PAREA
PSYCHEDELIC ACCESS AND RESEARCH EUROPEAN ALLIANCE

Mental health innovation should be part of the European Biotech Act

Briefing note for Health Ministers

The European Biotech Act is an opportunity to strengthen Europe's health innovation capacity, improve competitiveness, and help ensure that scientific progress reaches patients faster. Its core purpose is to address market and regulatory failures that prevent promising innovation from being developed, scaled and made available in Europe.

Mental health is one of the clearest examples of such failure.

Mental health conditions represent one of the largest and most persistent unmet needs in Europe. Approximately 143 million people in the WHO European Region live with a mental health condition, yet only 6.9% receive optimal, effective treatment. Poor mental health results in more years of ill-health than cardiovascular disease, cancer, diabetes and chronic respiratory illnesses combined, and costs Europe over 1 trillion Euros each year.

Despite this burden, mental health innovation remains weak. Psychiatry has seen decades of limited therapeutic progress and ranks last among therapeutic areas in terms of the share of commercial R&D trials in the EU. Europe also faces a serious access gap. Over the past 15 years, the US FDA approved 62 treatments across eight psychiatric conditions, while only 23 received approval from the EMA. Only a fraction of these ultimately became broadly available to patients across Europe.

The General Pharmaceutical Legislation has already recognised that unmet medical needs exist in mental health and that promising medicinal products in this area should benefit from early and enhanced support. It also reflected mental health in compassionate use provisions for serious cases involving severe psychological or emotional distress and impaired daily functioning. The Biotech Act should now be consistent with that direction.

The objective is not to create a separate mental health chapter or lower safety standards. The objective is to ensure that the Act's existing tools can also address one of Europe's most urgent and under-served areas of health innovation.

Member States could help ensure that mental health is reflected across the main instruments of the Act:

- Regulatory sandboxes, so that complex mental health innovations can be developed and assessed where standard pathways are unclear or methodologically constrained
- Strategic mapping and foresight, so that Europe identifies high-burden areas where innovation is not translating into patient benefit
- Strategic and high-impact projects, where mental health initiatives demonstrate clear Union added value
- Investment and support mechanisms, so that under-invested fields such as mental health can access risk-tolerant capital and regulatory support
- Data and AI infrastructure, including high-quality datasets on functioning, quality of life, longitudinal outcomes, treatment adherence and real-world implementation

This is particularly important for complex mental health interventions where outcomes depend not only on the product itself, but also on how it is administered, supported, monitored and integrated into care. Examples include treatment models combining pharmacological and psychotherapeutic elements for treatment-resistant mental health conditions or for psychological distress in serious or life-limiting conditions, such as emerging psilocybin-assisted therapy.

For Member States, this is not only a research or competitiveness issue. It is a health system, workforce, social and economic resilience issue. Mental health needs are carried directly by national health systems, social services, labour markets and families. Europe should not remain dependent on innovation developed elsewhere, nor allow promising approaches to emerge through fragmented national pathways without coordinated learning.

PAREA encourages Member States to support the inclusion of mental health innovation in the Council position on the European Biotech Act.

Europe invests in infrastructure - from clean energy and semiconductor production to digital connectivity and AI. It should treat mental health in the same way: as critical infrastructure that unlocks human potential and fuels economic growth.

About PAREA

Psychedelic Access and Research European Alliance (PAREA) is 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 integration of psychedelic-assisted care into European health systems, making psychedelic therapies reimbursable and accessible for those who do not benefit from existing treatments.