EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Member of the European Parliament
European Parliament
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3 March 2023

European Medicines Agency
EMA/41105/2023

Dear Mr Agius Saliba, Ms Ries, Mr Duda, Mr Biedroń, Ms Cerdas and Ms Metz,

Re: On substances with psychedelic properties

Thank you for your letter of 16 February. In your letter you refer to recent evidence demonstrating that psychedelic-assisted therapies can be a highly effective treatment for mental health conditions and that the risk profile for this drug category appears to be low. You also refer to number of research, policy, and regulatory advancements in the United States and Australia and express concern about the lack of similar progress happening in the EU. You invite EMA to play a more active role in this area, propose several examples to this end and suggest closer collaboration between the EMA and European Monitoring Centre for Drugs and Drug Addiction (EMCDDA).

Firstly, I want to reassure you that EMA recognises that mental health conditions and substance use disorders are one of the highest public health challenges in Europe. EMA is also aware that psychedelic-assisted therapies is a fast-growing area and EMA is closely following the developments in this field, including international research and regulatory activities related to the potential clinical use of psychedelics for those conditions, notably for treatment resistant depression, PTSD, and substance abuse, as also mentioned in your letter. While these developments look promising, it should be highlighted that requirements for marketing authorisation applications for medicinal products containing active substances classified as psychedelic substances are the same as for any other marketing authorisation in the EU/EEA. For a medicinal product to receive a marketing authorisation in the EEA, the particulars and documents which must accompany the application for marketing authorisation must demonstrate that potential risks are outweighed by the therapeutic benefits of the product.

Secondly, in response to your concern about the lack of progress in the EU, I would like to let you know that EMA recognises the need to support the developers of psychedelics and therefore engages with them to this end. There are currently 11 ongoing clinical trials in EU with psilocybin for a range of central nervous system conditions, 4 trials are ongoing with MDMA and one trial with LSD (EU Clinical Trial Register[1], 17 February 2023). EMA and members of its Central Nervous System Working Party[2] are actively engaged with academic researchers from the European College of

[1] Clinical Trials in the European Union - EMA (euclinicaltrials.eu)
[2] Central Nervous System Working Party | European Medicines Agency (europa.eu)

Neuropsychopharmacology (ECNP). This close cooperation has resulted in a recent publication (10 Feb 2023) in *The Lancet* articulating the European regulatory and scientific challenges related to the topics, and an encouragement for all developers (academic and industry) to engage with EU regulators[3]. A session with EMA and members of Central Nervous System Working Party is planned at the upcoming ECNP New Frontiers Conference on psychedelics (19-20 March 2023)[4].

Thirdly, I take note examples you provided on how EMA could further expand its activities in this field. Proposed paths of action will be considered internally and followed-up as appropriate. I am pleased to inform you that a multi-stakeholder workshop is being planned for Q3/Q4 2023 focusing on promoting the development of psychedelics that address unmet medical needs. I would also like to let you know that EMA has an established framework for interaction with EMCDDA, having signed the first official working arrangement already in 2010. This Working Arrangement[5] allows EMA and EMCDDA to cooperate and have regular exchanges at the technical level on matters falling under their respective mandates, such as exchange of information on new psychoactive substances and on abuse of medicinal products, and to develop an effective line of cooperation on psychedelic substances.

I remain available should you have any further questions.

With kind regards,

Signature on file

Emer Cooke

Executive Director

[3] https://doi.org/10.1016/S0140-6736(23)00264-7
[4] ECNP New Frontiers Meeting 2023: Psychedelics
19-20 March 2023
[5] Memorandum of Understanding on Working Arrangements between the European Medicines Agency (EMA) and the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) (europa.eu)