



2024/2488

19.9.2024

COMMISSION IMPLEMENTING DECISION (EU) 2024/2488

of 11 September 2024

on the request for registration, pursuant to Regulation (EU) 2019/788 of the European Parliament and of the Council, of the European citizens' initiative entitled 'PsychedeliCare'

(notified under document C(2024) 6086)

(Only the English text is authentic)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) 2019/788 of the European Parliament and of the Council of 17 April 2019 on the European citizens' initiative ⁽¹⁾, and in particular Article 6(2) and (3) thereof,

Whereas:

- (1) A request for registration of a European citizens' initiative entitled 'PsychedeliCare' was submitted to the Commission on 24 July 2024.
- (2) The aims of the initiative as expressed by the organisers are to call on the Commission 'to foster equitable, timely, affordable, safe, and legal access to innovative psychedelic-assisted therapies'. These aims are further defined by the organisers through three objectives. The first objective calls on the Commission to 'support the establishment of an expert consensus on standards of psychedelic care, with psychological support, therapist training, ethical guidelines and safety measures, to ensure the safe and effective rollout of psychedelic therapies' and to 'back capacity building efforts for multidisciplinary training programs on mental health, specifically designed for psychedelic therapy training for healthcare providers'. Through the second objective, the organisers call on the Commission to 'boost EU-funded research into the therapeutic applications of psychedelics to strengthen the evidence of their safety and efficacy' and to 'support the development of research networks focusing on innovative therapies'. The third objective calls for the adoption of 'common positions within UN fora to advocate for pragmatic, progressive transnational regulations concerning psychedelic compounds' and 'appropriate recommendations for the rescheduling of psychedelic compounds in the 1971 UN Convention on Psychotropic Substances'.
- (3) An annex to the initiative provides further details on the subject matter, objectives and background to the initiative. It states that '[t]here is a mental health crisis in the EU' and that '[u]p to 50 % of patients do not respond to the psychiatric treatments currently available'. The annex explains that 'a growing body of scientific evidence indicates the effectiveness of psychedelic-assisted therapies' and considers that 'the Commission should build on this momentum to proactively establish the legal framework and medical conditions for integrating psychedelics into therapy in the EU'. The organisers thus call for the recognition of 'the unique specificities of psychedelic therapies and their potential to meet high unmet needs for mental health conditions and substance use disorders', which they consider 'impose a burden on individuals, healthcare systems, societies, and economies'.
- (4) As regards the first objective of the initiative, the Commission could submit a proposal for a legal act to support the safe and effective rollout of psychedelic therapies based on Article 168 of the Treaty on the Functioning of the European Union (TFEU), as long as, in accordance with Article 168(7) TFEU, this does not interfere with the competence of the Member States in the field of reimbursement of medicines or therapies.
- (5) As regards the second objective of the initiative, the Commission could submit a proposal to boost EU-funded research into the therapeutic application of psychedelics to strengthen the evidence of their safety and efficacy, based on Article 182 TFEU.

⁽¹⁾ OJ L 130, 17.5.2019, p. 55, ELI: <http://data.europa.eu/eli/reg/2019/788/oj>

- (6) Finally, concerning the third objective, the Commission could submit, based on Article 218(9) TFEU, a recommendation for a Council decision establishing the position to be adopted on the Union's behalf concerning psychedelic compounds in United Nations bodies set up by an agreement that adopt acts having legal effects.
- (7) For those reasons, the Commission considers that none of the parts of the initiative manifestly falls outside the framework of the Commission's powers to submit a proposal for a legal act of the Union for the purpose of implementing the Treaties.
- (8) That conclusion does not affect the assessment of whether the concrete substantive conditions required for the Commission to act, including compliance with the principles of proportionality and subsidiarity and compatibility with fundamental rights, would be met in this case.
- (9) The group of organisers has provided appropriate evidence that it fulfils the requirements laid down in Article 5(1) and (2) of Regulation (EU) 2019/788 and has designated the contact persons in accordance with Article 5(3), first subparagraph, of that Regulation.
- (10) The initiative is not manifestly abusive, frivolous or vexatious, nor is it manifestly contrary to the values of the Union as set out in Article 2 of the Treaty on European Union or to the rights enshrined in the Charter of Fundamental Rights of the European Union.
- (11) The initiative entitled 'PsychedeliCare' should therefore be registered.
- (12) The conclusion that the conditions for registration under Article 6(3) of Regulation (EU) 2019/788 are fulfilled does not imply that the Commission in any way confirms the factual correctness of the content of the initiative, which is the sole responsibility of the group of organisers of the initiative. The content of the initiative only expresses the views of the group of organisers, and can in no way be taken to reflect the views of the Commission,

HAS ADOPTED THIS DECISION:

Article 1

The European citizens' initiative entitled 'PsychedeliCare' shall be registered.

Article 2

This Decision is addressed to the group of organisers of the citizens' initiative entitled 'PsychedeliCare', represented by Théo GIUBILEI and Flavio CANDELI acting as contact persons.

Done at Brussels, 11 September 2024.

For the Commission
Věra JOUROVÁ
Vice-President