



PAREA
PSYCHEDELIC ACCESS AND RESEARCH EUROPEAN ALLIANCE

POLICY PAPER

LEADING NOT LAGGING

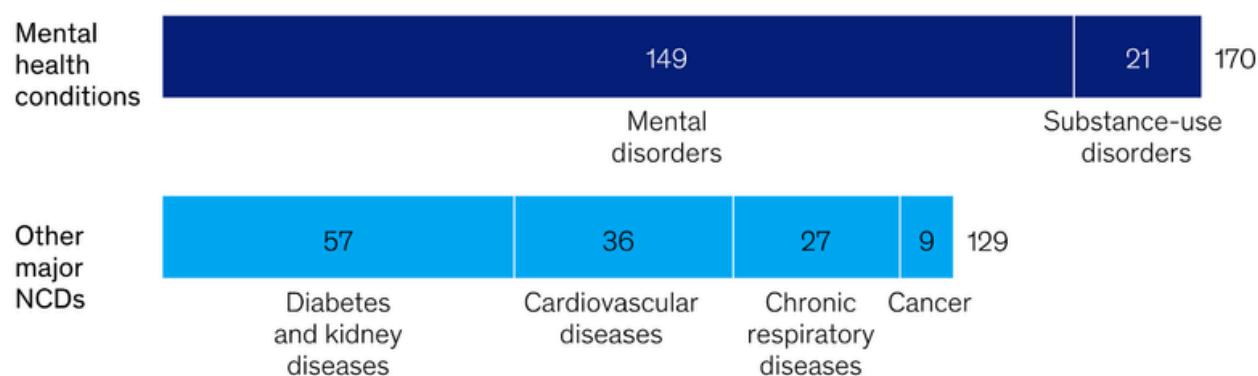
Putting mental health at the core of Europe's
innovation and competitiveness agenda



Mental health is not just another disease area

It is a foundational layer that cuts across all aspects of human life and societal functioning. It shapes our ability to work, learn, connect, and care for ourselves and others. As a core component of overall health, poor mental health not only worsens outcomes for physical illnesses, but also increases their risk - for instance, depression has been shown to triple the risk of cardiovascular disease. At present, mental health conditions cause more years of poor health globally than cardiovascular disease, cancer, diabetes, and chronic respiratory illness combined, making them the single largest contributor to long-term ill health.

Years lived with disability (YLDs) for mental health conditions¹ vs 4 other major noncommunicable diseases (NCDs), millions of YLDs as of 2025



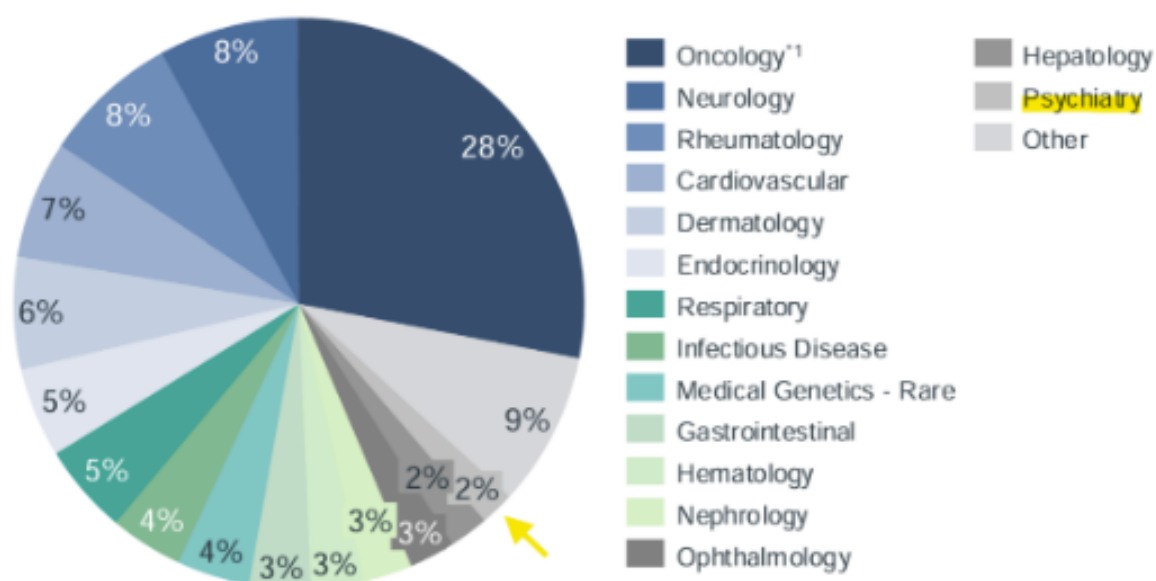
¹Mental and substance-use disorders.

Source: "Burden of disease scenarios for 204 countries and territories, 2022–2050: A forecasting analysis for the Global Burden of Disease Study 2021," *Lancet*, Dec 2024, Volume 404, Number 10,469; *Global Burden of Disease study 2021: Findings from the GBD 2021 study*, Institute for Health Metrics and Evaluation, May 16, 2024

McKinsey & Company

Yet, despite its centrality, mental health remains one of the most neglected areas in health and research policy. Globally, the percentage of government health budgets spent on mental health is hovering around 2%. Innovation remains very scarce, especially when compared to other therapeutic areas. Psychiatry ranks last among all therapeutic areas in the share of commercial clinical trials conducted in the EU — highlighting that innovation in the mental health space remains structurally disadvantaged. The complexity of the human brain remains a major challenge for therapeutic development. This is compounded by high barriers to entry, limited financial incentives, persistent stigma, and regulatory systems still tailored to conventional drug development. All these factors contribute to chronic underinvestment and a stark mismatch between the burden of mental illness and the availability of new treatments.

Share of commercial clinical trials by therapy area
(Phase 1-4, EEA, 2023)



Share of commercial clinical trials by therapy area in the EEA (Phases 1-4, 2023).
Source: EFPIA & IQVIA, "Clinical Trials in Europe: State of Play," EFPIA Report (October 2024).

As a result, most pharmacological psychiatric treatments are still based on mechanisms discovered over 50 years ago, while the prevalence of conditions like depression, anxiety, PTSD, and substance use disorder is rising. Over 143 million people in the WHO European Region live with some form of mental health condition – and only 6.9% receive optimal, effective treatment, with the single biggest barrier being that many do not recognise or believe they need help. This treatment gap has devastating consequences, from 120,000 suicides each year (there are an estimated 20 attempts for each suicide) to reduced productivity and spiralling healthcare costs. Mental health problems are now becoming the leading cause of disability-related early retirement in many Member States, costing society hundreds of millions of working hours. Depression accounts for up to 50% of chronic sick leave across the EU. In Germany, the number of sick days taken due to mental health issues has doubled over the past decade, while in France, mental illness has become the number one health insurance expense.

Europe's Moment Of Unique Opportunity

Despite the negative backdrop, this moment offers a unique opportunity for Europe. Europe has often been seen as lagging behind the US in biopharma innovation, but mental health treatments is a field where Europe once led and can again leap ahead. At a time when uncertainty and restrictive policies are undermining scientific freedom across the Atlantic, the EU is positioning itself as a safe, attractive home for global researchers and innovators. This moment offers Europe a unique chance not just to catch up, but to lead - particularly in mental health, where global momentum is shifting and the policy window is wide open.

As the EU prepares to launch new strategic initiatives - including the Life Sciences Strategy, European Research Area Act, Start-up and Scale-up Strategy, Biotech Act, and others - mental health must be positioned as a flagship priority as cancer has been. With public trust in science and global researcher mobility in flux, Europe is uniquely positioned to lead in mental health innovation — not just follow.

Five Key Actions

PAREA calls on EU institutions to seize this opportunity through five key actions:

1

Launch a “moonshot” mission for mental health

The EU should initiate a flagship mission-oriented programme for mental health, akin to the Horizon Europe Cancer Mission.

This EU-wide initiative would unify research, clinical, and policy efforts behind ambitious targets - such as halving suicide rates or doubling remission in depression. The upcoming Brain Health Partnership can serve as the backbone of this mission by streamlining fragmented efforts, coordinating investment, and bringing together interested Member States around a shared European agenda for brain and mental health.

To be truly transformative, the mission must move beyond a purely biomedical lens. It should embrace a comprehensive approach that recognises the complex interplay of biological, psychological, social, and environmental factors that shape mental health. This includes investing in prevention, community-based services, and people-driven models of recovery, while ensuring co-creation with those directly affected.



2

Establish a long-term European Mental Health Strategy



Beyond ad hoc initiatives, the EU urgently needs a comprehensive mental health strategy to coordinate policy across sectors and Member States - backed by a dedicated budget of €3–5 billion, with clear goals, sustained stakeholder engagement, and long-term investment. Such a strategy would provide a structured framework to coordinate action across all relevant sectors - health, education, employment, digital, and social policy - ensuring mental health is integrated into broader EU goals. By anchoring mental health as a cross-cutting EU priority, the strategy would ensure continuity of ambition beyond electoral cycles and provide a stable platform for sustained funding, legislation, and innovation.

3

Boost Research & Development Incentives and Funding

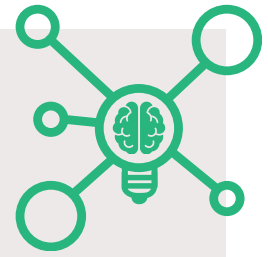


The EU should introduce specific incentives for developing breakthrough therapies in psychiatry, similar to incentives used for orphan, paediatric, and now antimicrobial resistance drugs introduced in the revision of the EU pharmaceutical legislation. Mental health innovators - particularly smaller biotech and digital health developers — face substantial scientific and financial challenges plus reimbursement uncertainty. The EU should strengthen early-stage regulatory support frameworks — including the EMA's PRIME scheme, protocol assistance, and related tools — to proactively include mental health.

In parallel, the EU should substantially increase public funding for mental health R&D. Horizon Europe and national research programmes should earmark funds for mental health innovation on a scale commensurate with its burden. The EU could, for instance, create a dedicated European Mental Health Innovation Fund to co-invest in promising startups and SMEs, leveraging the European Investment Bank or other instruments.

4

Create a European Mental Health Innovation Hub



Developing a European Mental Health Innovation Hub - a network that connects researchers, clinicians, industry, and patient organisations - would break down silos, accelerate cross-border research, build data platforms, and drive training.

The hub could coordinate multi-centre clinical trials across Member States, accelerating enrolment and ensuring diverse populations in studies. It could foster EU-wide data platforms for mental health (e.g. large patient cohorts and databases), enabling researchers to apply AI at scale to identify new treatment targets or personalise care.

Additionally, Europe should increase its investment in human infrastructure. The hub could support scaling multidisciplinary training programmes on mental health for health professionals, modelled on the EU-PROMENS project. This would help train thousands of medical professionals in best practices and standards of care, including for psychedelic therapies.

5

Ensure Upcoming Regulatory Tools Support Mental Health Innovation



As the EU prepares regulatory sandboxes to accelerate innovation in health, it is essential that these innovative regulatory frameworks explicitly support novel approaches in mental health care. This includes enabling real-world evaluation of complex interventions - such as the use of ketamine in depression and psilocybin in end-of-life care - where traditional regulatory pathways may be difficult to apply. Ensuring mental health is represented from the outset will help embed safe, scalable innovation into future care systems and offer a space to explore real-world evidence generation, delivery models, and oversight mechanisms tailored to the realities of mental health practice.

A Competitive Advantage For Europe

These steps would address not only major health challenges, but also create a competitive advantage for Europe — generating jobs, research capacity, and healthier communities.

The EU must now turn ambition into action and leadership. By placing mental health at the core of its societal objectives, and at the heart of its innovation and competitiveness agendas, Europe can shape a future where no one is left behind and where wellbeing becomes a foundation of economic and societal resilience. This is not only a moment of urgent need, but also a rare window of opportunity: for the first time in decades, transformative solutions are within reach.



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:

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