# MINISTRY OF HEALTH

**1937**

Pursuant to Article 108, paragraph 3 of the Medicinal Products Act (Official Gazette 76/13), the Minister of Health hereby issues the

# ORDINANCE

## ON BENCHMARKS FOR THE CLASSIFICATION OF MEDICINAL PRODUCTS AND ON THE PRESCRIPTION AND DISPENSING OF PRESCRIPTION MEDICINAL PRODUCTS

Article 1

This Ordinance lays down the benchmarks for the classification of medicinal products with regard to their method of dispensing, and the manner of prescription and dispensing of prescription medicinal products.

Article 2

This Ordinance transposes the following directives into the legal order of the Republic of Croatia:

1. Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (SL L 311, 28.11.2001),
2. Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/83/EC of 6 November 2001 on the Community code relating to medicinal products for human use (SL L 136, 30.4.2004),
3. Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare (SL L 88, 4.4.2011),
4. Commission Implementing Directive 2012/52/EU of 20 December 2012 laying down measures to facilitate the recognition of medical prescriptions issued in another Member State (SL L 356, 22.12.2012).

Article 3

The manner and place of dispensing medicinal products is determined by the decision on the granting of the marketing authorisation that is issued by the Croatian Agency for Medicinal Products and Medical Devices (hereinafter: Agency).

Article 4

With regard to their manner of dispensation, medicinal products are classified in the following manner:

– medicinal products subject to a prescription,

– medicinal products not subject to a prescription (over-the-counter).

Article 5

With regard to the place of dispensation of medicinal products, the following groups are classified:

1. prescription medicinal products that are dispensed in a pharmacy,
2. over-the-counter medicinal products that are dispensed in a pharmacy,
3. over-the-counter medicinal products that are dispensed in a pharmacy and specialised shops for the retail sale of medicinal products.

Article 6

(1) On its website, the Agency publishes the list of medicinal products having marketing authorisation in the Republic of Croatia, with regard to the manner and place of dispensation.

(2) The Agency publishes the list of prescription medicinal products on its website pursuant to Article 111 of the Medicinal Products Act (hereinafter: Act).

Article 7

(1) By way of derogation from the provisions of Articles 4 and 5 of this Ordinance, the Agency may, pursuant to new findings about the medicinal product, re-examine its prior decision on classification of the medicinal product, if it deems that it is necessary, for the purpose of protecting the health of the population, to alter the manner and/or place of dispensation of the medicinal product, and shall inform the marketing authorisation holder thereof.

(2) In the case from paragraph 1 of this Article, the marketing authorisation holder, pursuant to the Agency notification, is obliged within a deadline of 30 days from the date of delivery of the notification, to initiate the appropriate procedure for the authorisation of amendments to the manner and place of dispensation of the medicinal product, in accordance with the Act and the ordinances adopted pursuant to the Act.

Article 8

(1) The doctor's prescription is a public document that is issued on a prescribed form by a medical doctor or doctor of dental medicine having authorisation for independent work (hereinafter: authorised person).

(2) The public document from paragraph 1 of this Article may be issued electronically as an electronic document (hereinafter: e-prescription) pursuant to the Electronic Documents Act (Official Gazette 150/05) and must contain all data and the prescribed form.

(3) By way of derogation from paragraph 1 of this Article, medicinal products for the treatment of drug addition (methadone, buprenorfin and buprenorfin+naloxon) may be prescribed by specialist doctors in the field of mental health care, prevention and the outpatient treatment of drug addition in the manner as laid down in paragraphs 1 and 2 of this Article.

(4) By way of derogation from paragraph 1 of this Article, a doctor of veterinary medicine with authorisation for independent work may prescribe medicinal products for the treatment of animals as needed in the official assessment.

(5) The list of medicinal products (according to their generic name) that may be prescribed by doctors of veterinary medicine, is adopted by the minister responsible for health (hereinafter: minister) at the proposal of the Croatian Veterinary Chamber, with the prior opinion of the Croatian Pharmacy Chamber.

Article 9

(1) In the procedure of making, renewing or authorising amendments to the marketing authorisation for a medicinal product, the Agency determines the manner of its prescription as:

1. renewable prescription,
2. non-renewable prescription,
3. special prescription,
4. restricted prescription.

(2) Galenic and magistral preparations that are dispensed on a prescription are prescribed in the manner outlined in paragraph 1 of this Article.

Article 10

(1) A renewable prescription is a prescription in which a medicinal product may be dispensed multiple times, and must bear the code "repetatur" or "repeat" with a denotation of the number of repeat dispensations permitted.

(2) A medicinal product may be dispensed a maximum of 12 times on a renewable prescription.

(3) Renewable prescriptions may be used to prescribe only those medicines for which the Agency has listed this manner of prescription in the marketing authorisation.

Article 11

A non-renewable prescription is a prescription for which the medicinal product may be dispensed only once, that has no code that indicates the possibility of repetition, or bears the code "non repetatur".

Article 12

(1) A special prescription is a non-renewable prescription used to prescribe the following medicinal products:

1. those that contain the drugs included in the List of drugs, psychotropic compounds and plants from which drugs may be obtained and compounds that may be used in the production of drugs (Official Gazette 50/09, 2/10 and 19/11) in the framework of significance of the international convention in force, such as the United Nations

Conventions from 1961 or 1971, with the exception of medicinal products that contain psychotropic substances from the List of psychotropic compounds for which logbooks on drugs and psychotropic compounds are not kept (hereinafter: List) in Appendix III which is printed with this Ordinance and which forms its integral part;
2. for which, if improperly applied, there is the possibility of their abuse, if they are used on an unauthorised basis for unpermitted purposes or they cause addiction;
3. medicinal products containing new ingredients or due to their properties are classified into the group from point 2 of this paragraph, in the sense of precautionary measures.

(2) The form of the special prescription that is printed in Appendix I of this Ordinance and forms its integral part, with the data from Article 14 of this Ordinance, must also contain the ordinal number from the logbook on the trade of drugs.

Article 13

A restricted prescription is a prescription that prescribes medicinal products intended for use in specialised areas, as follows:

1. a medicinal product that due to its pharmaceutical properties, or for the protection of public health, is intended for treatment only in hospitals, treatment facilities, clinical institutions and health departments;
2. a medicinal product that is applicable for the treatment of diseases that must be diagnosed in hospitals, treatment facilities, clinical institutions and health departments with the corresponding diagnostic equipment, regardless of whether application and control are possible in other places;
3. a medicinal product intended for treatment at the primary level, though its application could cause very serious adverse reactions, and therefore requires a special prescription or recommendation of a specialist physician, and very specific supervision over the course of treatment. The primary health care physician (general practitioner) may prescribe the medicinal product pursuant to the recommendation of a specialist physician.

Article 14

(1) The following data must be entered on the stipulated prescription form printed in Appendix II of this Ordinance and which forms its integral part:

1. in the administrative part of the prescription:

   – name and surname, date of birth and address of patient,
   – diagnosis code in accordance with the International Classification of Diseases and Related Health Problems (last publication of the ICD, $10^{th}$ edition);
   – the header of the prescription must bear a printed or stamped name, telephone number and address of the health care institution or private practice prescribing the prescription;
   – signature and seal of the authorised person prescribing the medicinal product, and seal of the health clinic;
   – date of the prescription;

2. in the professional section of the prescription:
   - name of the medicinal product, form and strength of the medicinal product;
   - quantity of the medicinal product (expressed in the number of original packages or duration of treatment);
   - dosage and manner of use of the medicinal product.

(2) If the medicinal prescribed is a magistral or galenic preparation, in the professional part of the prescription, instead of the name of the medicinal product, information is stated on the composition with the names of ingredients for magistral or galenic preparation.

Article 15

In the Republic of Croatia, a medicinal product with marketing authorisation may, in accordance with the provisions of the Act, be dispensed on the basis of a prescription issued by an authorised person from another European Union Member State.

Article 16

The prescription written by the authorised person for the prescription of medicinal products from a European Union Member State must contain, at least:

1. Information on the patient:
   - name and surname,
   - date of birth;
2. Information on the prescription:
   - date of the prescription;
3. Information on the authorised person in the European Union writing the prescription:
   - name and surname,
   - professional qualifications,
   - work address, including the European Union Member Stated,
   - contact information (e-mail, telephone number or fax),
   - signature (hand-written or electronic);
4. Information on the prescribed medicinal product:
   - name of the medicinal product (international non-proprietary name – INN),
   - proprietary if a biological medicinal product is prescribed, or in the cases when the authorised person in the European Union explicitly stated that no substitute medicinal product may be dispensed,
   - pharmaceutical form,
   - strength, quantity and dosage.

Article 17

The physician’s prescription, pursuant to which the medicinal product is dispensed at the expense of the Croatian Health Insurance Fund (hereinafter: Fund) may, in addition to the information from Article 12, paragraph 2 and Article 14 of this Ordinance, contain other information and codes as laid down in the general bylaws of the Fund.

Article 18

(1) One prescription may contain a prescription for only one medicinal product for one person, in the quantity that corresponds to the objective health condition of the person and the nature of the disease, in the maximum quantity sufficient for treatment over 30 days.

(2) By way of derogation from paragraph 1 of this Article the Fund may, in its regulations, enable for certain chronic conditions the prescription of a medicinal product in a quantity sufficient for treatment over more than 30 days.

(3) In the case of the provision of emergency outpatient medical assistance, one non-renewable prescription may prescribe a medicinal product in the quantity necessary for treatment over a maximum of three days, or the smallest available original package of medicinal product that meets the said timeline, with the mandatory entry of one of the codes from Article 25 of this Ordinance onto the prescription.

(4) The prescription must be written legibly and indelibly, either by hand or by computer printout.

Article 19

(1) A non-renewable prescription is valid for 15 days from the date of the prescription, while a renewable prescription is valid for a maximum of 12 months from the date of prescription.

(2) If the prescription prescribes a medicinal product with antibiotic effect, the prescription shall be valid for 3 days from the date of the prescription, and if the prescribed medicinal product contains the drug from Article 12, paragraph 1, item 1 of this Ordinance, the prescription shall be valid for 5 days from the date of the prescription.

Article 20

(1) A prescription form may only prescribe a medicinal product having marketing authorisation.

(2) By way of derogation from the provision of paragraph 1 of this Article, a prescription may prescribe a medicinal product that does not have marketing authorisation in the Republic of Croatia, if this concerns an urgent, medically justified and documented need in line with the conditions laid down in Article 129 of the Act.

Article 21

(1) The name of the medicinal product on the prescription is written in the proprietary or non-proprietary name, and may not be abbreviated.

(2) The name of the compounds in the magistral preparation are written on the prescription, as a rule in Latin, and according to the names from the Croatian or European Pharmacopeia or the professionally accepted names in the methodology of making medicinal products of the *Formulae magistrales* and may be abbreviated in the manner laid down by the Croatian or European Pharmacopeia. The quantity of compounds is expressed in grams (g) in Arabic numerals, and the number of capsules, drops, etc. is listed in Roman numerals.

(3) The name of the galenic preparation is written pursuant to the name in the professional literature, or the composition of the galenic preparation is written in the manner as determined for the magistral preparation.

Article 22

(1) Instructions on dosage and the instructions for use of the medicinal product must be completed on the prescription for the medicinal product. It is not permitted only to write "as instructed" or similar.

(2) The instructions on the prescription for the medicinal product for which it is determined that it shall be administered by an authorised person shall bear the words "by a doctor" or "Ad manum medici".

Article 23

(1) If the prescription lists a medicinal product which is found on the market in various pharmaceutical forms, strengths and packaging, the authorised person is required to state on the prescription the form, strength and packaging of the medicinal product.

(2) The strength and concentration and expressed in the metric system, except for therapy that uses standard units.

(3) The number of packages of the medicinal product is marked with Roman numerals and letters, and if greater than one, also with the Latin name for the number.

Article 24

If the authorised person prescribes a greater dose of the medicinal product than the maximum dose, or prescribes a different dosage from that listed in the authorised package leaflet included with the medicinal product, or if the magistral formula prescribed contains a compound in a quantity greater than the maximum permitted dosage than listed in the professional literature, in addition to the number, the number must also be written in letters with an exclamation mark (!) signature and stamp.

Article 25

If due to the nature of the disease the medicinal product needs to be dispensed urgently, the authorised person is required to write one of the following codes on the prescription: "cito", "statim" or "periculum in mora".

Article 26

The authorised person is obliged, on the renewable prescription, to write in hand, or on the e-prescription in the technical programme form of entering content in electronic form, the code "repetatur" or "repeat" if they wish for the prescribed medicinal product to be renewed on the same prescription. The number of repetitions must be marked with a Roman numeral and letters, and the printed form of the prescription is certified with the signature and stamp, while for the e-prescription, the electronic signature is entered in the technical program form of entering content in electronic form.

Article 27

Every correction in the professional part of the prescription written by the authorised person must be confirmed with the signature and stamp of the person, or for the e-prescription, the electronic signature is entered in the technical program form of entering content in electronic form.

Article 28

(1) Medicinal products containing drugs included on the List of drugs, psychotropic compounds and plants from which drugs may be obtained and substances that may be used for making drugs, may be prescribed only if their use is of the utmost necessity.

(2) Medicinal products containing drugs for the treatment of drug addiction may be prescribed only by authorised persons that have concluded an agreement with the Fund.

Article 29

(1) Medicinal products, galenic or magistral preparations containing drugs, may be prescribed on a special prescription in the quantity necessary for treatment for a maximum of 30 days.

The total quantity of prescribed drugs for 30 days of treatment may not be greater than:

1. 0.6 g buprenorphine,
2. 6.0 g morphine,
3. 15.0 g pentazocine,
4. 7.5 g codeine,
5. 1.0 g fentanyl,
6. 2.4 g methadone,
7. 15 g oxycodone.

(2) The quantity of medicinal product that contains the drug and is used for the treatment of drug addition and which may be prescribed on a single prescription will be determined in the bylaws of the Fund.

Article 30

(1) Medicinal products containing drugs and psychotropic substances, with the exception of psychotropic substances from the List in Appendix III of this Ordinance, are prescribed on a special prescription form that is kept locked in special safe-like cabinets.

(2) A special prescription for the prescription of medicinal products containing drugs and psychotropic substances, with the exception of the psychotropic substances from the List in Appendix III of this Ordinance, and are prescribed to insured persons of the Fund, are written in duplicate.

(3) A copy of the special prescription from paragraph 2 of this Article for insured persons of the Fund are kept in the records of the pharmacy and are entered into the drug logbook.

Article 31

(1) The authorised person, the master of pharmacy with authorisation for independent work (hereinafter: pharmacist) and doctor of veterinary medicine with authorisation for independent work are obliged to keep a logbook on the prescribed and dispensed prescriptions for medicinal products containing drugs and psychotropic substances.

(2) The logbook from paragraph 1 of this Article contains data on the written prescriptions for medicinal products containing drugs and psychotropic substances.

(3) The form and content of the logbook from paragraph 1 of this Article is laid down in a special regulation by the minister.

(4) The provisions of paragraph 1 of this Article are not applied to medicinal products that in their singular form of the medicinal product do not contain more than:

- 100 mg pholcodeine, i.e. less than 2.5% in the undivided form of the medicinal product,
- 30 mg codeine in combination with other substances in the singular form of the medicinal product, i.e. less than 2.5% in the indivisible form of the medicinal product (calculated on the base).

(5) For medicinal products containing psychotropic substances from the List in Appendix III of this Ordinance, the logbook from paragraph 1 of this Article is not kept.

Article 32

Prescription medicinal products may only be dispensed by pharmacists.

Article 33

(1) A pharmacist may dispense a prescription medicinal product only if it is prescribed in accordance with the provisions of the Act, the Ordinance laying down the conditions and manner of handling drugs and medicinal products that contain drugs, and this Ordinance.

(2) By way of derogation from paragraph 1 of this Article, the pharmacist may dispense a medicinal product to a medical doctor with valid authorisation for independent work, exclusively upon showing the valid membership card of the relevant chamber, except for medicinal products from Article 30, paragraph 1 of this Ordinance.

Article 34

(1) If the pharmacy, or medicine depot, does not have the prescribed medicinal product, the pharmacist is obliged to take measures to obtain the medicinal product, or at the request of the patient or person picking up the medicinal product, to obtain the medicinal product no later than within three days.

(2) By way of derogation from paragraph 1 of this Article, if the pharmacy does not have the prescribed medicinal product at the time of dispensation due to its unavailability on the market of the Republic of Croatia, the pharmacist has the right, without prior agreement with the authorised person, or with the doctor of veterinary medicine holding authorisation for independent work who prescribed the medicinal product, to dispense the generic medicinal

product to the person, under the condition that the authorised person, or doctor of veterinary medicine holding authorisation for independent work who prescribed the medicinal product and did not note on the prescription that the medicinal product may not be substituted, and that the person is in agreement with the substitution of the medicinal product.

(3) The pharmacist is obliged to note the substitution of the medicinal product in the case from paragraph 2 of this Article on the prescription at the time of dispensing of the medicinal product.

(4) If the person does not consent to the substitute medicinal product, the pharmacist will return the prescription and refer them to the authorised person or doctor of veterinary medicine holding authorisation for independent work who prescribed the medicinal product, for the purpose of prescribing another medicinal product.

(5) If the authorised person does not list the number of repetitions next to the word "repetatur" or "ponoviti", then the medicinal product may be dispensed only one additional time.

(6) If the authorised person prescribing the medicinal product on a renewable prescription, next to the word "repetatur" or "repeat" lists a higher number of repetitions by which the dispensing of the medicinal product would mean dispensing a quantity of medicinal product higher than that prescribed in accordance with Article 18, paragraph 1 of this Ordinance, the pharmacist may reduce the number of repetitions of dispensing the medicinal product. The pharmacist should note the reduction of the number of repetitions on the form of the prescription.

(7) The manner of dispensing the medicinal product prescribed in accordance with Article 18, paragraph 2 of this Ordinance will be laid down by a general regulation of the Fund.

(8) The pharmacist may not, in place of the prescribed medicinal product, dispense a medicinal product with a similar composition.

Article 35

The pharmacist will deny the dispensing of the medicinal product if:

- he assesses in his expertise that the medicinal product could harm the health of the patient,
- if the prescription prescribed on the form does not contain all the data laid down in Article 14 and Article 16 of this Ordinance.

Article 36

(1) Medicinal products may only be dispensed in their original packaging.

(2) Unless otherwise stated on the prescription, a maximum of one original packaging of the medicinal product of the lowest strength may be dispensed on the prescription.

(3) Exceptionally, the medicinal product may be dispensed in larger packaging if administered in a hospital institution.

Article 37

(1) If the prescription is not written in line with the provisions of this Ordinance, the pharmacist must warn the person who wrote the prescription thereof, though in such a way that does not arouse the suspicion of the person for whom the medicinal product was prescribed of the correctness of the work of the authorised person or the pharmacist.

(2) If, in the case from paragraph 1 of this Article, the pharmacist cannot come to an agreement with the authorised person, or doctor of veterinary medicine holding authorisation for independent work who prescribed the medicinal product, the pharmacist will act in the following manner:

- if the prescription is not legibly written, and it cannot be determined which medicinal product it refers to, it will be returned to the patient with the necessary explanation,
- if the prescription prescribes a medicinal product in which the maximum dose has been exceeded, and the authorised person prescribing it did not write the stipulated codes, the medicinal product in the mean therapeutic dose will be dispensed, and the correction noted on the prescription. In that case, the pharmacist will retain the prescription, and the person for whom such a medicinal product was prescribed will be issued a copy of the prescription,
- if the form of the medicinal product is incorrectly stated, the most appropriate form of the medicinal product will be dispensed, with regard to the package leaflet,
- if the incorrect dose is listed, the medicinal product will be dispensed in the lowest dose,
- if the packaging size is incorrectly stated, the smallest packaging will be dispensed.

(3) All corrections on the prescription must be marked and certified with a signature and stamp, or with the electronic signature on the e-prescription.

Article 38

In the dispensing of prescription medicinal products, the pharmacist has the right to request the person picking up the medicinal product to show their personal identity card or passport.

Article 39

Upon each dispensing of a medicinal product, the pharmacist must do the following with the prescription:

- apply the stamp of the pharmacy,
- state the date of dispensing of the medicinal product,
- on a renewable prescription, state the quantity of the dispensed medicinal product (number of original packages),
- sign the prescription, or add the e-signature on an e-prescription.

Article 40

(1) After dispensing of the medicinal product, a non-renewable prescription is not returned to the patient, but is entered into the Book of prescription copies and remains in the pharmacy records.

(2) For a renewable prescription, the pharmacist dispenses the medicinal product pursuant to the instructions and returns it to the patient, with certification of dispensing of the medicinal product on the back of the prescription by writing the date of dispensing of the medicinal product and applying the stamp of the pharmacy and signature of the pharmacist issuing the medicinal product, and entry into the Book of prescription copies.

(3) The right to repeat the dispensing of a medicinal product prescribed on a renewable prescription may be achieved, as a rule, no earlier than 7 days prior to the date envisaged for the next dispensing of the medicinal product.

(4) After the final prescribed dispensing of the medicinal product on a renewable prescription, or after the expiry of 12 months from the date of prescribing the prescription or the prescribed number of repeated dispensations of the medicinal product, the prescription is no longer returned to the patient, but is entered into the Book of prescription copies and remains in the records of the pharmacy.

Article 41

If the prescription does not state the quantity and types of expedients necessary for creating the magistral preparation, the pharmacist is obliged to state on the prescription the quantity and type of expedients used in making up the preparation.

Article 42

If the authorised person prescribes using an abbreviated name a complex magistral preparation which is envisaged in the professionally accepted names in the methodology of making up medicinal products (*Formulae magistrales*), the pharmacist is obliged in the dispensing of such a medicinal product to write all its integral parts and quantity of those integral parts on the prescription.

Article 43

If there is a suspicion that the medicinal product or galenic preparation with a valid expiry date is no longer adequate or that the product is counterfeit, the pharmacist is obliged to halt all further dispensation of the medicinal product or galenic preparation and to inform the Agency, pharmaceutical inspection and wholesale distributor from which the medicinal product was procured thereof.

Article 44

(1) Upon receiving the prescription for making up a magistral preparation, the pharmacist is obliged to issue confirmation to the person submitting the prescription, which will be used to pick up the preparation.

(2) The confirmation from paragraph 1 of this Article shall be made in duplicate.

(3) The original confirmation is handed to the person submitting the prescription, and the copy is appended to the prescription.

(4) The confirmation shall contain the following data:

– name, address and telephone number of the pharmacy,
– number of the confirmation,
– date and time the preparation may be picked up.

Article 45

Magistral and galenic preparations are dispensed in packaging suitable to the pharmaceutical form of the preparation, as follows:

1) fluids in narrow necked bottles,
2) fluid powders in wide necked bottles,
3) ointments and pastes in tubes or plastic containers,
4) eye ointments in sterile tubes,
5) eye drops in sterile bottles with built-in dropper,
6) undivided powders in round cardboard or plastic containers,
7) divided powders:

   mass to 1 g, depending on the nature of the substances comprising the powder, in medicinal gelatinous, starch capsules or capsules of clean white or wax paper; mass greater than 1 g in bags of plasticised paper,

8) teas in paper bags in stackable cardboard boxes,
9) suppositories and globules individually wrapped in aluminium foil in a cardboard box,
10) pills, medicinal gelatinous capsules, starch capsules, tablets and pastilles in cardboard boxes,
11) medicinal products that may be altered under the influence of light in dark containers,
12) medicinal products with strong or very strong activity that are used in drops in drop bottles with a built-in dropper.

Article 46

(1) The labelling of magistral and galenic preparations according to their manner of use is:

– white labels for internal use,
– red labels for external use.

(2) If the magistral or galenic preparation is in liquid form and has sediment, it is necessary to add the words: “Shake before using”.

(3) If the magistral preparation should be kept in a cold place, it is necessary to add the words: “Keep chilled”.

Article 47

(1) The label for the packaging of the magistral preparation must contain the following information:

– name and address of the pharmacy in which the magistral preparation was prepared,
– form of the magistral preparation,
– quantity of the magistral preparation,

- instructions for use,
- number of its entry in the Laboratory journal,
- confirmation number under which the patient can pick up the magistral preparation,
- date of preparation of the magistral preparation,
- initials of the person preparing the magistral preparation.

(2) The label on the packaging of the galenic preparation must contain the following information:

- name and address of the pharmacy in which the galenic preparation was prepared,
- name or content of the galenic preparation,
- instructions for use,
- quantity of the galenic preparation,
- order number or Laboratory logbook number,
- date of preparation of the galenic preparation and expiry date or date of use,
- initials of the person preparing the galenic preparation.

(3) The pharmacist is required to familiarise the patient or person picking up the magistral or galenic preparation with the proper and safe use of the preparation, and if necessary, to add written instructions certified with the signature of the pharmacist and stamp of the pharmacy.

(4) At the time of dispensing the magistral preparation containing a substance with strong or very strong activity, it is necessary to enter the prescription for the preparation into the Book of prescription copies.

(5) At the time of dispensing a magistral preparation containing drugs, it is necessary to enter the prescription for the preparation into the Book of prescription copies and the Drug logbook.

Article 48

At the time of dispensing of a medicinal product, the pharmacist must familiarise the patient or person picking up the medicinal product with the proper and safe use of the medicinal product.

Article 49

As of the date of entry of this Ordinance into force, the Ordinance on the manner of classification of medicinal products and the prescription and issuance of medicinal products (Official Gazette 82/10) shall cease to have effect.

Article 50

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

Class: 011-02/13-02/100

Reg no: 534-10-1-2-2/4-13-1

Zagreb, 28 June 2013

Minister
**Prof. Rajko Ostojić, MD, PhD,** m.p.

# APPENDIX I

# SPECIAL PRESCRIPTION

| Name, address and telephone number of the health care institution or private health clinic |
|---|
| Name and surname |
| Date of birth |
| Address |
| Diagnosis (ICD) |
| Number from Drug logbook |
| Rp.<br><br>Date Signature and stamp |
| Date of dispensation<br><br>Code and signature of pharmacist dispensing the medicinal product and stamp of pharmacy |

Size of form is 21 x 14.5 cm (A-5 format).

# APPENDIX II

# STIPULATED PRESCRIPTION FORM

| Name, address and telephone number of the health care institution or private health clinic issuing the prescription |
|---|
| Name and surname |
| Date of birth |
| Address |
| Diagnosis (ICD) |
| Rp.<br><br>Date Signature and stamp |
| Date of dispensation<br><br>Code and signature of pharmacist dispensing the medicinal product and stamp of pharmacy |

Size of form is 21 x 14.5 cm (A-5 format).

**APPENDIX III**

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

| Psychotropic substance (Croatian) | Psychotropic substance (international non-proprietary name - INN) | 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-fluorphenyl)-2,3-dihydro-2-oxo-1H-1,4-benzodiazepin-3-carboxylate |
| fludiazepam | Fludiazepam | 7-chloro-5-(o-fluorphenyl)-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-trifluorethyl)-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 |

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| 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-tetrahydroxsazolo-[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-carboxilic 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-fluorphenyl)-1-methyl-4H-imidazo[1,5-a][1,4]benzodiazepine |
| 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 |

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| temazepam | Temazepam | 7-chloro-1,3-dihydro-3-hydroxy-1-methyl-5-phenyl-2H-1,4-benzodiazepin-2-one |
| 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 |