European Parliament

Brussels, 16th of February 2023

To: Alexis Goosdeel, Director, European Monitoring Centre for Drugs and Drug Addiction (EMCDDA)

Dear Mr. Goosdeel,

For several decades, substances with psychedelic properties such as psilocybin and MDMA have been portrayed as highly dangerous drugs with no medical applications. This is reflected in the UN scheduling where they remain in the most restrictive category with the highest potential for abuse, alongside highly addictive drugs like crack cocaine and heroin. However, research has shown that psychedelics are actually among the least harmful drugs, as shown in the 2010 Lancet publication and the 2015 study by EU drug experts "European rating of drug harms".

Crucially, recent evidence demonstrates that psychedelic-assisted therapies can be a highly effective treatment for mental health conditions, including addictions, as suggested by the rapidly growing, rigorous, and compelling body of research.

As a result, the US FDA granted Breakthrough Therapy Designation for trials investigating psilocybin for depression and MDMA for PTSD between 2017-2019. The US Administration is anticipating the regulatory approval of psilocybin and MDMA assisted therapies in the next couple of years for treating depression and PTSD, and is exploring establishing a Federal Task Force to address the issues associated with these novel therapies. In parallel, US Senators introduced a Breakthrough Therapies Act legislation that may enable the Drug Enforcement Agency to make the findings necessary to transfer therapies involving Schedule I substances such as MDMA and psilocybin to a lower schedule.

Most recently, in February 2023, Australia made an announcement of a "Change to classification of psilocybin and MDMA to enable prescribing by authorised psychiatrists". Starting on July 1st, Australia will make history by becoming the first country to legalize the use of MDMA and psilocybin for the treatment of PTSD and treatment-resistant depression.

No effective medicine is without risk and the benefits of a medicinal product always need to be weighed up against its risks. There are risks to taking psychedelics, such as creating emotionally challenging experiences, but the risk profile for this drugs category appears to be low overall.

We believe that the international drug-scheduling system needs to be reformed to ensure that psychedelics with strong medicinal potential are more accessible to scientists and patients before they are approved by regulators like EMA and FDA.

The most restrictive scheduling of psychedelic compounds reinforced misinformation and stigmatization, and directly contributed to a scientific stagnation by detracting scientists from conducting research on these substances. Likewise, governments and EU bodies have been discouraged from supporting psychedelics research. The lack of public funding has been further undermining the ability of academics to pursue psychedelics research. Disadvantaged scientists, who are not affiliated with the industry, are often less resourced than their industry counterparts. Consequently, industry and private donors typically fund psychedelic trials. This situation artificially stifles competition, therapeutic innovation, and access by granting monopolies to companies that develop proprietary therapeutics. As such, the regulatory constraints and patent incentives create a pharmaceutical landscape that privileges high-cost synthetic variants over existing substances. For these reasons, relying predominantly on industry-supported research to achieve the regulatory approval is not an equitable solution to rescheduling psychedelics with medicinal properties.

And yet, currently approval of scheduled medicines (by regulators such as EMA) and rescheduling are effectively synonymous. We reiterate that the existing rescheduling process favours patentable and

expensive synthetic substances over existing inexpensive alternatives. It also restricts research opportunities to only select groups. This is because rescheduling of substances is not possible without regulatory approval.

Therefore, relevant compounds - often scheduled based on little scientific evidence - should have their classifications reviewed based on the recent scientific and medical progress, independent of their possible regulatory approval as medicines. This could allow for scheduling them at a level of control that will prevent harm caused by their inappropriate use and - at the same time - will not act as a barrier to R&D and access.

In view of the developments and challenges mentioned above, we would like to invite the EMCDDA to play a more active role in promoting an evidence-based understanding of issues surrounding psychedelic compounds with therapeutic properties. There is a need to educate the EU institutions and member states about the medical potential of psychedelic compounds and the recent scientific progress which has taken place in this area. EMCDDA's experience in providing high-quality scientific evaluation of psychoactive substances could help raise awareness about the importance of easing the legal barriers to conducting research with those compounds, considering broader scientific and societal impact. The EU should also create ample funding opportunities to research promising psychedelic substances and to better understand the societal implications of their adoption.

The EMCDDA is also well positioned to foster discussions about the EU's potential role in re-examining the scientific evidence behind the current scheduling of promising psychedelic compounds in the UN conventions.

This could mean developing a report or a series of reports on the scientific, clinical, and regulatory issues related to making psychedelics available to treat mental health conditions and substance use disorders. The report could discuss areas like i) the existing evidence supporting the medical use of psychedelics, ii) the impact that the current UN scheduling has on the European R&I, particularly with a reference to hurdles faced by academic research, iii) the role the EU could play in revising the scientific evidence behind the current scheduling, iv) examples and case studies of other approaches taken by non-EU/European countries to allow the medical use of psychedelics and expand access.

To address these challenges and opportunities in a meaningful and inclusive manner, the EMCDDA should consider organizing a workshop with representatives from relevant EU institutions and agencies, national authorities, the scientific community, and patient organizations. In order to make the best use of the existing European expertise, we believe that a close collaboration with the European Medicines Agency will be the most efficient way forward. The EMA and EMCDDA have a major opportunity to furnish EU policymakers, including European Parliament Members, with the vital information and direction they need in order to make informed decisions that impact the health of the European population and serve as a model for policymakers globally.

Yours sincerely,

Signatories:

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