



MEDICAL CANNABIS IN THE CZECH REPUBLIC

legislation and practice

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Medical Cannabis in the Czech Republic in legislation and practice

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The legal framework of the Czech Republic

Any activities associated with Cannabis for medical purposes are governed particularly by the following regulations:

- **Act No. 167/1998 Coll.**, on Dependency-producing Substances and Amendment to some other acts, as amended
- **Decree no. 236/2015 Coll.**, stipulating the conditions of prescribing, preparation, distribution, dispensing and use of magistral formulas containing cannabis for medical use
- **Act No. 378/2008 Coll.**, on Pharmaceuticals and on Amendment to Some related Acts.

Decree no. 236/2015 Coll.,

stipulating the conditions of prescribing, preparation, distribution, dispensing and use of magistral formulas containing cannabis for medical use

Defines:

- 1. Cannabis species:** *Cannabis sativa L.*, *Cannabis indica L.*
- 2. The range of active substances:** THC 0.3-21.0% and CBD 0.1-19.0%
Determination of the variance (+/- 20% of the declared value)
- 3. The limit for prescribing and dispensing** cannabis for medical use
(180g/1 month/1patient)
- 4. Quality** of cannabis for medical use (Annex no. 2)
- 5. Specialization** of doctors who can prescribe cannabis for medical use
- 6. Indications** for medical cannabis prescription (Annex no.3)

State Institute for Drug Control

The State Institute for Drug Control under the Addictive Substances Act no. 167/1998 coll, performs tasks of the State Agency for medical cannabis (SAKL)

- **SÚKL grants the license to grow** cannabis for medical use on the basis of a public tender, according to addictive substances act and the public procurement act
- SÚKL determines the **maximum offer price** in the tender through the market research in countries that can export cannabis, whose parameters correspond to the procurement procedure

State Institute for Drug Control

- The licensed grower is obliged to transfer the produced and harvested cannabis **exclusively to SÚKL** (state becomes the owner of the product)
- SÚKL buys out all the crops of grown and harvested cannabis for medical use, where the **quality is proofed** by the certificate of analysis, issued by the control laboratory whose activities are allowed under the Act on Pharmaceuticals (378/2008 coll)
- SÚKL buys out harvested cannabis no later than **4 months** after its harvest
- SÚKL ensures **safe storage, transport and distribution** of cannabis, only through other subjects under the contract

State Institute for Drug Control

- SÚKL transfers produced cannabis to pharmacies only in order to prepare an **individually prepared medical product (IPMP - magistral formula)**
- SÚKL and the operator of the pharmacy conclude a **written contract**
- SÚKL **determines the purchase price** for medical cannabis for the operators of pharmacies.
- The purchase price is the producer's price increased by the costs for the cannabis distribution (the purchase price is non-profit)

Cannabis for medical use – exact description

- Cannabis for medical use is an **active substance** (list of active substances and excipients is in Decree no. 85/2008 Coll.)
Cannabis sativae flos, Cannabis indicae flos (dried female inflorescences)
- Cannabis for medical use is an **addictive substance** (Government Regulation on lists of drugs, regulation no. 463/2013 Coll.)
- Cannabis for medical use (Appendix 1) is cannabis intended for the preparation of medicinal products with a standardized content of *tetrahydrocannabinol* (0.3 to 21.0%)
- Intended for preparation of **individually prepared medicinal products (IPMP)** containing cannabis for medical use (pharmacy)
- **Quality certificate for cannabis** issued in accordance with Decree no. 236/2015 Coll.

Avaliability of cannabis in the Czech Republic

Criterion	Imported Cannabis	<u>Czech-produced cannabis</u>
State ownership	NO	YES
Price	Imported cannabis price is not the subject of the public tender of the Czech Republic	The Institute determines the purchase price for medical cannabis for the operators of pharmacies
Qualitative criteria determined by the Decree no. 236/2015 Coll.	YES	YES
Contracted distributor	NO	YES
Contract between pharmacies and SÚKL	NO	YES

Cannabis for medical use – permissions and contracts

- Producing cannabis for medical use is only authorized with the **license for cultivation** (SÚKL) and the **handling permit** (IOPL – Ministry of health)
- The license may be granted only to selected suppliers in the procurement procedure carried out by SÚKL under the Act on Public Contracts, for a period of maximum **5 years**.
- SÚKL and the suppliers conclude a **written contract** for the transfer of cannabis (the parameters of which are defined by the Act on AS: precise **specification of harvested cannabis, quantity, quality, purchase price**, compliance with the conditions of the public contract)
- SÚKL becomes the **sole owner** of the purchased cannabis
- **Unredeemed - unsatisfactory** cannabis becomes **plant waste**

Prescription, preparation and dispensing of individually prepared medicinal product containing cannabis for medical use

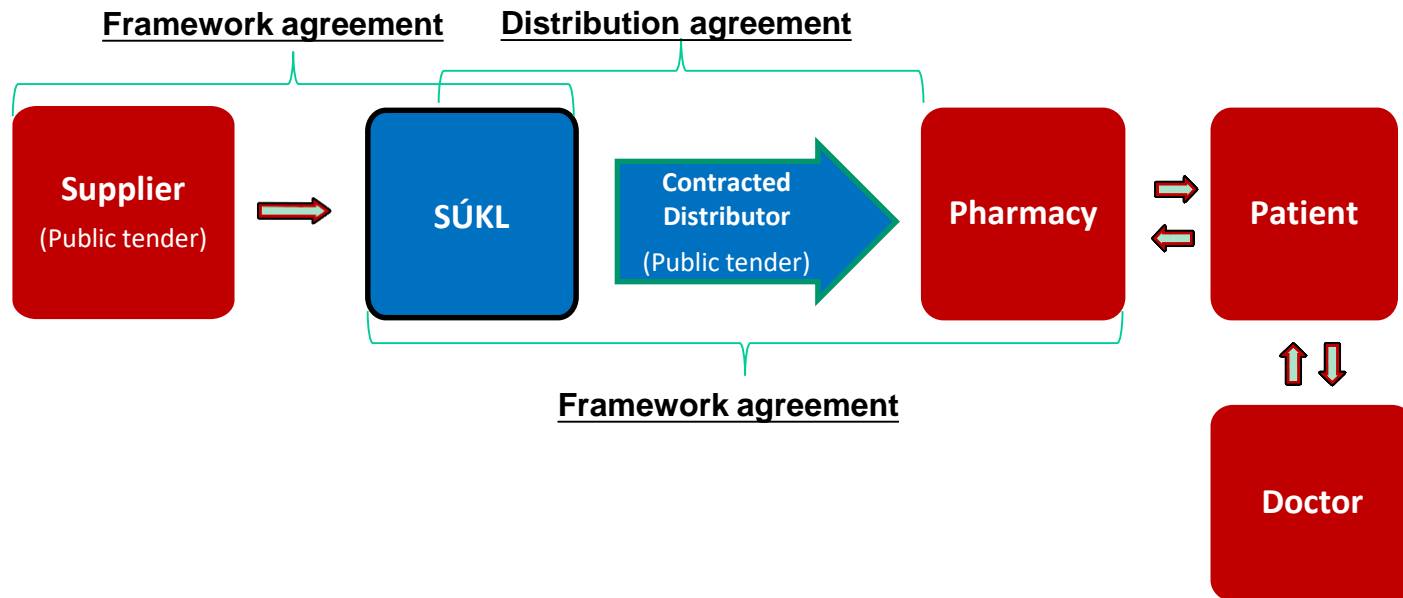
- **Act no. 378/2007 Coll., determines the procedure for prescribing individually prepared medicines containing cannabis for medical use**
- Prescribers issue an **electronic prescription** for IPMP containing cannabis for medical use
- The prescriber is obliged to send the electronic prescription to the **central repository of electronic prescriptions**, which promptly retrieves the identification sign (and communicates it to the patient)
- The central repository communicates with the **Registry for Limited Medicines** in order to ensure compliance with the implementing regulation (Decree no. 236/2015 Coll.)
- Register for Limited Medicines provides cost-free and uninterrupted access for **prescribing MDs** and **dispensing pharmacists**
- The register is not publicly accessible
- Access for the Czech Police

Indication	Specialised qualification of the doctor
<p>Chronic intractable pain (in particular pain in connection with oncological diseases, pain associated with degenerative diseases of musculoskeletal system, systemic diseases of the connective tissues and immunopathological states, neuropathic pain and pain treatment in glaucoma)</p>	<p>Clinical oncology, radiation oncology, neurology, palliative medicine, pain therapy, rheumatology, orthopaedics, infectious medicine, internal medicine, geriatrics, ophthalmology</p>
<p>Spasticity and associated pain in multiple sclerosis or in spinal cord injury, painless permanent spasticity substantially limiting motion and mobility or breathing, kinetic syndromes caused by neurological disease or other health complications resulting from neurological disease or injury of the brain or spine with damage of the spinal cord, neurological tremor caused by Parkinson disease and other neurological problems</p>	<p>Neurology, geriatrics</p>

Indication	Specialised qualification of the doctor
Nausea, vomiting, stimulation of appetite in connection with the treatment of oncologic diseases or with the treatment of HIV disease	Clinical oncology, radiation oncology, infectious medicine, dermatovenerology, geriatrics
Gilles de la Tourette syndrome	Psychiatry
Treatment of dermatoses and mucosal lesions	Dermato-venerology, infectious medicine, geriatrics

Quantity of cannabis for medical use per month and one adult patient - limited to 180 g

Description of the legislative system to ensure the availability of cannabis grown in the Czech Republic (subjects and contractual relations)



Production of medical cannabis – the **public tender 05/2017**
the selected supplier – Elkoplast Slušovice s.r.o.

VZSAKL 02/2017

Subject: continuous supply of cannabis that has been grown, harvested, basically processed, packaged, retained, transported, physically processed, certified, adjusted in 10.0 g packages

Result: a framework agreement (4 years) with **one selected bidder**,
Orders = partial purchase contract following the market needs.

40 kg of cannabis with a commitment of **min. 20 kg** of cannabis

The contract ends after the delivery of 40 kg of cannabis or the expiration of the 4-year period

Determining the price of cannabis for medical use

- SÚKL determines the purchase price of cannabis for medical use in accordance with the Addictive substances act.
- SÚKL sets the price of cannabis for the operators of the pharmacies. The basis of the purchase price upon transfer of cannabis to the operators of the pharmacies is the purchase price from the grower increased by the costs for the distribution (the purchase price is non-profit)

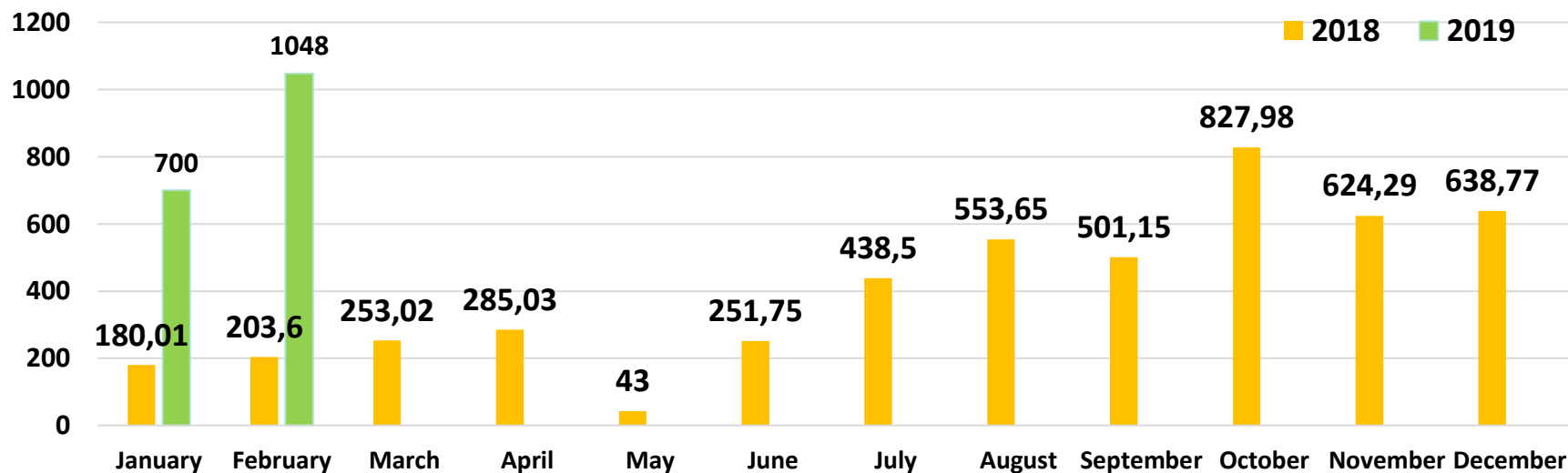
CZK 139,00 (VAT excl.) + CZK 9.75 (VAT excl.) = CZK 148.75 (VAT excl.)

5,42€ + 0,38€ = 5,80€

- Medical cannabis is not covered by health insurance
- The price of cannabis for medical use is unregulated (**unreimbursed**), therefore the operators of the pharmacies can **apply different levels of trade margins**

2015	836 g
2016	2577 g
2017	1227 g
2018	4800 g
2019 – January + February	1748 g

2018 and 2019 - amount of cannabis dispensed per month



Diagnosis	2018	2019 (January + February)
Chronic intractable pain (R521)	90.2 %	90 %
Multiple sclerosis (G35)	3.4%	2.9 %
Disorder of central nervous system, unspecified (G969)	1.2%	0.7 %
Parkinson disease (G20)	-	3.3 %
Other	5.2%	3.1 %

	2015	2016	2017	2018
Unique number of the patients*	30	130	125	447
Number of registered doctors	4	13	18	58

* Number of patients to whom medical cannabis has been prescribed and dispensed at least one time

50% of the registered medical doctors prescribed medical cannabis at least one time in 2018

Till the 27th of March 2019 - 83 medical doctors have been registered

Average consumption of medical cannabis per patient and month – 6.3 g

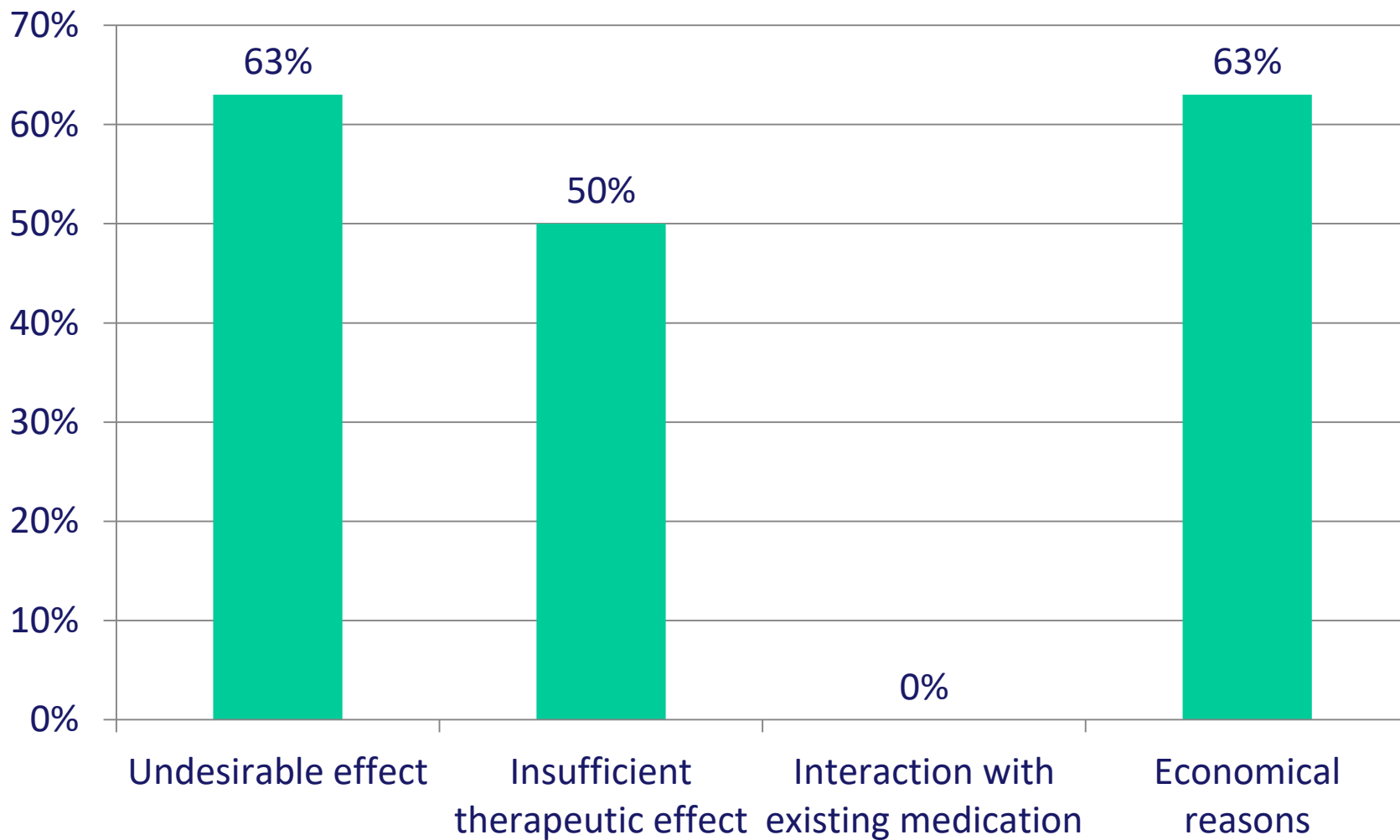
Most of the prescribed cannabis is dispensed in the form of hard capsules (0.1 or 0.2 g/cps) prepared in the pharmacy

State Institute for Drug Control asked 58 prescribing medical doctors to fill a questionnaire with 25 questions with the ability to select multiple options

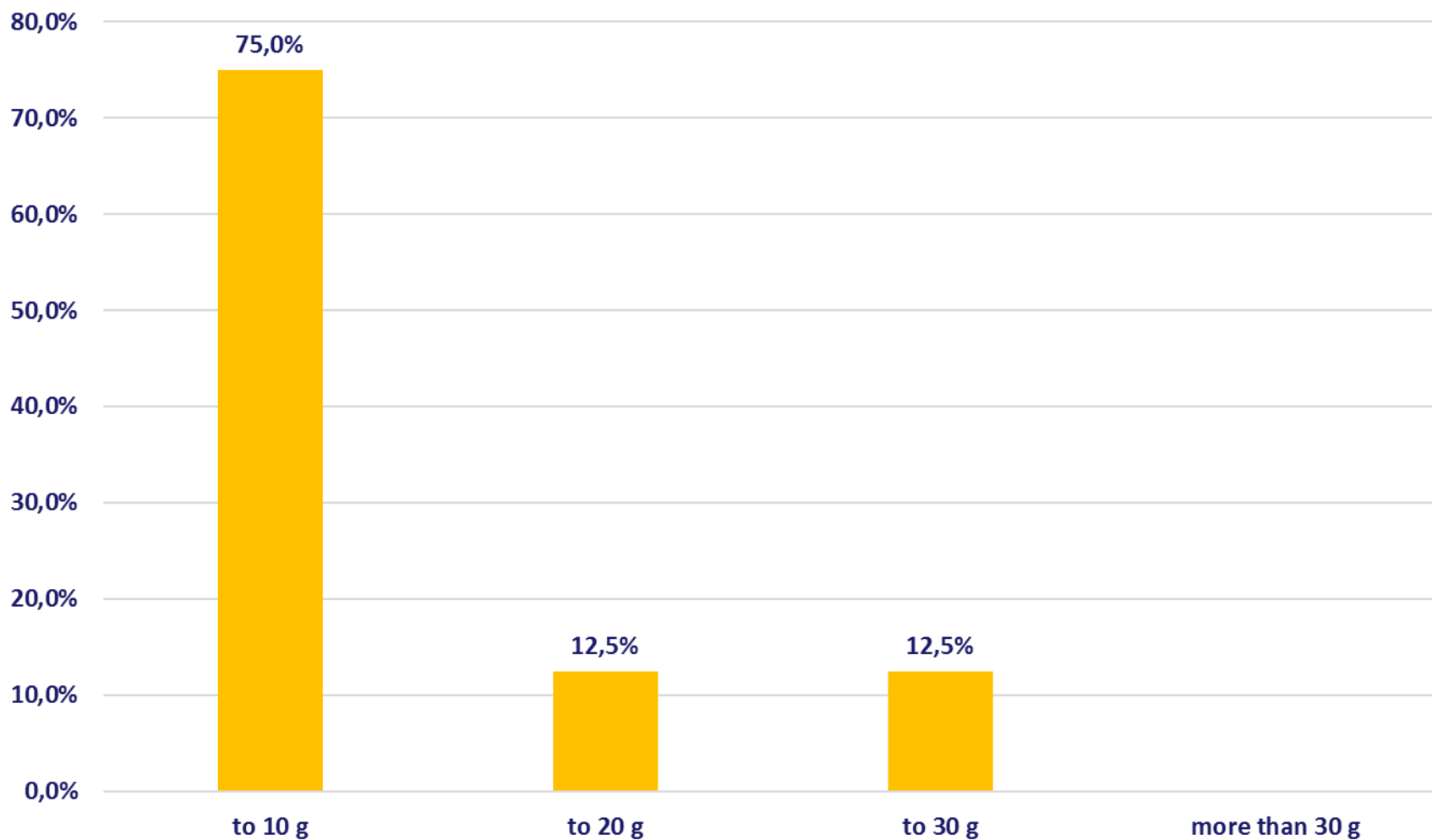
The questions were related to :

- 👁 Indications**
- 👁 Reason/s for the termination of the treatment**
- 👁 Amount of prescribed cannabis per patient and month**
- 👁 Opinion on the possibility to have the treatment reimbursed by public health insurance**
- 👁 Opinion, based on the previous professional experience, whether the treatment with cannabis can be considered beneficial or not**
- 👁 Sources of information**

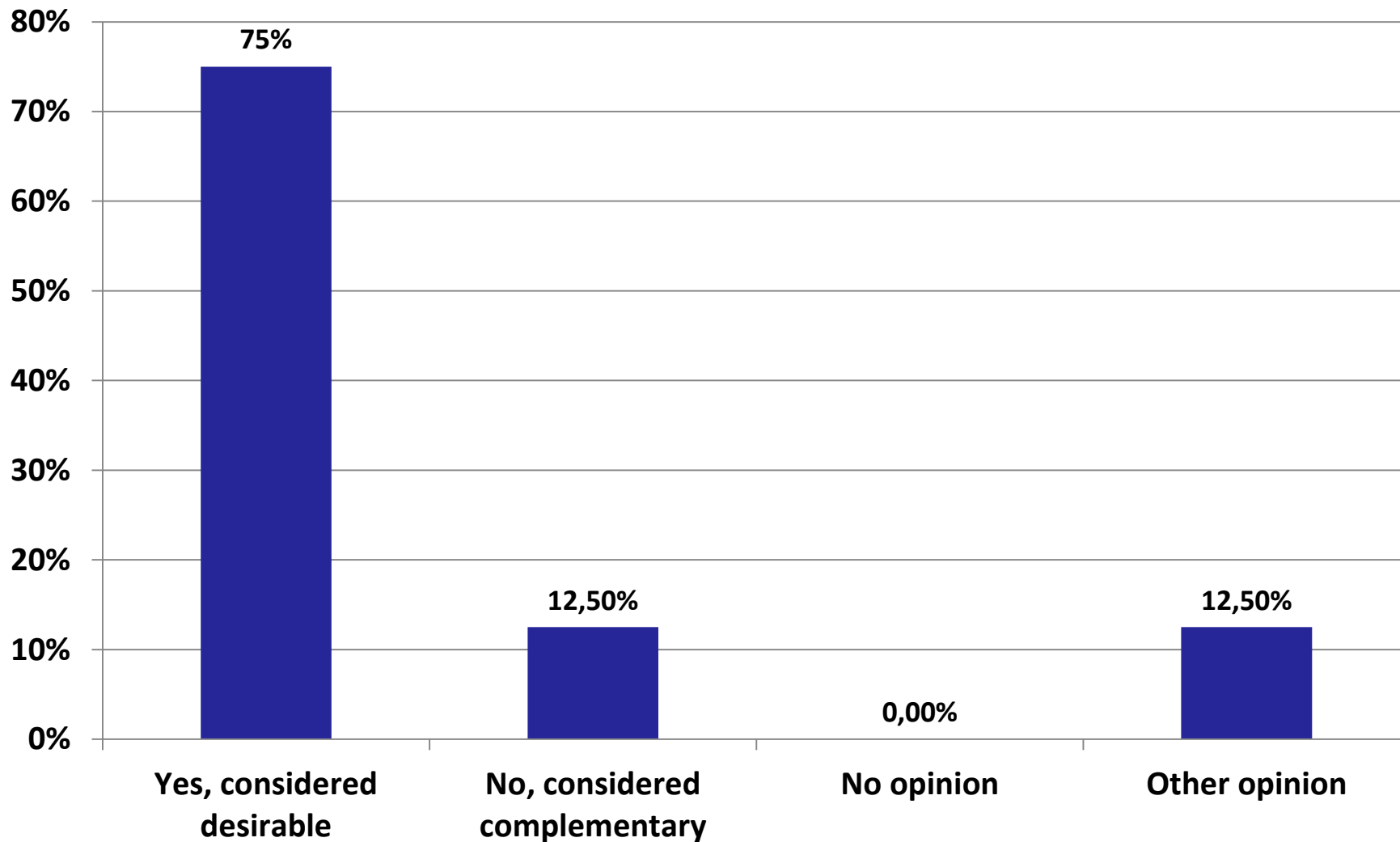
Reasons for treatment termination



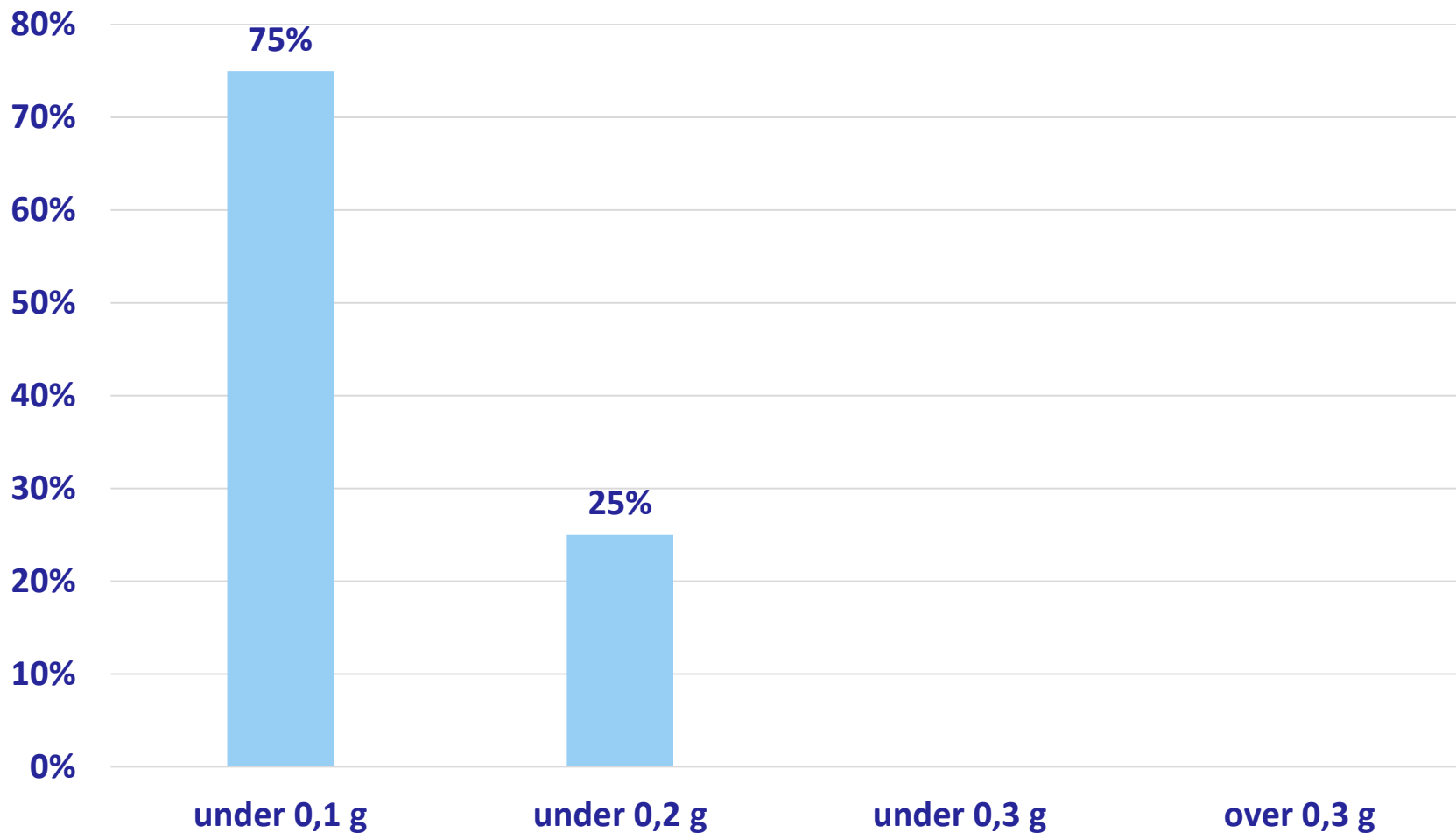
Average amount of prescribed cannabis per patient and month



Opinion on possibility to cover the treatment from public health insurance



Recommended total daily dose of medical cannabis



Opinion, based on previous professional experience, whether the treatment with cannabis can be considered beneficial or not

- 👁 Highly beneficial – 50.0 %**
- 👁 Medium beneficial – 50.0 %**

Sources of information

- 👁 Presentation of technical information by colleagues of the doctors 87.5%**
- 👁 Internet 62.5 %**
- 👁 Website of the State Institute for Drug Control/State Agency for Medical Cannabis 62,5%**
- 👁 Literature 50%**
- 👁 Participation to professional conferences on medical cannabis - 50%**

Ministry of health has proposed to have the treatment with medical cannabis reimbursed by a public health insurance in the amount of 90 %, provided that:

- 🕒 The indication corresponds to the ones set in the Decree 236/2015 Coll.**
- 🕒 The maximum covered amount is 30 g (in exceptional justified cases even higher amount can be paid)**
- 🕒 The price for 1 g is regulated**
- 🕒 The data on efficacy and safety are collected and evaluated on the base of reports on clinical experience of medical doctors**
- 🕒 All the requirement of e-prescription have been fulfilled**

Published data and statistics (SÚKL/SAKL)

www.sakl.cz

- A list of MDs who prescribe medical cannabis
- Statistics on expenditure of cannabis for medical use

www.sukl.cz

- Prescription of cannabis for medical use (e-prescription, procedure, free telephone line)
- Framework agreement with SÚKL (text attachments, procedure for concluding contracts)
- Ordering cannabis (order form) and Complaining Procedure (complaint report)
- Pricelist of cannabis for medical use, contractual distributor, list of pharmacies with framework agreement

Thank you for your attention!

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