PAREA

PSYCHEDELIC ACCESS AND RESEARCH EUROPEAN ALLIANCE

POLICY PAPER

FROM LAGGING TO LEADING

A Policy Toolkit for Mental Health Innovation "Made In Europe"

Psychedelic therapies as a test of Europe's innovation capacity

Introduction:
Europe's innovation gap and neglected mental health

Europe is facing a mental health crisis alongside a widening innovation gap. Mental health is "not just another disease area - **it is a foundational layer that underpins every aspect of human life and societal functioning**[1]. Poor mental health erodes quality of life, workforce productivity, learning potential, and social cohesion. Yet this critical field remains structurally neglected: governments devote only around 2% of health budgets to mental health[2], and innovation in psychiatric treatment has stagnated for decades[3]. In fact, **psychiatry ranks last among all therapeutic areas in the share of commercial R&D trials in the EU**[4], highlighting a chronic underinvestment despite enormous unmet needs. As a result, most medications for mental illness still target the same pathways discovered over 50 years ago, even as depression, anxiety, and substance use disorders have risen to record levels. Today, mental health conditions cause more years of ill-health globally than cardiovascular disease, cancer, diabetes, and chronic respiratory illness combined[5], yet few new therapies reach patients.

At the same time, Europe's overall life-science innovation ecosystem has been losing ground. Stakeholders warn of a growing innovation and investment gap between Europe and the US and China, evidenced by Europe's declining share of R&D spending, fewer clinical trials, and loss of biotech investment to other regions[6]. This gap is especially pronounced in **mental health, an area historically seen as both scientifically and economically challenging for industry**. The extraordinary complexity of the human brain and the lack of clear biomarkers for mental illness have long made this field high-risk for drug development, leading many pharmaceutical companies to scale back their psychiatric R&D efforts[7]. Traditional clinical development has favoured treatments that patients take daily and that yield clear short-term symptom outcomes. Innovative mental health therapies - like psychedelics - often do not fit this mold, as many aim to produce **lasting remission with only a few treatment sessions rather than continuous medication**. Such one-and-done approaches, while potentially transformative for patients, offer slimmer profit opportunities under the prevailing paradigm. Consequently, commercial incentives have steered innovation away from psychiatry and other "less profitable" disease areas, resulting in fewer new medicines for mental illnesses. This dynamic has contributed to a **decades-long stagnation in psychiatric drug development globally**[3]. Europe, in particular, has seen its neuroscience and mental health research programmes under-funded and its biotech startups struggle to scale, which puts it at risk of falling further behind as new breakthroughs finally emerge.

[1] PAREA | Leading Not Lagging - Putting Mental Health at the Core of Europe 's Innovation and Competitiveness Agenda | 2025
[2] IQVIA | EFPIA-VE | Assessing the Clinical Trial Ecosystem in Europe | 2024
[3] D. Nutt | Drug development in psychiatry: 50 years of failure and how to resuscitate it | The Lancet Psychiatry | 2025
[4] World Health Organization | Mental Health Atlas 2020 | 2021
[5] McKinsey Health Institute | Investing in the future: How better mental health benefits everyone | 2025
[6] EFPIA response to the European Commission's 'Competitiveness Compass' | 2025
[7] Hyman SE | Revolution stalled | Sci Transl Med | 2012

A moment of opportunity:
From stagnation to leadership

Paradoxically, **Europe now stands at an inflection point where it could leap ahead in mental health innovation** – if it seizes the opportunity. **"For the first time in decades, transformative solutions – including psychedelic therapies – are within reach. Europe has the opportunity not just to catch up, but to lead"** [1]. This rallying call from patient and research groups is timely. Europe has world-class scientists and a strong public health tradition; it once led in developing mental health treatments (from pioneering psychoanalysis to discovering early antidepressants) and could lead again. With the right policies, **mental health could become a European success story**, demonstrating how an area of high societal value but low commercial interest can be turned into an innovation engine.

Importantly, **EU policymakers are waking up to mental health as a strategic priority**. In 2023, the European Commission released a "comprehensive approach to mental health"[8]. In response, the European Parliament called on the Commission to draw up a long-term, comprehensive and integrated EU Mental Health Strategy, recognising that **mental well-being underpins economic and social progress** [9]. There is a pressing need for such a strategy to anchor all efforts and give them long-term direction. Notably, recent high-level reports by Mario Draghi and Enrico Letta have both highlighted the **strategic importance of brain science and mental health innovation for Europe's future competitiveness**[10][11].

One flagship EU proposal is the European Innovation Act, aimed at strengthening research capacity, intellectual assets and regulatory sandboxes to foster innovation. **Mental health should be at the heart of this agenda. It is a field ripe for the kind of bold, coordinated effort the EU now aspires to.** Just as Europe has launched missions in areas like cancer, it can champion a **"moonshot" for mental health** – a mission-driven initiative to catalyse research, investment and the implementation of new treatments. In this context, the forthcoming European Brain Health Partnership could serve as a key platform to align and amplify efforts across stakeholders [12]. By doing so, the EU would not only address a pressing health crisis but also position itself as a **global leader in an emerging innovation domain aligned with European values and societal needs.**

This paper builds on PAREA's earlier policy paper "Leading Not Lagging - Putting Mental Health at the Core of Europe 's Innovation and Competitiveness Agenda" [1], which set out a broad agenda for strengthening mental health innovation. While that work covered the field as a whole, this paper narrows in on psychedelic innovation as a test case for Europe's competitiveness and innovation agenda.

The following sections examine key challenges that currently hinder mental health and psychedelic innovation in Europe, and propose strategic solutions. These recommendations align with the EU's goals of boosting competitiveness and innovation capacity, but focus on an area long overlooked by market forces. The core thesis is that **access to effective mental health care tomorrow depends on investing in innovation today – and that Europe's policy choices now in funding, regulation, and incentives will determine whether we lead or lag in delivering the next generation of mental health treatments.**

[8] Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on a comprehensive approach to mental health | 2023
[9] European Parliament resolution of 12 December 2023 on mental health
[10] European Commission | Align, act, accelerate. Research, technology and innovation to boost European competitiveness | 2024
[11] European Commission | Letta Report "Much More Than a Market" | 2024
[12] European Commission | European Partnership for Brain Health | 2025

Commercialisation challenges and fragmented market access

A central barrier to mental health innovation in Europe is the commercialisation landscape: getting new therapies from lab to market is uniquely difficult in this field, especially in the EU's fragmented market. Even when a promising new treatment is developed, companies face 27 different national health systems for pricing and reimbursement. This fragmentation forces innovators to navigate a country-by-country rollout, negotiating separately with each health authority – a slow, complex, and costly process that delays patient access.

Many EU countries have stringent cost-effectiveness thresholds and often compare new therapies to cheap generic drugs (like decades-old antidepressants) as the benchmark. **This makes it hard for breakthrough treatments to demonstrate "value for money" on paper,** even if they offer superior long-term outcomes. For example, a psychedelic therapy that requires only one or a few administrations and may induce long-term remission could have a high upfront cost compared to generic daily pills, leading some payers to balk. Conservative reimbursement frameworks therefore risk undervaluing innovative cures simply because their benefits (improved functioning, reduced hospitalisations, etc.) accrue over years and across sectors, whereas costs are immediate.

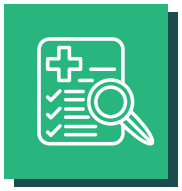
Moreover, many **psychedelic treatments are hybrid interventions – the medication may be paired with therapist-delivered care** and often supported by digital tools such as preparation apps and integration platforms. Health systems today struggle to regulate and reimburse such combinations. If a health insurer or national system agrees to pay for a new drug but not the hours of psychotherapy required to deliver it, the treatment effectively remains out of reach. This misalignment in coverage could result in psychedelic therapies only being offered in private clinics for those who can pay out-of-pocket, exacerbating inequality. In the absence of clear reimbursement for both components, innovators also face uncertainty on their return, further disincentivising investment. Additionally, stigma and misconceptions around psychedelics can influence decision-makers: if regulators or payers hold outdated views that these treatments are fringe or risky, they may impose extra hurdles or usage restrictions, dampening uptake even after approval.

All these factors create a challenging market environment in Europe. Indeed, even medicines granted EMA (European Medicines Agency) approval can **struggle for reimbursement in multiple countries for years**, especially in smaller markets with tight budgets. This stands in contrast to the United States, where a single Food and Drug Administration (FDA) approval opens access to a large unified market with generally faster uptake (albeit at higher prices). The EU's slower, fragmented access means companies may not recoup investments for a long time, if ever. It is no surprise then that **many mental health biotech firms focus their clinical trials and product launches in the US first, viewing Europe as an eventual, secondary market.** From a patient perspective, Europeans end up waiting longer for new therapies; from an innovation perspective, Europe sends a signal of lower reward for high-risk R&D, reinforcing the cycle of underinvestment in psychiatric drug development.

What can be done? At the EU level, there is a strong case for **reducing fragmentation and reforming Health Technology Assessment (HTA)/reimbursement processes for high-impact therapies.** The new Joint Health Technology Assessment regulation offers a platform to harmonise how new medicines are evaluated across Member States[13]. Mental health should be prioritised in this effort. **Tailored evaluation frameworks need to be developed** for transformative mental health interventions such as psychedelic therapies – for instance, outcomes-based assessments that consider quality-of-life gains and long-term remission rates, rather than just short-term symptom reduction. If traditional cost-effectiveness models cannot fully capture the value of a one-time therapy that yields lasting benefits, payers should explore alternative payment models (such as installment payments or outcomes-based agreements).

[13] European Commission | Joint Clinical Assessments | 2025

Here, Europe can also draw on the **WHO EURO Access to Novel Medicines Platform (NMP)**, which brings together 51 countries and 49 non-State actors in a neutral forum to improve patient access to effective, novel and high-cost medicines[14]. The NMP is advancing work on transparency, solidarity and sustainability, including developing shared principles for pricing, reimbursement and managed entry agreements, as well as piloting tools such as joint horizon scanning and demand pooling. **Integrating mental health into these discussions** would help ensure that breakthrough psychiatric treatments – often undervalued in current systems – are assessed in a way that reflects their true long-term benefit. The EU could align its own reimbursement reforms with the NMP's outputs, so that smaller or less wealthy countries can participate in joint solutions and patients across the region can gain equitable access. By **innovating in reimbursement – treating cures as investments rather than costs** – Europe can encourage development of therapies that fundamentally alter the course of mental illness.



Regulatory and trial design obstacles: Adopting frameworks for novel mental health therapies

Europe's regulatory environment – the rules governing drug development, clinical trials, and approvals – has a profound impact on innovation. In mental health it poses unique challenges, partly due to the **unconventional nature of emerging therapies such as psychedelics and partly due to uncertainty around the regulatory and commercial pathway.** Established pharma companies in Europe and beyond have also largely stayed on the sidelines of psychedelic R&D. One reason is strategic: these therapies are resource-demanding and don't fit the prevailing business model of daily pills, as discussed, but another is regulatory – developers fear unclear approval pathways and integration into care.

Regulators are used to evaluating a single new drug on its own merits. Psychedelic therapies, however, incorporate a non-pharmacological element - they represent a **psychopharmacological model**, with the drug and psychotherapy often thought to work in synergy, neither as effective on its own. This paradigm is very different from standard psychiatric pharmacotherapy, where a pill alone is expected to drive outcomes. The **innovation lies in treating the medicine and therapy as a bundled intervention** – yet current systems are not designed to assess such combinations[15]. As a result, the pharmaceutical industry has little incentive to investigate the importance of the psychotherapy component, due to increased costs and regulatory complexity.

The FDA's review of MDMA-assisted therapy in 2024 illustrates the mismatch. Regulators acknowledged that "FDA does not regulate the practice of psychotherapy," limiting their ability to review the therapeutic component[16]. In practice, though, the psychotherapy may not be a confounder but the key mediator of effect.

This points to a broader gap: while procedures like surgery are subject to oversight, psychotherapy remains largely unregulated despite strong evidence for interventions such as CBT. Psychedelics highlight the need for regulatory processes that can evaluate drug–therapy combinations as integrated treatments. Regulators must treat this integration as a feature. Collaborations with professional societies and medical bodies should be sought to determine best use practices, training and credentialing, and oversight and risk evaluation strategies.

[14] World Health Organization EURO | Report of the consensus-building meeting of the WHO Regional Office for Europe Access to Novel Medicines Platform: Copenhagen, Denmark, 2–3 July 2024
[15] Wolff, M., Gukasyan, N., Roseman, L., & Liknaitzky, P. | Reframing psychedelic regulation: Tools, not treatments | Drug Science Policy and Law, 11
[16] U.S. Food and Drug Administration | FDA briefing document: Psychopharmacologic Drugs Advisory Committee meeting – Lykos Therapeutics' MDMA-assisted therapy for PTSD | Silver Spring, MD | 2024

Modernising regulatory guidance to encompass such combination products is necessary. PAREA's proposal - suggested in the policy paper targeting the EU revision of its pharmaceutical package - is to **establish a specialised EMA working party or "centre of excellence" for combination therapies** (including digital and psychotherapeutic components)[17]. By doing so, regulators would provide developers with a clear roadmap and ensure that patient safety is holistically considered for these novel approaches.

Another regulatory hurdle is **the controlled-substance status of many psychedelics**. Substances like psilocybin, MDMA or LSD are Schedule I drugs in most jurisdictions, meaning they are officially deemed to have no medical use and high abuse potential. This legal status imposes **heavy bureaucratic burdens** on research: special licenses, strict storage and transport rules, and often a tangle of national authorisations for multi-site trials[18]. Despite growing evidence of medical benefits, drug control laws in Europe have not caught up; they remain **misaligned with scientific progress**. The result is added cost and delay for European researchers, and a fragmentation of efforts. To foster innovation, Europe should consider a **coordinated rescheduling, or re-evaluation of research and medical use controls, imposed on certain substances with scientifically demonstrated therapeutic potential.** The WHO Expert Committee on Drug Dependence and various national bodies have already begun acknowledging that substances like ketamine, psilocybin and MDMA can have legitimate medical uses; the EU could provide a unified approach so that researchers across all Member States operate on a level playing field with manageable regulations. Updating these rules would remove unnecessary red tape while maintaining appropriate safeguards.

A further **challenge lies in clinical trial design and evidence requirements.** Traditional trials favour placebo-controlled, double-blind designs with easily measurable endpoints. But for psychiatric treatments – especially with compounds that have obvious subjective effects like psychedelics – **blinding becomes difficult if not impossible:** patients and therapists can usually tell who got the active drug due to the profound psychological experience. Outcomes in mental health are also more complex - without measurable biological outcomes, they often rely on standardised symptom scales which may not entirely capture real lived benefits, such as improved quality of life or social functioning over months/years). Alongside the non-pharmacological component, these factors mean that psychedelic therapies pose challenges for traditional double-blind placebo-controlled trials. Regulators may need to **embrace more innovative trial methodologies for these treatments.** Encouragingly, both EMA and national agencies have shown openness to adaptive and novel trial designs. Platform trials, umbrella trials, and use of real-world evidence alongside Phase III data are ideas gaining traction. Europe should actively support such methodological innovation. The Accelerating Clinical Trials in the EU (ACT EU) initiative and the new Clinical Trials Regulation are opportunities to enable multi-country trials and complex designs more easily. Mental health could greatly benefit from these improvements, since currently many psychiatric trials in Europe are small, single-site studies rather than robust multi-nation efforts. By **harmonising protocols and simplifying trial approvals across countries, the EU can facilitate larger trials that generate solid evidence. In short, adapting regulatory requirements to the realities of novel mental health interventions** – through clear guidance, flexible endpoints, acceptance of digital measures or caregiver reports, etc. – will lower the barrier to bringing innovative therapies to market.

Finally, it is worth noting that the European Commission's planned Life Sciences Strategy and Biotech Act aim to streamline regulation and remove obstacles to biotech development. As highlighted by industry groups, simplifying and accelerating regulatory processes can "ensure that patients in Europe get faster access to medicines [6]. Mental health novel therapeutics should not be left out of this reform. If anything, they stand to gain the most from a more enabling regulatory environment, because they have been laggards under the old system. **By creating pathways for combination products, aligning drug control policies with medical science, and embracing innovative trial approaches, Europe can make its regulatory ecosystem a comparative advantage rather than a bottleneck for mental health innovation.**

[17] PAREA Position Statement. Leveraging the EU Pharmaceutical Package. A Life Cycle Approach to Address High Unmet Needs and Foster Mental Health Innovation by Incentivizing Psychedelic Novel Medicines | 2023
[18] EMA multi-stakeholder workshop on psychedelics – Towards an EU regulatory framework | Presentation - Legal status of psychedelics and impact in research and development (T. Hawrot) | 2024 |

Limited opportunities for testing solutions: Sandboxes and real-world evidence

Even after clinical trials, a critical question remains: **how can we safely and swiftly translate innovation into real-world practice?** The transition from tightly controlled clinical trials to the complexities of real-world care is far from straightforward. Clinical trials operate under highly controlled parameters that rarely reflect the variability, patient diversity, and resource limitations encountered in practice. In psychedelic therapies the gap between an approved innovation and its widespread implementation can be especially large, as health systems need time to build capacity (train therapists, set up clinics) and often adopt new treatments cautiously. Clear clinical pathways also need to be established so innovations can be integrated consistently into care. One striking fact is that without deliberate efforts, it can take over a decade for clinical breakthroughs to become standard care – indeed, up to **17 years' delay has been observed between a new discovery and its routine use in practice**[19] [20]. For patients struggling today, that wait is far too long. The concept of **regulatory "sandboxes" and enhanced use of real-world evidence (RWE)** - attracting increasing policy attention in Europe - can **bridge the transition from lab to health system** by allowing controlled early access to innovations and by gathering practical evidence in parallel to traditional trials.

The European Commission has proposed including sandbox provisions in the revision of pharmaceutical legislation, an approach that has since gained support from both the European Parliament and Council[21]. Regulatory sandboxes would establish **pilot, time-limited environments where novel therapeutic approaches are tested in practice under regulatory oversight**, before full market authorisation. Regulatory sandboxes are applicable to areas where traditional regulatory frameworks pose limitations, such as psychedelic therapies. These tools could help develop innovative interventions, while enabling controlled access for populations with critical unmet needs, rather than making patients wait years for a large Phase III trial to conclude. For example, in end-of-life anxiety, long placebo-controlled trials are ethically and practically challenging (patients are severely ill and running out of options) and clinical benefits are differently defined, i.e. quality of life improvement. They could also support the application of an adjunct psychotherapeutic intervention in a real-world setting.This kind of"controlled roll-out", with informed consent, robust monitoring and systemic data collection, could generate valuable evidence on safety, efficacy and optimal protocols for the treatment, feeding into regulatory decisions: for instance, supporting a centralised approval, reimbursement considerations or refining guidelines on how best to use the therapy.

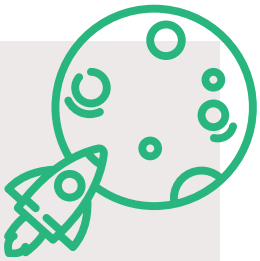
Psilocybin, LSD and MDMA are in late-stage trials for conditions like depression, anxiety and PTSD[22]. While FDA approvals may come as early as 2026–2027, Europe does not need to wait. European regulators have the tools to act on their own initiative - for example through early access programmes or regulatory sandboxes under certain conditions. For instance, a **sandbox might allow ketamine-assisted psychotherapy for severe depression in a limited number of pilot hospitals, or psilocybin for palliative care in patients with end-of-life anxiety** – treating a defined group under regulated protocols while outcomes are monitored. Through such pilots, European regulators and providers would **gain valuable implementation experience and evidence, informing broader roll-out.** Crucially, these early access mechanisms must be coupled with proper data collection and evaluation, so that temporary access can transition into full approval or guidelines if the results are positive.

[19] Morris ZS, Wooding S, Grant J. | The answer is 17 years, what is the question: understanding time lags in translational research | Journal of the Royal Society of Medicine | 2011
[20] Rubin R | It Takes an Average of 17 Years for Evidence to Change Practice – The burgeoning field of implementation science seeks to speed things up | JAMA | 2023;
[21] Council of the EU | Proposal for a Regulation of the European Parliament and of the Council laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing rules governing the European Medicines Agency | 2025
[22] Psychedelic Alpha | Q3'25 Bullseye Chart. The Psychedelic Drug Development Pipeline | 2025

From recommendations to reality:
Policy solutions for a leading role

To transform Europe's mental health innovation landscape, targeted policy action is required. Using psychedelic therapies as a test case, this paper outlines a toolkit of interconnected measures—spanning investment, coordination, regulation, and infrastructure—that can collectively elevate Europe from lagging to leading in this critical field. The recommendations that follow reinforce those first put forward in PAREA's policy paper Leading Not Lagging – Putting Mental Health at the Core of Europe's Innovation and Competitiveness Agenda [1], now framed within the context of the European Innovation Act. Because novel treatments like psychedelics can only flourish within a supportive mental health ecosystem, the toolkit zooms out to set a bold, system-wide vision for innovation in this area as a whole.

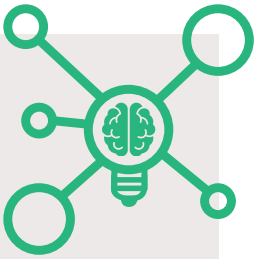
1 Launch a "moonshot" mission for mental health



Europe needs a bold, moonshot initiative to drive mental health innovation at scale, similar to the missions it has already launched on cancer. Such a moonshot should be developed alongside – and ideally embedded within – a future EU Mental Health Strategy, which the Parliament has already called for but which has yet to be delivered. An EU-wide mental health mission would mobilise funding, align stakeholders, and set ambitious goals – for example, halving suicide rates or doubling recovery rates in severe mental illness by 2030. Beyond research, such a mission could provide a major boost to mental health care more broadly – strengthening the workforce, supporting community-based services, and creating closer links between health, education and social systems so that innovation translates into real improvements in people's lives.

For psychedelic therapies, the moonshot would provide the high-risk, high-reward research support that smaller biotech firms and academic groups cannot secure on their own. The science is still nascent, and we know relatively little about mechanisms, optimal treatment protocols, or long-term outcomes. Substantial public investment is needed to run large-scale trials with innovative designs, including transdiagnostic studies that can test the potential of psychedelics across multiple conditions. A moonshot could also support building the infrastructure for safe delivery in health systems – from specialised clinics to trained professionals – ensuring that psychedelic therapies do not stall at the implementation stage.

2 Create a European Mental Health Innovation Hub



Establish a pan-European network or "hub" to coordinate expertise and resources for mental health innovation. This could be a virtual hub linking centres of excellence in different countries or a new coordinating entity under the European Innovation Council. Its roles might include providing scientific and regulatory advice to start-ups (a one-stop shop to navigate EMA, national regulators and ethics approvals for

novel mental health therapies); fostering collaboration by linking academia, industry and patient groups; maintaining shared infrastructure such as patient registries or biobanks for mental health research; and disseminating best practices across Europe. Such a hub could also support training and workforce development, recognising that human capacity (e.g. therapists and clinicians skilled in new methods) is essential to implement innovations. In essence, a hub would act as an innovation accelerator – ensuring that good ideas don't falter due to lack of guidance or connectivity, and helping smaller countries or labs participate in Europe-wide projects. It would symbolise Europe's commitment to lead in mental health by uniting efforts continent-wide.

For psychedelic therapies, the hub could serve as a one-stop platform where developers, clinicians, and regulators collaborate to address specific challenges – from controlled substance licenses to safe therapy protocols. It would accelerate translation of psychedelic science into practice, while embedding it in a broader innovation ecosystem.

3 Establish a European mental health care capacity initiative

Europe must recognise that **innovation is not just about discovery, but also delivery.** A breakthrough therapy is of little use if there are no clinics equipped to provide it or no professionals trained to do so. A coordinated European mental health care capacity initiative should therefore be launched to prepare health systems for the next generation of treatments. This would mean **investing not only in research, but in the infrastructure, workforce and digital tools** needed to translate innovation into real-world care.

For psychedelic therapies, this would involve creating safe treatment spaces in hospitals or clinics (for example, quiet rooms for supervised sessions) and establishing certification programmes for therapists. Currently, Europe has a shortage of such specialised infrastructure – not enough facilities or personnel to meet widespread demand if psychedelics for depression were approved tomorrow. This bottleneck can be addressed through capacity-building now: using EU structural funds, recovery plans or dedicated health budgets to convert existing facilities or create new ones geared toward innovative interventions.

Training is a critical component. Large-scale programmes for mental health professionals in emerging therapies, including psychedelics, should be launched. Without **proactive investment in people**, even an approved therapy may sit unused due to lack of providers. An EU-coordinated curriculum, with mutual recognition of qualifications across Member States, would allow trained professionals to move where they are needed. Alongside this, qualified bodies should supervise trained professionals to ensure quality and safety – likely a national competence, but with EU standards setting a common baseline as with curricula.

Finally, digital technologies can extend care capacity further – telemedicine, digital therapeutics and AI decision support should be integrated into the initiative, with appropriate sandbox testing. By investing in infrastructure, workforce and digital tools together, Europe can ensure that breakthroughs do not stall at the point of delivery, but reach patients quickly, safely and equitably.

4 Pilot a psychedelic therapies regulatory sandbox

Several psychedelic compounds are progressing through advanced clinical trials that may lead to authorisation. However, these trials face practical challenges when applied to this emerging class of therapies. Some challenges are methodological - for example, conventional double-blind designs often fail because the drug's distinctive psychoactive effects make blinding difficult to maintain. Other challenges are structural - for instance, psychedelic therapies often combine a pharmacological compound with guided psychotherapy, creating a hybrid model that poses additional challenges and does not fit neatly into existing approval or reimbursement categories. In addition, many of the most urgent applications – such as support for terminally ill patients – attract little commercial investment despite clear public health need. Moreover, as a new therapeutic modality, safe and effective deployment of psychedelic novel treatments will require building clinical expertise, training, and infrastructure well in advance of market entry.

A sandbox approach would complement traditional pathways by allowing supervised, early pilot implementation of psychedelic therapies under regulatory oversight, combined with structured real-world data collection. This would enable regulators, clinicians and researchers to jointly examine safety, efficacy, and delivery models while preparing health systems for wider access. Sandboxes could also serve as practical testing grounds for workforce training, infrastructure development, and reimbursement models, helping to bridge the gap between research and implementation.

In the case of psilocybin for end-of-life anxiety and distress, sandbox programmes could bridge the gap between promising clinical research and safe, structured access for patients with limited treatment options. Conventional large-scale trials are difficult to conduct in this population for ethical and practical reasons, with patient-relevant outcomes more complex to define. A regulated sandbox framework would allow controlled delivery within selected hospitals, enabling real-world data collection on feasibility, safety and patient well-being while ensuring consistent clinical standards and equitable access. In practice, it could help operationalise compassionate use across Member States, also utilising existing structures for palliative care - building upon existing European research on psychedelics.

Experience with ketamine in psychiatry further illustrates the gap that sandboxes could address. Current frameworks are not designed to support the repurposing of generic medicines, often leaving safe and affordable options underused while incentivising expensive reformulations. In the absence of viable approval pathways, off-label ketamine use has proliferated in unregulated settings with inconsistent oversight and therapeutic support. A sandbox could create a lawful, structured environment for such interventions, ensuring data generation, equity, and patient safety, and allowing real-world testing alongside established psychotherapeutic care pathways.

Participating hospitals and research centres could evolve into European centres of excellence for psychedelic therapy, hosted within public or academic institutions. These hubs would concentrate expertise, act as referral centres, and provide high-quality evidence to inform future regulatory, clinical and reimbursement decisions.

Ultimately, psychedelic sandboxes would advance three strategic priorities: generating robust and regulatory-relevant evidence, ensuring the feasibility of implementation, and strengthening public system readiness. By embedding this initiative within Europe's public health agenda, the EU could build the expertise, infrastructure, and governance models needed to safely translate psychedelic science into sustainable care.

Conclusion:
Turning a crisis into a European success story

Mental health is both Europe's great challenge and, if we choose, a great opportunity to demonstrate leadership in innovation. It is often said that Europe should focus on areas of "strategic autonomy" and societal value – and what could be more valuable than empowering our citizens to live mentally healthy lives? The cost of inaction on mental illness is measured not only in economic terms (hundreds of billions lost in productivity, healthcare and social costs) but in human potential and dignity. Conversely, **the upside of innovation in this space is enormous:** improved well-being, increased productivity, reduced strain on healthcare systems, and lives saved from suicide and despair. **By placing mental health at the centre of its innovation and competitiveness agenda,** Europe can address a pressing social need and carve out a niche where it can excel globally.

Europe has the ingredients for success – top-tier researchers, a collaborative ethos, strong public systems and now a political recognition that mental health can no longer be sidelined. What has been missing is a concerted strategy to overcome the market's failure to prioritize this field. That is why initiatives like a Mental Health Moonshot, a dedicated EU strategy, a European mental health care capacity initiative, and better incentives and adaptive regulation are so crucial. They fill the gap that pure market forces left, ensuring that innovators are rewarded for tackling mental health and that effective solutions don't languish in the lab. As the Competitiveness Compass rightly notes, closing the innovation gap requires bold policy action and new frameworks. **Mental health should be a flagship case** where Europe proves it can do this – by simplifying rules, overcoming fragmentation and championing high-risk, high-reward research. If Europe moves decisively, **mental health could become a story of European leadership**, not lagging. We could see, within the next decade, breakthroughs developed and first implemented here in Europe – from advanced psychotherapies to digital diagnostics and preventive tools – *to novel approaches such as psychedelic therapies*. All could then be exported or emulated worldwide, demonstrating that Europe can lead not only in science but in building the policy frameworks that turn fragile innovation into sustainable care.

In sum, access to better mental health treatments tomorrow depends on stimulating innovation today. The EU's emerging policies and initiatives – the European Innovation Act, the upcoming European Brain Health Partnership, Health Union measures, and new research funding programmes – offer a historic window to drive this change. Mental health innovation aligns with Europe's values of equity and solidarity (as it aims to help some of the most vulnerable populations) and with its economic interests (a mentally healthy population is a precondition for productivity and growth). By taking up the recommendations above, the EU can **ensure that the next generation of treatments for depression, anxiety, PTSD, substance use disorders and beyond – such as psychedelic therapies - are "made in Europe,"** and that Europeans in need gain access to them without unnecessary delay. The time is ripe to turn Europe's mental health crisis into a catalyst for policy innovation and scientific progress, forging a healthier, more resilient future for all.

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Who Are PAREA?

We are a pan-European multistakeholder platform representing patient organisations, professional 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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