



PAREA

PSYCHEDELIC ACCESS AND RESEARCH EUROPEAN ALLIANCE

# ANNUAL REPORT

2023

Psychedelic Access and  
Research European Alliance



[tadeusz@parea.eu](mailto:tadeusz@parea.eu)



[www.parea.eu](http://www.parea.eu)

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# Thank You For Supporting Our Mission



Our mission is to lead the charge in reshaping mental healthcare through the integration of safe, modern, and ethically responsible psychedelic-assisted therapies into mainstream European health services. From education to impacting policy, we are committed to making these therapies accessible and affordable as registered and reimbursed medical treatments for all. Our influence and collaborations extend to established European forums and EU institutions, fostering cooperation and formulating guidelines for responsible implementation.

## FULL MEMBERS



## ASSOC MEMBERS & OBSERVERS



## INDUSTRY PARTNERS



MindMed



## COMMUNITY SUPPORTERS



## A WORD FROM OUR FOUNDER

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### Tadeusz Hawrot

Dear friends, colleagues, and supporters,

2023 was an exceptional year for PAREA, marking a significant phase in our journey as we firmly established our role as a key convener in the European psychedelic space. Throughout the year, we achieved numerous important policy milestones, significantly influencing European Union health policies. These achievements not only underscore our commitment to the field but also reinforce our position as a pivotal player in shaping the future of psychedelic research and therapy within Europe.

As we reflect on these accomplishments, we wish to extend our heartfelt gratitude to everyone who has been a part of our journey. Crucially, PAREA is more than just an advocacy organization; it embodies a community of like-minded organizations and individuals. This is aptly captured by the Greek word "parea" denoting the sense of community, connection, and togetherness. United by a common goal, we strive to provide additional therapeutic options for those in need, aiding in their mental health recovery and overall wellbeing.

We look forward to continued collaboration and fostering meaningful partnerships as we work closely together in the upcoming year.

With my very best wishes,

*Tadeusz Hawrot*

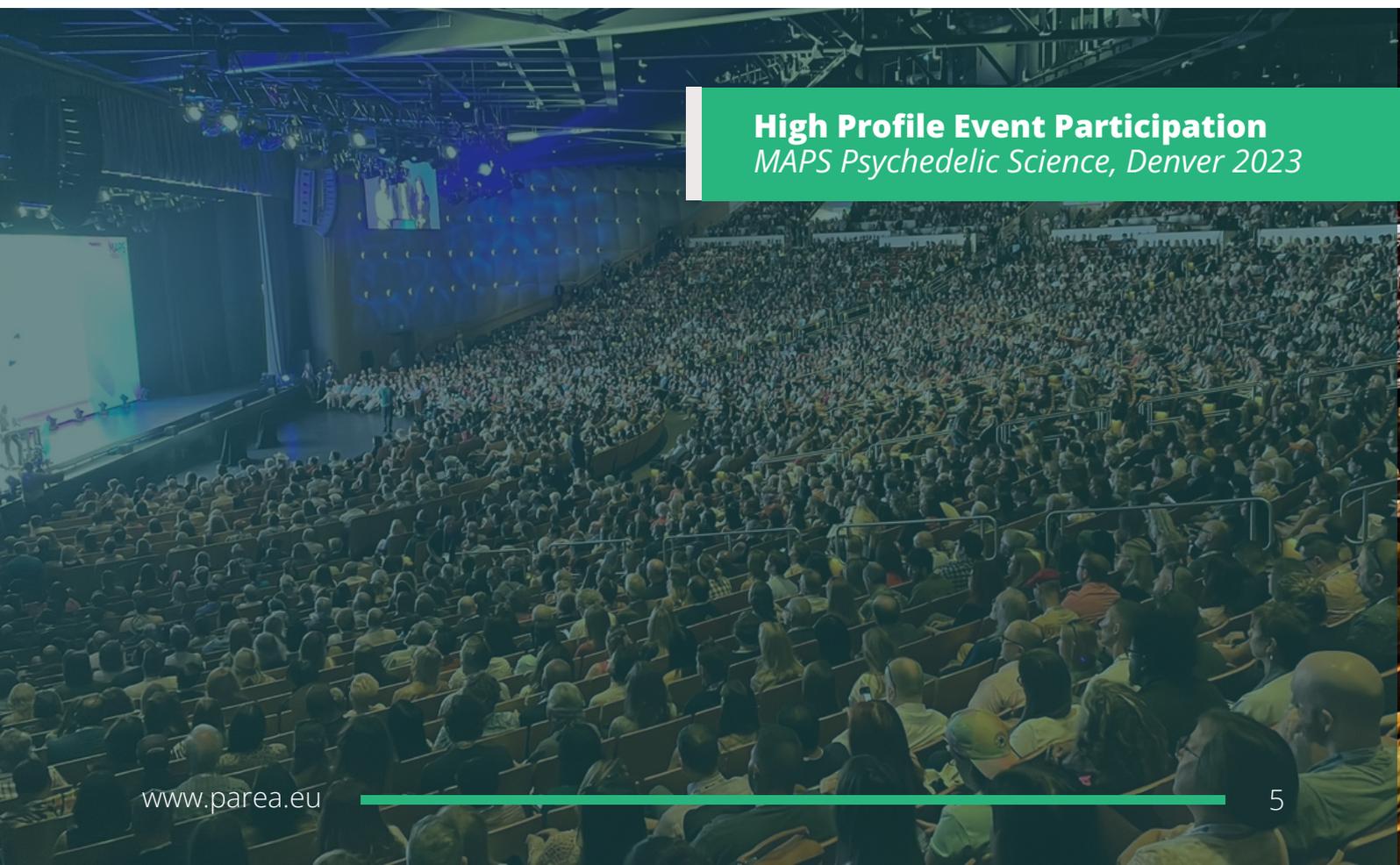


# 2023 Review

## Overview

In 2023, PAREA marked its first full calendar year with successful stakeholder engagements, several policy papers, being featured in numerous conferences in Europe and beyond, and the co-creation of the Members of the European Parliament Action Group on the Medical Use of Psychedelics. Notably, PAREA influenced the inclusion of psychedelics in an official EU document on mental health. The year culminated in a significant European Parliament event that we co-organized with PsychedelicsEUROPE. It was a key milestone, marking the launch of PAREA third policy paper this year, centred on the critical topic of unmet medical needs.

The momentum continued with our PAREA partnership annual meeting in Brussels. These two meetings reinforced our dual role as both a policy influencer and a vibrant community of like-minded organizations and individuals. These achievements, alongside various collaborations, define PAREA's progress in 2023, providing a robust foundation as we enter 2024. The organisation remains dedicated to advancing dialogue and contributing responsibly to the medical use of psychedelics.



**High Profile Event Participation**  
*MAPS Psychedelic Science, Denver 2023*

# Meetings & Conferences

## Overview

In 2023, PAREA actively participated in key events, including an expert meeting in Lisbon dedicated to psychedelics hosted by the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA). It is noteworthy that in 2024 the EMCDDA will expand its mandate, assuming the role of the EU Drug Agency.

A notable achievement during this period was the launch of the MEP Action Group for the Medical Use of Psychedelics in May. This collaborative effort between PAREA and PsychedelicsEUROPE brought together a total of 10 MEPs. These developments represent crucial milestones, highlighting the proactive role PAREA played in shaping the discourse surrounding psychedelic therapies.

MAR

### **EMCDDA (EU Drug Agency) "Technical meeting on the medical use of psychedelic substances: opportunities and concerns"**

PAREA Founder spoke at this meeting about psychedelics medicines to guide the EMCDDA work in this field.

MAR

### **2023 Congress of the European Federation of Psychology Students' Associations**

PAREA presented at the Congress, emphasizing the future role of the psychological profession.

JUN

### **MAPS Psychedelic Science, Denver 2023**

PAREA Founder shared more about PAREA's work in a policy session "From research to regulatory changes: Australia, the EU, and beyond"

JUL

### **PSYCH Symposium, London**

PAREA Founder and Members of the European Parliament shared a panel on the future of the psychedelics field within the EU.

AUG

### **INSIGHT, Berlin**

PAREA Founder spoke with other experts on the panel: Investing in Therapies or Molecules? Patients vs. Patents

SEP

### **New Molecules, Prague**

PAREA contributed to a series of discussions on the latest advancements in psychoactive molecules, their research, and legislative dimensions.

## Meetings & Conferences

Contd...

OCT

### **Annual Congress of the European Pain Federation EFIC, Budapest**

where, thanks to PAREA efforts, for the first time globally psychedelics were discussed among the pain scientific community. This is important as winning trust and engagement from scientific and clinical communities is a critical step in advancing psychedelic science and then integrating psychedelic care into routine clinical practice.

We are very grateful to PAREA's Vice-Chair Deirdre Ryan for making the following possible, and to James Close for taking up the challenge.

OCT

### **Advancing mental health research through networking and collaboration in Europe, the COST Association, Brussels**

PAREA Vice Chair Frederic Destrebecq presented about our work. Established in 1979, the COST Association - European Cooperation in Science and Technology - is dedicated to bridging the gap between science, policymakers, and society across Europe and beyond. It facilitates the creation of research networks, known as COST Actions, which are instrumental in fostering collaboration among scientists and propelling research advancements and innovation.

NOV

### **ALPS Geneva Conference, Geneva**

PAREA Founder, spoke on the panel "Policy, Regulation and Access"

NOV

### **Family Offices meeting of funds allocators**

PAREA Founder sat on the panel.



**T. HAWROT SPEAKING AT ENCP**  
*New Frontiers, Nice*

## Policy Meetings 2023

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- WHO Europe senior policy advisor **Sarah Garner** leading the WHO Novel Medicines Platform (*January*)
- EFPIA R&D Working Group (*February*)
- **Patrick Boisseau**, DG, MedTech Europe (*February*)
- EMA CMO **Steffen Thirstrup** (*March*)
- **Stefan Schreck** DG SANTE (*April*)
- The office of MEP **Bartosz Artukowicz** (*May*)
- MEP **Radka Maxova** (*May*)
- MEP **Alex Agius Saliba** (*May*)
- The office of MEP **Alviina Alametsä** (*May*)
- **Christine Kriza**, DG RTD, EC (*May*)
- EURACTIVE reporter **Giedre Peseckyte** (*May*)
- **Loukas Georgiou**, Permanent Representation of Cyprus (*May*)
- The office of MEP **Cyrus Engerer** (*May*)
- EMA CMO **Steffen Thirstrup** (*October*)
- **Tim Raemaekers**, DG Research (*November*)
- **Luisa Antunes**, European Parliament Science Technology Options Assessment (*November*)

## Advocacy

Day-to-day advocacy is our bread and butter work and, while often invisible, plays a critical role in advancing the field. The 2023 highlights included:

In two letters, inspired by PAREA, six senior Members of the European Parliament (MEPs) have urged the European Medicines Agency and the EU drug agency EMCDDA to take a more active role in addressing challenges associated with the adoption of psychedelic therapies. The letters highlighted the opportunity for these agencies to collaborate and provide crucial information and guidance to EU policymakers, facilitating well-informed decisions which could also serve as a model for global policymakers.

In response to the letters, the two EU agencies expressed their support for a need to explore psychedelic therapies to address mental health conditions, and announced a tighter collaboration in this regard. Moreover, following the request from the MEPs, the EMA announced plans to hold a multi-stakeholder workshop focusing on promoting the development of psychedelics that address unmet medical needs.



16/02/23

EP Letters to:

- > **EMA**
- > **EMCDDA**



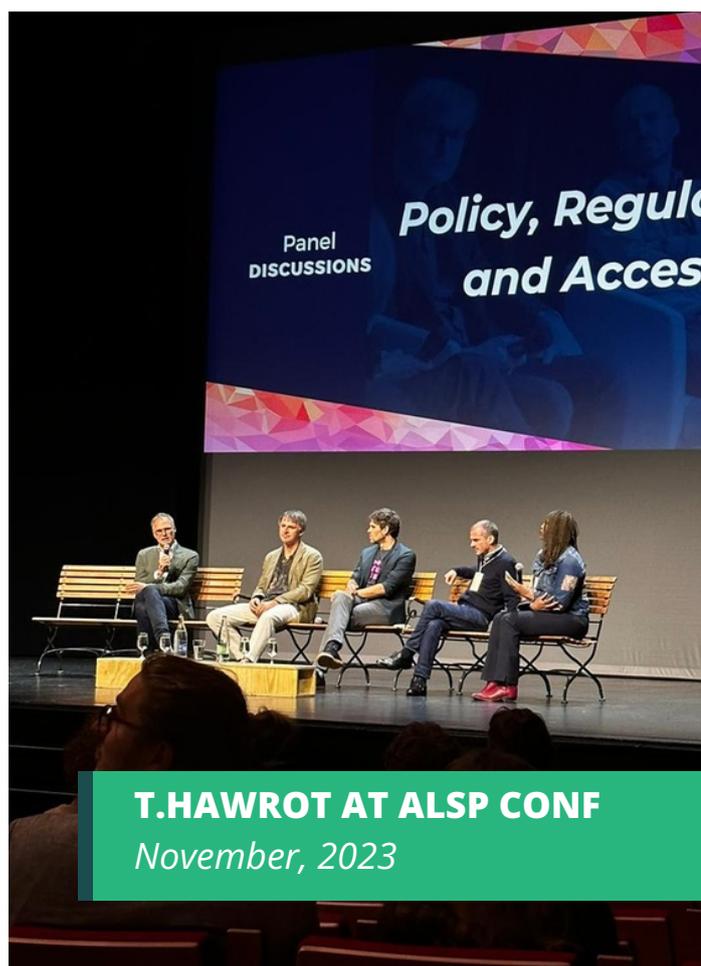
03/03/23

**EMA reply**  
to MEPs letter



23/03/23

**EMCDDA reply**  
to MEP letter



## MEP Action Group

MEP Action Group for the  
Medical Use of Psychedelics

### MEP Action Group For The Medical Use Of Psychedelics

We are proud to have played a pivotal role in the launch of the MEP Action Group for the Medical Use of Psychedelics which was launched in May, marking the European Mental Health Week. MEPs are now coming together to actively shape the course of action in this area. Among its objectives, the group comprising 10 MEPs serves as an educational resource and platform for EU policymakers to increase awareness of evidence-based psychedelic science and decrease associated stigma.

At the inaugural meeting of the MEP Action Group for the Medical Use of Psychedelics held in May at the European Parliament in Brussels, co-organized by PAREA and PsychedelicsEUROPE, diverse stakeholders, including researchers, industry representatives, patients, and policy advocates, convened to discuss the clinical application of psychedelics in the EU.



**Prof. David Nutt**  
*MEP Action Group Launch, May 23*

The first external meeting of the Action Group took place in November, coinciding with the ongoing discussions on the revision of the EU pharma package. It focused on creating a supportive regulatory environment to foster innovation in novel mental health treatments, particularly psychedelic therapies. The gathering underscored the urgency of addressing unmet medical needs in the EU and the potential of psychedelic therapies to offer rapid, durable improvements for conditions such as depression and PTSD.



[Visit MEP Action Group for the Medical Use of Psychedelics on our Website](https://www.parea.eu)

# Policy Papers & Consultations

Complementing our advocacy efforts, PAREA has been shaping the EU policies by offering our recommendations on crucial scientific, regulatory, and policy advancements relevant to psychedelic therapies. In 2023 PAREA, released the following policy recommendations:

## Policy Papers

In 2023 PAREA released multiple policy papers and an EU elections manifesto to further the agenda of progressing scientific based policy reform and therapeutic potential for novel medicines, including psychedelics.

Position statement:

### **Leveraging the EU Pharma Package**

The comprehensive document, initially framed as a response to the EU Pharmaceutical Package, extended its reach to cover the full lifecycle of medicines, emphasizing the urgent need to incentivize the development of novel mental health treatments, particularly psychedelic therapies, which had shown promising results in reducing mortality and morbidity in several mental health conditions and substance use disorders.

➤ [Read This Paper](#)



### **Laying the groundwork for psychedelic therapies: insights for the EMA workshop and beyond**

In September, PAREA submitted a policy brief to the EMA calling for the establishment of a multidisciplinary advisory body. Prepared in anticipation of the EMA's upcoming multistakeholder workshop on psychedelic therapies, the brief underscores the critical need for the active involvement of psychedelic organizations in shaping the future of these transformative treatments. Following this, PAREA received a response from the EMA who said it is committed to seriously considering the content of our brief and to dedicating the necessary time and resources to ensure that the workshop is both broad and comprehensive.

➤ [Read This Paper](#)

## Policy Papers Contd...

PAREA EU 2024

### Elections Manifesto

In October, PAREA announced the release of its manifesto for the EU Parliament elections in 2024, focusing on transforming mental health care through psychedelic therapies. As Europe grapples with a rising mental health crisis, it offers a forward-thinking approach, advocating for the EU to prioritize mental health and explore innovative treatments. The manifesto also proposes the creation of an EU inter-institutional task force to establish guidelines for the safe and equitable use of psychedelic therapies.

➤ [Read This Paper](#)



POLICY PAPER

### Unmet Medical Needs

In conjunction with the November meeting of the MEP action group, we launched a policy paper challenging the narrow definition of high unmet medical needs. The paper urged urgent expansion of criteria to include the prevalence of conditions and their societal impact, emphasizing the chronic burden of mental health and substance use disorders. To address these issues, PAREA called for the establishment of a European Hub for Mental Health R&D, aiming to unite institutions, member states, funders, and organizations to drive innovation and address substantial unmet medical needs in mental health care across Europe.

As the EU revised its pharmaceutical legislation, PAREA's policy paper served as a vital voice advocating for a recalibrated approach aligning medicine development with public health priorities and societal needs, urging action from policymakers and healthcare professionals across Europe.

➤ [Read This Paper](#)

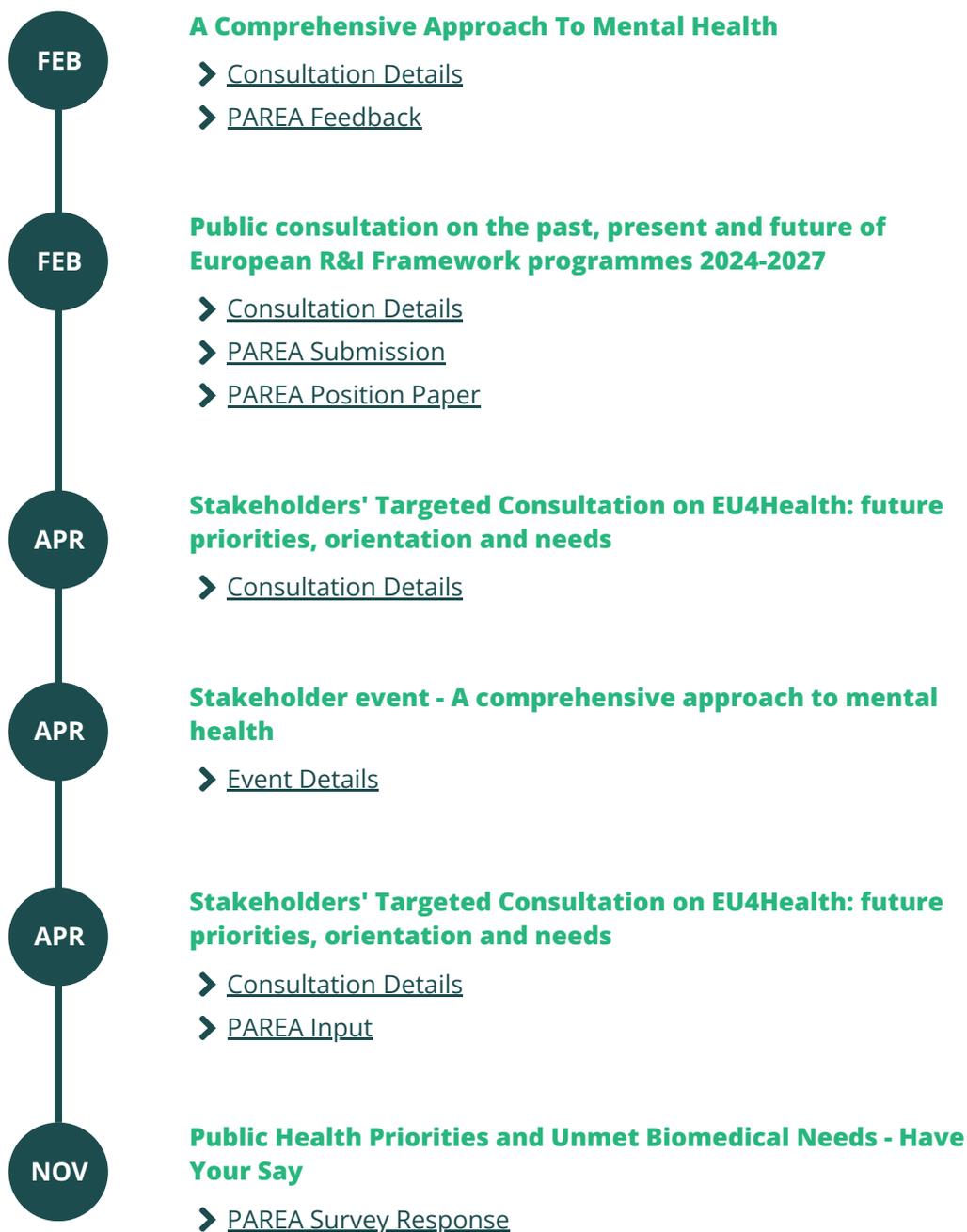


### First Official Recognition In EU Document

In a historic move, psychedelic therapies were officially recognized in an EU document for the first time as the European Economic and Social Committee (EESC) adopted an opinion entitled "**Measures to Improve Mental Health,**" in response to a request by the Spanish EU Presidency. The opinion acknowledged the potential of psychedelic therapies for severe conditions like depression, PTSD, and alcohol use disorder, urging increased research funding and development. PAREA, having advocated for this inclusion, is heartened by the EESC's recognition of the promise of psychedelic novel medicines.

# Policy Consultations

In addition, we participated in the following EU policy consultations:



## EU Insights

In 2023, PAREA launched its newsletter “EU Insights”. The goal is to share the latest relevant policy news from Europe such as the EU funding opportunities, updates on the clinical trials and reimbursement landscape, Health Technology Assessment developments as well as changes in drug policies. The insights also cover ongoing PAREA work and achievements. The newsletter is going out regularly every 4-6 weeks and 8 issues were released in 2023. There is a free and PRO version for paid subscription.

### 2023 Issues

- [Issue 1](#)
- [Issue 2](#)
- [Issue 3](#)
- [Issue 4](#)
- [Issue 5](#)
- [Issue 6](#)
- [Issue 7](#)
- [Issue 8](#)



## News Releases

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PAREA news releases aim to highlight and educate our community on significant milestones, including research and clinical trials, international policy changes, medical healthcare, and other noteworthy events. The following news released were distributed in 2023:

- [Confirmation of a second successful Phase 3 trial of MDMA-assisted therapy for PTSD](#) *January*
- [Rapid and durable response demonstrated in the first placebo-controlled study exploring a short-duration psychedelic for depression](#) *January*
- [Australia becomes the first country to introduce psychedelic novel therapies to its medical healthcare](#) *February*
- [EMA, national regulators, and ECNP's Lancet commentary "The Therapeutic Potential of Psychedelics: The European Regulatory Perspective"](#) *February*
- [PAREA Annual Report, FAQ and scientific event on psychedelics in Europe](#) *March*
- [The American Medical Association \(AMA\) has issued its first CPT code for psychedelic treatments](#) *April*
- [MEP Action Group for the Medical Use of Psychedelics launched](#) *May*
- [Behind the scenes of psychedelic trials: participant's perspective](#) *June*
- [News release: UN, EMCDDA & FDA reports + Nature study on critical periods](#) *June*
- [News flash: EESC report on mental health](#) *July*
- [Position statement: Leveraging the EU Pharma Package](#) *July*
- [European Parliament event spotlights PAREA's policy paper on rethinking unmet medical needs criteria](#) *November*
- [Submission of New Drug Application to the U.S. FDA for MDMA-Assisted Therapy for PTSD](#) *December*
- [EMA to host a "multi-stakeholder workshop on psychedelics – Towards an EU regulatory framework" in April 2024 in Amsterdam](#) *December*

## Collaborations

PAREA fostered collaborative endeavors by co-signing impactful statements, advocating for sustainable funding for civil society organizations, alongside active participation in initiatives within the European Parliament.



**Mental  
Health  
Europe**

**The HPP Mental Health in all Policies  
Thematic Network Joint Statement**

PAREA Co-Signed



**Support Pledge for Science calling for the  
prioritisation of brain research & innovation  
in the EU**

PAREA Co-Signed



**Joint statement on sustainable funding for  
(health) civil society organisations (CSOs)**

PAREA Co-Signed

# Media Engagement

We continue to make great strides by engaging with strategic media such as POLITICO Europe which has been covering our work on multiple occasions. Selected media coverage includes:

	<p><b><u>Brain health conditions: Excellence in psychedelic treatments</u></b></p>	<p><b><u>POLITICO wrote about positive results from the MDMA third stage trial and about PAREA news release announcing it</u></b></p>
<p><b><u>Psychedelic Health number 2 of #PsychedelicMoments for 2022 was the launch of PAREA and number 6 was our EP event and appeal to the policymakers</u></b></p>		<p><b><u>The emergence of psychedelic-assisted therapies</u></b> T. Hawrot featured in the Video Journal of Neurology podcast</p>
<p><b><u>PAREA 2023: campaigning for psychedelic therapy in Europe</u></b></p>	<p><b><u>In what marks an important development for Europe, a number of EU bodies have published a joint commentary in the world-leading medical journal, The Lancet, acknowledging the therapeutic potential of psychedelics</u></b></p>	
	<p><b><u>Europe needs faster action on magic mushroom, MDMA therapies, urge MEPs</u></b> February re. the EMA/EMCDDA letter</p>	
<p><b><u>MEPs urge European regulators to move faster on psychedelics</u></b></p>	<p><b><u>The Medical Potential of Psychedelics: A View from the European Union</u></b></p>	

# Media Engagement Contd...

<p><b><u>Morning Healthcare Bulletin</u></b> 10th March, 2023</p> <p>POLITICO</p>	<p><b><u>European Medicines Agency to hold psychedelics workshop in 2023</u></b></p> <p>PsychedelicHealth</p>	
<p><b><u>The EU is Inching Closer to a Psychedelic Renaissance</u></b></p> <p>Psychedelics, Consciousness Technologies, and the Future of Wellness LUCID NEWS</p>	<p><b><u>Morning Healthcare Bulletin</u></b> 30th March, 2023</p> <p>POLITICO</p>	<p><b>Why Europe needs to catch up with psychedelic research</b></p> <p>David Nutt FMedSci, Chair Drug Science and PAREA, Prof of Neuropsychopharmacology at Imperial College London, explores why Europe needs to catch up with psychedelic research.</p> <p>Why Europe needs to catch up with psychedelic research PAGE 1   PAGE 2</p> <p>OPEN ACCESS GOVERNMENT</p>
<p><b><u>Building for the future: preparing for equitable access to psychedelic medicines in the EU</u></b></p> <p>PsychedelicHealth</p>	<p><b><u>Morning Healthcare Bulletin</u></b> 13th April, 2023</p> <p>POLITICO</p>	
<p><b><u>Morning Healthcare Bulletin</u></b> 24th May, 2023</p> <p>POLITICO</p>	<p><b><u>Global Conversation On Psychedelic Therapy: Perspectives From Europe And The UK</u></b></p> <p>BENZINGA</p>	
<p><b><u>European Parliament launches medical psychedelics action group</u></b></p> <p>Mugglehead MAGAZINE</p>	<p><b><u>EU lawmakers to steer discussions on therapeutic use of psychedelics</u></b></p> <p>EURACTIV</p>	
<p><b><u>Psychedelics milestone for Europe: MEP Action Group launches</u></b></p> <p>PsychedelicHealth</p>	<p><b><u>Psychedelic therapies: The case for a new focus in the EU's mental health care approach</u></b></p> <p>OPEN ACCESS GOVERNMENT</p>	<p><b><u>PSYCH Symposium: the future of psychedelic medicine in the EU</u></b></p> <p>PsychedelicHealth</p>
<p><b><u>Australia becomes first country to legalise medical psychedelics</u></b></p> <p>TVP WORLD</p>	<p><b>THE DRUG SCIENCE PODCAST</b></p> <p><b>Psychedelics in Europe</b></p> <p>Hosted by: Prof David Nutt Featuring: Tadeusz Hawrot and Frédéric Destrebecq</p> <p><b><u>Psychedelics in Europe with Tadeusz Hawrot and Frédéric Destrebecq</u></b></p> <p>Drug Science</p>	

## Media Engagement Contd...

**Psychedelics should be at forefront of EU mental health efforts, urge PAREA**



**Morning Healthcare Bulletin**

24th July, 2023

POLITICO

**Experienced trippers should advise on Europe's use of psychedelics, says lobby.**

5th September, 2023

POLITICO

**PAREA calls for psychedelic advisory body.**

**| Morning Healthcare Bulletin**

6th September, 2023

POLITICO

**Experienced trippers should advise on Europe's use of psychedelics, says lobby.**

9th September, 2023

POLITICO

**Psychedelics advisory body needed in Europe, says PAREA**

13th September, 2023



**PAREA launches psychedelics manifesto for mental health in Europe**

25th September, 2023



**EMA developments and PAREA input re. the workshop | Morning Healthcare Bulletin**

15th September, 2023

POLITICO

**PAREA Promotes Psychedelic Access and Research Across Europe**

15th September, 2023



**Unmet needs position paper, MEP AG | Morning Healthcare Bulletin**

6th November, 2023

POLITICO

**PAREA's psychedelic push: improving policy for mental health innovation in Europe**

9th November, 2023



**MEP Action Group Meets in Brussels to Discuss Regulatory Pathways for Psychedelics**

8th November, 2023



**MEPs call for EU to support research into the use of psychedelic drugs in treating mental health disorders**

9th November, 2023

POLITICO

**Psychedelics are "driving the day", reflecting the latest updates on efforts across several EU countries to facilitate access to psychedelics as medicines.**

8th December, 2023

POLITICO

# Expanded Membership & Support

PAREA is dedicated to fostering a sense of community, promoting collaboration and knowledge-sharing among professionals, researchers, and individuals interested in advancing the field. PAREA strives to create a supportive network that enhances the impact of psychedelic therapies and contributes to the growth and acceptance of these innovative approaches within the European Union.

## COMMUNITY SUPPORTERS



## ACKNOWLEDGEMENTS TO OUR DONORS

In a year filled with growth and significant milestones, our achievements were made possible through the generous support of our donors. We extend our deepest gratitude to the Osmond Foundation (now, Norrsken Mind), MindMed, and Cybin for their unwavering belief in our mission. Additionally, we are profoundly thankful for an anonymous philanthropic donation that has greatly contributed to our efforts. Each contribution has been a cornerstone in advancing our initiatives, enabling us to make strides in psychedelic research and access. Your support empowers us to continue our work, fostering innovation and expanding therapeutic options for mental health. Thank you for being an integral part of our journey and for your commitment to making a difference in the lives of those we serve.



MindMed



## WEB STATS

UNIQUE VISITORS

**9K**

+ 32% yr/yr

PAGEVIEWS

**19K**

+ 35% yr/yr

VISITS

**11K**

+ 25% yr/yr

**Viewing Geography:** 96 countries, 6 continents



# PAREA

PSYCHEDELIC ACCESS AND RESEARCH EUROPEAN ALLIANCE

## Who Are PAREA?

We are a non-profit, membership-led, multistakeholder and multidisciplinary partnership. We bring together patient organizations, medical associations, scientific societies, umbrella coalitions, psychedelic foundations, and for-profit sector.

For more information & to support our mission:

 [www.parea.eu](http://www.parea.eu)

 [tadeusz@parea.eu](mailto:tadeusz@parea.eu)

**TADEUSZ HAWROT**

Founder and Executive Director

## FULL MEMBERS



## ASSOCIATE MEMBERS & OBSERVERS



## INDUSTRY PARTNERS