



PAREA
PSYCHEDELIC ACCESS AND RESEARCH EUROPEAN ALLIANCE

POLICY PAPER

Unmet Medical Needs

Aligning Medical Innovation with Societal Health Needs



Introduction

PAREA is a membership-based organization committed to the safe, modern, and ethically responsible integration of psychedelic therapies for mental health into mainstream European health services.

Following our 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," we are pleased to release this policy paper on the topic of unmet medical needs.

Unmet Needs in Defining “Unmet Needs”

A shift toward a public health and societal approach

The availability of medical treatments is largely shaped by the incentives and rewards that public authorities offer for innovation. Numerous obstacles exist when it comes to accessing medicines, but the fundamental issue is whether effective treatments have been developed in the first place.

Understandably, pharmaceutical innovation is predominantly fuelled by commercial interests. However, this focus can create a misalignment with urgent societal health needs. Therefore, rethinking our approach to incentivizing innovation is crucial, especially in underserved areas. A key element of this shift involves redefining what constitutes 'high unmet medical needs,' as this criterion largely dictates what receives priority and funding. Such a recalibration is essential for ensuring that medicine development aligns more closely with public health priorities and needs.



Given that poor health has a profound impact on societies and communities, high unmet medical needs must be evaluated within the broader context of public health and societal challenges; failing to do so risks missing the opportunity for significant impact. Europe must prioritize and promote meaningful needs-driven innovation that places people and public health at the forefront.

The current approach to unmet and high unmet medical needs mainly focuses on life-threatening or severely debilitating conditions for which no treatment exists, with particular emphasis on rare diseases.

While this approach addresses some key aspects of unmet needs, it overlooks a broader health and societal context, including factors like prevalence. The latter is especially relevant for conditions like mental health and substance use disorders, which may not be immediately life-threatening – though many are - but impose a **massive chronic burden on individuals, healthcare systems, societies and economies**. Moreover, the current criteria fall short in highlighting the potential for a positive impact on quality of life, particularly for conditions that are chronic rather than acute.

Is Our House on Fire?

The soaring prevalence of mental health conditions

As we consider the broader landscape of unmet medical needs, one area emerges as particularly pressing: mental health. The WHO has emphasized that mental health is critically important to everyone, everywhere. Yet, it stands out as an area with some of the most glaring unmet needs.

Key statistics and facts on mental health disease burden

Prevalence and onset

- According to the OECD, half of the population will experience mental illness during their lifetime.⁽¹⁾
- A randomly selected sample of 1.5 million individuals from Denmark's population, ranging from birth to 100 years old and spanning from 1995 to 2018, showed that four out of five people received a mental health disorder diagnosis and/or were prescribed psychotropic medication at some point in their lives.⁽²⁾
- In the EU, 7.2% of people, or 32 million, suffer from chronic depression,⁽³⁾ a disorder associated with a high risk of suicide.
- Post-traumatic stress disorder affects 8 million Europeans.⁽⁴⁾ It is a real medical emergency, an eminently treatable condition, and a blind spot in Europe.
- Mental health conditions can manifest at any stage of life, but most symptoms appear by age 14, and nearly 90% peak during a person's 20s. This pattern is unique compared to other chronic physical health conditions, which typically peak in a person's 50s. The early onset of mental health and substance use conditions can lead to lifelong disability.⁽⁵⁾

Treatment Gaps

- WHO Europe estimates that three out of four people with major depression do not receive adequate treatment.⁽⁶⁾
- Up to 50% of the treated patient population experiences incomplete treatment response or treatment resistance.⁽⁷⁾
- Nearly one-third of people with treatment-resistant depression will attempt suicide at least once in their lifetime.⁽⁸⁾

Mortality and suicide

- Every year in Europe, 130,000 people die by suicide,⁽⁹⁾ meaning that between 2016 and now, one million Europeans have lost their lives to suicide.
- Individuals with severe mental disorders have a life expectancy that is 10 to 20 years shorter than the general population.⁽¹⁰⁾

Co-morbidities

- Depression increases the risk of anxiety disorders, substance abuse disorders and other non-communicable diseases, such as diabetes and heart disease. The opposite is also true, meaning that people with these other conditions have a higher risk of depression.

Economic & Societal Impact

- The total costs of mental health conditions account for more than 4% of GDP across EU countries, or over EUR 600 billion.⁽¹¹⁾
- In many Western countries, mental disorders are the leading cause of disability, responsible for 30-40% of chronic sick leave.⁽¹²⁾
- The World Economic Forum's Global Risks Report 2023 identifies the deterioration of mental health as a significant risk to economies and societies.⁽¹³⁾

Future Projections

- By 2030, WHO predicts that depression will become the leading cause of disease burden.⁽¹⁴⁾
- Current estimates suggest that by 2040, we will only be able to prevent 14% of the burden arising from mental health conditions.⁽¹⁵⁾ Notably, mental health ranks last on the long list among numerous other conditions.

The Neglected Epidemic

Alcohol use disorder

Alcohol and other addictions represent one of the most significant unmet medical needs.

- An estimated 55 million adults in the EU drink to harmful levels, 23 million of whom are considered addicted.⁽¹⁶⁾
- Alcohol consumption is responsible for approximately 195,000 deaths each year in the EU.⁽¹⁷⁾ According to WHO data, cancer accounts for 29% of alcohol-attributable deaths in the EU.⁽¹⁸⁾
- Alcohol abuse ranks as the third leading cause of early death and illness in the EU, trailing only tobacco and high blood pressure. It is directly responsible for around 60 diseases and health problems, including lung diseases, breast cancer, mental and behavioural disorders, cardiovascular issues, and foetal and reproductive disorders.⁽¹⁹⁾
- Eight of the ten countries with the highest levels of alcohol consumption globally are in the EU, which has the highest level of alcohol consumption in the world.⁽²⁰⁾
- Alcohol-related harm is a major public health concern in the EU, accounting for over 7% of all ill health and early deaths.⁽²¹⁾
- Despite its significant prevalence and tremendous burden on individuals and societies, treatment for alcohol use disorder is rare and often ineffective. While the disorder affects 5% of the adult population, only 16% of those affected receive treatment, and of those, 75% relapse within 12 months.⁽²²⁾

Overlooked and Underfunded

Unmet needs in mental health

Our current approach to the escalating crisis of mental health disorders is woefully insufficient.

Research and Public Health Funding

- A recent discussion paper from the European Commission titled "Scoping Study on Evidence to Tackle High-Burden Under-Researched Medical Conditions," identifies mental disorders as the number one under-researched area.⁽²³⁾
- Despite estimates suggesting that the return on investment for research in mental health stands at 37%⁽²⁴⁾ - the highest among all biomedical research fields - only 4% of global scientific research grants from 2015 to 2019 were allocated to mental health.⁽²⁵⁾
- In the majority of European countries, a mere 3.6% of the total health budget is dedicated to mental health.⁽²⁶⁾

Scarcity of Novel Treatments

- There are approximately 30 different antidepressants, 20 antipsychotic drugs, seven mood stabilizers for bipolar disorder, and six different classes of drugs for ADHD available. Regrettably, almost none of these are more effective than the medications we had three decades ago, although some have improved side-effect profiles.⁽²⁷⁾
- Last year, not a single one of the 89 new medicines recommended for approval by the European Medicines Agency targeted mental health conditions.⁽²⁸⁾
- Since 2015, only seven neuropsychiatric drugs have been approved globally, in stark contrast to the 80 drugs approved in the field of oncology.⁽²⁹⁾

Bridging The Chasm

Between R&D priorities and unmet mental health needs

These stark disparities highlight a disconnect between current incentives and commercial R&D choices, and the pressing societal mental health needs that remain unaddressed. We must do better. Tens of millions of Europeans affected by mental health conditions and substance use disorders are often in desperate need of improved treatments, and we owe it to them to act.

Mental health issues stand as a prime example of an area with significant unmet medical needs. EU prioritization and concrete initiatives are crucial to spur R&D in this field.



For example, this could be achieved through a European Hub for Mental Health R&D, bringing together EU institutions, member states, healthcare funders, and philanthropic organizations. This research infrastructure could provide guidance and support for evidence-based decision-making in mental health and setting effective incentives, helping to set priorities and maximize the impact of all resources invested in R&D for mental health conditions.

Now more than ever, it's clear that we can no longer afford to soft-pedal the agenda of our mental health and well-being. **Mental health must be addressed as a central pillar of sustainable development.**

The time for action is now.

References

- 1. OECD (2021), [A New Benchmark for Mental Health Systems: Tackling the Social and Economic Costs of Mental Ill-Health](#), OECD Health Policy Studies, OECD Publishing, Paris
- 2. Kessing LV, Ziersen SC, Caspi A, Moffitt TE, Andersen PK. [Lifetime Incidence of Treated Mental Health Disorders and Psychotropic Drug Prescriptions and Associated Socioeconomic Functioning](#). *JAMA Psychiatry*. 2023;80(10):1000–1008. doi:10.1001/jamapsychiatry.2023.2206
- 3. Eurostat, 2021, [7.2% of people in the EU suffer from chronic depression](#), viewed 8 June 2023
- 4. Nemeroff, Charles B., and others, 'Trauma and PTSD in Europe', in Charles B. Nemeroff, and Charles Marmar (eds), *Post-Traumatic Stress Disorder* (New York, 2018; online edn, Oxford Academic, 1 Sept. 2018), <https://doi.org/10.1093/med/9780190259440.003.0008>, accessed 20 Oct. 2023.
- 5. [What is brain health?](#) McKinsey & Company, viewed 18 October 2023
- 6. United Nations Moldova, 2017, [3 out of 4 people suffering from major depression do not receive adequate treatment](#), viewed 8 June 2023
- 7. European Medicines Agency 2016, [Concept paper on the need for revision of the guideline on clinical investigation of medicinal products in the treatment of depression](#), European Medicines Agency, viewed 8 June 2023,
- 8. Bergfeld IO, et al. *Journal of Affective Disorders*. 2018;235:362–367; 7. Dong M, et al. *Epidemiology and Psychiatric Sciences*. 2019;29
- 9. WHO Europe 2022, [Statement – First meeting of the WHO/Europe Mental Health Coalition – From debate to action](#), viewed 8 June 2023
- 10. World Health Organization, [10 facts on mental health](#), World Health Organization, viewed 8 June 2023
- 11. OECD, Health at a Glance: Europe 2018, <https://www.oecd.org/health/health-systems/OECD-Factsheet-Mental-Health-Health-at-a-Glance-Europe-2018.pdf>, viewed 20 October 2023
- 12. WHO Europe, [Mental Health](#), viewed 31 October 2023
- 13. World Economic Forum, [Global Risks Report 2023](#), viewed 30 October 2023
- 14. WHO [Global burden of mental disorders and the need for a comprehensive, coordinated response from health and social sectors at the country level](#), viewed 18 October 2023
- 15. Remes, J. et al. [Prioritizing health: a prescription for prosperity](#). McKinsey 2020, viewed 18 October 2023
- 16. European Commission Factsheet, Alcohol, https://ec.europa.eu/health/ph_determinants/life_style/alcohol/documents/alcohol_factsheet2_en.pdf, viewed 20 October 2023
- 17. European Commission Factsheet, Alcohol, https://ec.europa.eu/health/ph_determinants/life_style/alcohol/documents/alcohol_factsheet2_en.pdf, viewed 20 October 2023
- 18. WHO, New €10 million WHO–EU project will translate evidence into action to reduce alcohol consumption and harms <https://www.who.int/europe/news/item/07-12-2022-new--10-million-who-eu-project-will-translate-evidence-into-action-to-reduce-alcohol-consumption-and-harms>, viewed 20 October 2023
- 19. European Commission Factsheet, Alcohol, https://ec.europa.eu/health/ph_determinants/life_style/alcohol/documents/alcohol_factsheet2_en.pdf, viewed 20 October 2023

References contd...

- **20.** WHO, New €10 million WHO–EU project will translate evidence into action to reduce alcohol consumption and harms <https://www.who.int/europe/news/item/07-12-2022-new--10-million-who-eu-project-will-translate-evidence-into-action-to-reduce-alcohol-consumption-and-harms>, viewed 20 October 2023
- **21.** European Commission, Alcohol Overview, https://health.ec.europa.eu/alcohol/overview_en, viewed 20 October 2023
- **22.** [Treatment rates for alcohol use disorders: a systematic review and meta-analysis](#) by Tesfa Mekonen
- **23.** European Commission, DG Research, Tuyl, L., Zinger, N., Heide, I. et al., Scoping study on evidence to tackle high-burden under-researched medical conditions – Discussion paper, 2023, <https://data.europa.eu/doi/10.2777/311040>
- **24.** Health Economics Research Group, Office of Health Economics, RAND Europe. Medical Research: [What's it worth? Estimating the economic benefits from medical research in the UK.](#) London: UK Evaluation Forum; 2008
- **25.** Eva Woelbert et al., [Accounting for mental health research funding: developing a quantitative baseline of global investments](#), The Lancet Psychiatry
- **26.** WHO, [Rethink mental health: invest in and design better systems for a more resilient European Region](#), viewed on 18 September 2023
- **27.** Insel, T., 2022. [Healing: The Path from Mental Illness to Mental Health](#)
- **28.** European Medicines Agency 2022, [Human Medicines Highlights 2022](#), viewed 8 June 2023
- **29.** Fortune, 2022. [Psychedelic startups want to solve the mental health crisis](#), viewed 8 June 2023



PAREA

PSYCHEDELIC ACCESS AND RESEARCH EUROPEAN ALLIANCE

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:

 www.parea.eu

 tadeusz@para.eu

TADEUSZ HAWROT

Founder and Executive Director

FULL MEMBERS



ASSOCIATE MEMBERS & OBSERVERS



INDUSTRY PARTNERS

