

MINISTRY OF HEALTH

2092

Pursuant to Article 108, paragraph 3 of the Medicinal Products Act (Official Gazette 76/13 and 90/14), the minister of health hereby issues the

ORDINANCE

ON AMENDMENTS TO THE ORDINANCE ON BENCHMARKS FOR THE CLASSIFICATION OF MEDICINAL PRODUCTS AND ON THE PRESCRIPTION AND DISPENSING OF PRESCRIPTION MEDICINAL PRODUCTS

Article 1

In the Ordinance on benchmarks for the classification of medicinal products and on the prescription and dispensing of prescription medicinal products (Official Gazette 86/13, 90/13 and 102/14), in Article 1, after paragraph 1, paragraph 2 is added and reads:

“A medicinal product in the sense of this Ordinance implies a medicinal product, magistral and galenic preparation.”

Article 2

In Article 3, after paragraph 1, paragraph 2 is added and reads:

“Magistral and galenic preparations may only be dispensed in pharmacies.”

Article 3

(1) In Article 8, paragraph 2, the words: “(Official Gazette 150/05)” are deleted.

(2) After paragraph 3, a new paragraph 4 is added and reads:

“Medicinal products containing tetrahydrocannabinol (hereinafter: THC), dronabinol or nabilon are prescribed by the selected medical doctor in the activity of general/family medicine, health care of preschool children and health care of women at the recommendation of a medical doctor of the specialisations neurology, internal medicine in oncology, oncology and radiology, infectology and paediatrics with a subspecialisation in neuropaediatrics on a non-repeatable prescription.”

(3) The previous paragraphs 4 and 5 become paragraphs 5 and 6.

Article 4

In Article 12, paragraph 1, item 1, the words: “(Official Gazette 50/09, 2/10 and 19/11)” are deleted.

Article 5

In Article 15, the period at the end of the sentence is replaced by a comma and the words: “with the exception of medicinal products that are prescribed on a special prescription.”.

Article 6

In Article 29, paragraph 1, after the words: “Medicinal products”, the comma and the words: “galenic and magistral preparations” are deleted.

Article 7

After Article 30, Articles 30a, 30b, 30c, 30d and 30e are added and read:

“Article 30a

Medicinal products containing THC, dronabinol and nabilon may be prescribed to alleviate the symptoms of multiple sclerosis, carcinoma, epilepsy and AIDs.

Article 30b

(1) Medical doctors from Article 8, paragraph 4 of this Ordinance are obliged to stipulate the following on a prescription for a magistral preparation:

- the quantity of THC per individual dose,
- the type of herbal drug and herbal preparation from which the magistral preparation is made,
- number of individual doses,
- medicinal form,
- dosage and instructions for use.

(2) Medicinal products containing THC may be prescribed on a prescription in the quantity necessary for treatment for up to 30 days.

(3) The total quantity of prescribed THC for 30 days of treatment may not exceed 7.5 g.

Article 30c

Magistral preparations for medical inhalation are made using the dried flowering buds of the female plant of *Canabis sativa* L.

Article 30d

(1) Herbal preparations from the plant *Canabis sativa* L. for the making of magistral and galenic preparations must have a determined amount of THC (standardised herbal preparations).

(2) The quantity of the herbal preparation necessary for making the magistral preparation from Article 30c of this Ordinance is determined by the pharmacist at the time of making the preparation.

Article 30e

The medical doctor from Article 30b of this Ordinance may prescribe galenic preparations that contain THC, which are made pursuant to the expert literature, in compliance with good practice standards for galenic laboratories.”

Article 8

In Article 45, in item 8, after the words: “paper”, the words “or plastified” are added.

Item 10 is amended and reads:

“10) medicinal capsules of confirmed quality,”.

Article 9

Appendix III of the Ordinance on benchmarks for the classification of medicinal products and on the prescription and dispensing of prescription medicinal products (Official Gazette 86/13, 90/13 and 102/14) is amended with a new Appendix III which is found in the Appendix of this Ordinance and which forms its integral part.

Article 10

This Ordinance shall enter into force on the eighth day from the date of its publication in the *Official Gazette*.

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Reg no: 534-02-1-1/2-15-01

Zagreb, 30 September 2015

Minister
Prim. Siniša Varga, DDM,
m. p.

APPENDIX

APPENDIX III

LIST OF PSYCHOTROPIC SUBSTANCES THAT DO NOT REQUIRE ENTRY IN LOGBOOKS FOR DRUGS AND PSYCHOTROPIC SUBSTANCES

Psychotropic substance (Croatian)	Psychotropic substance (international proprietary name)	Psychotropic substance (chemical name, English)
alprazolam	Alprazolam	8-chloro-1-methyl-6-phenyl-4H-s-triazolo[4,3-a][1,4]benzodiazepine
bromazepam	Bromazepam	7-bromo-1,3-dihydro-5-(2-pyridyl)-2H-1,4-benzodiazepin-2-one
brotizolam	Brotizolam	2-bromo-4-(o-chlorophenyl)-9-methyl-6H-thieno[3,2-f]-s-triazolo[4,3-a][1,4]diazepine
delorazepam	Delorazepam	7-chloro-5-(o-chlorophenyl)-1,3-dihydro-2H-1,4-benzodiazepin-2-one
diazepam	Diazepam	7-chloro-1,3-dihydro-1-methyl-5-phenyl-2H-1,4-benzodiazepin-2-one
estazolam	Estazolam	8-chloro-6-phenyl-4H-s-triazolo[4,3-a][1,4]benzodiazepine
etil-loflazepat	Ethyl loflazepate	ethyl-7-chloro-5-(o-fluorophenyl)-2,3-dihydro-2-oxo-1H-1,4-benzodiazepin-3-carboxylate
fludiazepam	Fludiazepam	7-chloro-5-(o-fluorophenyl)-1,3-dihydro-1-methyl-2H-1,4-benzodiazepin-2-one
flurazepam	Flurazepam	7-chloro-1-[2-(diethylamino)ethyl]-5-(o-fluorophenyl)-1,3-dihydro-2H-1,4-benzodiazepin-2-one
halazepam	Halazepam	7-chloro-1,3-dihydro-5-phenyl-1-(2,2,2-trifluoroethyl)-2H-1,4-benzodiazepin-2-one
haloksazolam	Haloxazolam	10-bromo-11b-(o-fluorophenyl)-2,3,7,11b-tetrahydro-oxazolo[3,2-d][1,4]benzodiazepin-6(5H)-one
kamazepam	Camazepam	7-chloro-1,3-dihydro-3-hydroxy-1-methyl-5-phenyl-2H-1,4-benzodiazepin-2-one-dimethylcarbamate (ester)

ketazolam	Ketazolam	11-chloro-8,12b-dihydro-2,8-dimethyl-12b-phenyl-4H-[1,3]oxazino[3,2-d][1,4]benzodiazepin-4,7(6H)-dione
klobazam	Clobazam	7-chloro-1-methyl-5-phenyl-1H-1,5-benzodiazepin-2,4(3H,5H)-dione
kloksazolam	Cloxazolam	10-chloro-11b-(o-chlorophenyl)-2,3,7,11b-tetrahydroksazolo-[3,2-d][1,4]benzodiazepin-6(5H)-one
klonazepam	Clonazepam	5-(o-chlorophenyl)-1,3-dihydro-7-nitro-2H-1,4-benzodiazepin-2-one
klorazepat	Clorazepate	7-chloro-2,3-dihydro-2-oxo-5-phenyl-1H-1,4-benzodiazepin-3-carboxylic acid
klordiazepoksid	Chlordiazepoxide	7-chloro-2-(methylamino)-5-phenyl-3H-1,4-benzodiazepin-4-oxide
klotiazepam	Clotiazepam	5-(o-chlorophenyl)-7-ethyl-1,3-dihydro-1-methyl-2H-thieno[2,3-e]-1,4-diazepin-2-one
loprazolam	Loprazolam	6-(o-chlorophenyl)-2,4-dihydro-2-[(4-methyl-1-piperazinyl)methylene]-8-nitro-1H-imidazo[1,2-a][1,4]benzodiazepin-1-one
lorazepam	Lorazepam	7-chloro-5-(o-chlorophenyl)-1,3-dihydro-3-hydroxy-2H-1,4-benzodiazepin-2-one
lormetazepam	Lormetazepam	7-chloro-5-(o-chlorophenyl)-1,3-dihydro-3-hydroxy-1-methyl-2H-1,4-benzodiazepin-2-one
medazepam	Medazepam	7-chloro-2,3-dihydro-1-methyl-5-phenyl-1H-1,4-benzodiazepine
midazolam	Midazolam	8-chloro-6-(o-fluorophenyl)-1-methyl-4H-imidazo[1,5-a][1,4]benzodiazepine
nabilon	Nabilone	(6aR,10aR)-1-hydroxy-6,6-dimethyl-3-(2-methyloctan-2-yl)-7,8,10,10a-tetrahydro-6aH-benzo[c]chromen-9-one
nimetazepam	Nimetazepam	1,3-dihydro-1-methyl-7-nitro-5-phenyl-2H-1,4-benzodiazepin-2-one
nitrazepam	Nitrazepam	1,3-dihydro-7-nitro-5-phenyl-2H-1,4-benzodiazepin-2-one
nordazepam	Nordazepam	7-chloro-1,3-dihydro-5-phenyl-2H-1,4-benzodiazepin-2-one
oksazepam	Oxazepam	7-chloro-1,3-dihydro-3-hydroxy-5-phenyl-2H-1,4-benzodiazepin-2-one

oksazolam	Oxazolam	10-chloro-2,3,7,11b-tetrahydro-2-methyl-11b-phenyloxazolo[3,2-d][1,4]benzodiazepin-6(5H)-one
pinazepam	Pinazepam	7-chloro-1,3-dihydro-5-phenyl-1-(2-propinyl)-2H-1,4-benzodiazepin-2-one
prazepam	Prazepam	7-chloro-1-(cyclopropylmethyl)-1,3-dihydro-5-phenyl-2H-1,4-benzodiazepin-2-one
temazepam	Temazepam	7-chloro-1,3-dihydro-3-hydroxy-1-methyl-5-phenyl-2H-1,4-benzodiazepin-2-one
tetrahidrokanabinol (THC)	Delta-9-tetrahydrocannabinol	(6aR,10aR)-6,6,9-trimethyl-3-pentyl-6a,7,8,10a-tetrahydro-6H-benzo[c]chromen-1-ol
dronabinol	Dronabinol	
tetrazepam	Tetrazepam	7-chloro-5-(1-cyclohexen-1-yl)-1,3-dihydro-1-methyl-2H-1,4-benzodiazepin-2-one
triazolam	Triazolam	8-chlor-6-(o-chlorophenyl)-1-methyl-4H-s-triazolo[4,3-a][1,4]benzodiazepine
zolpidem	Zolpidem	N,N,6-trimethyl-2-p-tolilimidazo[1,2-a]pyridin-3-acetamide