Rulebook on the form and content of a prescription, criteria for classification of medicines, as well as the manner of prescribing and dispensing medicines

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I. BASIC PROVISIONS

Article 1

This Rulebook shall regulate the form and content of a prescription, criteria for classification of medicines, as well as the manner of prescribing and dispensing medicines.

Article 2

The terms used in this Rulebook for natural persons in masculine gender shall also refer to the same terms in feminine gender.

II. THE FORM AND CONTENT OF A PRESCRIPTION

Article 3

Prescription shall contain the following information:

1) MONTENEGRO - HEALTH INSURANCE FUND;
2) prescription bar code;
3) fascimile number of a doctor prescribing a medicine;
4) health booklet number;
5) base and type of insurance;
6) indication on contribution of the insured person to the cost of medicine (contribution): yes - no;
7) price of medicine at the expense of mandatory health insurance;
8) amount of contribution paid by the insured person to the cost of medicine;
9) realization only with identification document;
10) name, surname and year of birth, telephone number, e-mail address and medicine user identification number;
11) medical record (protocol) number;
12) name and stamp of a health care institution prescribing a medicine;
13) name, surname, facsimile and signature of a doctor prescribing a medicine;
14) date of prescribing;
15) name and stamp of a pharmacy dispensing a medicine;
16) name, surname, facsimile and signature of a pharmacist dispensing a medicine;
17) medicine code;
18) quantity of dispensed medicine;
19) price of medicine - raw materials;
20) date of dispensing;
21) generic or protected name of medicine;
22) pharmaceutical form of medicine (form, strength and packaging);
23) method of administration;
24) diagnosis code, in accordance with the International Classification of Diseases - Tenth Review (MKB-10) for prescribed medicine;
25) label of a regime for prescribing a medicine;
26) label of specialty in prescribing a medicine; and
27) medicine dispensation label.

If a medicine is not prescribed at the expense of mandatory healthcare insurance, the data referred to in paragraph 1, 2 to 8 of this Article shall not be completed.

Prescription shall have dimensions of 20 cm x 11.3 cm and shall be given on the form which forms an integral part of this Rulebook (Annex I).

III. CRITERIA FOR CLASSIFICATION OF MEDICINES

Article 4

Criteria for classification of medicines - prescription-only shall be the following:

- likelihood that proper use of a medicine poses indirect or immediate danger to the user, if used without medical supervision;
- improper and frequent use of medicines, which is why there is a high likelihood of indirect or immediate danger to the health of the user;
- the contents of substances or preparations whose effect or adverse effects require further investigation; and
- pharmaceutical form for parenteral use.

Medicines that meet the criteria referred to in paragraph 1 of this Article may be classified as non-prescription medicines, provided that the maximum single dose, strength, pharmaceutical form, packaging or other conditions correspond to the criteria for classification of medicines referred to in Article 6 of this Rulebook.

Article 5

Criteria for classification of medicines - non-prescription medicines shall be the following:

- low general toxicity and no relevant reproductive toxicity, genotoxic or carcinogenic
- properties;
- great therapeutic width and overdose safety;
- minimal interactions with commonly used medicines, which can produce serious adverse reactions;
- indications well-known to the patient-user and self-treatment purpose, without the doctor's advice, with a reduced likelihood of irregular recognition of the disease and untimely treatment;
- low risk of unexpected serious adverse reactions;
- not intended to eliminate symptoms that may be relevant to various diseases, so that the user can not see the difference between these diseases; and
- no risk of developing resistance to medicine, in the event of a possibility of wide use.

More detailed criteria for determining a regime of dispensing medicines (prescription-only medicines and non-prescription medicines) are determined in accordance with the European Commission Guidelines on changing the classification for the supply (Notice for Applicants Vol 2C - Regulatory Guidelines on changing the classification for the supply of a medicinal product for human use - 2006).

Article 6

Medicines that are dispensed without prescription shall be intended for shorter periods of self-treatment, marked to allow for safe treatment, contain instructions with sufficiently clear data on the medicine and have a low treatment risk, even if:

- used when not indicated;
- used for a longer period than recommended;
- the recommended dose is exceeded; or
- warnings and contraindications are not followed during the use.

IV. PRESCRIBING MEDICINES

Article 7

Prescription-only medicines shall be prescribed by a doctor of medicine or a doctor of dentistry (hereinafter referred to as: “doctor”) who is licensed to work (a chosen doctor, a doctor specialist from the Mental Health Center, Center for Children with Developmental Disabilities, the Center for Pulmonary Diseases and Tuberculosis) and a doctor specialist of secondary or tertiary health care level (a doctor specialist - infectologist and doctor specialist - endocrinologist).

Article 8

Prescription shall, as a rule, be made in electronic form (hereinafter referred to as: “electronic prescription”), and may also be in writing (hereinafter referred to as a: “written prescription”).

Written prescription shall be written with black or blue ink, legibly and indelibly.

Article 9

One prescription may be prescribed for only one medicine, in a quantity corresponding to the objective health condition of a patient and nature of the disease, with indication of the dosage and method of administration, and maximum in quantity sufficient for treatment for up to 30 days unless otherwise provided in this Rulebook.

Article 10

Prescription may be:

- renewable (multiple-use) prescription -RPr;
- non-renewable (single-use) prescription - NrPr;
- special prescription - SPr; and
- restricted prescription - RPr.

Article 11

Renewable prescription shall be prescribed for a long-term use or for treatment of chronic diseases or recurrent disorders.

Medicine shall be dispensed up to three times based on a renewable prescription.

Renewable prescription can not be a written prescription.

Notwithstanding paragraph 3 of this Article, renewable prescription may also be a written prescription when prescribing antiretroviral medicines used in the treatment of HIV infection.

Renewable prescription shall contain the "RPr" tag and the "repetatur" tag or "renew" if the prescribed medicine on that prescription is re-dispensed.

The number of times the medicine is re-dispensed shall be indicated on the prescription in Roman numerals and letters.

Article 12

Non-renewable (single-use) prescription shall be prescribed for a medicine dispensed on a single-use basis.

Non-renewable prescription shall contain the tag "NrPr" and the tag "non repetatur" or "do not renew".

Non-renewable prescription shall be valid for one month from the day of prescribing.

Article 13

Special prescription shall prescribe a medicine that:

- contains drugs, as well as other substances that can be used for drug production;
- contains a matter or a substance that is new or has special properties, which means that classification in this subgroup constitutes a preventive measure in terms of precautionary measures; and
- if improperly used, there is a possibility of being used for unauthorized purposes or causing addiction.

Special prescription shall contain the tag "SPr".

Article 14

Restricted prescription shall prescribe a medicine intended for use in specialized areas, namely, a medicine which:

- due to its pharmaceutical properties or for the protection of public health, is intended for treatment only in hospital health care institutions;
- is used for treatment of diseases diagnosed in hospital health care institutions with appropriate diagnostic equipment, regardless of whether administration and control are possible elsewhere;
- intended for primary health care, but its administration could cause serious adverse reactions, and which is prescribed based on a report of doctor specialist;
- it is used in health care institutions at primary health care level due to the manner of use which requires administration or supervision of a healthcare worker.

Restricted prescription shall contain the tag "RPr".

Article 15

If a prescription is prescribing an antibiotic medicine, the prescription shall be valid for three days from the day of prescribing, and if it prescribes a medicine that contains drugs and other substances that can be used for drug production, the prescription shall be valid for five days from the day of prescribing.

Article 16

Prescription that prescribes a medicine that is dispensed urgently due to the nature of disease shall contain one of the following indications "cito" - "fast", "statim" - "urgent" or "periculum in mora" - "dangerous to hesitate".

Article 17

Prescription that prescribes a medicine, for which no other suitable medicine may be dispensed because of the health and safety risks for the patient, shall contain the following indication "Do not replace!" and the prescription shall be verified by doctor’s signature.

Article 18

Name of the medicine on a prescription shall be generic and/or protected name and shall not be shortened.

Names of the substances of magistral medicine shall, as a rule, be written in Latin, according to the names of European Pharmacopoeia or professionally-recognized names in the methodology of medicine production Formula magistrales and may be shortened in the manner established by the European Pharmacopoeia.

Quantities of substances shall be expressed in grams (g) by Arabic numerals, and the number of capsules, drops and the like shall be indicated in Roman numerals and letters.

Name of the galenic medicine shall be written in accordance with the name used in the literature or the composition of the galenic medicine shall be written in the manner prescribed for the magistral medicine.

Article 19

Prescription shall clearly and completely indicate the method of administration of a medicine.

For medicines determined to be administered by a doctor, prescription shall contain the tag "to the doctor's hands" or "Ad manum medici".

If prescribing a medicine placed on the market in a variety of pharmaceutical forms, strengths and packaging, the form, strength and packaging of the medicine shall be indicated on the prescription.

Strength and concentration of a medicine shall be expressed in the metric system, except for the therapy for which standard units shall be used.

The number of packagings of a medicine shall be indicated by Roman numerals and letters, and if there are more than one packaging by Latin numerals as well and shall contain the tag "Necesse est".

Article 20

If a doctor prescribes a higher dose than a maximum dose or prescribes a different dose than the one listed in the instructions that accompany the medicine, or if the prescribed magistral medicine contains a substance in an amount greater than the maximum dose allowed in the literature, the number of doses shall be written in letters and with an exclamation mark and signature of the doctor who prescribed the medicine.

Article 21

Medicines containing drugs or substances that have been determined by a regulation establishing a list of drugs, psychotropic substances and plants that can be used for drug production shall be prescribed only if their use is necessary.

Medicines referred to in paragraph 1 of this Article shall be prescribed on a special prescription.

Notwithstanding paragraph 2 of this Article, medicines containing psychotropic substances listed in Annex II to this Rulebook and forming part thereof shall be prescribed on a non-renewable prescription.

Prescription for medicines referred to in paragraph 1 of this Article shall be prescribed in two copies, marked "replica" on the second copy, and both the original and the replica of the

prescription shall contain the ordinal number from the record sheet under which the prescription is collected at the health care institution in which it is prescribed.

Doctor shall be obliged to keep records of special prescriptions.

The records of special prescriptions shall be kept in electronic or paper form.

The records referred to in paragraph 6 of this Article shall be kept in the form of hardcover books composed of the record sheets certified by the health care institution.

The contents of the record sheet referred to in paragraph 7 of this Article shall be given on the form which forms an integral part of this Rulebook (Annex III).

Article 22

For dispensation of a medicine on a single-use basis, a special prescription may be prescribed for a medicine containing maximum of:

1) 0.6 g of buprenophrine;
2) 6.0 g of morphine;
3) 15.0 g of pentazocine;
4) 7.5 g of codeine;
5) 1.0 g of fentanyl;
6) 2.4 g of methadone;
7) 15.0 g of oxycodone.

Notwithstanding paragraph 1 of this Article, in therapy of malignant diseases, for dispensation of a medicine on a single-use basis, a drug-containing medicine may be prescribed, in the quantity required for a maximum of 14 days of therapy.

Medicines containing cocaine chloride may be prescribed and dispensed only for the needs of health care institutions, only in the form of solutions containing up to 20% cocaine, or in the form of eye ointment containing up to 2% cocaine.

Cocaine chloride may be dispensed only on the basis of a written request from a health care institution.

Article 23

Provision of Article 21, paragraph 2 of this Rulebook shall not apply to medicines which, in dosage form, do not contain more than:

- 100 mg of folcodine in a single dose, or more than 2.5% in undivided form of a medicine;
- 30 mg of codeine in combination with other medicinal substances in a single dose, or more than 2.5% in undivided form of a medicine (converted to base).

Article 24

For certain medicines, restrictions in the prescription and administration regime shall be established in relation to:

- diagnosis of a disease established in accordance with ICD-10;
- degree of disease expression;
- age of the insured person;
- population group;
- opinion of a doctor of medicine of the appropriate specialty which is valid until the next examination by that doctor;
- suggestion of medical advisory board - opinion of three doctors of medicine of the appropriate specialty, which is valid until the next examination of these doctors specialists;
- time and quantity restriction of medicine use;
- a health care institution that, in accordance with the approval of a state administration body responsible for health care, carries out a health care program with the medicine.

If a medicine is prescribed at the expense of mandatory health insurance, the prescription shall contain special indications of the regime of prescription and administration of the medicine, namely:

1) R - medicine is dispensed on the basis of prescription prescribed by the doctor referred to in Article 7 of this Rulebook;

2) RS - medicine is dispensed on the basis of the chosen doctor's prescription, which is prescribed on the basis of a report of the doctor of a particular branch of medicine;

3) RZ - medicine is dispensed on the basis of the chosen doctor's prescription, which is prescribed on the basis of the therapy proposed in a discharge note;

4) RK - medicine is dispensed on the basis of the chosen doctor's prescription, prescribed based on the opinion of medical advisory board consisting of doctors of relevant specialties of the Clinical Center of Montenegro and of the opinion of the Health Insurance Fund of Montenegro;

5) Z - medicine is administered in a primary health care institution;

6) SZ - medicine is administered in a hospital health care institution;

7) SZK - medicine is administered in a hospital health care institution, based on the opinion of medical advisory board consisting of doctors of relevant specialties of the Clinical Center of Montenegro and of the opinion of the Health Insurance Fund of Montenegro;

8) # -reserve antibiotic;

9) § drug is prescribed on a separate recipe in two copies, with a "replica" mark and contains information on: the number and date of the report of doctor specialist, code of the doctor specialist and the record number of drug-containing medicines.

V. DISPENSING MEDICINES

Article 25

Pharmacist (doctor of pharmacy, master of pharmacy, graduate pharmacist) who has a work license shall dispense a medicine prescribed on a prescription only if the prescription is prescribed in accordance with this Rulebook.

Pharmacist shall not dispense a medicine of similar content instead of the prescribed medicine.

Pharmacist may refuse to dispense a medicine if he shall estimate that the medicine could endanger health of the patient.

Article 26

If a pharmacy does not have a prescribed medicine - the protected name of the medicine, the pharmacy may, without prior agreement with the doctor, dispense a generic medicine, provided that the prescription does not contain the "Do not Replace" tag.

Pharmacist shall type in the prescription an indication on the replacement of a medicine, in the case referred to in paragraph 1 of this Article, when dispensing a medicine.

If the patient does not agree to a medicine replacement, pharmacist shall return the prescription and refer the patient to the doctor for prescription of another medicine.

If the doctor does not indicate the number of repetitions next to the "repetatur" or "repeat" tag, the medicine may be dispensed only once.

If a doctor who prescribes a medicine on a renewable prescription lists a higher number of repetitions next to the tags "repetatur" or "repeat" according to which a larger quantity of medicine is dispensed than prescribed, the pharmacist shall be required to reduce the number of re-dispensations of the medicine and to type in the prescription the reduced number of repetitions.

Article 27

Medicine shall be dispensed in the original packaging.

If the prescription does not prescribe otherwise, the prescription may dispense maximum one original packaging of the medicine of minimum strenght.

Notwithstanding paragraph 1 of this Article, medicine may be dispensed in a larger packaging, provided that the pharmacist provides a safe packaging with the entered data referred to in Article 29 of this Rulebook or if medicine is administered in a hospital medical facility.

Article 28

If the doctor does not prescribe the form, size, strength or other mark in accordance with this Rulebook when prescribing a finished medicine which is placed on the market in a variety of forms, sizes or strengths, the pharmacist shall be obliged to warn the doctor before dispensing the medicine and try to come to an agreement with him, if possible.

If the pharmacist, in the case referred to in paragraph 1 of this Article, can not come to an agreement with the doctor, he shall proceed as follows:

- if the prescription is not legibly written and it can not be determined which medicine is in question, he shall return the prescription to the patient with the necessary explanation;

- if the prescription prescribing a medicine exceeds the maximum doses, and the doctor has not entered the prescribed tags, he shall dispense the medicine in a medium therapeutic dose, write the correction on the prescription and retain the prescription;
- if the wrong form of medicine is indicated, he shall issue the most appropriate form of medicine, given the instructions for its use;
- If the wrong dose is indicated, the medicine is dispensed in the smallest dose;
- If the wrong packaging size is indicated, the smallest packaging is dispensed.

Pharmacist shall record all corrections in an electronic or written prescription.

Article 29

.At each medicine dispensation, pharmacist shall indicate on the prescription:
- quantity of medicine;
- name and stamp of a pharmacy dispensing medicine;
- name, surname, facsimile and signature of a pharmacist dispensing medicine; and
- date of dispensing a medicine.

In addition to the data referred to in paragraph 1 of this Article, pharmacist may indicate:
- medicine code;
- price of medicine - raw materials;
- cost of services at the expense of mandatory health insurance; and
- amount paid by the person to whom the medicine is dispensed.

Article 30

Non-renewable, special and restricted prescription shall not be returned to the patient after the medicine has been dispensed.

Pharmacist shall dispense a medicine on a renewable prescription and write on the back of the prescription the date of dispensing, name and strength of medicine, quantity of medicine, name and surname of a pharmacist and certifie it with a stamp of the pharmacy, signature and facsimile, and shall return the prescription.

The right to re-dispense a medicine prescribed on a renewable prescription may be acieved at the earliest seven days before the deadline for the next collection of medicine.

After the last dispensation of medicine on a renewable prescription, ie after three months from the date of prescribing or prescribed number of medicine dispensations, the pharmacist shall retain the prescription.

Special prescription shall be recorded and kept, together with medicines, in a separate safe for drugs.

Records of special prescriptions shall be kept in electronic or paper form.

The records referred to in paragraph 6 of this Article shall be kept in the form of hardcover books composed of the record sheets certified by a health care institution.

A copy of the special prescription and the record sheet shall be signed by the person collecting the medicine, while providing insight into the identification document.

The contents of the record sheet referred to in paragraph 7 of this Article shall be given on the form which forms an integral part of this Rulebook (Annex IV).

VI. MAGISTRAL AND GALENIC MEDICINES

Article 31

When taking over the prescription for manufacture of magistral medicine that is prescribed on a non-renewable prescription, pharmacist shall issue a certificate on the basis of which the medicine is being collected after manufacturing.

The original copy of the certificate, pharmacist shall deliver to the prescription holder and a copy of the certificate shall be attached to the prescription.

The certificate referred to in paragraph 1 of this Article shall contain the following information:
- name, address and telephone number of the pharmacy;
- certificate number; and
- date and time of collecting the magistral medicine.

If the type and quantity of excipients required for manufacture of a magistral medicine are not listed on the prescription, pharmacist shall write on the prescription the amount and type of excipients used for manufacturing the medicine.

Article 32

If a doctor shall prescribe a complex magistral medicine which is contained in the professionally accepted regulations for manufacture of medicines (Formulae magistrales) under the abbreviated name, pharmacist shall when dispensing such a medicine write on the prescription the type and quantity of excipients used for manufacturing the medicine.

Article 33

For labeling magistral and galenical medicines, by method of use, the following labels shall be used:

- white, for internal use;
- red, for external use.

If magistral or galenical medicine is in liquid form and has a precipitation, it shall be necessary to place the label "Shake Before Use".

If magistral medicine is stored in a cold place, it shall be necessary to place the label "Keep in cold place".

Article 34

Label on a magistral or galenic medicine shall contain information that corresponds to the data from the prescriptions or data from the valid pharmacopoeias and magistral formulas, namely:

- name and address of the pharmacy in which magistral medicine was manufactured, ie name of a galenic laboratory of a pharmacy or a health care institution in which a galenic medicine was manifactured;
- form and quantity of magistral or galenical medicine;
- method of administration;
- date of manufacturing of magistral or galenic medicine and expiry date; and
- signature of the person who manifactured the magistral medicine.

Article 35

When dispensing a magistral medicine containing substances of strong or very strong effect, a pharmacist shall enter the prescription in the records of drug-containing medicines.

Pharmacist shall inform a patient or a person collecting a magistral or galenic medicine, on the proper and safe use of medicine and, if necessary, submit a written instruction that is certified with signature of the pharmacist and stamp of the pharmacy.

VII. TRANSITIONAL AND FINAL PROVISIONS

Article 36

Provisions of this Rulebook relating to renewable prescription shall apply from 1 October 2015.

Article 37

Provisions of the Rulebook on More Detailed Conditions for Exercising Rights under Mandatory Health Insurance (Official Gazette of the Republic of Montenegro 69/06) shall cease to apply in respect of the manner and procedure for exercising the right to medicines from the day of entry into force of this Rulebook.

Article 38

This Rulebook shall enter into force on the eighth day following that of its publication in the Official Gazette of Montenegro.

***Editor's Note**: Attachments in PDF format can be downloaded by clicking on the following link:*

Annexes

ANNEX 1

PRESCRIPTION FORM

MONTENEGRO – HEALTH INSURANCE FUND

Prescription bar code	Doctor's facsimile number

……..……

Health care institution (name)

…….

Name and surname (medicine user)

……..……

Residential address

……	……	……
Telephone number	E-mail	Year of birth

Personal identification number | Insurance base | Type of insurance

Health booklet number | YES NO Contribution | Medical record number

_____ Label of a regime for prescribing a medicine (R, RS, RZ, RK)	_____ Medicine prescription label	Diagnosis code
_____ Label of specialty in prescribing a medicine – type of prescription (RPr, NrPr, SPr, RPr)		

……..

Pharmacy (name)

……	……..
Name, surname, facsimile and signature of pharmacist doctor	Name, surname, facsimile and signature
PLACE STAMP	PLACE STAMP

Medicine code | Quantity | Price of medicine – raw material

Price at the expense of the Fund | Amount of paid contribution

REALIZATION ONLY WITH IDENTIFICATION DOCUMENT

ANNEX II

List of psychotropic substances not prescribed on a special prescription, and prescribed on a non-renewable prescription

Psychotropic substance	**Psychotropic substance (international unprotected name)**	**Psychotropic substance (chemical name)**
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
ethyl-loflazepate	Ethyl loflazepate	ethyl 7-chloro-5-(o-fluorophenyl)-2,3-dihydro-2-oxo-1H-1,4-benzodiazepine-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
haloxazolam	Haloxazolam	10-bromo-11b-(o-fluorophenyl)-2,3,7,11b- tetrahydrooxazolo[3,2-d] [1,4]benzodiazepin-6(5H)-one
camazepam	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
clobazam	Clobazam	7-chloro-1-methyl-5-phenyl-1H-1,5-benzodiazepine- 2,4(3H,5H)-dione
cloxazolam	Cloxazolam	10-chloro-11b-(o-chlorophenyl)-2,3,7,11b-tetrahydro-oxazolo- [3,2-d][1,4]benzodiazepin-6(5H)-one
clonazepam	Clonazepam	5-(o-chlorophenyl)-1,3-dihydro-7-nitro-2H-1,4-benzodiazepin- 2-one
clorazepate	Clorazepate	7-chloro-2,3-dihydro-2-oxo-5-phenyl-1H-1,4-benzodiazepine3-carboxylic acid

chlordiazepoxide	Chlordiazepoxide	7-chloro-2-(methylamino)-5-phenyl-3H-1,4-benzodiazepine-4- oxide
clotiazepam	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
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
oxazepam	Oxazepam	7-chloro-1,3-dihydro-3-hydroxy-5-phenyl-2H-1,4- benzodiazepin-2-one
oxazolam	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-propynyl)-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
tetrazepam	Tetrazepam	7-chloro-5-(1-cyclohexen-1-yl)-1,3-dihydro-1-methyl-2H-1,4-benzodiazepin-2-one
triazolam	Triazolam	8-chloro-6-(o-chlorophenyl)-1-methyl-4H-s-triazolo[4,3- a][1,4] benzodiazepine
zolpidem	Zolpidem	N,N,6-trimethyl-2-p-tolylimidazo[1,2-a]pyridine-3-acetamide

ANNEX III

RECORD SHEET_____

Sheet number: _____

NAME OF HEALTH CARE INSTITUTION PRESCRIBING A MEDICINE

No.	Date of prescribing	Generic or protected name of medicine; pharmaceutical form, strength and packaging; method of administration	Diagnosis code (ICD: 10)	Name and surname, personal identification number, telephone number and address of the person to whom the medicine is prescribed	Name and surname, telephone number and address of the person collecting medicine, identification document number and place of dispensing	Name and surname and facsimile number of a doctor prescribing a medicine

ANNEX IV

RECORD SHEET_____

Sheet number: _____

NAME OF PHARMACY DISPENSING A MEDICINE

No.	Date of dispensing	Generic or protected name of medicine; pharmaceutical form, strength and packaging; method of administration	Name of supplier of delivered medicine – number and date of delivery note under which the medicine is delivered	Name and surname, personal identification number, telephone number and address of the person to whom the medicine is prescribed	Name and surname, telephone number and address of the person collecting medicine, identification document number and place of dispensing	Name of health care institution where the medicine is prescribed	Name and surname and facsimile number of the doctor prescribing a medicine	Name and surname and facsimile number of the pharmacist dispensing a medicine