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Proposed Changes Expected to Boost the Medical Cannabis Business in the Czech Republic

Introduction

Step by step, the Czech Republic is cultivating its legal framework for medical cannabis. After overcoming an initial lack of availability and other struggles, on 1 January 2020 the cost of medical cannabis finally began to be reimbursed from the national health insurance. This change led to a boom in medical cannabis prescriptions, and record amounts of medical cannabis were dispensed. In 2020 the market almost quadrupled in size in comparison with 2019. And January 2021 saw the largest-ever monthly amount of medical cannabis dispensed.

Recognising the potential of medical cannabis, the Czech government aims to take down further barriers to the medical cannabis business in hopes of reducing the financial cost of medical cannabis treatment for both the public health insurance system as well as patients. Accordingly, the government proposed an amendment to the current law that, if passed, would allow for the export of medical cannabis to other countries. The Czech Republic could thus become a medical cannabis hub in Europe.

This article will provide background information about the current legal regulation of medical cannabis in the Czech Republic as well as an overview of upcoming significant changes being proposed by the government.

Introduction of medical cannabis

The Czech Republic was one of the first countries in Europe to allow cannabis for medical use. The relevant regulation (ie, an amendment to the Act on Pharmaceuticals and related implementing decree, the “Medical Cannabis Decree”) was passed in 2013. However, the first medical cannabis was not dispensed until January 2015. This was due to a delay in the launch of the Register of Restricted Medicinal Products, which was and still is essential for monitoring the amounts of medical cannabis dispensed to individual patients and thus prevents the dispensing of medical cannabis over the statutory limits.

Interestingly, the first medical cannabis ever dispensed in the Czech Republic was imported from abroad, specifically from the Netherlands. In fact, the need for imports persisted for all of 2015, as the relevant Czech authority, the State Institute for Drug Control (SÚKL) failed to secure any medical cannabis from local growers. The lack of cannabis from local growers was the result of legal restrictions.

The law sets out that there can be only one local grower of medical cannabis, which must be chosen in a public tender organised by the SÚKL. Only the winner of the tender can be authorised (given a licence) to grow medical cannabis and then sell it to the SÚKL, which by law is the only entity allowed to purchase the locally grown cannabis from the grower and then distribute it to pharmacies.

The first locally grown medical-grade cannabis was not available until March 2016; however, after delivery of the initial supply, subsequent batches failed to meet the quality levels declared in the tender. This led the grower’s agreement with the SÚKL being terminated and a new public tender was initiated, or rather multiple tenders, because the first public tender failed to produce any winners as neither of the two participants met the required criteria, and the second tender had to be cancelled for lack of participants. This total failure of the system based on public tender for a sole licence meant that, until 2018, the only medical cannabis available had to be imported from abroad, from the Netherlands and Canada.

Growing demand for treatment

Locally grown medical cannabis finally became available in 2018. As the product became more readily available, there was a sharp increase in the volume of medical cannabis prescribed by physicians to patients. In 2018 mere dozens of prescriptions were issued per month on average; by 2019 it grew to hundreds and in 2020 more than a thousand prescriptions a month were issued on average. Likewise, the number of unique patients grew at the same rate.

As demand for medical cannabis grew steadily, it became evident that the locally grown product was unable to meet

the market needs for various reasons. For one, locally grown medical cannabis was at times actually more expensive than imported product because the local grower had to deliver to the SÚKL exact amounts of medical cannabis. In order to ensure that it would be able to deliver on its obligations, the local grower had to cultivate a larger number of cannabis plants, and then the excess would have to be disposed of properly.

Moreover, it is worth mentioning that locally grown medical cannabis is required to have specific properties. The public tender required the medical cannabis to be provided in two variants with specific THC and CBD content (the specifications being: Cannabis sativa L., 19% THC and 0.1% CBD and Cannabis sativa L. 6% THC and 7.5% CBD). Since some patients needed different specifications to meet their needs than what was being produced locally, imported medical cannabis had to and still has to be used. In 2020 the ratio between locally grown and imported medical cannabis dispensed to patients was approximately 2:3 in favour of imported medical cannabis.

Reimbursement from public health insurance

Initially, medical cannabis was not covered by public health insurance. Only in exceptional circumstances would reimbursement be available – where the medicinal product in question (such as medical cannabis) was the only suitable treatment with respect to the patient's condition. Since this exceptional reimbursement was at the discretion of the insurance company physician (except, for example, in life-threatening cases) it often led to highly publicised disputes, as insurers were reluctant to green-light reimbursement.

As it was often pointed out by the media, without reimbursement some patients simply could not afford to be treated with medical cannabis. This especially applied to patients with serious health conditions, in need of above-average monthly amounts of medical cannabis, often living exclusively on insufficient state support. Thus, the lack of reimbursement limited the potential market for medical cannabis.

On 1 January 2020 medical cannabis finally became reimbursable. The public health insurance currently covers 90% of the price of up to 30 grams of medical cannabis per month per patient. If approved by the insurance company physician, this amount can be increased to 180 grams per month per patient.

The introduction of reimbursement was expected and is proving to have a significant impact. Medical cannabis has become more accessible to patients as it became less of a financial burden; this correlation is evidenced by statis-

tics published by the State Agency for Medical Cannabis (a subdivision of the SÚKL, which is responsible for specific agendas relating to medical cannabis). In 2019 an average of about 1,400 grams of medical cannabis was dispensed to some 300 unique patients per month; in 2020 the average monthly amount dispensed rose to about 5,500 grams, with about 1,000 unique patients, with January 2021 showing a further increase, as demand keeps growing.

Prescribing medical cannabis

Another statistic which has seen growth is the number of physicians authorised to prescribe. Under the current regulation, only physicians with a specific specialisation may prescribe medical cannabis, and only for specific indications according to their specialisation. Both the specialisations and corresponding indications are stipulated in Annex 3 of the current Medical Cannabis Decree which was issued by the Ministries of Health and Agriculture.

Medical cannabis can be used as an auxiliary treatment to alleviate symptoms accompanying such indications as chronic constant pain, spasticity and related pain from multiple sclerosis, nausea or vomiting in association with cancer or HIV treatment, Tourette syndrome and surface treatment of dermatoses and mucosal lesions. Physician specialisations include, in particular, clinical and radiation oncology, rheumatology, neurology, psychiatry, etc.

As the kinks slowly get ironed out of the medical cannabis supply and approval chain, the number of prescribing physicians is also rising. Physicians are free to choose to prescribe medical cannabis. They must apply to the SÚKL for authorisation to prescribe. However, the application is filed via a simple electronic form, and the SÚKL merely verifies the physician's specialisation without the need to provide any documentation.

The Medical Cannabis Decree also stipulates quality criteria for medical cannabis (Annex 2). Only cannabis that meets these quality criteria is considered medical cannabis under Czech law. Furthermore, the Medical Cannabis Decree divides medical cannabis into groups based on the species (indica or sativa) and their THC and CBD content (Annex 1). Each group is assigned a specific code for prescription and dispensing purposes.

Importation and distribution of medical cannabis

Medical cannabis is considered an addictive substance under Czech law. Importers and distributors must therefore abide by both the Act on Addictive Substances and Act on Pharmaceuticals, which jointly set the rules for the import and distribution of medical cannabis to pharmacies. In par-

particular, they stipulate which licences and certificates are required.

The importer must provide cannabis that meets the quality criteria for medical cannabis, provide relevant certificates and secure an import/export permit. The specific requirements and conditions for import vary based on the country of origin, but in general it is necessary to adhere to GMP.

The only permissible medical cannabis format which can be imported is dried inflorescence. Only pharmacies are entitled to use the medical cannabis to prepare medicinal products for individual patients (so called individually prepared medicinal products containing medical cannabis, or IPMP) based on their specific needs. The only formats currently allowed for the IPMPs are capsules containing medical cannabis (oral use) and medical cannabis for vaporisation (inhalation).

Barriers to further growth of the medical cannabis business

The regulation related to medical cannabis is quite complex and lays down numerous restrictions. This can be attributed to international obligations of the Czech Republic, such as those under the Single Convention on Narcotic Drugs (1961). Under the international legal framework, cannabis is considered to be an addictive substance; therefore, national regulations must provide for sufficient control mechanisms to enable legal access to medical cannabis but to preclude illegal use of cannabis.

Currently, the national legal regulation sets out two major legal barriers to further growth of the medical cannabis market:

- the single licence for local cultivation; and
- the export ban on medical cannabis.

Current legislation

The problems associated with the fact that the current regulation only allows for the existence of a single local grower of medical cannabis are evident from the experience gathered in the past years. As described above, the system based on a single local grower selected through a public tender led to the failure of several public tenders, insufficient supply due to quality issues, and even complete supply outages. Locally grown medical cannabis was also criticised for its relatively high price.

In fact, the price of imported medical cannabis is significantly lower than that of product produced by the single local grower. Moreover, the current system puts additional costs on the state, as currently the regulation does not

appropriately address the shelf life of the medical cannabis purchased by the SÚKL from the single local grower. If the pharmacies fail to buy all the medical cannabis acquired by the SÚKL from the grower, then the SÚKL is obliged to ensure the disposal of any unused medical cannabis at the expense of the state.

Although technically, the law entitles the SÚKL to export medical cannabis; a lack of implementing provisions on such export makes the export impossible in practice. Therefore, under the current regulation, medical cannabis cannot in reality be exported from the Czech Republic. This applies to both locally grown and imported medical cannabis. Therefore, the medical cannabis must be either dispensed to patients or destroyed, which has an obvious effect on the price.

Proposal to remove the barriers

The Czech government recognises both obstacles (the single licence system for local cultivation and the ban on medical cannabis exports) and declared the current system to be unsustainable. In order to remove these obstacles, the government proposed an amendment to the relevant regulation which – if passed – would, in particular, allow the export of medical cannabis and replace the current single local grower system with a multiple grower system.

If the amendment is adopted in its current form, any legal entity or individual carrying out business who has a registered office in the Czech Republic or another EU member state, EEA or Switzerland could become a grower of medical cannabis in the Czech Republic. The essential licences and certificates a prospective local grower must first acquire are:

- a good manufacturing practice (GMP) certificate;
- a handling licence (ie, a licence permitting the handling of addictive substances); and
- (most significantly) a cultivation licence.

GMP certificates and handling licences are currently commonly required for, eg, manufacturers of medicinal products. A cultivation licence, on the other hand, would be a somewhat new requirement, as currently only the winner of the public tender can hold this licence. It is proposed that the cultivation licence would be issued by the SÚKL for five-year extendable periods.

The SÚKL could issue the cultivation licence only after carrying out an inspection of the applicant's grow room. Although understandable, this requirement could be limiting for many applicants since the applicant would first have to have a fin-

ished grow room even before submitting the application. The amendment also establishes that after being awarded the cultivation licence the grower would have to secure its grow room and storage area with a CCTV system and implement additional safety measures, which would be laid out in an implementing decree.

The amendment would also lift the export ban on medical cannabis. Currently importers only import as much medical cannabis as they are certain can be sold. According to the proposed wording, the procedure for exporting medical cannabis would be similar to the export of any other addictive substance, ie, an export permit would be required. Lifting the export ban could greatly reduce the cost of growing medical cannabis in the Czech Republic as surplus medical cannabis could be exported; or larger-scale growing could be established in order to benefit from economies of scale.

Conclusion

Given that currently the legislative efforts of the government are focused on urgent issues related to the COVID-19 pandemic, it is impossible to predict whether the amendment will be passed before the upcoming parliament elections in October 2021. Nevertheless, even if lawmakers fail to pass it in time, it is likely to reappear after the election, since the issues it targets are well known and considered to cause unnecessary barriers to the medical cannabis business and, more significantly, to patients' access to treatment by medical cannabis.

Finally, it should be noted that cannabis has become more of a public issue in recent years—not only in relation to medical cannabis, but also when it comes to cannabis for recreational use. To give an example, *Piráti a Starostové* (Pirates and Mayors) is a newly formed liberal political alliance comprising two popular parties, the Czech Pirate Party and the Mayors and Independents party. They are seen as serious contenders for a win in the election as popularity for the governing ANO party wanes. They have specifically listed further relaxation of cannabis regulation in their programme.

Considering that even the current government as well as some of the opposition parties have shown support for broader access to medical cannabis, it appears likely further relaxing of restrictions on medical cannabis and its use will continue into the future.

PRK Partners is a leading full-service law firm with over 100 legal and tax professionals. With nearly 30 years' experience in providing outstanding service in Central Europe, the firm has worked on many of the region's largest and most complex transactions, combining its profound knowledge of the local legal system with an international perspective. PRK is well suited for cross-border matters between the Czech Republic and Slovakia, with offices in both countries. The firm has a team of lawyers specialis-

ing in legislation and other specifics of drugs, biologics, medical devices and related products. They can advise established or start-up firms in life sciences and healthcare on issues ranging from R&D to manufacturing and sale, IP legal issues, data protection, compliance, enforcement, litigation, transactions, public procurement, antitrust and competition issues. The firm has garnered significant international and national awards and has a strong commitment to corporate social responsibility and pro bono work.

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