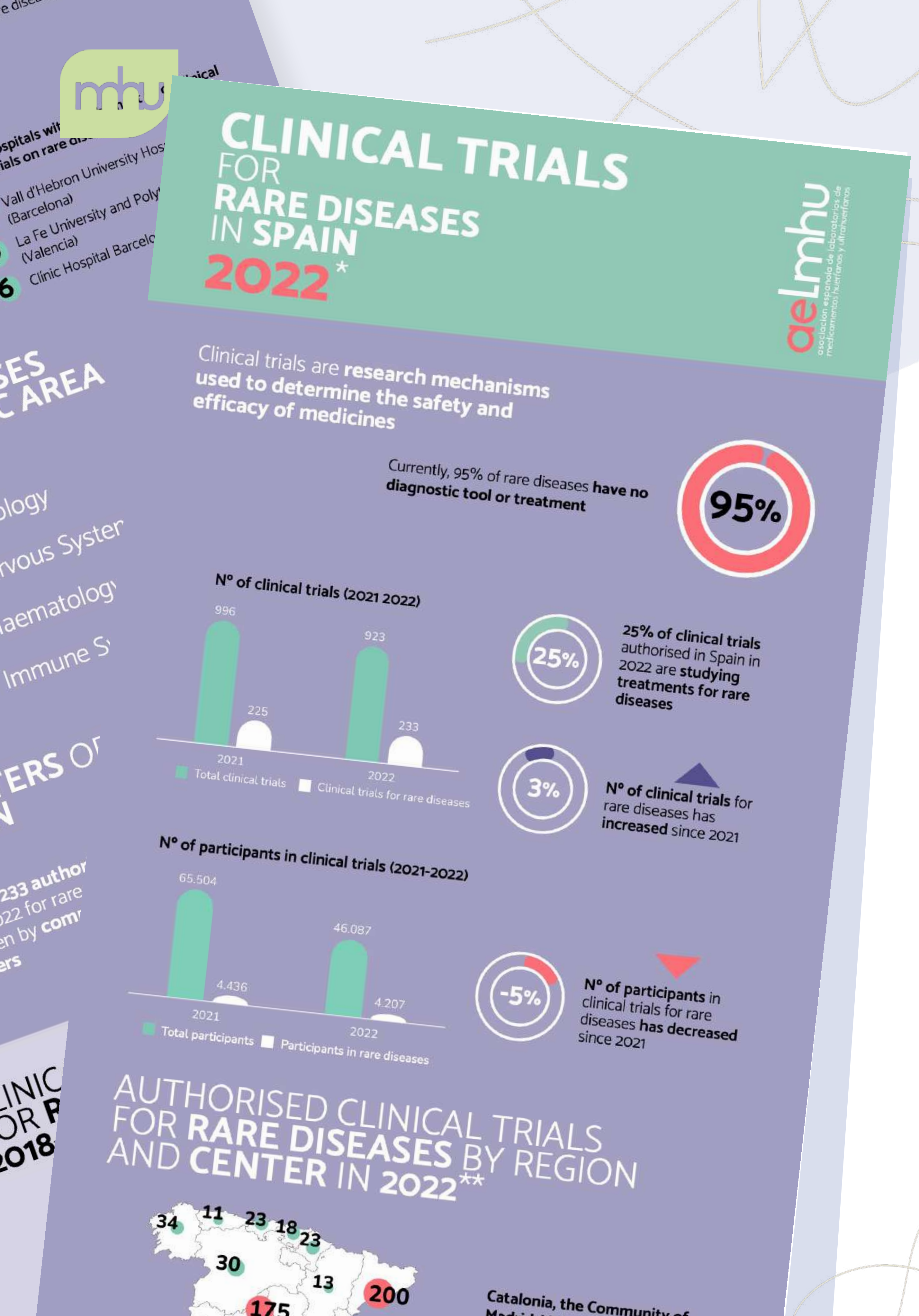

CLINICAL TRIALS FOR RARE DISEASES IN SPAIN 2022*

Clinical trials are **research mechanisms used to determine the safety and efficacy of medicines**

Currently, 95% of rare diseases **have no diagnostic tool or treatment**

95%

Nº of clinical trials (2021 2022)

25%

25% of clinical trials authorised in Spain in 2022 are **studying treatments for rare diseases**

3%

Nº of clinical trials for rare diseases has **increased** since 2021

Nº of participants in clinical trials (2021-2022)

-5%

Nº of participants in clinical trials for rare diseases **has decreased** since 2021

AUTHORISED CLINICAL TRIALS FOR RARE DISEASES BY REGION AND CENTER IN 2022**

Catalonia, the Community of

In the therapeutic field, research in the fields of oncology, the nervous system, haematology and the immune system was noteworthy. Also notable is the 30% increase in research into genetic phenomena, with 10 clinical trials in this therapeutic area.

97% of the clinical trials were **promoted by the pharmaceutical industry**, reflecting the effort invested by the industry to make new treatments for rare diseases available.

With the publication of this report, AELMHU promotes the need to continue driving innovation in Spain in the specific field of clinical analysis and underlines the strong commitment by the members of the Association to research and development of new treatments.

3.2

CONTRIBUTIONS TO THE MINISTRY OF HEALTH

The **cooperation** between the pharmaceutical industry, regulatory authorities and healthcare professionals is essential to ensure timely and safe access to innovative treatments for rare and minority diseases in Spain.

The drug approval process reflects this shared objective by starting with the positive decision of the Committee for Medicinal Products for Human Use (CHMP), which urges pharmaceutical companies to communicate their marketing decision in Spain to the **Spanish Agency for Medicines and Medical Devices (AEMPS by its Spanish acronym)**.

In this context, the year 2023 was marked by the expectation of the publication of two Royal Decrees in Spain related to **Financing and Pricing** and **Health Technology Assessment**. These decrees seek to establish a **regulatory framework** that promotes **adequate access** to orphan medicinal products (OMPs). To achieve this goal, the Association proposed recommendations structured around guidelines, criteria and processes.

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Recommendations for early access for medicinee with orphan designation or for rare diseases in Spain

One of the proposals put forward was the **suggestion of developing specific official guidelines for economic evaluation and budget impact studies related to OMPs.**

The creation of a joint commission between the Administration and the pharmaceutical industry supports such a contribution to **developing specific assessment models for rare diseases**.

The use of methodologies that take into account the uniqueness of these drugs was also recommended, such as the evaluation of single-arm clinical trials, where all patients receive the experimental treatment, as well as the use of evidence generated from real-world data in Spain.

Another proposal along the same lines is to **differentiate the assessment of clinical and financial uncertainty**, taking into account the limitations for generating evidence due to the limited availability of patients in clinical studies.

Making the pharmacoclinical protocol procedure more visible, especially for these low-prevalence medicines, and the inclusion of the possibility of creating ad-hoc expert groups were other valid conclusions, according to the experts' criteria.

A proposal was also made to assess an annual budgetary impact limit and to establish a new category of **medicines in a temporary funding situation**, where authorisation is conditional. This is in order to collect real-life data during this period for final pricing decisions.

To improve the financing and pricing process for orphan drugs, it was suggested that a process of early and continuous dialogue be established between the public administration and the pharmaceutical companies developing these treatments.

The use of multi-criteria decision analysis, the inclusion of the patient perspective in the decision-making process and the development of the Spanish Registry of Rare Diseases (ReeR by its Spanish acronym) were also raised.

Recommendations on the process of Access and Evaluation of orphan drugs in Spain

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3.3 AELMHU NETWORKING MEETINGS

A total of **nine meetings** have been organised this year, five of them face-to-face and four in online format. These meetings have made it possible to promote **dialogue** between the sector's agents and **exchange opinions** and **experiences** on current issues affecting the future of the sector, previously analysed by the Association's different working groups. An indication of the interest generated by these sessions has been the **high participation** registered by bringing together more than 200 attendees, members of the AELMHU working groups.

The meetings held were:

- March: **Raquel Ballesteros** (lawyer), **José Javier Castrodeza** (former Secretary General for Health and Consumer Affairs) y **Jorge Mestre** (health economist).
- April: **Igor Beitia**, Senior Director for Market Access Southern Europe Region PTC.
- Two meetings in May:
  - **Margarita de la Pisa**, Vox MEP.
  - **Elena Casaus**, Head of Division of the Advanced Therapies Unit of the Madrid Regional Government.
- July: **Carlos Martín Saborido**, Member Advisor to the General Directorate for the Common Portfolio of Services of SNS and Pharmacy of the Ministry of Health.
- October: **Despacho Faus & Moliner**, with Lluís Alcover and Joan Carles Bailach, lawyers specialising in Pharmaceutical Law.
- Two meetings in November:
  - **Antonio Blázquez**, Head of the Department of Medicinal Products for Human Use of the AEMPS.
  - **Sol Ruiz**, Head of the Biologics, Biotechnology and Advanced Therapies Division of the AEMPS.
- December: **Daniel de Vicente**, Member of the EURORDIS Board of Directors and Member of the Board of Directors of Spanish Federation for Rare Diseases (FEDER by its Spanish acronym).


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AGENCIA ESPAÑOLA DE MEDICAMENTOS Y PRODUCTOS SANITARI

3.4 CONFERENCE ON “The Future of Advanced Therapies for Rare Diseases”

Promoted by AELMHU's Advanced Therapies group, with the support of Bioinnova, the conference "The future of Advanced Therapies in Rare Diseases" was well attended by stakeholders from the healthcare sector. Leading members of the public administration, national associations, employers' associations, healthcare professionals and media representatives participated in the session held at the Carlos III University of Madrid, where the need for a **cooperative approach** to address the regulatory and economic challenges limiting **access to innovative treatments was highlighted**.

Speakers at the conference agreed on the need for greater investment in research, more efficient and flexible regulation, procurement policies that guarantee accessible prices, and consideration of non-economic factors in the evaluation of these therapies. The urgent need to establish mechanisms to ensure fair and sustainable access to treatment for patients in need, and to promote cooperation between health system actors to achieve this shared goal, was also highlighted.

The presence of renowned experts and leaders in the field of health gave the meeting a high profile. Among them were **Cesar Hernández**, Director General of the Common Portfolio of Services of the SNS and Pharmacy of the Ministry of Health; **Eva Bermejo**, Director of the Institute for Research on Rare Diseases, of the Carlos III Health Institute; **María Luz de los Mártires**, Director General of Research and Teaching of the Madrid Regional Government; **Sol Ruiz**, Head of the Division of Biological Products, Advanced Therapies and Biotechnology of the Spanish Agency of Medicines and Medical Devices; **Andrés Nascimiento**, Coordinator of the Neuromuscular Pathology Unit of the Hospital Sant Joan de Déu; **Elena Casaus**, Head of Division of the Advanced Therapies Unit of the Madrid Regional Government; **Nekane Murga**, coordinator of the Osakidetza Area of Personalised Precision Medicine and Advanced Therapies; **José Luis Poveda,** coordinator of the Advanced Therapies Group and the Rare Diseases Group of the Spanish Society of Hospital Pharmacy (SEFH by its Spanish acronym) and head of the Pharmacy Service of the University and Polytechnic Hospital La Fe de Valencia; among others.

3.5 PARTNERSHIP ACTIVITIES with FEDER

During 2023, AELMHU carried out **4 training actions** together with FEDER, divided into two themes:

- **Three training sessions** aimed at helping the associative movement to understand the process that rare disease medicines must follow; an overview of the course of action of these medicines, from clinical development, orphan designation, marketing authorisation at European and national level, to the price-reimbursement decision and its end with the placing on the market.

  These sessions took place separately and specifically with the FEDER technical team first, then with representatives of the associative movement and finally with the FEDER Board of Directors and Management.

- **The fourth action** focused on the development of competencies for federation spokespersons. The aim of this session was to provide the necessary communication skills to a group made up of members of the Board of Directors, representatives of the associative movement and FEDER's management, in order to exercise the role of spokesperson.

The initiative for these training actions has its origins in the **partnership agreement** that has been in place for years with FEDER and which, on this occasion, was led by the Patient Co-creation working group.

In this way, AELMHU is strengthening its commitment to promoting awareness and visibility of rare diseases and access to their treatments, as well as the close collaboration with patient associations with these diseases.

3.6 AELMHU AWARDS

The AELMHU Awards are the result of the work carried out by the Association over the course of the year to recognise **the best care projects, professional careers, awareness** and **communication** about rare diseases. The award ceremony is the culmination of a process where every effort is made to ensure the success of the awards. Along the way, the applications are carefully evaluated, the winners are selected, and the logistical details of the ceremony are organised.

The annual celebration of the Awards reflects AELMHU's commitment to promoting knowledge about rare diseases and orphan drugs, as well as recognising the exceptional work done by professionals and organisations in this field of such social and health relevance.

The following categories were established for the 2023 edition:

- Best Rare Disease Care Project.
- Best Career in the Field of Rare Diseases.
- Best Work on Dissemination, Outreach and/or Awareness Raising on Rare Diseases.
- AELMHU Honorary Award for Work or Contribution to Improving the Lives of People with Rare Diseases.

Participation was open to individuals and legal entities dedicated to research, dissemination or awareness of this type of disease, with residence or business activity in Spain.

In addition to the award, the winners had the opportunity to select a public or private non-profit beneficiary to receive a financial donation for research projects on rare diseases and/or orphan drugs.

The presentation of these awards aims to improve knowledge and awareness of rare diseases, as well as to distinguish outstanding work in this field during the year.

The jury for the 5th edition was external and independent, made up of the following professionals of recognised prestige in the research of these diseases, in the field of health and communication:

- **Mr Jesús Aguilar,** President of the General Council of Pharmaceutical Associations (CGCF by its Spanish acronym).
- **Mrs Eva Bermejo**, Director of the Institute for Research on Rare Diseases of the Carlos III Health Institute (ISCIII by its Spanish acronym).
- **Mr Emilio de Benito,** Vice-President of the Board of Directors of the National Association of Health Informers (ANIS by its Spanish acronym).
- **Mr Javier García**, President of the Federation of Spanish Scientific Medical Associations (FACME by its Spanish acronym).
- **Mr Antoni Gilabert**, Director of Innovation and Partnership at the Health and Social Consortium of Catalonia.
- **Mrs María Esperanza Marcos**, President of the Health Law Section of the Madrid Bar Association.
- **Mr Jorge Mestre**, health economist.
- **Mr José María Millán**, member of the Spanish Association of Human Genetics (AEGH by its Spanish acronym).
- **Mr Jordi Nicolás**, Vice-President of the Spanish Society of Hospital Pharmacy (SEFH).
- **Mr Manuel Pérez**, President of the Orphan Drugs and Rare Diseases Foundation (Mehuer by its Spanish acronym).
- **Mrs Marian Corral**, Director of AELMHU (non-voting).

The jury's decision meeting took place on 27 September and, after the winners were announced, work began on organising the award ceremony.

Prize-giving Ceremony

Journalist María Rey was in charge of the awards ceremony on **7 November** at the **Espacio Bertelsmann** in Madrid.

At the inauguration, María José Sánchez Losada, president of AELMHU, took the opportunity to acknowledge the **high level of participation**, as well as the work carried out by the jury. In addition, she acknowledged and appreciated the role of partners during the year 2023 and highlighted the need to focus public and health care on rare diseases. Finally, she stressed the importance of the legislative reforms to be undertaken at the European, national and regional levels.

Explaining the process of evaluation and selection of the award winners was **Eva Bermejo**, director of the Institute for Rare Diseases Research at the Carlos III Health Institute (ISCIII), on behalf of the jury. During her speech, she took the opportunity to congratulate the award winners on the quality of their projects, urging them to continue to do their utmost in research to improve the lives of patients.

The V Edition of the AELMHU Awards recognised the following initiatives:

- In the category of **Best Rare Disease Care Project, the Duchenne Parent Project Spanish Association** was awarded for its Comprehensive Telematic Care service for people affected by Duchenne and Becker Muscular Dystrophy. This project, aimed at patients, relatives, professionals and public and private institutions, offers a response to the health, educational, legal-administrative and social demands derived from the disease, improving the social inclusion, autonomy and quality of life of patients. **Eva Bermejo** and **Emilio de Benito**, members of the jury, presented the award to the **Director of the Association, Esther Sabando.**

Dravet Foundation (Spanish delegation) was honoured by RetoDravet de Syndrome, as Best Work on Dissemination, Outreach and/or Awareness-raising on Rare Diseases. RetoDravet is a solidarity platform that was created with the aim of promoting, raising awareness and making Dravet Syndrome more visible in society through solidarity sport and other cultural and social events, promoted and supported by the Foundation's own families. The prize was collected by **Luis Enrique Villanueva** and **Magali Sánchez** on behalf of the Spanish delegation, from **María Esperanza Marcos** and **Antoni Gilabert**, members of the jury.

- **Dr Ángel María Carracedo Álvarez** was awarded the **Best Career in the Field of Rare Diseasess**. Dr. Carracedo is, among other positions, director of the Fundación Pública Galega de Medicina Xenómica, coordinator of the Genomic Medicine Group at the University of Santiago de Compostela (USC), professor of Legal Medicine at the University of Santiago de Compostela and president of the International Academy of Legal Medicine (IALM). **María Jesús Lamas**, director of the Spanish Agency for Medicines and Medical Devices, presented the award together with **Manuel Pérez**, president of Mehuer, after paying a heartfelt tribute to the professional and personal career of Dr. Carracedo. In addition, his colleagues wanted to participate from Galicia joining in the congratulations for the recognition of his professional career through a video projected at that moment of the ceremony.

Finally, the Honorary Award 2023, a posthumous award**,** was presented to **Mr Julio Sánchez Fierro,** for his dedication, commitment and contribution to improving the lives of people with rare diseases. **César Hernández**, Director General of Common Portfolio of Services of the National Health System and Pharmacy, accompanied by the **Board of Directors** of AELMHU, on behalf of all its members, presented the Award to **Raquel Sánchez**, daughter of Mr Julio Sánchez Fierro. During the presentation of this honorary award, a video was once again shown, in which colleagues and friends of Sánchez Fierro shared various anecdotes with him and recalled his work in favour of improving the quality of life of people with rare diseases. Finally, Raquel Sánchez thanked on her own behalf and on behalf of her family for the tribute paid to her father and recalled the values that he himself transmitted: honour, struggle, commitment and life.

The award winners agreed about the need to continue promoting research into rare diseases and to work together to further progress in the field of rare diseases and orphan drugs, reaffirming the commitment of the medical and scientific community to these important causes.

César Hernández closed the event by stressing the social commitment of all parties involved to people suffering from rare diseases. The Director General for the Common Portfolio of Services of the National Health System and Pharmacy stressed that the Ministry of Health is working to incorporate new medicines more quickly into the public portfolio and thus facilitate their access to patients, although he acknowledged pending challenges, such as the diagnosis and screening of these diseases, as well as the improvement of care for these people.

To end the event, the athlete **Álex Roca** shared his personal experience in a speech entitled "*You Set the Limit*". He reviewed the major milestones in his life and career, from when doctors told his parents when he was just six months old that if he survived, he would be bedridden for the rest of his life, to completing the marathon in less than six hours. Through his story of overcoming, Álex Roca aims to raise awareness among those who listen to him that living with a disability or a rare disease does not necessarily mean failing to meet the challenges that a person sets for themselves. With his testimony, Roca conveyed to the audience the need to persevere in one's objectives and goals, to set one's own limits, through hard work and perseverance, a message of hope for rare disease patients and their families.

👉 *Full video of the ceremony*


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PREMIOS
2023


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Espacio Bertelsmann


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4. Working Groups

In 2020, AELMHU created the working groups, which aim to energise the Association's activity, taking into account both developments in the health sector and the various political and institutional developments that are of interest to members.

During 2023, AELMHU has maintained four active working groups:

- Access
- Advanced Therapies
- Political Affairs and Legislative Agenda
- Co-creation with RD Patients' Associations.

Each working group has one spokesperson, except for the Access group, which has two. As part of its activity, **monthly meetings** are held to define strategies and share information to **promote different projects** and **prepare** the **documents** that are circulated throughout the year.

During this period, the companies' interest in joining these working groups has been confirmed, which have been reinforced with the entry of 16 new members, bringing the total number of members to 53.

Through the different working groups, different documents have been developed, such as the *Recommendations on Access and Evaluation of Orphan Drugs, Recommendations for Early Access to Orphan Drugs or Challenges and Opportunities for Advanced Therapies with Orphan Designation*. Likewise, activities such as the first Conference in Madrid on this type of treatment or the updating of the key institutional messages that have defined the organisation's position at events and institutional meetings where members of the Association have participated have also been launched.

As a result of these initiatives, **meetings** were held with members of the **public administrations** specialised in the field of Advanced Therapies, with **representatives from the Ministry of Health** and the **European Parliament**. These meetings enabled AELMHU's proposals to be conveyed to the main political parties in view of the various elections to be held in 2023.

Furthermore, through various groups, **recommendation documents** were developed and agreed upon to enable participation in consultations and public hearings, at regional, national and European levels.

Another working group resulted in the agreement reached with the Spanish Federation for Rare Diseases (FEDER), a framework for cooperation to implement various training activities for its technical team, board of directors and associative movement, as well as to hold quarterly meetings between the two organisations and to hold the meeting with EURORDIS.

In this sense, and thanks to the promotion and development of new initiatives, documents, events and collaborations that have been developed in the various working groups, AELMHU has continued its work to **raise awareness** among public administrations of the **importance of continuing research** into rare diseases, to achieve **diagnosis and access**, both **quick** and **equitable** access to **orphan drugs**.

They have also cooperated with other associations to spread general knowledge about these rare diseases, thus improving the quality of life of patients and their families. For all these reasons, and in view of the interest generated by the initiatives developed in the various working groups, the Association will continue to promote and give visibility to the activity developed within these groups, which have become a reference inside and outside the organisation due to their high level and degree of knowledge.

5. Institutional meetings

AELMHU has made a significant contribution to raising awareness of the reality of research into rare diseases and the importance of facilitating access to new treatments and improving early diagnosis as the cornerstone of an integrated health policy capable of meeting the needs of all patients.

In 2023, the Association **consolidated institutional relations** with key players in the various public administrations, as the main and qualified spokesperson for the sector and the interests they represent.

The main task of this institutional work was to ensure that the Association played a **crucial role** in the **decision-making processes**.

With this objective in mind, and taking into account the new political context arising from the elections, AELMHU intensified its political agenda to learn about the **priorities and lines of action** set by the new government teams, both from the central and regional administrations, to give continuity to the work and projects initiated, as well as to seek new spaces for institutional cooperation for the benefit of patients and families affected by rare diseases.

COMMENTS ON
THE REVISION OF
THE GENERAL
PHARMACEUTICAL
LEGISLATION

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ultra-orphan drug laboratories

5.1 PUBLIC PARTICIPATION *in* regulatory projects

In this regard, the Association participated in various public consultations and hearings at regional, national and European level.

At regional level:

Pharmacoeconomics Observatory of Madrid's Regional Government

In April, AELMHU participated in the public consultation on the Draft Order of the Department of Health Care creating the Pharmacoeconomics Observatory of the Madrid Regional Government and noted the interest of this new body in access to innovation.

aelmhu
PARTICIPATION
in PUBLIC
CONSULTATION

The Association recommended:

- **The effective participation of actors involved, including the pharmaceutical industry**, with the aim of enabling open and effective institutional cooperation, integrating the perspectives of patient associations and industry, so that we can put the patient at the centre of decisions in the short, medium and long term.
- Carry out a **specific economic-financial analysis for OMPs**, which would take into account the particularities of OMPs and incorporate multi-criteria parameters in the evaluation of new treatments, such as the improvement in the quality of life of patients or real clinical need, among others. In addition, the establishment of **defined deadlines** for the submission of results and follow-ups was suggested, thus increasing transparency and enabling the implementation of necessary improvements.

Neonatal screening in *Castilla-La Mancha*

At the beginning of June, Castilla-La Mancha launched a public consultation on the Draft Order regulating congenital endocrine and metabolic diseases subject to early neonatal screening. The consultation had, in AELMHU's view, the potential to improve the quality of life of patients and neonatal screening for rare diseases.

Thus, the Association recommended:

- **Recognising the efforts of Castilla-La Mancha** in this diagnostic area and to explain the benefits of extending neonatal screening to the largest number of RDs.
- **Requesting the inclusion of the greatest possible number of RDs** in the neonatal screening programme, prioritising the incorporation of all those diseases for which a safe, cost-effective screening technique is available and for which treatment has been approved and included in the Basic Common Portfolio of the National Health System.
- **Demanding the recognition of the speciality of Clinical Genetics**, in order to align with Europe, as Spain is the only EU country that does not have this speciality, and thus speed up access to patients.

Neonatal Screening in the Balearic Islands

In mid-June, the Balearic Department of Health Care launched a public consultation on the Draft Decree establishing the complementary health provision of the neonatal screening programme for endocrine-metabolic diseases in the Balearic Islands in order to extend neonatal screening to the largest possible number of RDs and thus contribute to improving the quality of life of patients.

For this reason, AELMHU recommended:

Regulatory solutions:

- **Including the greatest possible number of RDs** in the neonatal screening programme as a common tool for early and accessible detection, prioritising the incorporation of all those pathologies for which a safe and effective screening technique is available and for which treatment has been approved and included in the Basic Common Portfolio of the SNS.
- **Recognising the speciality of Clinical Genetics** to align with Europe and speed up access to patients.

Non-regulatory solutions:

- Promoting the field of **preventive healthcare** as a tool for the early detection of pathologies, enabling early and better treatment that will result in an improvement in the quality of life and standard of living of citizens.

Neonatal Screening Commission of Andalusia

In December, Andalusia launched a public consultation on the Draft Decree creating the Regional Commission for Population Screening and Preventive Early Detection Activities and regulating the proposals related to them. AELMHU welcomed that Andalusia wanted to create such a Regional Commission with the aim of improving effective administrative coordination in order to make strategic decisions on population-based screening and preventive early detection activities, to achieve a good balance between benefits and adverse effects at the population level, and to avoid equity issues.

Among the recommendations, AELMHU suggested:

- **Recognising Andalusia's efforts in the field of preventive healthcare** and its commitment to improving efficiency and equity in early diagnosis.
- **Setting Andalusia as an example of good practice for other autonomous regions.**
- **That all the agents involved**, such as scientific societies, patient associations and industry, **participate with voice and vote**, or alternatively with a single voice, in the development of this Commission.
- **That the Commission should be founded and underpin** its functioning under a **process of transparency** in its composition, meetings and any other activities of importance to all actors involved.

At national level:

Prior public consultation on the Draft Royal Decree regulating Health Technology Assessment

The Spanish Association of Orphan and Ultra Orphan Drug Laboratories (AELMHU) participated in the prior public consultation on the Draft Royal Decree regulating the assessment of health technologies. The open process was an extraordinarily important opportunity to raise the awareness of rare and ultra-rare diseases (RDs), educate about the value of orphan drugs (OMPs) and ultra-orphan drugs, cooperate with various entities to improve the treatment of RDs, and support research to bring new OMPs to the market.

AELMHU recognised the importance of Health Technology Assessment (HTA) processes to ensure effective treatments and advocated for a fairer and more flexible system that involves all relevant parties, including rare disease patients and their families. It also supported the initiative to strengthen the current legislation and expressed its readiness to assist in building a modern HTA process.

The Association also proposed the creation of a National Council to jointly address the challenges of the sector with the consensus of the agents involved.

It also stressed the need to allocate adequate resources, both financial and human, to implement an effective HTA system in Spain.

Finally, it stressed the importance of clear governance to avoid duplication and to establish concrete assessment deadlines in the context of the implementation of the European HTA Regulation.

It noted that the current Health Technology Assessment framework has limitations when assessing Orphan Drugs, as it ignores their particularities, such as the size of the target population, or their challenges in data collection and the scale of innovation.

The social and economic benefits of these medicines are also not considered, which impacts on limited or delayed access to them.

Despite improvements in the funding of OMPs, the average waiting time for inclusion in the National Health System is 23 months, according to AELMHU data. It is therefore crucial to consider these aspects in the development of the current regulatory framework in order to improve the situation.

Recommendations

A. Guides

The Draft Royal Decree highlighted the imperative need to establish a **methodological guide** for the proper evaluation of OMPs.

Given this premise, AELMHU proposed the creation of a **Joint Commission**, made up of representatives from government and the pharmaceutical sector, to develop these guidelines in a cooperative and consensual manner.

The Association proposed:

- Addressing the particularities of OMPs, such as the size of the target population, the inherent challenges of data collection and the scale of innovation, in the evaluation of these treatments.
- Employing methodologies that allow for a comprehensive assessment of the benefits of medicines, as well as the consideration of specific aspects such as single-arm clinical studies and the use of Real World Evidence (RWE).
- Collecting data from routine clinical practice, especially in Centres, Services and Reference Units of the National Health System (CSUR by its Spanish acronym), to ensure the objectivity and transparency of the evaluation process.
- Developing and systematising the Spanish Registry of Rare Diseases (ReeR) to collect information and generate clinical evidence, as well as to determine the number of patients.
- Including all rare diseases known or approved in Europe, with the participation of the autonomous regions.

- Using pragmatic methodologies in the evaluation of the available evidence, considering the difficulties in rare disease research and the limitations in the design of clinical trials.
- Differentiating the assessment of clinical and financial uncertainty by technical ministries, taking into account the limitations in evidence generation due to the small number of patients available.
- Ensuring transparency in the development of the pharmacoclinical protocol, especially in the definition of inclusion criteria and in the use as a funding tool, especially for low prevalence OMPs.

B. Criteria

Article 92 of the revised text of the Law on Guarantees and Rational Use of Medicines and Medical Devices establishes criteria for the selective financing of new medicines, highlighting the seriousness of diseases, the specific needs of certain groups, the therapeutic and social value, the cost-effectiveness ratio, the rationalisation of public spending and the degree of innovation.

In the experience of different partners, the most commonly used criteria for funding decisions on orphan drugs are therapeutic-social and budgetary impact.

In this context, AELMHU put forward a series of **recommendations** for developing a cooperative evaluation framework, including:

- attributes beyond cost-effectiveness;
- additional criteria, such as life-threatening or disease-modifying capacity;
- clinical, ethical and social impact considerations, as well as recognition of therapeutic innovation; and
- application of non-traditional evaluation criteria.

RESPONSE TO
THE PRIOR
PUBLIC
CONSULTATION
THE DRAFT

C. Processes

The process for assessing orphan drugs should be streamlined, avoid duplication and encourage dialogue between all agents involved.

In view of this situation, AELMHU proposed:

- Establishing an **early and continuous dialogue** between the Administration and the companies, with face-to-face meetings to exchange information.
- Establishing a **horizon scanning** process to identify R&D breakthroughs and prioritise innovations.
- Incorporating the **patient view** and **clinical experts**, as well as considering the use of multi-criteria decision analysis.
- The importance of **reevaluating** in case of **new scientific evidence**.

CONTRIBUTIONS
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D. Advanced Therapies

Advanced therapies, such as cell and gene therapies, represent a significant change in the treatment of diseases, especially rare diseases. However, they face unique challenges, such as the difficulty in obtaining long-term data due to the potentially curative nature and uncertainty in their value.

Therefore, the traditional framework for evaluation is not adequate enough to capture its full value.

AELMHU proposed:

- Including **additional elements** of value.
- **Recognising the challenges** in conducting **clinical trials** and adopting flexible approaches in evaluating available evidence.
- Taking a **pragmatic view** of **real-life data collection** to address long-term uncertainties while minimising the administrative burden.

👉 *AELMHU Contributions Public Consultation prior to the draft Royal Decree on THA*

At European level:

Reform of EU Pharmaceutical Legislation

In early November, AELMHU participated in the review of the EU Pharmaceutical Legislation, where it expressed its commitment to continuous improvement and welcomed the opportunity to participate in the consultation to address these challenges and ensure a brighter future for rare disease patients.

At present, EU legislation is based on the following key points:

- The distinction between unmet medical needs (UMN) and high unmet medical needs (HUMN) raises concerns about restrictive definition and uncertainty in innovation, affecting research into rare diseases.
- The proposed changes to trade protection, both in the period of exclusivity and in therapeutic indications, could discourage research and development of treatments for rare diseases by imposing stricter requirements and limiting exclusivity.
- The search for equity in access and innovation among Member States is challenging due to complex markets and unrealistic timelines, which could make access to treatments for rare diseases even more difficult.
- Changes in data protection, with shortened periods and inflexible criteria, could hinder research and development of treatments for rare diseases by not taking into account their unique characteristics.
- While seeking to speed up access times to orphan drugs, it is essential to also address the evaluation and funding processes at the national level to ensure timely access to treatments, especially for patients with rare diseases.

The Association undertook to work with the European Commission and other institutions to ensure that these suggestions are taken into account during the review of the approval process.

In this regard, AELMHU proposed:

- **Consensus** on a broad and balanced definition of unmet medical needs (UMN) and high unmet medical needs (HUMN), prepared by a committee with the participation of all relevant parties, taking into account the specificities of each pathology.
- **Separating obtaining incentives** from compliance with ambiguous concepts such as UMN and HUMN, especially when they are the only way to maintain the incentives of the current framework.
- **Maintaining an exclusivity period** of ten years, with the option to extend it according to different criteria, without initially reducing it.
- **Eliminating the reduction of the exclusivity period** related to the active substance in order to maintain the incentive to explore the potential of a molecule.
- **Incorporating flexible criteria** when assessing ongoing distribution compliance with the supply chain, considering existing barriers, access times and characteristics of patients with rare diseases.
- **Maintaining or extending** the regulatory data protection period to eight years, with the possibility of extension under different criteria, without making it conditional on access in all Member States.
- **Considering differences between Member States** when implementing common criteria, adapted to orphan drugs, through a dialogue between medicines agencies and all parties involved in the process.
- Ensuring an **active dialogue with all interested parties** in areas where the European Medicines Agency issues scientific guidance to consider all factors surrounding the implementation of the Regulation and the Directive.

👉 *AELMHU Recommendations for the revision of EU Pharmaceutical Legislation*

5.2 INSTITUTIONAL MEETINGS

Throughout 2023, AELMHU held **numerous working meetings** with different **institutional representatives**, both from the executive and **parliamentary spheres at national level:**

- The Director General for the Common Portfolio of Services of the SNS and Pharmacy of the **Ministry of Health**, César Hernández.
- The Secretary General for Research by the **Ministry of Science**, Raquel Yotti.
- Spokespersons for the **Republican Parliamentary Group,** Xavier Eritja and for the **Popular Parliamentary Group** of the Congress of Deputies, Elvira Velasco and Ana Pastor.

At regional level:

- The Director General of Benefits and Pharmacy of the Department of Health Care **of Balearic Islands**, Joan Simonet.
- The Director General of Planning, Organisation and Health Inspection and Pharmacy of the Department of Health Care **of Castilla-La Mancha**, Carmen Encinas.
- The Director General of Planning, Pharmacy and Pharmaceutical Research of the Department of Health Care **of Murcia**, Jesús Cañavate.
- The Director General of Pharmacy of the Department of Health Care of **Valencian Region**, Elena Gras.
- The Deputy Director of Pharmacy and Medical Devices, of the Department of Health Care of the **Madrid Regional Government**, María José Calvo
- And the Head of the Department of Health Care **of Aragon**, José Luis Bancalero.

Meetings have also been held with the **main associations and federations (2) of the pharmaceutical industry**, such as Farmaindustria and the Federation of Spanish Scientific and Medical Associations.

The **objective of these meetings** was to raise awareness of AELMHU's work, position and the challenges it faces, sharing the different projects developed by the Association, such as the report on access to orphan drugs and the report on clinical trials for rare diseases in Spain. Likewise, these institutional meetings **shared proposals for improvement on various political, legislative and institutional developments of interest in the field of rare diseases** and orphan drugs, in addition to encouraging cooperation with the various agents that make up the health sector value chain with the aim of increasing the arrival of innovation and improving the quality of life of patients with rare diseases.

6. AELMHU *at* External Events

Thanks to the work developed over the last 12 years by the Association and to the knowledge, promotion and advancement of treatments for rare diseases, AELMHU has achieved **greater participation**, **involvement** and **projection** in the main forums and events organised in the health sector.

6.1 EVENTS *with* PARTICIPATION *of* AELMHU

During this year, the Association participated in a total of **22 meetings,** nine more than in 2022, which have helped **strengthen** its **position** as a **leader** in the field of orphan drugs. From the Roadmap to its prominent participation in the XVI International Congress on Rare Diseases, AELMHU contributed to advancing the better understanding and treatment of these diseases, as well as bringing the reality of patients and their families closer.

Rare Disease Roadmap

(17/01/2023)

In person, the **director** of our organisation, **Marian Corral**, took part in the second meeting of the *Roadmap on Rare Diseases*. Promoted by the company Takeda, it was attended by a large number of leaders in the sector. In addition to highlighting the sector's advances, achievements and challenges, he offered various **key points for improving access** to new treatments and boosting research, in a year marked by elections, legislative changes and the Spanish Presidency of the EU. The subsequent round table discussion included the participation of Jorge Aboal Viñas, former Director General of Health Care of the Galician Health Service; Cristina Ruiz, Deputy Director General of Planning and Care Organisation of the Department of Universal Health and Public Health of the Valencian Regional Government; and Carolina Rodriguez Gay, Head of Information and Patient Care of the Department of Health Care of the Madrid Regional Government.

Europe Rare Disease Summit 2023

(15/02/2023)

The **President** of AELMHU, **María José Sánchez Losada**, participated in the *Europe Rare Disease Summit 2023*. Held in person in Madrid, this event brought together representatives of the Administration, the European Union, the pharmaceutical industry, patient associations and researchers. The **legislative changes**, **access to and financing** of orphan drugs, the **innovation** or **role of patients** with diseases, among other topics, were discussed.

María José Sánchez Losada presented data from the latest *Annual Report on Access to Orphan Drugs in Spain*, prepared by AELMHU, and shared some of the proposals submitted to the Ministry of Health to improve and address the challenges of access to orphan drugs in view of the imminent legislative changes in the Law on Guarantees and Rational Use of Medicines and Medical Devices and the Royal Decree on the Financing and Pricing of Medicines.

Conference on Rare Diseases

(23/02/2023)

In the *online* debate organised by the journal IM Médico under the title *Rare Diseases: more refined diagnoses, more specific treatments*, the Association was represented by its **secretary and member, Beatriz Perales**.

During his speech, she highlighted AELMHU's work in the **research, development and commercialisation** of innovative therapies to improve the quality of life of patients with rare and ultra-rare diseases. She also referred to recent data from the *Annual Report on Access to Orphan Drugs in Spain 2022*, which served as a framework to analyse, together with the other speakers, the current challenges in research, diagnosis, regulation and access to treatments.

She highlighted the **need to address these challenges**, cooperatively and urgently, to ensure early diagnosis and rapid access to treatments for rare disease patients.

1st Haemophilia Gene Therapy Forum

(24/02/2023)

The **Director** of our organisation, **Marian Corral**, participated in the *1st Haemophilia Gene Therapy Forum*, organised by CSL Behring in Madrid. Issues related to unmet needs, the specialist perspective and clinical research into haemophilia were discussed at this meeting.

AELMHU was present at the final panel on access to funding for advanced therapies, where funding models and access challenges were discussed.

Marian Corral offered the **key points** of the *Annual Report on Access to Orphan Drugs in Spain* focusing on the main **challenges** affecting the **funding of advanced therapies** in rare diseases, as well as regulatory, management and health training aspects.

World Rare Disease Day

(28/02/2023)

At the 2^{nd} *Conference on Minority Diseases* at the Hospital 12 de Octubre in Madrid, AELMHU was represented by **Marian Corral**, who took stock of access data and highlighted the importance of 2023 for the pharmaceutical industry in Spain through the development and **revision of key regulations** for the sector such as the Law on Guarantees and Rational Use of Medicines and Medical Devices, the European Regulation on Orphan Medicinal Products or the Spanish Presidency of the Council of the EU.

Several patient associations had the opportunity to share their experience and offer proposals for improvement to ensure continuity of care for patients.

Priorities for Evaluating and Financing Medicines and Health Products in Spain.

(21/03/2023)

Beatriz Perales, **secretary** of AELMHU, participated in person in a new edition of the conference **Post Ispor** 2023 and **Diariofarma**, entitled on this occasion *Priorities for Evaluating and Financing Medicines and Health Products in Spain*.

The speakers focused on key aspects related to evaluating and financing medicines, in a meeting that included the intervention of the Director General for the Common Portfolio of Services of the SNS and Pharmacy, César Hernández.

2nd Conference: Más Visibles

(24/03/2023)

Marian Corral represented AELMHU at the *2nd Conference on Rare Diseases*, in order to raise their visibility and demand more research.

Held in Jaén, the speakers coincided in calling for a more humanitarian vision of low prevalence diseases, as well as requesting more efforts in research, resources and multidisciplinary patient care.

During the day, experts and professionals discussed **research and access** to orphan drugs, **visibility** of rare diseases, **psycho-social care** and **palliative care**.

Conference: How will the European Pharmaceutical Strategy affect Orphan Drugs?

(11/09/2023)

Beatriz Perales, secretary of AELMHU, spoke at the day of reflection *How will the European Pharmaceutical Strategy affect Orphan Drugs?*

Organised by BioInnova Consulting, the secretary of the Association expressed her **concerns** about the **European Commission's proposal** which, in her opinion, does not favour innovation or the competitiveness of the pharmaceutical industry. She emphasised the management of uncertainty as a crucial factor in attracting companies to invest in Spain and highlighted deadlines as the main challenge of the new European regulatory framework.

She also highlighted the **importance of clearly defining unmet medical needs** within the regulation of the data protection period.

University of Castilla-La Mancha Summer Courses

(20/09/2023)

Once again, the Association participated in the summer course organised by the University of Castilla-La Mancha with cooperation from the Weber Foundation. This year **Marian Corral** represented the Association at the table *European, National and Regional Strategies: Towards an Equitable and Sustainable System*. The director highlighted the changes affecting orphan drugs and agreed on the need to establish a dialogue and reach agreements that include all the actors involved, in an event that included the participation of the Ministry of Health and the Madrid Regional Government. The director was accompanied by Cristina González del Yerro Valdes, Deputy Director General of the Portfolio of Services of the National Health System and Compensation Funds of the General Directorate of the Common Portfolio of Services of the National Health System and Pharmacy; Carolina Rodriguez Gay, Head of Patient Information and Care; María Ángeles Gómez Mateos, Deputy Directorate General for the Humanisation of Care, Bioethics and Patient Information and Care of the Department of Health Care of the Madrid Regional Government and Roberto Saldaña, representative of the European Patients' Academy (EUPATI).

4th Symposium of the Health Observatory

(03/10/2023)

The 4th *Symposium of the Healthcare Observatory*, organised by El Español and Invertia, was attended by prominent healthcare sector leaders and government representatives. At the discussion on the needs and contributions of the pharmaceutical industry, AELMHU was represented by its **president**, **María José Sánchez**, who highlighted the **challenges in access** to orphan drugs in Spain and the need to **accelerate** their **approval** in order to benefit patients.

The event addressed the most pressing challenges facing the National Health System, including the financing of industry innovations and the digitalisation of the sector.

Retina Murcia Congress

(06/10/2023)

Marian Corral represented the Association at the *Retina Murcia Congress*, on the panel "*Orphanet and orphan drugs*". The director gave a detailed overview of the current situation of these diseases, including data on their **impact on society** and the **challenges** faced by those suffering from them. The focus was on orphan drugs, their relevance to the pharmaceutical industry and ongoing research. It delved into the approval and marketing process for these medicines, as well as the challenges associated with access to them and the regulations surrounding them.

To conclude, AELMHU identified the main **challenges and needs of the Spanish healthcare system** in relation to rare diseases and orphan drugs, providing a comprehensive overview of the situation and areas for improvement. The Congress promoted the best available professional practices relating the diagnosis and treatment of defects and diseases of the visual apparatus, with the knowledge and insight that patients themselves and patient organisations could offer in this respect.

16 th International Congress on Rare Diseases

(25/10/2023)

Marian Corral, representing AELMHU, participated in the *16th International Congress on Rare Diseases*, organised by the Catholic University of Murcia and the D'Genes Association.

The event brought together patient associations, researchers and various representatives of the public administration. The director highlighted the **advancement** registered in **rare disease research** in Spain resulting from the increase in the number of authorised clinical trials in our country and expressed the importance of taking advantage of this opportunity to improve the country's efficiency and attractiveness in rare disease research.

Conquistando Escalones Association

(27/10/2023)

The Conquistando Escalones Association organised the *Vila-real Congress for Science and Innovation: research as a cure for millions*, together with the Vila-real City Council, at the Municipal Auditorium.

The event addressed clinical research in neuromuscular diseases, gene therapy and access to orphan drugs.

On behalf of AELMHU, **Marian Corral** emphasised the need to introduce **changes in the evaluation and funding** of medicines to improve early access to treatment.

José Alcamí, Juan Vílchez, Rubén Artero and María Jesús Vicent participated, among other renowned experts and prominent figures outside the field of healthcare, such as the athlete Álex Roca and the former football coach Juan Carlos Unzué.

Rare Disease Event at the Spanish Congress of Deputies

(20/11/2023)

María José Sánchez, **president** of the Spanish Association of Orphan and Ultra-Orphan Drug Laboratories (AELMHU), explained in this event organised by FEDER *Towards a comprehensive European plan for rare diseases: the participation of Spain*, the perspective and situation of these treatments in our country. David Sánchez, spokesperson for the International Action Committee of FEDER, complemented this vision by emphasising the need to broaden and adapt the effective participation of patients in all processes that affect them. The meeting, inaugurated by the President of the Congress of Deputies, Francina Armengol, is the result of FEDER's alliance with EURORDIS and RPP Group, together with Farmaindustria and AELMHU.

Medical-scientific meeting about RDs

(21/11/2023)

AELMHU, represented by **Director Marian Corral**, closed the conference *The Future of Access to Orphan Drugs: Humanising Rare Diseases*, which was held at the Cervantes Institute Headquarters in Madrid.

Coordinated by the Teófilo Hernando Foundation, the event explored **access to treatments** for rare diseases and their **human impact**. The director of AELMHU highlighted the crucial regulatory moment for the pharmaceutical sector and the importance of working together to benefit patients with new treatments.

Experts such as Marta Trapero, Gloria Palomo and Antoni Gilabert analysed the future of access to orphan drugs, while Mónica Rodríguez, Julio Zarco Rodríguez and Concepción Martínez discussed other relevant aspects at the meeting.

Rare Disease Congress in Elche

(14/12/2023)

Elche hosted the 2nd *Rare Diseases Congress* in 2023 to discuss and train the health and educational community. The presentations focused on the need to train teachers and health workers in order to acquire greater knowledge and awareness to achieve a more inclusive and just society.

The **Director** of AELMHU, **Marian Corral** addressed the situation of medicines and clinical trials in Spain, highlighting a **constant increase in research** into rare diseases and orphan drugs.

Based on data from the Annual Access Report, she highlighted the need to define a **specific model for evaluating and financing** orphan drugs, to simplify processes and provide certainty, agility and transparency in the processes. She shared the Association's proposals submitted to the Ministry of Health for a new early access model for treatments that allows for agile collaboration, patient and clinician involvement, as well as outcome-based funding, all of which are crucial to improve the availability of life-saving medicines.

The experts agreed on the importance of focusing on improving social empathy through knowledge and spreading information, under the slogan *Juntos Sumaremos (Let's Join Forces)*.

The Congress called for the need to offer support and help to families whose children are diagnosed with a rare disease, both in the bureaucratic and medical processes, as well as in the day-to-day treatment.

Other events with participation of AELMHU

- Master's Degree Camilo José Cela University.
- Rare Diseases, organised by *Canal Sanitario*.
- Talent in Rare Diseases, organised by Hays.
- Haemoglobinopathies in Spain, organised by Vertex Pharmaceuticals.
- Master's Degree in Rare Diseases and Orphan Drugs.

6.2 OTHER EVENTS in the SECTOR

The Spanish Association of Orphan and Ultra-Orphan Drug Laboratories reinforced its presence at relevant events and meetings on rare diseases with **participation in 25 events** in 2023.

The Association's active presence at these events is proof of the commitment and support offered to patients affected by rare and ultra-rare diseases. AELMHU also attended various meetings with experts and health authorities to learn about the legislative developments that are setting the agenda for the sector.

The AELMHU Board and Management were present at the following events over the first months of 2023: the ***Legislative Observatory*, organised by Alexion** on 31 January; the *European Pharmaceutical Strategy*, organised by Diariofarma on 6 February; *Address and treatment of haemophilia*, organised by Sobi on 21 February; *Conference in the Spanish Congress of Deputies on Epilepsy*, organised by the Spanish Epilepsy Federation on 30 March; and campaigns on the occasion of World Rare Disease Day (22 and 29 February, 15 and 16 March).


feder
HAZ QUE EL TIEMPO VAYA
A NUESTRO FAVOR


feder


FEDERACIÓN ESPAÑOLA DE ENFERMEDADES RARAS
feder
HAZ QUE EL TIEMPO VAYA
A NUESTRO FAVOR
Fundación feder
para la investigación de
Enfermedades Raras


CELEBRATI
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Congreso de los Diputados

In May, the director of AELMHU, Marian Corral, attended an event organised by Bioinnova on European legislation on orphan drugs. She also participated in several online meetings: the FUNCAS Seminar, held on 31 May; an event on Clinical Trials organised by the Platform of Patients' Organisations on 14 June; and the *Expert Meeting on Rare Diseases*, which took place on 15 June.

Throughout June and July, the Association participated in a breakfast with César Hernández, organised by Executive Forum on 20 June; an event organised by the law firm Faus & Moliner in Madrid on 29 June; and in the Post ISPOR 2023 Conference, organised by ISPOR Spain Chapter and Diariofarma on 7 July, under the title *Priorities in the Evaluation and Funding of Medicines and Medical Devices in Spain*.

AELMHU was also represented during September at the summer courses of the UIMP in Santander and the University of Castilla-La Mancha, focusing on new strategies and trends in the management of rare diseases, as well as at the *First National Course on Gene Therapy for Rare Diseases*, held on 22-23 September.

At the end of September, Marian Corral, representing AELMHU, also attended various congresses: the 7th *Congress of the Platform of Patients' Organisations*, held on 29 September, and the 3rd *Congress of the ASMD Association*, on 30 September.

On 10-11 October, a conference on *Rare Diseases and European Reference Networks*, was organised in Bilbao, where Marian Corral was also in attendance. At the end of the same month, *Executive Forum* organised an informative breakfast meeting with the Head of the Cantabrian Department of Health Care, César Pascual, on 18 October, where the Association was also represented.

Finally, the director of AELMHU attended three events in the Madrid Regional Government in November: the 20th Anniversary of the ASEM Federation (17 November), the ASEDEF Awards (27 November) and the *Conference organised by Biogen on Multiple Sclerosis* (29 November). In addition, José Luis Moreno, vice-president of AELMHU, participated in the presentation of the new Health Technology Assessment Regulation at an event organised by the European Commission in Seville on 22 November.

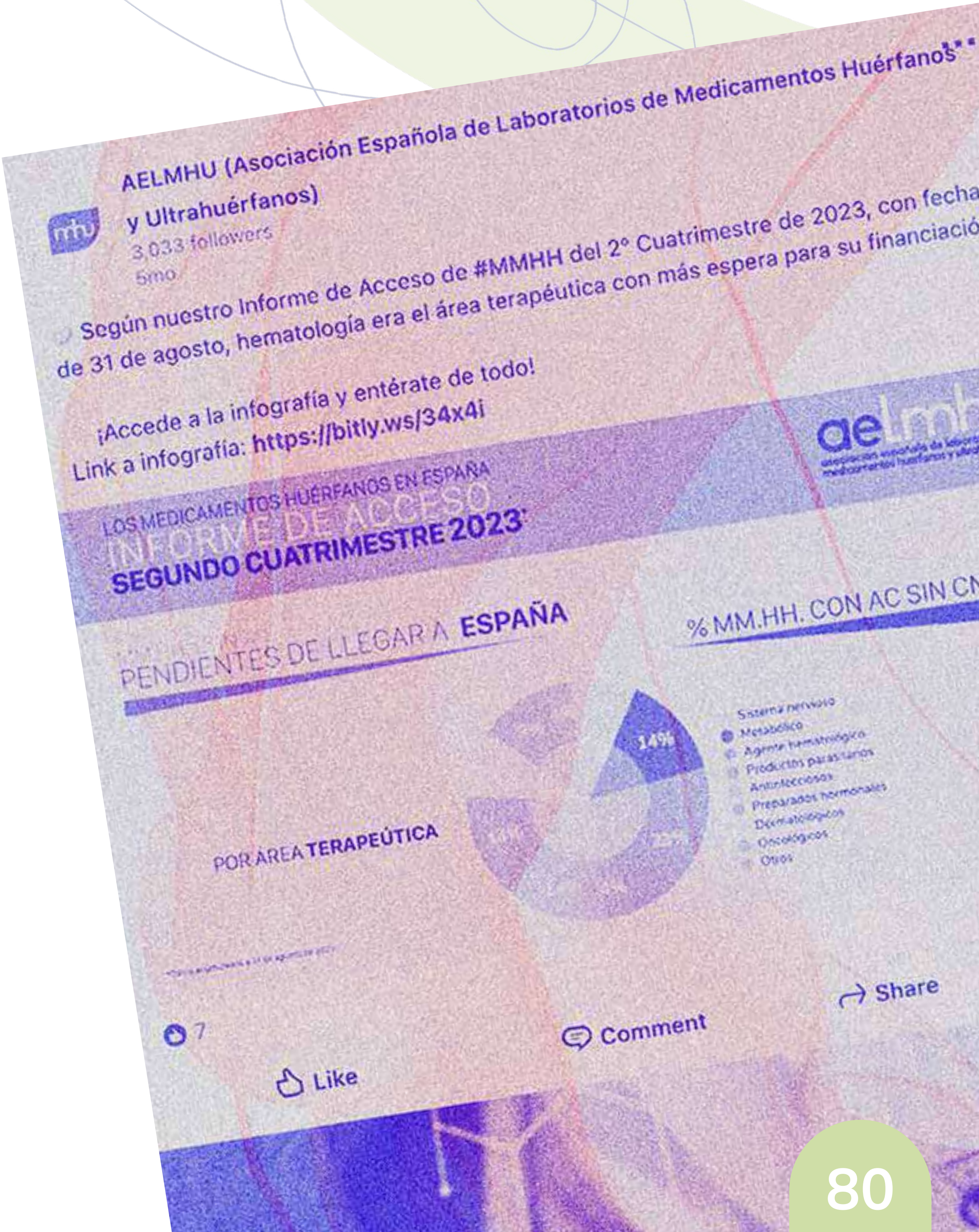
7. Communication

Communication remains a **critical part** of the interaction with the rest of the actors in the sector. The Association has continued its initiatives to develop content that contributes to making our commitment to research available to the public, development and promotion of innovative therapies that improve the lives of patients and their families.

This strategy of generating **regular information with high added value** has enabled us to strengthen the confidence of the sector's main actors and to continue to be a consistent information and training reference for the media, in an environment marked by increasing complexity, volatility and misinformation.

Throughout 2023, AELMHU has maintained a high communication profile through by distributing press releases, an active presence in social networks and updating website content.

Likewise, the Association's spokespersons have shown **an open and proactive attitude in their relations with the media** to attend to the different information requirements, which has served to gain in closeness with society.



AELMHU (Asociación Española de Laboratorios de Medicamentos Huérfanos y Ultrahuérfanos)
3,033 followers
5mo

Según nuestro Informe de Acceso de #MMHH del 2° Cuatrimestre de 2023, con fecha de 31 de agosto, hematología era el área terapéutica con más espera para su financiació

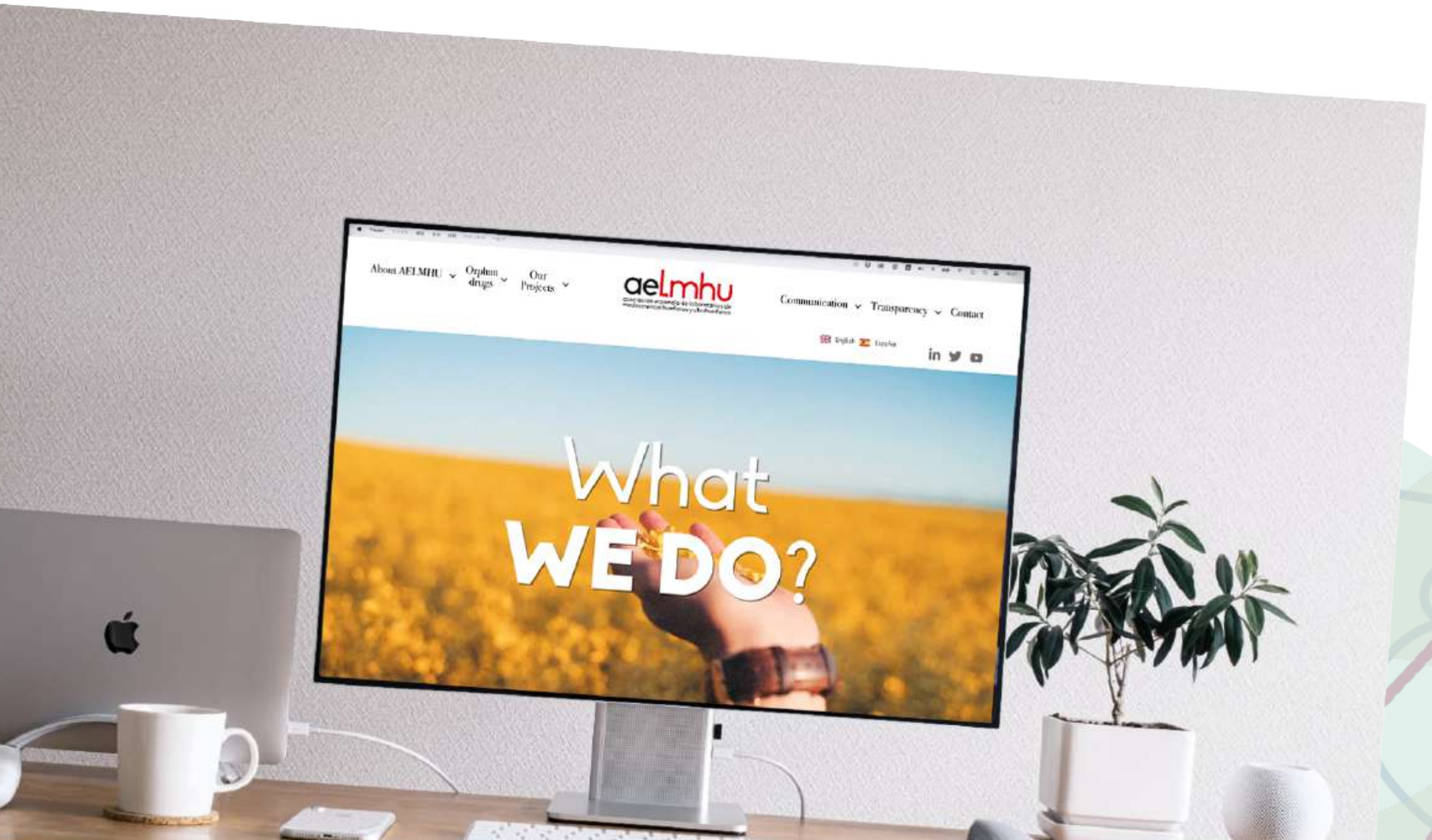
¡Accede a la infografía y entérate de todo!
Link a infografía: **https://bitly.ws/34x4i**

7.1 AELMHU in the MEDIA

Throughout this year, thanks to the launch of various press releases, the distribution of reports, events in which AELMHU has participated or attended and the proactivity of the media in talking about the issues that have a direct impact, a **total of 229 impacts have been achieved**, divided between general and specialised media.

The Association has launched **four press releases** which, in a media context that does not favour the publication of this type of content, have been well received.

- **Presentation of the Annual Access Report**: the publication of the results took place as two releases, which multiplied the reception of the press release.
- **Rare Disease Clinical Trials Report**.
- **AELMHU 2023 Awards Ceremony**.



AELMHU has appeared in **more than 100 different media**, both nationally and regionally, with digital format predominating. By type of media, **generalist media**, predominate, with impacts in El Mundo, Cadena SER and La Razón: **specialised health media account for 47%**, with impacts in Consalud, Redacción Médica and Diariofarma, among others. Impacts have also been generated in the economic media and news agencies such as EFE and Servimedia.

Although the communication sector has become complex and it is increasingly necessary to reinforce reader trust, **AELMHU continues to generate interest** in the media at different levels, indicating that society perceives the Association as a good intermediary, an expert in the field of rare diseases and orphan drugs.

elPeriódico de Aragón

d pública

ermedades raras en España: 60 medicament
en financiación

diciembre de 2022, España contaba con 123 medicamentos huérfanos
nifica que 60 productos huérfanos siguen pendientes de financiación en

ES NOTICIA | Guerra Ucrania | Viogen | Kroos | Alcaraz | Fórmula 1 | Final Four | Begoña Gómez | Karla Sofía Gascón | Taylor Swift

EL MUNDO España Opinión Actualidad Económica Internacional Deportes Cultu

Ciencia y Salud | Ciencia Salud Sostenibles

SALUD

El acceso a los medicamentos huérfan en España: 49 fármaco financiar y 26 meses espera

El último informe de la patronal de (Aelmhu) muestra cómo el avance disponibilidad de estas terapias todavía lenta

MANUEL F. BUSTELO
Madrid

Actualizado Sábado, 14 octubre 2023 - 01:53

elEconomista.es

MERCADOS Y COTIZACIONES IBEX 35 M.CONTINUO EMPRESAS

Salud

Los medicamentos para patologías raras tardan casi tres años en comercializarse en España tras el sí de la Aemps

Sanidad financia el 43% de los fármacos huérfanos que se autorizan en Europa

elEconomista.es

Y COTIZACIONES IBEX 35 M.CONTIN

Salud

medicamentos para patol
an casi tres años en comerc
España tras el sí de la A

lad financia el 43% de los fármacos huérfan

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diariofarma

POLÍTICA PROFESIÓN TERAPÉUTICA GESTIÓN OPINIÓN FARMACIA ASISTENCIAL FARMACIA HOSPITALARIA

Gestión

Julio Sánchez Fierro, a título póstumo, y Ángel Carracedo, premios Aelmhu 2023

Dos proyectos, uno de la Asociación Duchenne Parent Project España y otro de Dravet Syndome Foundation España, han completado las cuatro categorías de este año

---

redacción médica

4 MINUTOS

4 dic. 2023 16:30H

POR LAURA CAMACHO

TAGS › INDUSTRIA FARMACÉUTICA

---

iSanidad

PROFESIONALES ACTUALIDAD ANÁLISIS ENTIDADES PÚBLICAS Y

MEDICAMENTOS

España tarda tres años en financiar un medicamento huérfano, según el Informe Anual de Acceso de Aelmhu

En 2022, el tiempo medio desde el Código Nacional hasta la financiación pública de los medicamentos huérfanos es de 34 meses

29 de enero de 2023

Redacción

La Asociación Española de Laboratorios de Medicamentos Huérfanos y Ultrahuérfanos (Aelmhu) ha denunciado, en su Informe Anual de Acceso, que

---

diariofarma

POLÍTICA PROFESIÓN TERAPÉUTICA GESTIÓN OPINIÓN FARMACIA ASISTENCIAL FARMACIA HOSPITALARIA

Gestión

El acceso a medicamentos huérfanos en España mejora, pero aún se sitúa lejos de la media europea

El Segundo informe cuatrimestral de acceso a los medicamentos huér en 2023 de Aelmhu indica que siguen sin financiarse 49 medicament aprobados por la EMA y la espera media supera los dos años

---

SALUD

El acceso a los medicamentos huérfanos en España: 49 fármacos sin financiar y 26 meses de espera

El último informe de la patronal de estos fármacos (Aelmhu) muestra cómo el avance en la disponibilidad de estas terapias en nuestro país es todavía lenta

Eduardo Parra / Europa Press

Sanidad explora nuevas fórmulas de acceso al SNS para fármacos huérfanos

El Ministerio no descarta crear un fondo estatal para centralizar la compra de estos medicamentos

Exteriores del Ministerio de Sanidad.

SE LEE EN 2 MINUTOS

6 mar. 2023 13:20H

JOANA HUERTAS

MINISTERIO SANIDAD

Te puede interesar

Marta Torciado, presidenta del Colegio de Farmacéuticos de Ávila

---

HOME › PACIENTES

Uno de cada cuatro ensayos clínicos en España fue dedicado a las enfermedades raras en 2022

El Informe Anual sobre Ensayos Clínicos en España realizado por la AELMHU ha revelado que uno de cada cuatro ensayos clínicos autorizados en España en 2022 fue dedicado a enfermedades raras

7.2 INTERVIEWS

Over the course of 2023, AELMHU continued to project the work of the sector through the media, with a total of **19 interviews recorded**.

Notable contributions include appearances in the national media, such as the publication of an interview in the EFE news agency and an interview in the digital newspaper El Español.

Our presence has also been consolidated in various specialised newspapers, including Redacción Médica and IM Médico, with multiple mentions, as well as regular appearances in Diariofarma, Diario Médico and Consalud, among others.

diariofarma

POLÍTICA PROFESIÓN TERAPÉUTICA GESTIÓN OPINIÓN FARMACIA ASISTENCIAL FARMACIA HOSPITA

Terapéutica

Aelmhu urge a “un cambio de modelo” pa los medicamentos huérfanos

La entidad presenta su Informe Anual de Acceso 2022, que el que “se confirman las dificultades que sufren los pacientes con patologías minoritarias en España, donde sólo se financia el 43% de los producto huérfanos autorizados en Europa”

Diariofarma
13 FEBRERO 2023 - 13:55

La **Asociación Española de Laboratorios de Medicamentos Huérfanos y Ultrahuérfanos (Aelmhu)** ha presentado su **Informe Anual de Acceso a los Medicamentos**

el Periódico de España

SANIDAD PÚBLICA

Enfermedades raras en España: 60 medicamentos huérfanos no tienen financiación

A 31 de diciembre de 2022, España contaba con 123 medicamentos huérfanos con Código Nacional y 63 financiados, que significa que 60 productos huérfanos siguen pendientes de financiación en nuestro país

Un bote de medicamentos.

Nieves Salinas
Madrid 13 FEB 2023 12:30

Española de Laboratorios de **Medicamentos Huérfanos** y

el 'Informe Anual

SALUD

El acceso a los medicamentos huérfanos en España: 49 fármacos sin financiar y 26 meses de espera

El último informe de la patronal de estos fármacos (Aelmhu) muestra cómo el avance en la disponibilidad de estas terapias en nuestro país es todavía lenta

Parra / Europa Press

fras parecen haber mejorado en los
aún lejos de ser las deseadas. El acce
camentos huérfanos en España sigue
ión que, pese a considerarse prioritaria,

a con analizar los datos del último informe
Asociación Espa

EFE:Salud

Noticias Videoblogs efe.com Contacto

La reforma farmacéutica plantea desafíos para la innovación en enfermedades no cubiertas

La propuesta de reforma farmacéutica de la Comisión Europea podría hacer mella en la innovación para tratar enfermedades raras o no cubiertas en Europa, según representantes de la industria y asociaciones de pacientes consultadas por EFE, que piden mantener los incentivos actuales y encontrar otras fórmulas para combatir los problemas de acceso a fármacos.

---

redacción médica

Portada > Secciones > INDUSTRIA FARMACÉUTICA

¿Sumar al paciente a la regulación pharma?: "Es el impulsor del progreso"

Aelmhu defiende la inclusión de este agente, pues es el "principal motivador" de esta

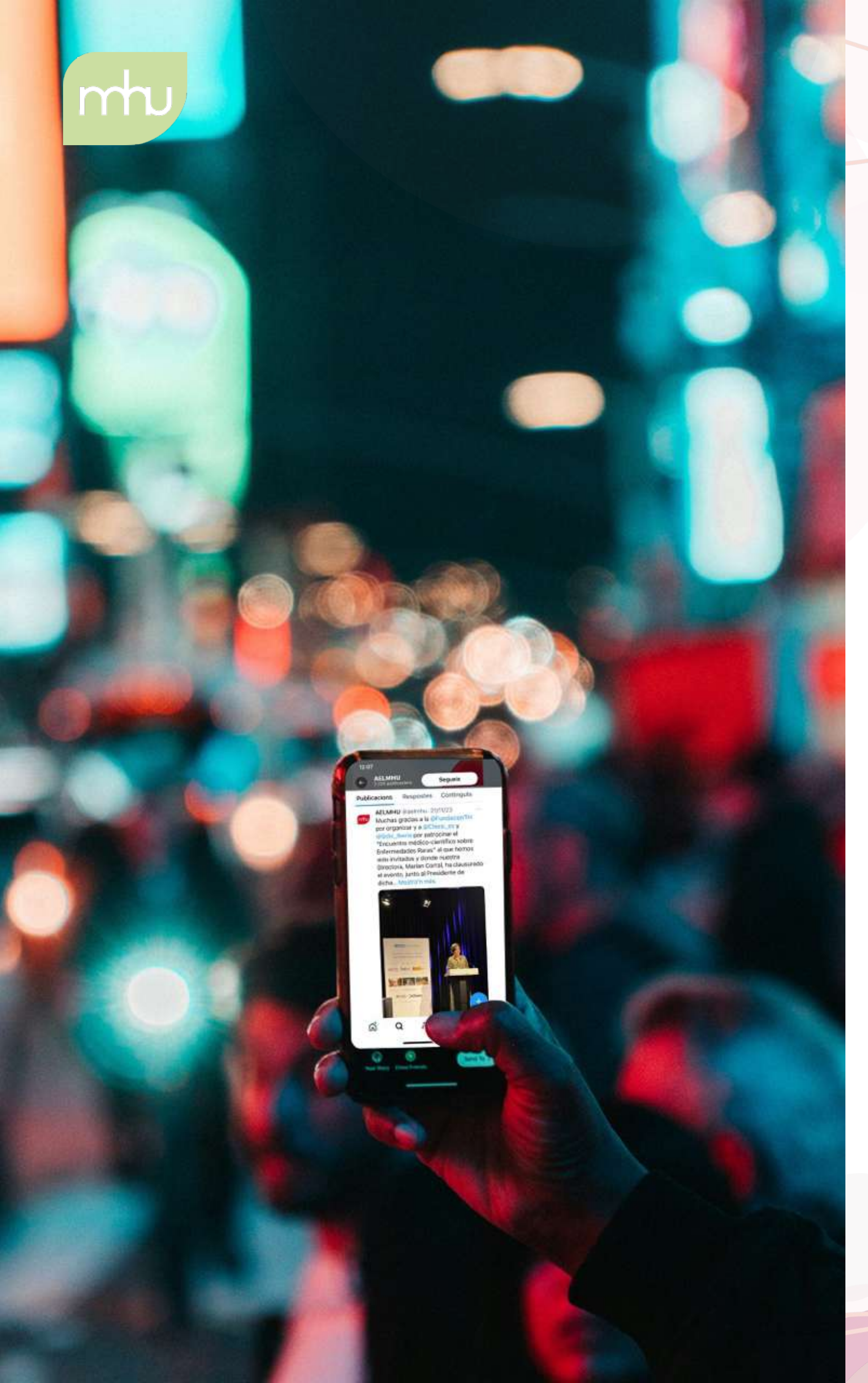
SE LEE EN 4 MINUTOS

4 dic. 2023 16:30H

POR LAURA CAMACHO

TAGS > INDUSTRIA FARMACÉUTICA COMISIÓN EUROPEA

los que conocen de primera mano sus patologías y cómo
de una voz que cada vez coge más



7.3 DIGITAL

The Association has consolidated its **presence** on the various platforms of **social networks**, segmenting and adapting its content to the different audiences. Since beginning its foray into Twitter in 2017 and LinkedIn in 2019, it has shown its willingness to distribute content of its own value related to its field of action, thus gaining a space of relevance in the field of digital communication.

This achievement has been possible thanks to a strategy focused on the expansion and distribution of quality information, as well as the modernisation of the way of sharing content, adapting to new information trends and making its proposal more attractive to users.

The primary objective of AELMHU is simply to continue **increasing its visibility and notoriety** among the companies and experts with whom the Association interacts, by promoting dialogue with the different interest groups. In this way, the aim is to promote relevant conversations for both scientific societies and society in general.

AELMHU (Asociación Española de Laboratorios de Medicamento...
3.037 seguidores
6 meses • Editado •

La Federación Española de Enfermedades Raras (FEDER ONG), acompañada y apoyada por asociaciones de pacientes, empresas y asociaciones de la industria farmacéutica y representantes de diferentes partidos políticos insta a Esp ...ver más

AELMHU (Asociación Española de Laboratorios de Medicamento...
3.037 seguidores
7 meses •

Desde AELMHU consideramos que la Reforma de la #LegislaciónFarmacéuticaEuropea es una buena ocasión para posicionar al paciente en el centro de la toma de decisiones así como para apostar por la investigación en #MMHH

#UE European Commission

Amplia la información sobre la reforma: https://ow.ly/GVig50PPwTP

AELMHU
@aelmhu

¡Calentando motores! En breves momentos dará comienzo la gala de entrega de los #PremiosAELMHU2023 para reconocer la labor de profesionales y organizaciones y distinguir a los mejores proyectos asistenciales, de divulgación y sensibilización sobre las patologías minoritarias. ¡No te lo puedes perder!

AELMHU
@aelmhu

Hoy celebramos el Día Europeo de los D
desde AELMHU queremos concienciar s
para mejorar la vida de los pacientes co

Descubre más sobre el #DíaEuropeode
bit.ly/41eBZbM

r. 2023 · **206** Reproducciones

AELMHU (Asociación Española de Laboratorios de Me
3.037 seguidores
7 meses •

📝 Según nuestro Informe de Acceso de #MMHH del 2º Cuatrime
fecha 31 de agosto de 2023, el 52% de los #MMHH con autorizació
encontraban financiados por el #SNS.

👇 ¡Accede a la infografía y entérate de todo!

Link a infografía: https://bit.ly/3PL3FR8

👍 2

AELMHU
@aelmhu

Ayer tuvo lugar la ceremonia de entrega de los Premios AELMHU

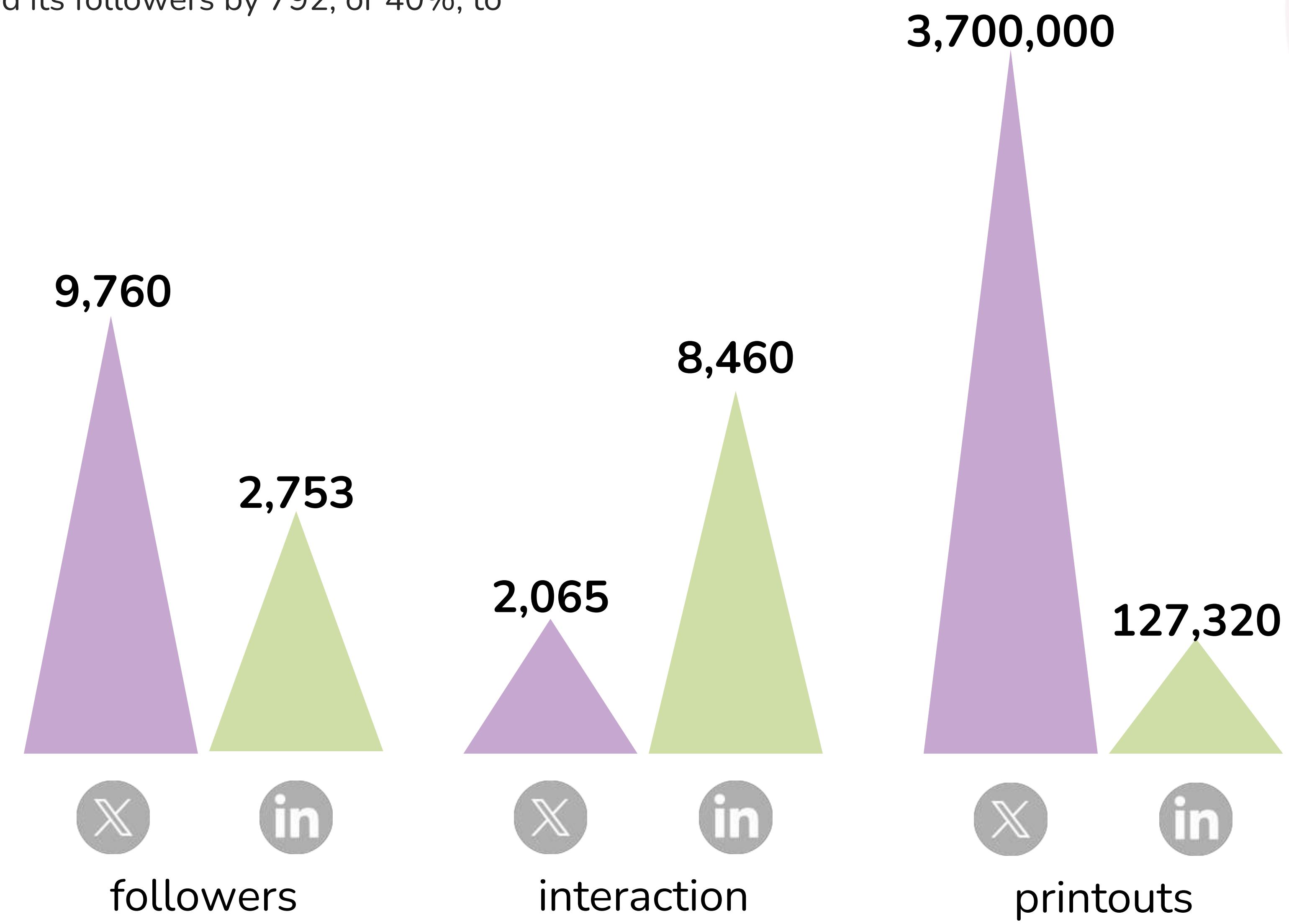
Un evento en el que de nuevo queda patente el esfuerzo, el compromiso y la involucración de asociaciones, investigadores, clínicos, instituciones e industria farmaceutica con las #enfermedadesraras

Enhorabuena a todos los proyectos y trayectorias premiadas y muchas gracias a todas las personas que han hecho posible estaedición de los premios.
#VEdiciónPremiosAELMHU

👉 ¡Entérate de todo! shre.ink/U2ci

AELMHU managed to increase its number of followers on **X** to 9,760 in 2023, 18% more than the previous year. The number of tweet impressions increased from 3.5M impressions to 3.7M in 2023.

This growth was also reflected in **LinkedIn**, where the Association increased its followers by 792, or 40%, to 2,753 in 2023.



8. Acknowledgements

All our work would not have been possible without the **backing**, **commitment and dedication of our partners**, whose collaboration and drive are essential to achieve the objectives we have set ourselves.

ALEXION AstraZeneca Rare Disease
Alnylam PHARMACEUTICALS
AMRYT PHARMA
argenx
biocryst
Biogen
BIOMARIN
Chiesi
CSL Behring Biotherapies for Life™
GenSight BIOLOGICS
ferrer for good
HORIZON
IMMUNOCORE
insmed
IPSEN Innovation for patient care
ITALFARMACO
Jazz Pharmaceuticals
KYOWA KIRIN
NOVARTIS
PTC THERAPEUTICS
sanofi
sobi
Takeda
ucb Inspired by **patients.** Driven by **science.**
ultragenyx
VERTEX

Thank you very much!
for your support and involvement

We would also like to express our deepest **gratitude to all the entities, personalities and institutions** that have worked and joined forces with us to contribute to improving the health and quality of life of people affected by rare diseases, to make them visible and to bring treatments closer to the patients who need them. We would like to make a **special mention to the Spanish Federation for Rare Diseases (FEDER)**, which represents and embodies the voice of patients, our very raison d'être.

feder
FEDERACIÓN ESPAÑOLA DE ENFERMEDADES RARAS
ASEDEF
ACE ASOCIACIÓN CONQUISTANDO ESCALONES
d'genes Asociación de Enfermedades Raras
Duchenne Parent Project España
AER ELX
AEGH ASOCIACIÓN ESPAÑOLA DE GENÉTICA HUMANA
agencia española de medicamentos y productos sanitarios

anis INFORMADORES DE LA SALUD
RETINA MURCIA
Bamberg Health
bio innova CONSULTING
canal sanitario
Castilla-La Mancha Consejería de Sanidad
Comunidad de Madrid CONSEJERÍA DE SANIDAD
Farmacéuticos Consejo General de Colegios Farmacéuticos

CSC Consorci de Salut i Social de Catalunya
CTO
EL ESPAÑOL
EURORDIS RARE DISEASES EUROPE
Executive Forum España
facme Federación de Asociaciones Científico Médicas Españolas
Fundación Weber
Faus Moliner

mehuer Fundación Medicamentos Huérfanos y Enfermedades Raras
SÍNDROME DE DRAVET FUNDACIÓN
FUNDACIÓN TEÓFILO HERNANDO I+D del Medicamento / Drug Discovery
visibles
GENERALITAT VALENCIANA Conselleria de Sanitat Universal i Salut Pública
GOBIERNO DE ARAGON

HAYS
SaludMadrid Hospital Universitario 12 de Octubre
ILUSTRE COLEGIO DE LA ABOGACÍA DE MADRID
IMMÉDICO
iier Instituto de Investigación de Enfermedades Raras
idis INSTITUTO DE INVESTIGACIÓN SANITARIA SANTIAGO DE COMPOSTELA
isc Instituto de Salud Carlos III

Conselleria de Salut Servei de Salut
ISPOR Spain Chapter
KREAB WORLDWIDE
LASKER
GOBIERNO DE ESPAÑA MINISTERIO DE CIENCIA E INNOVACIÓN
GOBIERNO DE ESPAÑA MINISTERIO DE SANIDAD
Región de Murcia Consejería de Sanidad

sefh Sociedad Española de Farmacia Hospitalaria
TORNOS ABOGADOS
Universidad Camilo José Cela
df
Universidad de Navarra
+++ 23_MonaLisas

Thank you very much!
for your support and involvement

Annual
REPORT
2023

aelmhu