PARLIAMENT OF THE CZECH REPUBLIC

Chamber of Deputies
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Amendment by MP Marek Benda

to the Government Bill amending Act No. 40/2009 Coll., the Criminal Code, as amended, Act No. 141/1961 Coll., on Criminal Procedure (Criminal Procedure Code), as amended, and other related acts

(Parliamentary press 861)

The government bill amending Act No. 40/2009 Coll., the Criminal Code, as amended, Act No. 141/1961 Coll., on Criminal Procedure (Criminal Procedure), as amended, and other related acts are amended as follows:

1) In Part Six, Article VIII, the following new points are inserted before the current point 1:

"X. In Section 2, at the end of paragraph 1, the full stop is replaced by a comma and the letter t) is added, which reads:

"t) psilocybin for medicinal use means psilocybin that is intended by the manufacturer for therapeutic purposes in humans.".

X1. In Section 3, paragraph 3 is added, which reads:

"(3) By way of derogation from Section 4, psilocybin may be used for limited therapeutic purposes in accordance with this Act in psychiatric hospitals and psychiatric hospitals under the direct jurisdiction of the Ministry of Health and in psychiatric outpatient, inpatient or inpatient care facilities that are part of hospitals under the direct jurisdiction of the Ministry of Health, only by a physician with specialized qualifications in the specialized field of psychiatry or special specialized qualifications in the additional field of medical psychotherapy, who will exercise special supervision pursuant to Section 35a. In healthcare facilities not under the direct jurisdiction of the Ministry of Health, psilocybin may be used for therapeutic purposes on the basis of a permit.".

The following points are renumbered.

2) In Part Six, Article VIII, the following new points are inserted after the current point 1:

"X2. In Section 8, at the end of paragraph 6, the full stop is replaced by a comma and the letter k) is added, which reads:

"k) a declaration by the applicant that the facility pursuant to Section 3(3), third sentence, which intends to use psilocybin for therapeutic purposes, has ensured the presence of a physician with specialized competence in the specialized field of psychiatry or special specialized competence in the additional field of medical psychotherapy, who will perform special supervision pursuant to Section 35a.".

X3. In Section 8, paragraph 14 is added, which reads:

"(14) The Ministry of Health shall issue a treatment permit upon application to a healthcare facility pursuant to Section 3(3) which proves that, on the date of application, it meets the conditions under this Act for administering psilocybin for therapeutic use; the Ministry of Health shall withdraw the treatment permit if the holder of the permit ceases to meet the conditions for administering psilocybin for therapeutic use.".

X4. In Section 13, paragraph 1, letter b), the words “or psilocybin ” are inserted after the word “cannabis.”.

The following points are renumbered.

3) In Part Six, Article VIII, a new point is inserted after the current point 2, which reads:

"X5. A new Title VIII is inserted after Title VII, which shall read as follows, including the title:

"TITLE VIII

MEDICINAL PSILOCYBIN

§ 35a

Psilocybin for medicinal use

(1) Psilocybin for medicinal use must meet the conditions set for its use for the preparation of an individually prepared medicinal product containing psilocybin for medicinal use in accordance with the legal regulation governing the conditions for the prescription, preparation, distribution, dispensing and use of individually prepared medicinal products containing psilocybin for medicinal use.

(2) Psilocybin for medicinal use is reserved for treatment in healthcare facilities pursuant to Section 3(3) with special supervision during its administration, carried out by a doctor with specialized qualifications who administered psilocybin for therapeutic use. Psilocybin for therapeutic use may only be administered in justified cases to a patient over 18 years of age. The administration of psilocybin for therapeutic use is guided by the clinical recommended procedure for assisted psychotherapy with psilocybin for therapeutic use.

(3) Special supervision includes repeated monitoring of the mental state and vital functions of a patient who has been administered psilocybin for therapeutic use during an individual session. The physician who administered psilocybin for therapeutic use shall keep a record of the course of each individual session; the record shall be kept for a period of at least 10 years from the date of the last entry.

(4) The duration of special supervision in the case of psilocybin for medicinal use shall be determined by the Government by regulation.”.

The previous Titles VIII to X shall be renumbered as Titles IX to XI. ".

The following points are renumbered.

4) In Part Six, Article VIII, a new point is inserted after the current point 3, which reads:

"X6. In Section 39, a new paragraph 5 is inserted after paragraph 4, which reads:

"(5) A person commits an offence if he

a) uses psilocybin for medicinal purposes in violation of Section 3(3),

b) as a doctor with specialized qualifications administering psilocybin for medicinal use, administers psilocybin for medicinal use in violation of Section 35a(2) to a person under the age of 18,

c) as a doctor with specialized qualifications administering psilocybin for medicinal use, does not carry out special supervision during the administration of psilocybin for medicinal use pursuant to Section 35a(2) or does not carry out special supervision for the specified duration,

d) as a physician with specialized qualifications administering psilocybin for therapeutic use, fails to keep and maintain records pursuant to Section 35a(3), or

e) administers psilocybin to a person for medicinal use or carries out special supervision despite not having the required specialized competence.”.

The previous paragraphs 5 to 9 are referred to as paragraphs 6 to 10.”.

The following points are renumbered.

5) In Part Six, Article VIII, the following point is added after the current point 5:

"X7. In Section 39, paragraph 11 is added, which reads as follows:

"(11) For an offence under Section 39(5), a fine of up to

a) CZK 300,000, if it is an offence under letter d),

b) CZK 500,000 if it is an offence under letter a), b), c) or e)..".

6) A new Part Eleven is inserted after Part Ten, which reads:

"PART ELEVEN

Amendment to the Pharmaceuticals Act

Article XIV

Act No. 378/2007 Coll., on pharmaceuticals and on amendments to certain related acts, as amended by Act No. 124/2008 Coll., Act No. 296/2008 Coll., Act No. 141/2009 Coll., Act No. 291/2009 Coll., Act No. 281/2009 Coll. , Act No. 75/2011 Coll., Act No. 375/2011 Coll., Act No. 50/2013 Coll., Act No. 70/2013 Coll., Act No. 250/2014 Coll., Act No. 80/2015 Coll. , Act No. 243/2016 Coll., Act No. 65/2017 Coll., Act No. 66/2017 Coll., Act No. 183/2017 Coll., Act No. 251/2017 Coll., Act No. 36/2018 Coll., Act No. 44/2019 Coll., Act No. 262/2019 Coll., Act No. 89/2021 Coll., Act No. 261/2021 Coll. , Act No. 326/2021 Coll., Act No. 366/2021 Coll ., Act No. 314/2022 Coll. , Act No. 456/2023 Coll., Act No. 241/2024 Coll., Act No. 387/2024 Coll., Act No. 338/2024 Coll. and Act No. …/2025 Coll., is amended as follows:

1. In the heading of Section 79a, the words " **or psilocybin " are inserted after the word " cannabis "** .
2. In Section 79a, new paragraphs 2 and 3 are inserted after paragraph 1, which read as follows:

"(2) For therapeutic purposes, an individually prepared medicinal product containing psilocybin for therapeutic use may be prescribed, dispensed and used in accordance with the Act on Addictive Substances in accordance with the implementing legal regulation. A medicinal product containing psilocybin for therapeutic use may only be prescribed on a request form with a blue stripe, which contains the name, surname and date of birth of the patient for whom it is intended. The dispensing of a medicinal product containing psilocybin for therapeutic use may only be carried out by a doctor with specialized qualifications, who administers it to the patient and who is responsible for ensuring that its prescription and administration comply with the conditions under the regulation issued pursuant to paragraph 3.

(3) The Government shall determine by regulation:

a) indications for which psilocybin can be used for medicinal purposes,

b) limiting the dispensing and use of an individually prepared medicinal product containing psilocybin for medicinal use in a specified quantity within a specified period,

c) requirements for the specialized competence of a physician who can individually prepare a medicinal product containing psilocybin for therapeutic use "prescribe for individual diagnoses".

The previous paragraphs 2 to 4 are referred to as paragraphs 4 to 6.

3. In Section 79a, paragraph 4, the number "3" is replaced by the number "5".
4. In Section 108, paragraph 1, letter m), the number "4" is replaced by the number "6".
5. In Section 108, paragraph 2, a new letter g) is inserted after letter f), which reads:

   "G) prescribes or administers a medicinal product containing psilocybin for medicinal use in violation of Section 79a(2),“.

   The previous letters g) and h) are referred to as letters h) and ai).
6. In Section 108(11)(c), the words “a), b), f), g) or h)” are replaced by the words “a), b), f), g), h) or i)”.
7. In Section 114, paragraph 1, the words "Section 79a, paragraphs 1 and 4" are replaced by the words "Section 79a, paragraphs 1, 2 and 6".
8. In Section 114, paragraph 4 is added, which reads:

   "(4) The Government shall issue a regulation to implement Section 79a, paragraphs 2 and 3.".

The following parts and articles shall be renumbered.'.

7) In the title of Part Twenty, the word "TWENTY" is replaced by the word "TWENTY".

Justification of the proposed changes

The amendment is based on the Government's Program Statement, which committed to regulating addictive and psychotropic substances according to their severity. With this in mind, the criminal penalties for drug offenses in the Criminal Code, to which this amendment relates, have also been changed.

the substances psilocybin and psilocin are considered to be effective means of primarily psychiatric, palliative and symptomatic treatment of selected diseases and conditions.

The currently valid ZoNL allows the use of psilocybin and psilocin only for very limited therapeutic and scientific purposes, while its individual provisions of the law practically completely exclude patients' access to this treatment option.

The substances psilocybin and psilocin are still included in Annex No. 4 of the Government Implementing Regulation to the ZoNL , which contains psychotropic substances for which the strictest regime is set, which practically excludes their use in the pharmaceutical industry (handling by doctors or pharmacists, import of medicinal products, etc.). Narcotic substances that have therapeutic uses (including, for example, cocaine, morphine or opium), on the other hand, are included in Annex No. 1 of the Government Implementing Regulation to the ZoNL , for which the ZoNL allows such use, and are therefore paradoxically in a much milder regime.

The 1971 United Nations Convention on Psychotropic Substances regulates the conditions under which the substances psilocybin and psilocin may be manufactured and distributed for limited medical or scientific use. According to the UN Conventions, the medical or scientific use of psilocybin and psilocin requires the establishment or designation of a state entity to control the handling of these substances for research and treatment purposes at the national level, with strict supervision of these activities and the need to keep records of these substances with a detailed description of their use. These facilities must also be under the direct control of the government or operate on the basis of its special permission.

The US state of Oregon passed a law in 2020 (*Oregon Psilocybin Services Act*), which came into effect on 1 January 2023 and regulates the legal conditions for the therapeutic use of Psilocybin . Australia has also legalized psilocybin and other psychedelics for therapeutic purposes. The amendment is inspired by these foreign regulations.

In relation to the facts described above, it should be noted that the Czech Republic already incorporated cannabis for medicinal use into its legal system in 2013. Subsequently, but only a few years later, in 2020, the UN Commission on Narcotics decided, on the recommendation of the World Health Organization, to reclassify cannabis from List IV with the strictest regime to List I with the most liberal regime of the UN Convention on Narcotic Drugs. The World Health Organization's recommendation aimed to remove obstacles to the availability of cannabis for medicinal purposes. This fact subsequently did not need to be reflected in the Czech legal system in any way, given the far-sighted legal regulation already enshrined in 2013.

The amendment certainly does not mean a breakthrough in the recreational use/abuse of these psychotropic substances, this use/abuse remains prohibited and, moreover, criminally treated. The bill limits the misuse of these substances for any other than medical and scientific purposes in accordance with international conventions.

Changes to the Act on Addictive Substances:

General: The amendment contains changes to allow treatment with psilocybin , which are analogous to the legal regulation of cannabis for medicinal use, which was enshrined in the Czech Republic in 2013. The proposal does not conflict with the UN Convention on Psychotropic Substances or with EU Directive 83/2001. The substance psilocybin remains included in Annex No. 4 of the Government Implementing Regulation to the Act on Addictive Substances. It is newly stipulated that psilocybin may be administered subject to strict restrictions for medicinal use within the framework of assisted psychotherapy. In this context, " psilocybin for medicinal use" will be included in List 5 of the Government Implementing Regulation to the Act on Addictive Substances, without deleting "non-medicinal" psilocybin from Annex No. 4. The reason for submitting this amendment is the fact that scientific studies show [1]that psilocybin has very good results in the treatment of psychiatric illnesses, in cases where common psychotropic drugs fail. This is especially the case for resistant depression. Limited therapeutic purposes in practice represent the fact that psilocybin can only be administered in healthcare facilities that are under the control of the government, or rather. The Ministry of Health and further on the basis of a permit granted by the Ministry of Health, and only to a healthcare facility (here the aim is to attract interest from outpatient psychiatrists who meet the conditions). Psilocybin will only be able to be administered on site within a session for selected, strictly defined psychiatric diagnoses. Only a psychiatrist who will supervise the session will be able to administer the medicine. It is assumed that it will be issued on a request form with a blue stripe only to the doctor who will administer the substance. The prescription of the drug is then allowed to a wider category of doctors, whose specialization is determined by government regulation. The intention is, for example, to allow palliative care in the terminal stage to prescribe this drug, which can help alleviate fears of death, while the administration of the drug will always be in the hands of psychiatrists in accordance with the proposed amendment.

In no way is this a permit for recreational use of the substance. The therapeutic potential of psilocybin could represent a breakthrough in the future in the field of treatment, whether for addiction, depression, post-traumatic stress disorder or other diseases, because, unlike classic psychotropic drugs, its action in connection with changing the psychological setting focuses on the cause of the problem and does not only address the consequence.

Amendments to the Pharmaceuticals Act:

General: In connection with the amendment to the Act on Addictive Substances, the Act on Pharmaceuticals is being amended. This is a similar legal regulation to that in the case of cannabis for medicinal use. Psilocybin will be able to be prepared as an individually prepared medicinal product. The government will subsequently specify in its regulation the conditions of the quantity limitation, the indications for which the medicinal product may be administered, the specialization of the doctor and the duration of special supervision during psychotherapy depending on the quantity administered. The amendments are in accordance with the legal order of the Czech Republic, European law and international conventions.

[1] https://www.nejm.org/doi/pdf/10.1056/NEJMoa2206443 - these are data published in an extremely respected medical journal of global importance.