…

GOVERNMENT REGULATION
of ...

on the conditions for the prescription, supply and use of individually prepared medicinal products containing psilocybin for therapeutic use

Pursuant to § 33l(4) of Act No 167/1998 on addictive substances and amending certain other acts, as amended by Act No 270/2025, and pursuant to § 79a(3) of Act No 378/2007 on pharmaceuticals and amending certain related acts (the Pharmaceuticals Act), as amended by Act No 270/2025, the Government hereby orders the following:

§ 1

Subject matter

This Regulation governs

a) the conditions for the prescription, supply and use of an individually prepared medicinal product containing psilocybin for therapeutic use;
b) the specialised qualifications of a physician who may prescribe an individually prepared medicinal product containing psilocybin for therapeutic use;
c) the duration of special supervision.

§ 2

Prescribing and administering individually prepared medicinal products containing psilocybin for therapeutic use

(For the implementation of § 79a(3)(a) and (c) of the Pharmaceuticals Act and § 33l(1) of the Addictive Substances Act)

(1) An individually prepared medicinal product containing psilocybin for therapeutic use may only be prescribed and administered in the context of health services provided by a physician with specialised qualifications in the field of psychiatry or with specific specialist qualifications in the subspecialty of medical psychotherapy, in cases of ineffectiveness or documented intolerance to treatment with authorised medicinal products and in accordance

with the recommended clinical procedure for assisted psychotherapy using psilocybin for therapeutic use, in the following indications:

a) depressive disorder associated with an oncological disease;

b) clinically significant depressive disorder without psychotic symptoms; or

c) sudden deterioration of another serious neuropsychiatric or mental disorder seriously jeopardising the patient's life, provided that such therapeutic use of psilocybin is sufficiently justified by scientific evidence.

(2) An individually prepared medicinal product containing psilocybin for therapeutic use may only be prescribed and administered in an oral pharmaceutical form.

(3) On the blue-stripe prescription form, the prescribing physician shall indicate the strength, pharmaceutical form and dosage of the individually prepared medicinal product containing psilocybin for therapeutic use. Additional information to be included on the blue-stripe prescription form is stipulated in legislation governing the rules for prescribing medicinal products when providing health services[1]).

§ 3

Restrictions on a medicinal product containing psilocybin for therapeutic use

(For the implementation of § 79a(3)(b) of the Pharmaceuticals Act and § 33l(1) of the Addictive Substances Act)

(1) For the prescription, supply and use of an individually prepared medicinal product containing psilocybin for therapeutic use, psilocybin for therapeutic use may be used in an aggregate quantity of not more than 75 mg of psilocybin for therapeutic use over a period of one calendar month.

(2) A single dose must not contain more than 35 mg of psilocybin for therapeutic use and the dosage must not exceed 0.4 mg/kg of the patient's body weight.

(3) An individually prepared medicinal product containing psilocybin for therapeutic use may be administered a maximum of three times per month, with a minimum interval of seven days between doses.

(4) If the patient does not experience a clinically significant positive effect after three consecutive doses, further use of the individually prepared medicinal product containing psilocybin for therapeutic use is excluded.

§ 4

Duration of special supervision

(For the implementation of § 33l(4) of the Addictive Substances Act)

(1) Special supervision during the administration of an individually prepared medicinal product containing psilocybin for therapeutic use, carried out by the physician who administered it, shall last for

a) at least 4 hours for doses of up to 14.99 mg of psilocybin for therapeutic use;

b) at least 6 hours for doses from 15 mg of psilocybin for therapeutic use.

(2) Special supervision may only be terminated after the effects of the individually prepared medicinal product containing psilocybin for therapeutic use have completely subsided, as determined by the physician who administered it.

§ 5

Technical regulation

This Regulation was notified in accordance with Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services.

§ 6

Effective date

This Regulation shall come into effect on …….. 2026.

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[1]) Decree No 329/2019 on the prescription of medicinal products when providing health services, as amended.