A Summary of Information about Medical Cannabis in the Czech Republic – the situation as of 25 March 2013

Act No. 50/2013 Coll. dated 30 January 2013, amending Act No. 378/2007 Coll., on pharmaceuticals, Act No. 167/1998 Coll., on addictive substances, and Act. No. 634/2004 Sb., on administrative fees, was promulgated in the Collection of Laws on 4 March 2013. The Act introduces the option of using cannabis for therapeutic purposes in the Czech Republic.

The Act complies with the international conventions concerning the control of narcotic and psychotropic substances. Therefore, patients will be provided with medical cannabis solely under a controlled regime of medical indication and it will only be available to them from pharmacies on a prescription basis. The individual growing of cannabis for medical use is not allowed by the Act. The system of prescribing and supplying medical cannabis as adopted features the following principal parameters:

1. the prescription of medical cannabis is conditioned by a physician's specialised qualifications;
2. the prescription and supply of cannabis will be subjected to restrictions (including treatment indication criteria and limits on the maximum quantity of the cannabis supplied according to the type of diagnosis/syndrome);
3. medical cannabis will be provided by means of electronic prescriptions only;
4. pharmacies will maintain records of their supply of cannabis as long as it is necessary to account for the restrictions specified under item 2. Afterwards the entry in the drug supply register will be deleted.

In addition, the repository of electronic prescriptions and the drug supply register will interact from the moment of cannabis being prescribed by a physician. This procedure dramatically reduces the risk of medical cannabis being misused.

The import, cultivation, and further handling and distribution are controlled in such a way as to minimise any diversion of medical cannabis and products made therefrom onto the illicit market, as well as preventing any other form of the legal market in medical cannabis merging with the illicit one.

The wording of the law results from the work and conclusions of the Joint Working Group of the Secretariat of the Government Council for Drug Policy Coordination and the Chamber of Deputies of the Parliament of the Czech Republic for the legislation and the relevant regulations governing the cultivation, processing, distribution, and use of non-industrial cannabis for medical and research purposes (hereinafter referred to as "the Working Group"), which was established in August 2011 as part of the Secretariat of the Government Council for Drug Policy Coordination at the behest of the Prime Minister of the Czech Republic and under the aegis of the Chair of the Chamber of Deputies of the Parliament of the Czech Republic.

Medical cannabis should mainly be indicated to alleviate pain, spasms, nausea, and vomiting as secondary manifestations of a primary disease. According to the opinions of the professional societies affiliated with the Jan Evangelista Purkyně Czech Medical Association, cannabis and preparations made therefrom may be used to treat especially the following illnesses and conditions:

- chronic pain, especially neuropathic and cancer-related
- post-encephalitic conditions (neuroinfections)
- post-herpetic neuralgias
- wasting syndrome in HIV/AIDS (loss of body mass and weight)
- polyneuropathy (mainly in HIV/AIDS)
- loss of appetite in patients with cancer and AIDS
- psoriasis
- atopic eczema
- lichen planus (an inflammatory disease of the skin and mucosa manifesting itself in the form of rashes, often in the area of the mouth)
- painful glaucoma (glaucomatous attack).

The amendments to the legal regulations under consideration become effective on 1 April 2013. However, some of them have had their effect postponed until 1 April 2014. Amended stipulations with postponed effect include those concerning the possibility of cultivating cannabis for medical use, the selection proceedings needed for the granting of a licence for cultivation, the processing of cannabis grown for medical use, and the purchase and transport of the medicinal product to pharmacies. The

State Institute for Drug Control, designated by the amended law as the National Agency for Medical Cannabis, will use the postponement period to set up the system in its entirety, including the procedures for the selection of growers. In the meantime, it will be possible to import medical cannabis under the supervision of the Inspectorate for Narcotic and Psychotropic Substances (an independent office of the Ministry of Health of the Czech Republic).

The cultivation of cannabis for medical use will be allowed to corporations and individual entrepreneurs who have been licensed to do so by the State Institute for Drug Control. A licence holder is not allowed to commence growing medical cannabis without having being granted authorisation to handle addictive substances and preparations.

An entity which has been granted a licence to cultivate medical cannabis is required:

a) to ensure that cultivation and processing take place in indoor premises suitable for this purpose,
b) to secure the premises where cultivation, harvesting, and processing take place against any misuse,
c) to ensure that formal records are maintained of any activities performed in relation to cultivation, harvesting, and processing,
d) to enable the State Institute for Drug Control to inspect, at all times and without prior notice, any premises used for growing and processing, as well as to make accessible to such an authority any formal records of the entity's activities and other relevant documents; similarly, a separate legal regulation will be used to govern the rights and obligations of both the inspectors and inspectees,
e) to ensure that all the vegetable waste is handled as envisaged by Section 10 and disposed of at that entity's own expense in a method specified in Section 14; vegetable waste will also mean any cannabis that does not conform to the tender dossier and technical specifications.

As an innovation, the Act introduced an electronic prescription system which makes it possible to check the quantity of medicinal products that have been dispensed. Prescriptions are kept in the central register of prescriptions as long as necessary to assure that the limit for the quantity to be dispensed per the given period of time (one month) has not been exceeded. In addition, prescriptions will be stored in the central repository of prescriptions. Both systems interact with the effect that a physician is prevented from making out a prescription in the event that the medicinal product has already been supplied in a quantity that exceeds the legal limit.

Important dates:

- 16 August 2011: a medical cannabis petition, http://www.lecebnekonopi.cz/, was made public.
- August 2011: the Working Group for making cannabis available for treatment and research in the Czech Republic (the Cannabis Working Group) was established; for more details see http://bit.ly/u5WRWo
- 15 September 2011: the first session of the Cannabis Working Group
- 8 December 2011: the Cannabis Working Group submitted an amendment bill to the Prime Minister and the Chair of the Chamber of Deputies of the Parliament of the Czech Republic.
- 11 December 2011: the final session of the Cannabis Working Group
- 1 February 2012: as a parliamentary motion, the bill was distributed among the members of the Parliament of the Czech Republic.
- 3 February 2012: the bill was submitted to the Government of the Czech Republic for consideration.
- 29 February 2012: the Government's statement was distributed among the deputies as Print 590/1 (comments).
- 8 June 2012: the first reading of the bill at the session of the Chamber of Deputies of the Parliament of the Czech Republic. The bill was passed on to the committees of the Chamber of Deputies for consideration.
- 26 June 2012: having considered the bill, the Committee on Agriculture of the Chamber of Deputies of the Parliament of the Czech Republic passed a resolution that was forwarded to the deputies as Print 590/2 *(discussion adjourned)*.
- 17 July 2012: having considered the bill, the Health Committee of the Chamber of Deputies of the Parliament of the Czech Republic passed a resolution that was forwarded to the deputies as Print 590/3 *(discussion adjourned)*.

- 11 September 2012: having considered the bill, the Committee on Agriculture of the Chamber of Deputies of the Parliament of the Czech Republic passed a resolution that was forwarded to the deputies as Print 590/4 *(proposals for amendments)*.
- 11 October 2012: having considered the bill, the Health Committee of the Chamber of Deputies of the Parliament of the Czech Republic passed a resolution that was forwarded to the deputies as Print 590/5 *(proposals for comprehensive amendments)*.
- 26 October 2012: the second reading of the bill and a general debate on it. The proposals for amendments were compiled in Print 590/6.
- 7 December 2012: the third reading of the bill. The bill was passed (Resolution No. 1400, Chamber of Deputies).
- 30 January 2013: the bill was considered during the fourth session of the Senate of the Parliament of the Czech Republic. The Senate passed the bill (Senate's Resolution No. 54).
- 15 February 2013: the Act was signed by Václav Klaus, the President of the Czech Republic.
- 4 March 2013: the Act was promulgated in the Collection of Laws, as No. 50/2013 Coll., under Item 22.

How the Act was adopted – a chronology of the legislative process:

Chamber of Deputies of the Parliament of the Czech Republic –
http://www.psp.cz/sqw/historie.sqw?o=6&t=590

Senate of the Parliament of the Czech Republic –
http://senat.cz/xqw/xervlet/pssenat/historie?ke_dni=14.3.2013&O=9&action=detail&value=3256