236/2015 Coll.

DECREE

of 4 September 2015

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

The Ministry of Health and the Ministry of Agriculture, having held consultations with the Ministry of Defence, Ministry of Interior, Ministry of Justice, and Ministry of Finance, pursuant to Section 114 of Act No 378/2007 Coll., on Pharmaceuticals and on Amendments to Some Related Acts (Act on Pharmaceuticals), as amended by Act No 50/2013 Coll. and by Act No 70/2013 Coll., to implement Section 77, paragraph 1(g), Section 79, paragraph 2, Section 79, paragraph 8(a), Section 79a, paragraph 1, and Section 80 of the Act on Pharmaceuticals, hereby stipulate as follows:

Section 1

Subject-matter of the Decree

This Decree stipulates the rules of good distribution practice for medical cannabis and the conditions for prescribing, preparation, dispensing, and use of magistral formulas containing medical cannabis.

Section 2

Species of medical cannabis and determination of quantitative limits

(1) Only the species of medical cannabis listed under Annex 1 hereto may be used for the prescribing, preparation, dispensing, and use of magistral formulas containing medical cannabis, in the cumulative quantity not exceeding the maximum of 180 g of dried vegetable drug per month.

(2) Only medical cannabis referred to under paragraph 1 which meets the criteria set forth by Annex 2 hereto may be used for the preparation of magistral formulas.

(3) The quality of medical cannabis intended for the preparation of medicinal products shall be evidenced by the submission of a document certifying the quality the active substance issued in the European Union by

a) a manufacturer of medicinal products authorised to perform control of active substances;

b) a manufacturer of active substances who is a holder of a valid certificate of good manufacturing practice in the manufacture of active substances; or

c) a laboratory which complies with the requirements of good manufacturing practice set forth by the European Commission and the European Medicines Agency and evidences compliance with the requirements of good manufacturing practice by means of a valid certificate of good manufacturing practice or an inspection report issued by the inspectors of the concerned authority of the Member State; such inspection report shall not be older than three years.

Section 3

Labelling of medical cannabis

Medical cannabis intended for the preparation of magistral formulas shall be labelled on the packaging in compliance with the characteristics referred to under Annex 1 hereto. The labelling of magistral formulas containing medical cannabis as referred to under Section 2 shall be governed by the Decree on Good Pharmaceutical Practice[1)].

Section 4

Prescribing of magistral formulas containing medical cannabis

(1) A magistral formula containing medical cannabis as per Section 2 may be prescribed in the provision of healthcare services for indications listed under Annex 3 hereto only by a medical doctor specialised as set forth by this Annex, and only to patients who have reached the age of 18 years.

(2) On the prescription, the prescribing doctor shall be obliged to specify the general particulars stipulated by the Decree on the method of prescribing medicinal products[2)], the dosage of the magistral formula containing medical cannabis pursuant to Section 2 and the route of administration. On the prescription, the doctor shall be, moreover, obliged to specify

a) the species of medical cannabis;

b) the percentage content of delta-9-tetrahydrocannabinol; and

c) the percentage content of cannabidiol.

(3) The magistral formulas containing medical cannabis as per Section 2 may be prescribed on a single prescription in

the maximum quantity equal to the dose safeguarding a one-month treatment for the respective indication.

Section 5

Dispensing of magistral formulas containing medical cannabis

A magistral formula containing medical cannabis may be dispensed only in case it has been prescribed on a valid electronic prescription which contains the particulars referred to under Section 4, paragraph 2.

Section 6

Closing provision

This Decree has been published in compliance with the Directive 98/34/EC of the European Parliament and of the Council of June 22 1998 laying down a procedure for the provision of information in the field of technical standards and regulations for information society services, as amended.

Section 7

Repeal provision

Decree No 221/2013 Coll., stipulating the conditions for the prescribing, preparation, dispensing, and use of magistral formulas containing medical cannabis, is hereby repealed.

Section 8

Effect

This Decree shall take effect as of the thirtieth day of the date of its pronouncement.

Minister of Health:

MUDr. Němeček, in his own hand

Minister of Agriculture:

Ing. Jurečka, in his own hand

Annex 1

Medical Cannabis Species

Mandatory data	Characteristics / Permissible values
Cannabis species	*Cannabis indica* or *Cannabis sativa L.*
Content of DELTA-9-THC (delta-9-tetrahydrocannabinol)	Content expressed as percentage ranging from 03% to 21.0%. Actual content of DELTA-9-THC in the medical cannabis shall not deviate by more than +-20% of the value specified by the grower.
Content of CBD (cannabidiol)	Content expressed as percentage ranging from 0.1% to 19.0%. Actual content of CBD in the medical cannabis shall not deviate by more than +-20% of the value specified by the grower.

Annex 2

Criteria Governing Medical Cannabis

Parameter	Method	Limit
Identity		
Macroscopic description	Visual	Whole or cut dried cymose inflorescence of dark green, grey-green to brown-green colour forming dense spikes. Small buds are covered with bracts, covered on top with secretive trichomes.
TLC[a)]	Cz.Ph.[b)] 2.2.27	Visual assessment
Purity tests		
Foreign admixtures	Cz.Ph. 2.8.2	max. 2%
Los by drying	Cz.Ph. 2.2.32	max. 10.0%
Pesticide residues	Cz.Ph. 2.8.13	as per limits set forth by Cz.Ph. 2.8.13
Heavy metals	Cz.Ph. 2.4.27	Pb - max. 5.0 µg/g Cd - max. 1.0 µg/g Hg - max. 0.1 µg/g
Aflatoxins - Aflatoxin B_1	Cz.Ph. 2.8.18	max. 2 µg/kg
- Total content of B_1, B_2, G_1 and G_2 aflatoxins		max. 4 µg/kg
Microbiological quality Cz.Ph. 5.1.4	Cz.Ph. 2.6.12 a 2.6.13	max. 10^3 CFU[e)]/g
- TAMC[c)] - TYMC[d)]		max. 10^2 CFU/g
Degradation products - cannabinol	HPLC[f)] - Cz.Ph. 2.2.29	max. 1%
Contents		
- THC (DELTA-9-tetrahydrocannabinol) - CBD (cannabidiol)	HPLC - Cz.Ph. 2.2.29	± 20% of declared THC or CBD content

a) Thin-layer chromatography.
b) Czech Pharmacopoeia.
c) Total aerobe microorganism content.
d) Total yeast and mould count.
e) Colony forming unit(s).
f) High-performance liquid chromatography.

Annex 3

Indications and specialisation of the prescribing doctor

Indication	Doctor's specialisation
Chronic continuing pain (particularly in cancer conditions, pain associated with degenerative motor diseases, with systemic connective tissue diseases and immunopathological conditions, neuropathic pain, glaucoma-related pain)	clinical oncology radiation oncology neurology palliative medicine treatment of pain rheumatology orthopaedics medicine of infectious diseases internal medicine ophthalmology dermatovenerology geriatrics
Spasticity and related pain in multiple sclerosis or spinal cord traumas, painless intractable spasticity essentially restricting movement and mobility or the breathing of the patient, involuntary kinesis caused by neurological conditions, and other medical complications arising from underlying neurological conditions or spine trauma with spinal cord damage or brain trauma, neurologic tremor caused by Parkinson's disease and other neurological problems as per the judgement of the treating doctor	neurology geriatrics
nausea, vomiting, stimulation of appetite in association with cancer treatment or HIV treatment	clinical oncology radiation oncology medicine of infectious diseases dermatovenerology geriatrics
Gilles de la Tourette syndrome	psychiatry
Surface treatment of dermatoses and mucosal lesions	dermatovenerology medicine of infectious diseases geriatrics

1) Decree No 84/2008 Coll., on good pharmaceutical practice, detailed conditions of handling of pharmaceuticals in pharmacies, healthcare facilities and at other operators and facilities dispensing medicinal products, as amended by Decree No 254/2013 Coll.

2) Decree No 54/2008 Coll., on the method of prescribing medicinal products, particulars to appear on medical prescriptions, and rules governing the use of medical prescriptions, as amended.