PAREA CALL TO ACTION

Psychedelic-Assisted Therapies in Europe

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Psychedelic-assisted therapies (PATs) show a promise of being a potent new class of treatments for mental, neurological, and substance use disorders, as suggested by the rapidly growing, rigorous, and compelling body of research published in journals such as Lancet, Nature Medicine, and New England Journal of Medicine.

The renaissance of research into psychedelic compounds represents one of the most promising initiatives in brain science and neuropsychopharmacology in recent times, especially given the vast unmet needs in the therapeutic areas that they show promise to treat and the lack of relevant pharmaceutical innovations in recent decades. Psychedelic compounds like psilocybin and MDMA have a relatively safe risk-benefit ratio. The fundamental therapeutic benefit of PATs comes from the combination of psychedelic medicine and psychotherapy.

European health systems are not prepared for these treatments - a lot remains to be done to pave the way for their effective rollout and to build a proper medical oversight into the psychedelic model. Without adequate actions, PATs may not reach patients who need them or may drive them to seek unregulated underground therapy as psychedelics' medical properties are coming into mainstream knowledge. The work must start now to ensure equitable, timely, affordable, safe and legal access to PAT in the near future. Patients should have them covered within their existing healthcare framework, where they live, by a trained therapist they trust, and paid by healthcare insurance. Otherwise, those most in need will be left without access, including in lower-income and socioeconomically deprived communities, which are disproportionately affected by mental health problems and addictions.

With this in mind, the following points represent PAREA Call to Action to European decision-makers:

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Boost EU-funded research for psychedelic science

- Address the regulatory, financial and cultural barriers which weigh on scientific research into the use of psychedelic compounds for medicinal and other purposes.
- Provide funding opportunities within existing EU programmes, such as Horizon Europe and Innovative Health Initiative, to meaningfully increase scientific and clinical evidence on the safety and efficacy of PATs.
- Prioritize clinical research on non-pharmacological factors, particularly around optimal and long-lasting support for participants at all treatment phases (i.e. before, during, and after treatment sessions).

Create robust European psychotherapeutic standards

- Develop and preserve high-quality standards of care and rigorous training criteria to ensure that participants are getting safe and qualified care, including sufficient quality post-session therapeutic support to mitigate any potential negative effects of challenging experiences that can arise during the session.
- Develop strong ethical guidelines charting work with patients in altered states of consciousness, and firm intervision and supervision guidelines.
- Increase general investment in mental health care and expertise which can be a critical enabler for effective integration of post-psychedelic-treatment care into existing frameworks such as community mental health care structures including organizations specialized in domestic, or sexual violence, etc.

Foster competitive clinical trials and regulatory framework for PATs in Europe

- Support and incentivise pharmaceutical innovation in the field of novel psychedelic treatments, especially through the upcoming EU Pharmaceutical Strategy, by leveraging a more agile and flexible regulatory framework to accelerate the drug development of PATs.
- Reassess Member States' current Health Technology Assessment methods to ensure that they are appropriate for the specificities of PATs, and consider new methods for evidence generation and assessment.
- Increase stakeholder collaboration, including patient groups, to agree on core data requirements and support policy action to produce high-quality data including real-world evidence.
- Establish an EMA committee for the assessment of PATs similarly to the Committee for Advanced Therapies.

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Foster evidence-based drug policies to catalyse psychedelic innovation in the areas of huge unmet needs

Despite their enormous healing potential, psychedelic compounds remain in the most restrictive category of the UN drug convention with "no accepted medical use with high potential for abuse". The EU should:

- ✓ Follow an evidence-based approach to drug policies and conduct a study to reassess the classification of psychedelic compounds such as psilocybin, MDMA, and LSD, taking into account the latest scientific progress.
- ✓ Make recommendations to the UN CND, if the evidence indicates a public health benefit for rescheduling those compounds. This will allow for scheduling them at a level of control that will prevent harm caused by their inappropriate use and - at the same time - will not act as a barrier to R&D and access to PATs.

Develop European standards regarding training and infrastructure - before PAT are approved - to build the patient access infrastructure that can meet the existing needs

PATs are a paradigm shift in the pharmacological space. They are a combination of a drug and psychotherapy - psychedelic medicine is a catalyst for treatment, not a treatment in itself. To successfully scale up those treatments, the EU should:

- ✓ Create a pipeline for training and credentialing PAT facilitators and generate a system of clinics through which they can practise.
- ✓ Develop certified European curricula for psychiatrists and therapists, including creating educational materials for other medical professionals. In the long term, this could create a pathway to make training in PATs available to medical schools as an accredited specialty.
- ✓ Identify additional healthcare or para-medical professionals that can be trained in psychedelic assisted therapy assistance.

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