Brain health conditions: Excellence in psychedelic treatments

openaccessgovernment.org/article/brain-health-conditions-excellence-in-psychedelic-treatments/150023

21 December 2022

Dr Rosalind Watts is seen in a treatment room with therapists at Imperial College London's Hammersmith Hospital Campus in London, Britain in this picture taken in 2019. Picture taken in 2019. Imperial College London/Thomas Angus/Handout via REUTERS

Psychedelic treatments open up an unparalleled window of opportunity, but we need to get ready for their roll-out

Mental healthcare is in crisis, and we don't have the tools to truly help millions of Europeans in need. In the EU, a shocking number of over 100 million people are affected by mental health conditions and alcohol use disorder and 56 000 die by suicide every year. And yet, few novel treatments have been developed by the pharmaceutical industry in the last several decades. We urgently need more innovation and psychedelic-assisted therapies (PATs) are emerging as a potent new class of novel treatments for mental, neurological and substance use disorders, as indicated by the rapidly growing, rigorous, and compelling body of research. In conjunction with proper psychosocial support, they hold the potential to provide safe, rapid-acting, and robust clinical improvements with durable effects.

Unlike current treatments that mostly address symptoms, psychedelic treatments and therapies help to confront the root causes of mental health problems or addictions. In doing so, they demonstrate a unique ability to restore a sense of purpose and connection. This, coupled with increased neuroplasticity, provides a deep foundation to embark on a healing process. A crucial aspect of PAT is that improvements are often seen across the board: e.g., someone treated for PTSD may also drink less, have a healthier relationship with food, and feel less depressed.

Psychedelic treatments are coming, and we need prepare for them

The US Administration expects that psychedelic treatments and therapies will be approved by FDA in 2024/2025. Soon after, the EU may follow, and millions of Europeans may be eligible to undergo PAT. This is an unparalleled opportunity which also calls for bold but thoughtful measures. We need to develop the infrastructure for the highest quality safe, affordable, and equitable access to PATs so that they can benefit the greatest number of people. This will include establishing good standards of practice, training of specialised therapists, credentialing and licencing, safe and ethical use monitoring, evidence-based protocols to support people with challenging experiences, engagement of communities and peer-support networks, and developing ethical guidelines and data standards.

Importantly, regulators are not equipped to evaluate the combination of a drug and therapy – traditionally they have been assessing the safety and efficacy of medications alone. Therefore, a close collaboration with the regulatory agencies is needed to overcome this challenge.

Many governments are waking up to the opportunity, but Europe is yet to follow

To address these opportunities and challenges proactively and in a timely manner, the Biden administration is establishing an inter-agency Federal task force. We urgently need to formulate a similar initiative in Europe to address numerous policy and regulatory considerations related to the future roll-out of psychedelic treatments. This could take the form of an EU-led Joint-Action, EU4Health project, EMA pilot, PAT sub-group within the Commission Expert group on Public Health, PAT EU Expert Forum, a horizon-scanning activity as part of the Oslo Medicine Initiative or part of the HTA Regulation and its work to identify emerging health technologies. Indeed, the EU institutions and WHO Europe are perfectly placed to develop and lead such efforts and the chances of succeeding will depend heavily on proactive measures from the EU Institutions and Member States in advance of potential EMA approval of PATs.

PAREA and Drug Science: we need an EU-led co-production approach

A broad range of stakeholders needs to be strongly involved from the outset of the process. This is why a new collaboration – the Psychedelic Access and Research European Alliance (PAREA) – has been officially launched earlier this year. It brings together nearly 20 members spanning patient organizations, professional associations, psychedelic foundations, and the for-profit sector. PAREA is coming together to galvanize action and provide evidence-based policy recommendations and expertise to the EU policymakers to drive systemic change at the highest level. It is chaired by Prof. David Nutt, a prominent PAT researcher from the Imperial College London who is also the Founder of the Drug Science charity.

Drug Science is working to provide evidence base free from political or commercial influence, creating the foundation for sensible and effective drug laws, and equipping the public, media and policymakers with the knowledge and resources to enact positive change. It recently created the Medical Psychedelics Working Group – a cross-sector collaboration that includes scientific experts, academics, policymakers, leaders of patient advocacy groups and industry representatives, collectively aiming to create a rational and enlightened approach to psychedelic research and clinical treatment.

EU institutions must ensure safe, ethical, accessible, and equitable access

The EU-led collaborative effort will help to lay strong and safe foundations for the rollout of the PATs by establishing European guidelines that the EU Member States could choose to follow as they put in place frameworks and structures to accommodate the medical use of psychedelics. Such central coordination would create an effective and efficient mechanism to advance the field, as opposed to having individual EU countries preparing in isolation.

Importantly, given the foreseeable bottleneck of qualified, trained providers based on a likely high demand, a phased rollout will need to be considered, balancing a need for widespread access with safety, monitoring and supervision.

Science is revealing that psychedelic substances can be powerful tools with considerable potential for alleviating human suffering. Though studies show that psychedelics are non-toxic and non-habit forming, and have a good physiological and psychological safety profile when delivered in controlled and supportive settings, these medicines do nevertheless come with a potential for serious risks. Their safety and efficacy are dependent upon their integration within a therapeutic framework, as well as thorough preparation, support and integration and aftercare in specialised healthcare settings. Through cooperative and EU- led stakeholder engagement, a short window of opportunity opens for the creation of a framework that can facilitate safe, ethical, accessible, and equitable access to PAT.

We must act now – we owe it to millions of EU citizens affected by brain disorders who are often in desperate need of better treatments.

Please Note: This is a Commercial Profile