PAREA
PSYCHEDELIC ACCESS AND RESEARCH EUROPEAN ALLIANCE

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

PAREA welcomes the EMA's proactive approach in investigating psychedelics as potential treatments for mental health conditions, as evidenced by the publication of the Lancet Comment. We are particularly heartened by the announcement of the EMA-led, multistakeholder workshop which aims to further the development of psychedelics that address unmet medical needs. In light of this, PAREA has prepared this brief to provide insights and recommendations that can guide the preparations and discussions for the upcoming workshop.

This year, PAREA has been at the forefront of advocating for the responsible and evidence-based development of psychedelic therapies. We have released two pivotal position statements:

1. A position paper regarding the revision of the EU pharmaceutical legislation, emphasizing the urgency of incentivizing the development of innovative mental health treatments. This statement also invites the EMA to consider the establishment of a dedicated body to streamline the development and approval of combination therapies, which includes psychedelic treatments.

2. A comprehensive outline detailing our recommendations for EU research priorities in the realm of psychedelic science for Horizon Europe 2025-2027 strategic plan.

Challenges and complexities of psychedelic therapies

Navigating the complexities of combination therapies is a challenge. The current regulatory system, designed for traditional medicines, does not fully address the intricacies of therapies like psychedelic treatments. Unlike many other treatments, psychedelic therapies require a controlled setting and likely further psychotherapeutic support, although more research and data are crucial to better elucidate the role of therapies in the psychedelic treatment paradigm.

As such, the transition from clinical trials to institutional healthcare settings presents its own set of challenges. The importance of ensuring that the therapeutic model adopted is evidence-based and in the best interest of the patients cannot be overstated.

Strategic planning and the role of the advisory body

Given these complexities, strategic planning and professional cohesion become paramount. Establishing expert consensus in areas like standards of care, training, ethical guidelines, and data collection standards is essential. To meet these needs, **we recommend the establishment of a multidisciplinary advisory body.** This body would benefit from the collective knowledge of various stakeholders, including the EMA, EMCDDA, national competent authorities, professional organizations, healthcare professionals and managers, psychedelic organizations, patients' organizations, drug developers, and the wider community. It would play a pivotal role in guiding policy and the implementation of psychedelic therapies in Europe. The advisory body could periodically issue reports with recommendations, providing insights and direction for the field.

EMA's leadership and the collective endeavour

The likelihood of a successful deployment will hinge significantly on proactive measures from the EU institutions and Member States. The EMA is ideally positioned to spearhead the development and approval of psychedelic therapies. Centralized coordination would offer an efficient mechanism to propel the field forward, rather than individual EU countries initiating their own work groups.

Training, accreditation, and professional oversight

If psychedelics gain approval for clinical use, they will likely be prescribed by specialists like psychiatrists. Training and accreditation of medical staff in the domain of psychedelic therapies are paramount. A potential solution could be to establish two tiers of psychedelic-focused training: one tailored for therapists administering psychedelic therapies and another for those prescribing the treatments. Eventually, the authority to prescribe and administer psychedelics could be expanded to include other medical professionals, such as general physicians, palliative care experts, nurses, and GPs, provided they attain the necessary accreditation. Both training programs and the clinicians partaking in them should be accredited through a specialized professional association. **We advocate for the creation of a dedicated cross-disciplinary professional entity to supervise the sector.**

Patient involvement and insights

The involvement of people with lived experience is vital. Patients are the real experts in their conditions, and their insights must be integrated at every step of the way. The advisory body would benefit immensely from the inclusion of these voices.

PAREA is keen to be actively involved in the preparations for the EMA workshop and be seen as an important player when discussing the post-workshop vision. We believe that our expertise and experience can provide valuable insights and contribute to the success of this work.

As preparations for the EMA workshop get underway, we hope this brief serves as a useful resource. We anticipate that the discussions and outcomes of the workshop will be instrumental in shaping the future of psychedelic therapies in the EU.