



PAREA
PSYCHEDELIC ACCESS AND RESEARCH EUROPEAN ALLIANCE

PAREA EU Elections Manifesto 2024

Transforming Mental Health Treatments
Through Psychedelic Therapies



The urgent need for new therapeutic approaches

In an era where mental health deterioration is recognized as a significant global risk to societies and economies (World Economic Forum's Global Risks Report, 2023), the urgent need for innovative therapeutic interventions is greater than ever. The OECD reports that half of the population will be affected by a mental illness at some point in their lives. Furthermore, the European Medicines Agency (EMA) notes that 50% of individuals treated for mental health issues experience resistance or an incomplete response to existing treatments. 7.2% of people in the EU, approximately 32 million, are burdened by chronic depression—a disorder closely associated with a high suicide risk. The severity of this crisis is emphasized by the tragic statistic of 130,000 suicides in Europe each year. In the timespan from 2016 until now, suicide has claimed over one million lives in Europe.

Current efforts to help people with mental health conditions are falling short in the face of the escalating crisis. For instance, in the past year, out of 89 new medicines recommended for approval by the EMA, not one targeted mental disorders. This highlights a concerning stagnation in innovation within the field of psychiatry over the past three decades, with the only advancement being the reduction of side effects for existing drugs. This lack of progress underscores the urgent need for novel, effective treatments for mental health disorders.



The EU must prioritize novel mental health approaches in its policy agenda, recognizing the urgency of the situation and the need to incentivize innovative solutions.

Psychedelic novel treatments are becoming reality across the globe

In the face of such challenging circumstances, psychedelic therapies are emerging as a powerful class of treatments, holding the potential to revolutionize our approach to mental health care. They offer hope for the many currently suffering, particularly for those who find little solace in existing treatment options. The global medical and regulatory community is beginning to recognize the value of psychedelic therapies. Australia has become the first country to regulate their medical use for treating PTSD and depression. The US might approve the first psychedelic therapies as early as 2024. **It's highly likely that Europe will follow suit, with psychedelic therapies reaching patients during the next term of the European Parliament—signifying a ground-breaking shift in mental health treatment.**



The EU must support the development and meaningful regulation of psychedelic therapies, recognizing their potential to transform mental health care.

The impact of psychedelic therapy: beyond symptom management

An increasing number of studies with these innovative therapies demonstrate effectiveness for conditions such as depression, anxiety, alcohol use disorder, or end-of-life distress. They unveil safe, rapid-acting, and significant clinical improvements with enduring effects. A pharma industry (EFPIA) **report** suggests that psychedelics (psychoplastogens) could reduce long-term antidepressant usage, diminish the need for informal care, and alleviate chronic healthcare system resource usage through the lasting benefits of therapy sessions.

Many existing mental health treatments manage symptoms. By contrast, psychedelic therapies are experiential treatments that guide patients to confront the root causes of their mental health issues by lowering psychological defence mechanisms. Coupled with a safe and supportive environment, they can catalyse a therapeutic state that fosters insight and emotional release, helping individuals to connect to their own innate healing intelligence. This shifts a focus from *“how to treat mental health conditions”* to *“how to help people engage in the process of recovery?”*.

Importantly, clinical research shows that psychedelic medicines without accompanying support systems and integration practices are often not enough. Meaningful and durable changes in lifestyle and thought patterns require further psychological guidance and can be most effective when integrated in a wider array of community-based mental health services, peer support groups and context-specific support structures.



The EU must recognize the unique combination of psychedelic medicines and therapy, support future aftercare provision, and promote the adoption of sustainable integration models.

Advancing Equitable Access and Collaborative Infrastructure in Europe

As we prepare for the likely approval of psychedelic medicines in Europe in the coming years, we need to begin developing the required expertise and infrastructure for safe, high-quality, affordable, and equitable access. We need to ensure that psychedelic novel treatments are accessible and affordable for those who need them most to prevent disparities in access. Otherwise, those who are most in need might be left without access, including lower-income, socio-economically deprived communities which are disproportionately affected by mental health problems and addictions.

While respecting each member state's area of competence in health, the EU can offer a platform and resources to aid countries in coordinating and preparing for the roll-out of psychedelic treatments. This can be achieved through piloting best practices and the establishment of European guidelines that countries can voluntarily follow as they devise frameworks and structures to integrate these therapeutic modalities into their healthcare systems. Such streamlined coordination would ensure the most efficient use of limited resources, as opposed to having individual EU countries working in isolation.

To start this work, an EU inter-institutional task force or a multi disciplinary advisory body could be created, involving a broad range of stakeholders, including scientists, policymakers, healthcare professionals, regulators, HTA bodies, patient organizations, mental health communities, psychedelic organizations and drug developers. It would enable building expert consensus towards standards of care and of training, as well as ethical guidelines of practice and safe and ethical use monitoring.



We call on the EU to foster collaboration and provide a platform and resources to aid in the development and implementation of effective and sustainable care provision models for psychedelic therapies.

Leveraging existing funding structures and policy initiatives

Existing health initiatives like the current revision of the pharmaceutical package and the newly published EU initiative on a comprehensive approach to mental health present an ideal opportunity to drive equitable access and incentivize innovative mental health approaches. Previously, the EU has demonstrated that it can prioritize certain therapeutic areas, such as cancer, rare diseases, and paediatric medicines, in response to high societal needs. It's time we extended this approach to innovative mental health treatments.

Given the overall shortage of mental health professionals, it is likely that the insufficient number of psychedelic therapists will create a critical bottleneck for access. In order to increase the pool of providers who are trained, a system needs to be created that also incentivizes therapists to adopt these new treatments. This will require education about the evidence for and value of those treatments and support for health professionals' training, including the development of standardizing training curricula. Eventually, training curricula should be integrated into existing mental health graduate programs so that clinicians can graduate with the qualifications they need to practice.

The development of evidence-based protocols for the delivery of psychedelic therapies, and education and knowledge sharing for HCPs can be supported through initiatives like the EU4Health Programme and the EU comprehensive approach to mental health.



The EU must incentivize the development of psychedelic therapies and ensure their accessibility and affordability when they become approved, as well as to support HCPs to make these therapies part of their practice by providing adequate resources.

Illuminating the pathway to psychedelic therapies: the demand for comprehensive scientific research in the EU

There is a pressing need for further research to examine the efficacy and safety of psychedelic drugs for brain disorders, including the effects of repeated exposure and potential interactions with existing pharmacological treatments. Additionally, studies should be pursued to shed more light on psychotherapeutic processes responsible for the therapeutic effects of psychedelics. Such studies can help refine treatment approaches and achieve better target engagement. From a fundamental neuroscience perspective, there is a need to elucidate what happens at molecular, cellular and network levels. The improved understanding could be used to develop better, safer, or more accessible substances or treatments. Moreover, uncovering the mechanisms of psychedelic drugs may show who exactly these drugs can help and in what contexts.



The EU must prioritize and fund basic research on psychedelic therapies under the Horizon Europe and other relevant research schemes.

In Closing

In this pivotal moment for mental health care, we must seize the opportunity to explore and embrace innovative solutions like psychedelic therapies. As PAREA, we are committed to fostering dialogue, enhancing research, and supporting policy changes to usher in a new era of mental health treatment in Europe. Together, we can ensure a healthier, more compassionate future for all, and bring tangible benefits to your constituents who are currently underserved by existing mental health care solutions.

We owe it to so many people who could benefit from these treatments and yet might be left without any real access once they are approved. We call on all prospective and incumbent MEPs and European commissioners, member states, and the broader community, to join us in this effort to support mental health care through the use of psychedelic novel therapies.

By supporting this initiative, you have a chance to demonstrate leadership in innovative healthcare solutions and ensure that Europe remains at the forefront of global health initiatives. Embrace this opportunity to make a lasting, positive impact on the lives of millions of Europeans.

Let us not let this opportunity pass. The need is urgent, the potential is enormous, and the time to act is now. In doing so, we can help transform mental health care in Europe and contribute to the wellbeing of millions of Europeans. Together, let's make this vision a reality.



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



tadeusz@para.eu

TADEUSZ HAWROT

Founder and Executive Director

OUR MEMBERS



BECKLEY
FOUNDATION

