

# Psychedelic therapies: The case for a new focus in the EU's mental health care approach

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## Tadeusz Hawrot, Founder and Executive Director of PAREA, states the case for a new focus in the EU's mental health care approach, that is the underserved area of psychedelic therapies

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As we navigate deeper into the 21st century, the importance of mental health care is gaining increasing recognition. But we still have a long way to go.

The OECD estimates that mental illness affects one in two individuals during their lifetime, making it an ever-present yet often overlooked aspect of overall well-being. <sup>(1)</sup> The World Economic Forum's Global Risks Report 2023 identifies mental health deterioration as a severe risk to economies and societies. <sup>(2)</sup> Yet, a startling reality is revealed in the WHO's 2022 report: governments allocate, on average, only 2% of their health budgets to mental health. Furthermore, though making up 30% of total mental health sector funding, philanthropic donations represent a mere 0.5% of all health contributions. <sup>(3)</sup>

A recent discussion paper by the European Commission titled Scoping study on evidence to tackle high-burden under-researched medical conditions highlights these imbalances further. Predictably, it found that mental disorders top the list, despite research suggesting that investments in mental health could yield up to a 37% return – the highest of all biomedical fields. <sup>(4)</sup>

Last year, the European Medicines Agency recommended 89 new medicines for approval; astonishingly, not a single one was for mental health conditions. <sup>(5)</sup> All the while, as many as 67% of people say they do not get the mental health support they need. This raises a crucial question: where is the innovation in mental health treatment? A white paper by IQVIA points out that only 20% of R&D in the Central Nervous System is dedicated to mental health. <sup>(6)</sup>

These disparities underline the pressing need for a shift in our approach to mental health care, treatment, and research funding. Right now, the EU is revising its pharmaceutical regulations, marking an opportune moment to reset our focus on mental health.

### A beacon of hope: Psychedelic therapies

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Amidst this bleak scenario, psychedelic therapies emerge as a beacon of hope. These novel treatments, still in their infancy, show great promise in clinical trials. Economic analyses, like the one by Elliot Marseille and his colleagues at the University of California, suggest they can be cost-effective. <sup>(7)</sup> Moreover, follow-up studies indicate lasting benefits, with significant proportions of patients reporting continued improvements months post-treatment (even though we still lack robust data on their long-term efficacy).

These innovative treatments' development and safe implementation require a supportive regulatory environment. The EU's largely successful approach to orphan drugs and paediatric medicines <sup>(8)</sup>, and, more recently, new incentives targeting antimicrobial resistance (AMR) offers an instructive model. As of 1999, the EU has been crafting targeted incentives to support R&D in these crucial areas and recently proposed a transferable data exclusivity voucher scheme to incentivise the development of new antimicrobials. <sup>(9)</sup> A similar model could stimulate innovation in mental health by incentivising the development and deployment of psychedelic therapies.

## **Learning from stroke rehabilitation**

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Inspiration can also be drawn from developing and implementing stroke rehabilitation in Europe. Establishing stroke units – specialised teams of healthcare professionals providing comprehensive stroke care – has been a game-changer. It took several decades for these units to mature fully, but the investment has paid off with significant improvements in stroke care.

The lessons from stroke rehabilitation can be applied to developing and implementing psychedelic therapies. Both require a multidisciplinary approach, evidence-based practice, and significant resource investment.

Crucially, stroke rehabilitation gained prominence because stroke became recognised as a significant public health issue, leading to increased research funding focusing on developing effective treatments. A similar shift in perspective is needed for mental health. The recent resurgence of research in psychedelic research is a promising start and could accelerate the pace of development in this field.

## **The influence of policy: Role of the EU**

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The EU can play a crucial part in this shift. The EU initiative on a comprehensive approach to mental health is about to be published, and the current revision of pharmaceutical rules presents an ideal opportunity to prioritise and incentivise mental health care. Previously, the EU has demonstrated that it can prioritise certain therapeutic areas, such as antimicrobial resistance, in response to high societal needs. It's time we extended this approach to mental health treatments.

But our efforts shouldn't end with policy changes. We also need to ensure that psychedelic novel treatments are accessible and affordable for those who need them most. This will demand strategic planning and thoughtful preparation to prevent disparities in access and ensure the benefits of these therapies are available to those who might benefit from them.

## **Psychedelic therapies are a path forward**

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As we find our way towards a future where psychedelic therapies become integral to mental health treatments, we must ensure our strategies are as innovative and forward-thinking as the treatments themselves. Now is the time for Europe to prioritise mental

health and invest in a healthier future for its citizens. A shift in focus, combined with regulatory incentives, increased funding, and fostering a supportive environment for R&D in this field, could turn the tide in our battle against mental health conditions.

We are at a turning point for mental health care, with the potential to transform lives on a massive scale. We must seize this opportunity, not just for the sake of innovation, but because mental health matters. It's not just about resource allocation; it's about prioritising mental well-being and recognising the enormous potential that psychedelic therapies hold.

Only through concerted, comprehensive efforts can we hope to make significant strides towards improved mental health care. We are on the cusp of a mental health revolution, and we must take advantage of it to transform lives and prioritise mental health.

## References

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