

Message 013

Communication from the Commission - TRIS/(2025) 3349

Directive (EU) 2015/1535

Notification: 2025/0687/CZ

Acceptance by the Commission of the invocation of urgency (article 6, paragraph 7, of Directive (EU) 2015/1535) and closure of the procedure for the provision of information.

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1. MSG 013 IND 2025 0687 CZ EN 19-11-2025 25-11-2025 COM URGENCY 19-11-2025

2. Commission

3. DG GROW/E/3 - N105 04/63

4. 2025/0687/CZ - C10P - Pharmaceuticals

5. article 6, paragraph 7, of Directive (EU) 2015/1535

6. On 18 November 2025, the Czech authorities notified under reference 2025/687/CZ the “Draft Government Decree on the conditions for the prescription, supply and use of individually prepared medicinal products containing psilocybin for therapeutic use”, and requested the urgent adoption procedure provided for in Article 6 (7) of Directive (EU) 2015/1535.

Following examination of the draft, the Commission is of the opinion that the claim for urgent adoption is justified.

The fact that the Commission accepts the urgency of this case in no way prejudices its assessment of the compatibility of the notified measure with European Union law.

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