PAREA

PSYCHEDELIC ACCESS AND RESEARCH EUROPEAN ALLIANCE

POLICY BRIEF

Mental Health Innovation in the European Biotech Act

Closing Europe's access and competitiveness gap

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Position in brief

Europe is falling behind in bringing new mental health medicines to patients: European approvals reach only around 30% of the US total.[1] Europe has the scientific capability to develop new mental health treatments, but fragmented reimbursement, uncertainty over the evidence needed for approval and payment, and weak commercial incentives discourage investment and delay patient access. The Commission's proposed European Biotech Act aims to help turn scientific advances into accessible treatments, but contains no explicit reference to mental health.[2]

The EU has already recognised serious mental health needs in the pharmaceutical reform's provisions on unmet need and compassionate use.[3] The European Parliament's draft compromise now takes a strong step in the same direction, recognising mental health across strategic mapping, foresight, developer support, cross-border networks and regulatory sandboxes.[4] Member States should carry this ambition into the Council position and strengthen it with practical support for public-led development and repurposing.

Four priorities for the final Act

1	**Direct innovation towards unmet mental health needs**	Use strategic mapping and foresight to prioritise projects that address unmet mental health needs and barriers to patient access.
2	**Build Europe's capacity to develop mental health treatments**	Bring clinical networks and regulatory support together to generate evidence for approval, reimbursement and safe delivery.
3	**Attract investment into mental health innovation**	Direct the Act's investment tools towards eligible mental health programmes held back by insufficient funding.
4	**Back public-led development and repurposing**	Support public and nonprofit developers with funding for clinical studies, evidence generation and regulatory work where commercial incentives are insufficient.

Why mental health belongs in the Act

Mental health determines whether people can learn, work, care for others and participate in society. More than 143 million people in the WHO European Region live with a mental health condition.[5]
The OECD estimated the annual cost to the EU-28 at over €600 billion in 2015 (4.1% of GDP), including around €240 billion in labour-market losses.[6] Wider valuations that also count lost health and wellbeing put the burden at roughly 6% to 8% of GDP across European regions.[7]

The costs also spill into the rest of healthcare. Depression often accompanies diabetes and other non-communicable diseases, and is associated with worse outcomes and higher costs. In one OECD review, depression alongside diabetes almost doubled individual healthcare costs and more than tripled hospital admissions for diabetes complications.[8]

143 million

people living with a mental health condition in the WHO European Region [5]

€600bn+

annual economic cost in the EU in 2015, including major labour-market losses [6]

38 vs 11

new psychiatric medicines approved by FDA and EMA respectively, 2016–2025 [1]

Investment has not kept pace with this burden. Psychiatry accounts for the smallest share of commercial clinical trials in Europe – a mere 2% of trials across all therapeutic areas.[9] Between 2016 and 2025, the US Food and Drug Administration (FDA) approved 38 new psychiatric medicines across seven indications, compared with 11 approved in Europe - roughly 70% fewer than the US. Only one was reimbursed across the five major European markets, and several therapies with new mechanisms were never submitted to the European Medicines Agency (EMA).[1] Across all therapeutic areas, industry estimates that around 40% of newly approved therapies never reach European patients.[10]

The commercial case is unusually fragile. A recent review estimates that bringing a psychiatric medicine to market can take up to 15 years and cost around US$1 billion.[11] An analysis of NHS England prescription data for 2022–23 found average unit payments seven times higher for diabetes medicines and fifteen times higher for anti-clotting medicines than for antidepressants.[11,12] Developers face long timelines, low prices, fragmented assessment and reimbursement, and no certainty about who will pay.

These difficulties are particularly acute for off-patent treatments. Racemic ketamine has a substantial evidence base in psychiatry, but because it is generic, companies have little commercial reason to develop it further.[13,14] Europe therefore needs a complementary public-interest pathway for treatments with high public health value but insufficient commercial incentives.

Psychedelic therapies as a test of Europe's ability to turn science into patient access



The first US approval of a psychedelic therapy could come within a few months, with other programmes in late-stage development. Leading developers are prioritising the US, while the timing of European access remains uncertain.[15] US authorities are actively supporting development and preparing for approval: the FDA has issued dedicated clinical-investigation guidance and granted accelerated-development status to multiple programmes.[15,16] ARPA-H (a US federal research agency) is committing up to US$139.4 million to behavioural-health therapeutics, including at least US$50 million to match state investment in psychedelic research.[17]

Europe already has some practical experience. Switzerland permits limited medical use through individual exceptional authorisations, Germany has authorised tightly controlled compassionate use, Czechia has created a supervised medical route, and Norway now offers off-label intravenous ketamine for treatment-resistant depression with nationwide public reimbursement and evidence collection.[18] Shared protocols, training and follow-up could turn these national experiences into evidence for European development programmes and help health services prepare.

Psychedelic therapies also expose a regulatory problem that goes beyond any single product. Treatment may combine a medicine, a distinctive subjective experience, the conditions of administration and structured psychological support, representing an innovative complex mental health intervention. The pronounced subjective effects of psychedelics make blinding difficult in clinical trials. Context may influence both safety and outcome, yet parts of the care model fall outside what clinical trials and medicines regulation are designed to assess when authorising a new treatment. The evidence must establish what needs to be standardised, what can remain flexible and which professional competencies are required.[16]



Europe should not make patients' future access depend on whether and when companies choose to enter its market.

The Biotech Act should make Europe a more attractive place to develop mental health treatments, and help build the evidence and clinical capacity needed for patient access. With the first approvals approaching in the US, psychedelic therapies will show whether Europe can support commercial development and prepare its health systems without waiting for companies to decide when to launch.

Making the Biotech Act deliver for people with mental health conditions

The mental health provisions in Parliament's draft compromise should be secured in both institutions' positions and the final Act. They build on the EU's recognition of serious mental health needs in pharmaceutical reform.[3,4]

1 Direct innovation towards unmet mental health needs

The scale of unmet mental health needs should influence where Europe directs its innovation effort. Giving mental health an explicit place in the Act's strategic mapping and foresight would help identify where promising research is held back by weak investment, limited clinical development or barriers to patient access. The findings must then guide the selection and support of eligible projects.[4]

People with lived and living experience should help define unmet needs and meaningful outcomes, including functioning and participation in work and society. Their involvement would help ensure that priorities reflect the improvements that matter in daily life.

2 Build Europe's capacity to develop mental health treatments

Developing complex mental health treatments requires clinical expertise, sustained investment, regulatory clarity, a credible route to reimbursement and services capable of delivering them safely. The EU Health Biotechnology Support Network and cross-border innovation networks can bring these capabilities together. For mental health, these networks should give eligible developers access to experienced trial centres, coordinated advice and shared protocols for evidence collection, including registries for long-term follow-up. They should also help health services prepare their workforce for safe delivery.[4]

Psychedelic therapies should be an early test case for regulatory sandboxes. Their effects can be shaped by a person's psychological state and expectations, the treatment environment and the support provided before, during and after administration - often described as "set and setting." These interacting components make psychedelic therapies complex interventions, requiring evidence on how the medicine and its therapeutic context work together.[19] Where existing trial requirements cannot adequately accommodate these features, the Act's sandbox provisions could help establish appropriate ways to assess the whole intervention: which support is necessary, what needs standardisation and which professional competencies are required. The aim is robust evidence that supports both regulatory assessment and safe delivery in clinical practice.[2,4]

A credible route to patient access also requires earlier clarity about reimbursement evidence. The Foresight Panel's proposed dialogue with public payers, alongside early regulatory and health technology assessment advice, should help developers identify evidence needs for both approval and reimbursement before committing to major trials, including lasting benefit, appropriate comparators and delivery costs.[4,20]

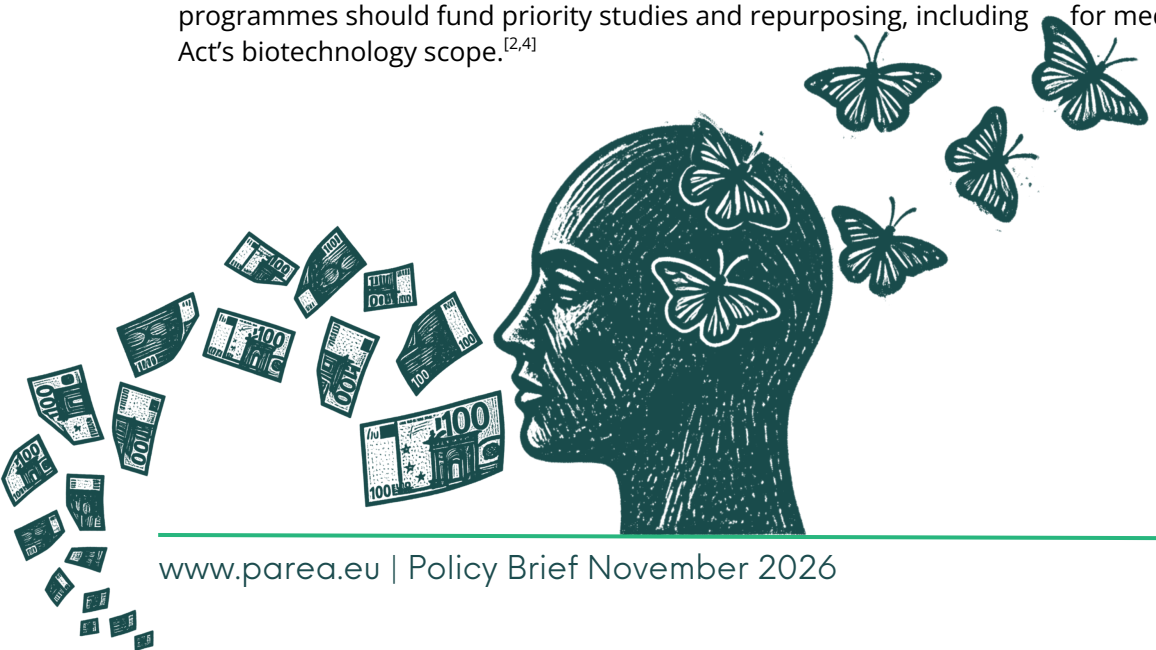
3 Attract investment into mental health innovation

High development costs, low expected revenues and uncertainty over reimbursement weaken the commercial case for investing in new mental health treatments in Europe. The Act's investment pilot could help mobilise capital for eligible programmes, alongside the proposed European Biotechnology Scale-Up Fund.[4] The proposed assessment of risk-sharing finance should explicitly address mental health financing gaps and lead to instruments that help promising programmes secure investment through clinical development.

Cross-border mental health collaborations that meet the Act's eligibility criteria should be considered for Pan-European high-impact strategic-project status, bringing coordinated scientific and regulatory advice together with priority consideration for funding. Public support should target demonstrated gaps, with transparent results, patient involvement and credible plans for access.[2,4]

4 Back public-led development and repurposing

Member States should use the Biotech Act and linked EU programmes to support public-led mental health development and repurposing. For eligible projects, the Act's Support Network should help public and nonprofit developers organise investigator-initiated trials and other clinical research, obtain regulatory advice and secure funding. Dedicated calls under EU research and health programmes should fund priority studies and repurposing, including for medicines beyond the Act's biotechnology scope.[2,4]



Funding should cover priority clinical studies, procurement of study medicines, regulatory dossiers and shared follow-up. Milestone-based grants and, where appropriate, innovation procurement can support work with high public value and weak commercial returns. France's publicly supported Phase 3 trial for alcohol use disorder with comorbid depression illustrates the contribution public-led psychedelic development can make.[21] Norway offers a complementary example: public clinical collaboration, shared treatment protocols and health technology assessment have supported nationwide public reimbursement of off-label generic ketamine for treatment-resistant depression, with continued evidence collection through registries or clinical studies.[22]

Article 50 of the pharmaceutical reform offers a route for nonprofit repurposing.[3] Putting it into practice requires funding for evidence generation and regulatory work, alongside early cooperation with marketing-authorisation holders.[14] Racemic ketamine is a practical example: coordinated studies, common protocols and safety follow-up should turn fragmented off-label use into evidence for an authorised psychiatric indication and reimbursement assessment. Support must cover access to study medicines, scientific advice and dossier preparation.[13,14]

Europe also needs a way to assess treatments whose developers do not seek European approval. The final Act should establish a clear route for EMA scientific opinions on medicines approved in countries with equally stringent standards, including where no European application is expected. Such opinions could inform national early-access and reimbursement assessments, while authorisation, funding and clinical oversight remain subject to the applicable rules.[4]

Member States should also support shared evidence generation through regulated national supervised-access programmes, drawing on Switzerland, Germany, Norway and Czechia. Common follow-up can inform further development, new indications and payer assessments, while each programme retains its legal basis and clinical oversight. Real-world evidence should complement trials and help establish safety and effectiveness in routine care.[18,23]

Turning Europe's innovation ambitions into patient benefit



The EU has already recognised the importance of serious mental health needs in pharmaceutical reform. The Biotech Act can carry that commitment into investment, development and clinical capacity. Parliament's draft compromise provides a substantial basis that both co-legislators should preserve.[3,4]

The Council should build on this progress with practical support for public-led development and repurposing. Europe needs conditions that attract commercial investment and enable public institutions to advance treatments where commercial incentives are insufficient. Patients' future access should not depend entirely on when individual companies choose to enter the European market.

The prospect of the first psychedelic therapy approvals in the US makes preparedness urgent. The capabilities Europe builds now can serve a much wider generation of mental health innovations.

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About PAREA

We are a pan-European multistakeholder platform representing patient organisations, medical associations, scientific societies, and community leaders. We work to expand access to quality mental health care by advancing mental health innovation across Europe. Our aim is to ensure the scientifically grounded, safe, equitable, and people-centred development and integration of psychedelic-assisted care into European health systems, making psychedelic therapies reimbursable and accessible for those who do not benefit from existing treatments.

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