Documents whose amendment is included in updated form

Order	1786	12.06.2025	23.06.2025	
Order	1476	18.03.2024	20.03.2024	
Order	183	22.01.2024	23.01.2024	

Ministry of Health

ORDER No. 63*)
of 10 January 2024
on the regulation of the methodology for monitoring the prescription and dispense at national level of medicinal products in the category of antibiotics and antimycotics for systemic use

***) Note:**
Includes all changes made to the official document, published in the Official Gazette of Romania, including those mentioned in:
Order of the Minister of Health no. 1.786/12.06.2025, Published in the Official Gazette of Romania no. 578/23.06.2025

On seeing approval report no. A.R. 301 of 9.01.2024 of the Pharmaceutical and Medical Devices Directorate of the Ministry of Health,

Taking into account the provisions of Art. 5 letter f), Art. 16 paragraph (1) letter b) and Art. 804 paragraph (2) of Law 95/2006 on healthcare reform, republished, as further amended and supplemented,

pursuant to Article 7 (4) of Government Decision no. 144/2010 on the organisation and operation of the Ministry of Health, as further amended and supplemented,

the minister of health hereby issues the following order:

Art. 1 - (1) This order regulates the methodology for monitoring the prescription and dispense at national level of medicinal products in the category

of antibiotics and antimycotics for systemic use, approved in the Index of medicinal products for human use, published by the National Agency for Medicines and Medical Devices of Romania ***(NAMMDR)*** on its own website.

(2) Medicinal products containing one or several substances, alone or in combinations, prescribed in master recipes prepared in the pharmacy are exempt from the provisions of this Order.

Art. 2 - For the purposes of this Order, terms used herein shall have the following meaning:

a) ***medicinal products in the category of antibiotics and antimycotics for systemic use*** - all medicinal products for human use registered in the Index of medicinal products for human use, which contain one or several substances, alone or in combinations, whose international non-proprietary name is provided in Annex 1, which is an integral part of this Order;

b) ***medical prescription*** - any prescription issued by a physician outside the social health insurance system and which includes at least one medicinal product from those mentioned in letter a), according to the model provided in Annex 2, which is an integral part of this Order.

Art. 3 - (1) For medicinal products in the category of antibiotics and antimycotics for systemic use prescribed outside the social health insurance system, exclusively the medical prescription defined in art. 2 letter b) is used.

(2) Medicinal products in the category of antibiotics and antimycotics for systemic use prescribed by physicians shall be dispensed to patients or their relatives by pharmacists employed within authorised pharmaceutical units, exclusively on basis of the medical prescription defined in Art. 2 letter b), which shall include at least the following data:

1. the batch and number of the medical prescription, unique, generated at the level of each prescriber;
2. the health unit identified by name, address and telephone number;
3. the data of the patient to whom the medicinal products defined in Art. 2 letter a) are prescribed, respectively:

a) for Romanian and foreign citizens with domicile or residence in Romania: National Identification Number (PERSONAL NUMERIC CODE (CNP)) or insured person identification code (CID), full name, age;

b) for foreign citizens who do not have residence in Romania: country code, passport number or EU (EC) card number, full name, age;

4. the diagnosis code used within the Single Integrated Information System of Social Health Insurance of Romania, in line with the international

classification of diseases (ICD), the standard diagnosis tool of the World Health Organisation;

5. the prescribed medicinal product, characterised by: international non-proprietary name, strength, pharmaceutical form, method of administration, quantity (expressed in therapeutic units), duration of treatment;
6. the prescriber's signature;
7. stamp code;
8. the date of dispense of the medical prescription.

(3) *By way of exemption from provisions of paragraph (1), pharmacists working in authorised pharmaceutical units may, in exceptional, emergency situations, dispense medicinal products from the category of antibiotics and antimycotics for systemic use, whose international non-proprietary name is marked with the sign "*" in Annex 1 to this Order, in the absence of a medical prescription, in the maximum quantity corresponding to the dose for 48 hours, dose calculated in accordance with the method of administration provided for in the Summary of Product Characteristics. The emergency dose may be dispensed only once during a patient's treatment, based on the statement whose model is provided for in Annex 3, which is an integral part of this Order.*

(4) *The dispense of the medicinal products provided for in paragraph (3) shall be carried out in line with the emergency dispense procedure of the Good Pharmaceutical Practice Rules and with the recommendations of the Pharmacist's Guide for counselling and dispense of the 48-hour antibiotic dose in the community pharmacy, provided for in Annex 4, which is an integral part of this Order.*

(5) *The dispense of the medicinal products provided for in paragraph (3) shall be carried out with the registration, at pharmacy level, of the following minimum information:*

1. patient data:

a) for Romanian and foreign citizens with domicile or residence in Romania: the PERSONAL NUMERIC CODE (CNP) or CID (insured person identification code), full name, age;

b) for foreign citizens who do not have a residence card: country code, passport number or EU (EC) card number, full name, age;

2. the dispensed medicinal product, characterised by: international non-proprietary name, strength, pharmaceutical form, route of administration,

quantity (expressed in therapeutic units);

3. name and signature of the pharmacist who dispensed the medicinal product;

4. diagnosis/pathological condition;

5. date of dispense of the medicinal product.

Art. 4 - (1) The validity of the medical prescription regulated by this Order may not exceed the last day of the treatment, according to the method of administration and the duration of the treatment recommended by the prescriber.

(2) The medical prescription provided for in Art. 3 paragraph (2) shall be retained in the pharmacy and may be dispensed in fractions only within the same pharmacy, without exceeding the total quantity prescribed.

Art. 5 - (1) Pharmaceutical units which dispense medicinal products from the category of those defined in Art. 2 letter a) for outpatient treatment are required to report daily all operations performed with these medicinal products, using the electronic reporting system developed by the Special Telecommunications Service and regulated through Order of the Minister of Health no. 1345/2016 on daily reporting of stocks and trade operations carried out with medicinal products for human use included in the National Catalogue of Prices for medicinal products authorised for marketing in Romania by medicinal product wholesalers, importers, authorised manufacturers and closed- and open-circuit pharmacies, as further amended and supplemented.

(2) For medicinal products from the category of those mentioned in Art. 2 letter a), the daily reporting shall include the following information:

a) series and number of the medical prescription;

b) the medicinal product: the medicinal product identification code (so-called "CIM code")

c) quantity, expressed in therapeutic units;

d) patient identification data, namely:

(i) for individuals, Romanian citizens or foreign citizens residing in Romania: the personal numeric code (CNP) or the CID (insured person identification code);

(ii) for individuals, foreign citizens: passport number or EU (EC) card number;

e) diagnosis code;

f) stamp code.

(3) By exemption from paragraph (2), the daily reporting of medicinal products dispensed under the conditions of Art. 3 paragraph (3) shall include the following information:

a)the medicinal product: the medicinal product identification code (so-called "CIM code")

b) quantity, expressed in therapeutic units;

c) patient identification data, namely:

(i) for individuals, Romanian citizens or foreign citizens residing in Romania: the personal numeric code (CNP) or CID;

(ii) for individuals, foreign citizens: passport number or EU (EC) card number.

(4) Within 48 hours from publication of this Order in the Official Gazette of Romania, Part I, the Ministry of Health shall publish on the page dedicated to the electronic reporting system on its own website the technical specifications of the web service, updated in line with paragraph (2).

(5) Within 105 days from entry into force of this Order, pharmaceutical units are required to adapt their own management information system in order to comply with the provisions of paragraphs (1) and (2).

Art. 6 - The Ministry of Health, the NAMMDR and the National Institute of Public Health have secure access to the information in the electronic reporting system regarding the data provided for in Art. 5 paragraph (1).

Art. 7 - The list of international non-proprietary names provided in Annex 1 is periodically updated by the Ministry of Health, at the proposal of the NAMMDR, in line with the update of the Index of medicinal products for human use.

Art. 8 - This Order shall be published in the Official Gazette of Romania, Part I.

Minister of health,
Alexandru Rafila

Annex 1

No.	*International Non-proprietary Name*
1	*AMIKACINUM*
2	*AMOXICILLINUM + ACIDUM CLAVULANICUM i.v.*
3	*AMOXICILLINUM + ACIDUM CLAVULANICUM oral**
4	*AMOXICILLINUM**
5	*AMPHOTERICINUM B*
6	*AMPICILLINUM + SULBACTAM*
7	*AMPICILLINUM**
8	*ANIDULAFUNGINUM*
9	*AZITHROMYCINUM*
10	*AZTREONAM*
11	*AZTREONAMUM + AVIBACTAMUM*
12	*BENZATHINI BENZYLPENICILLINUM*
13	*BENZYLPENICILLINUM*
14	*CASPOFUNGINUM*
15	*CEFACLORUM*
16	*CEFADROXILUM**
17	*CEFALEXINUM**
18	*CEFAZOLINUM*
19	*CEFEPIMUM*
20	*CEFIDEROCOLUM*
21	*CEFIXIMUM*
22	*CEFOPERAZONUM*
23	*CEFOTAXIMUM*
24	*CEFPODOXIMUM*
25	*CEFTAROLINUM FOSMIL*
26	*CEFTAZIDIMUM*
27	*CEFTRIAXONUM*
28	*CEFUROXIMUM*
29	*CHLORAMPHENICOLUM**
30	*CIPROFLOXACINUM*
31	*CLARITHROMYCINUM*
32	*CLINDAMYCINUM**
33	*COLISTIMETAT DE SODIU*
34	*COLISTINUM*
35	*COMBINATIONS (CEFOPERAZONUM + SULBACTAMUM)*

36	*COMBINAŢII (CEFTAZIDIMUM + AVIBACTAMUM)*
37	*COMBINATIONS (CEFTOLOZANUM + TAZOBACTAMUM)*
38	*CYCLOSERINUM*
39	*DALBAVANCINUM*
40	*DAPTOMYCINUM*
41	*DOXYCYCLINUM**
42	*ERAVACICLINUM*
43	*ERTAPENEMUM*
44	*ERYTHROMYCINUM*
45	*FIDAXOMICINUM*
46	*FLUCONAZOLUM*
47	*FOSFOMYCINUM*
48	*GENTAMICINUM*
49	*IMIPENEMUM + CILASTATINUM*
50	*IMIPENEMUM + CILASTATINUM + RELEBACTAMUM*
51	*ISAVUCONAZOLUM*
52	*ITRACONAZOLUM*
53	*KANAMYCINUM*
54	*LEVOFLOXACINUM*
55	*LINEZOLIDUM*
56	*MEROPENEMUM*
57	*METRONIDAZOLUM i.v.*
58	*METRONIDAZOLUM oral**
59	*MICAFUNGINUM*
60	*MINOCYCLINUM*
61	*MOXIFLOXACINUM*
62	*NITROFURANTOINUM**
63	*NITROXOLINUM*
64	*NORFLOXACINUM*
65	*NYSTATINUM**
66	*OFLOXACINUM*
67	*OXACILLINUM**
68	*PEFLOXACINUM*
69	*PHENOXYMETHYLPENICILLINUM**
70	*PIPERACILLINUM + TAZOBACTAMUM*
71	*POSACONAZOLUM*
72	*RIFAMPICINUM*
73	*RIFAXIMINUM*
74	*SPIRAMYCINUM*
75	*STREPTOMYCINUM*
76	*SULFAFURAZOLUM**

77	*SULFAMETHOXAZOLUM + TRIMETHOPRIMUM**
78	*SULTAMICILLINUM**
79	*TEICOPLANINUM*
80	*TETRACYCLINUM**
81	*TIGECYCLINUM*
82	*TINIDAZOLUM**
83	*TOBRAMYCINUM*
84	*VANCOMYCINUM*
85	*VORICONAZOLUM*

Annex 2

MODEL OF MEDICAL PRESCRIPTION

Series ..... No. .....

Healthcare unit .....
(name, address and telephone number) .....

Patient data ....., personal numeric code (CNP)/CID (insured person's identification code)/number
(full name, age)
of the passport/number of the EU (EC) card ....; Diagnosis .....
(code used within the single integrated health insurance information system of Romania)
.....
(descriptive diagnosis)

Medicinal product details:
Trade name and/or International Non-proprietary Name .....
Strength……; Pharmaceutical form .....
Route of administration .....
Quantity (expressed in therapeutic units) .....
Duration of treatment (no. of days/months) .....

Name and signature of the prescriber.....

Stamp code .....

Date of issuance of medical prescription .....

Annex 3

STATEMENT

Under the sanctions applied to the act of misrepresentation of facts mentioned in Law 286/2009 on the Criminal code, as further amended and supplemented, I, the undersigned, ..., residing in ....., street ..... no. ..., building number ..., stairway number ..., appartment number ..., county/sector ....., identity card series no. ....., personal numeric code (CNP) ....., I take it upon myself to declare that I did not pick up the maximum 48-hour dose of medication…… from another pharmaceutical unit during this treatment.

Date .....
Patient/patient's relative signature .....

***Annex 4**[*)]*

**) Annex 4 was introduced through Order no. 1786/2025 of 23 June 2025.*

PHARMACIST'S GUIDE
for counselling and releasing a 48-hour dose of antibiotics in a community pharmacy

Recommendations regarding patient counselling and dispense of a 48-hour antibiotic dose, as appropriate, in community pharmacies

Introductory aspects

This guideline is intended for pharmacists working in community pharmacies in Romania, in the context of approval of Order of the Minister of Health no. 63/2024 on the regulation of the methodology for monitoring the prescription and dispense at national level of medicinal products from the category of antibiotics and antimycotics for systemic use. This guide is intended for

pharmacists working in community pharmacies in Romania, in the context of the approval of the Order of the Minister of Health no. 63/2024 on the regulation of the methodology for monitoring the prescription and dispense at national level of medicines in the category of antibiotics and antimycotics for systemic use.

The information and situations presented in this guideline represent recommendations to be followed by pharmacists working in community pharmacies. In daily practice, pharmacists may encounter particular cases in which they will use their own experience and knowledge, and decisions will be made in agreement with the patient, based on the pharmacist's assessment, the patient's needs and in line with legal provisions.

This guideline covers the most common conditions for which patients go to community pharmacies with symptoms which may require the recommendation of antibiotic treatment, in accordance with the INNs approved through Order of the Minister of Health no. 63/2024, as further amended and supplemented, and which can be dispensed by the pharmacist for 48 hours without a medical prescription. For each condition described in this guide, the following structure is detailed:

1. *to whom is it addressed (categories with a low risk of side effects or less likely to have comorbidities, polypharmacy, etc. were chosen and for which similar guidelines already exist in other countries);*
2. *criteria for exemption;*
3. *patient counselling based on the symptoms described by the patient during the discussion with the pharmacist, counselling which follows the decision-making logic diagram, depending on the symptoms, and for which a pharmaceutical assistance sheet is issued for each individual case.*

The exemption criteria aim to:

- *avoid the patient postponing a medical consultation or medical intervention when the risk of not addressing a condition to the Emergency is very high;*
- *avoid confusion with other conditions which require a different therapeutic course, which is regulated by other protocols/guidelines or is included in other medical services.*

In applying the exemption criteria, the pharmacist will also consider the accessibility and availability of medical services for the patient - whether the necessary medical services are available in the geographical area, whether they are available in a timely manner and whether they are adapted to the financial possibilities of the patient (for example, uninsured patient). Thus, the pharmacist may decide to recommend a dose of antibiotic for 48 hours, in the absence of a medical prescription, when medical services are not accessible to the patient.

If a patient is in one of the situations described by the exemption criteria, the pharmacist makes sure to explain to the patient the medical course to be followed, as well as the importance and risks to which he/she is subject if he/she does not seek a type of medical assistance according to the recommendations.

The pharmacist applies the exemption criteria only to the extent that the information or symptoms are presented completely and correctly by the patient.

The decision-making scheme is followed exclusively based on the symptoms, signs or other relevant details provided, depending on the patient's perception and subjectivity.

Based on the symptoms or signs reported by the patient, the pharmacist does not establish a diagnosis, but rather brings to the patient's attention certain aspects that may indicate a possible cause of the health problem and always stresses out the importance of consulting a physician, as well.

The pharmacist has the possibility, respectively the right (and not the obligation) to recommend and dispense, following a discussion with the patient and depending on the symptoms reported by the patient, the antibiotic treatment necessary for 48 hours, in the absence of a medical prescription, in the situations described in this guideline or in other exceptional situations in which the patient's health takes precedence.

This guideline describes the most common conditions for which the patient shows up to the community pharmacy and which may indicate the need for the pharmacist to dispense an antibiotic treatment for 48 hours, within the limits of the provisions of Order of the Minister of Health no. 63/2024, as further amended and supplemented, without being limited to these. The dispense by the pharmacist may also be carried out in other exceptional situations, based on his/her own assessment, following patient counselling and within the limits of professional competence. This guideline will be updated periodically, including by supplementing with other conditions, as they will be evaluated and elaborated in detail.

A. Uncomplicated urinary tract infection

1.To whom is it addressed?

Counselling and dispensing an antibiotic for suspected uncomplicated urinary tract infection (UTI) is addressed to:

- female patients;

- patients over 16 years of age.

Male patients who contact a community pharmacy with a suspected urinary tract infection and associated symptoms will be referred to a physician, as other conditions may be present (e.g. prostatitis). In this case, the pharmacist may prescribe products to relieve symptoms, such as painkillers or antiseptics.

2.Exemption criteria for patients:

- pregnancy or suspected pregnancy;

- urinary catheter;

- serious symptoms reported by the patient that may indicate renal disease (such as suspected pyelonephritis) - for example, tenderness/pain in the lumbar region, myalgia, fever (axillary temperature > 37.9° C), +/- chills, nausea, vomiting;

- ongoing medicinal product treatment for other conditions:

- immunosuppressants (including corticosteroids);

- anticancer medication;

- antibiotic treatment in the last 3 months with nitrofurantoin, amoxicillin + clavulanic acid or sulfamethoxazole + trimethoprim (whatever the condition being treated);

- treatment for UTI with any antibiotic in the last 3 months;

- recurrent UTI (2 episodes in the last 6 months or 3 episodes in the last 12 months).

3. Counselling the patient with suspected uncomplicated urinary tract infection in the community pharmacy

When a patient with suspected uncomplicated urinary tract infection shows up to the pharmacy, if the signs and symptoms listed below are identified, it is mandatory to refer the patient to the emergency admission units (UPU)/ambulance service or other types of medical assistance (family physician, medical specialist, permanence centers, etc.):

- confusion, slurred speech, paleness, red spots on the skin, rapid breathing, increased heart rate are manifestations that may indicate serious conditions - the pharmacist will refer the patient to the emergency admission units (UPU) or the ambulance service;

- serious signs and symptoms, reported by the patient, which may indicate kidney disease (such as suspected pyelonephritis - a complicated UTI), for which the pharmacist will refer the patient to the family doctor/medical specialist/*emergency admission units (UPU)*/permanent centers, depending on the severity:*

• tenderness in the lumbar region;

• myalgia;

• reported fever (axillary temperature > 37.9), +/- chills;

• nausea, vomiting.

The pharmacist will also refer the patient to the family physician or medical specialist in the following cases:

- the patient complains of altered vaginal secretions occurring before the urinary ones: 80% of cases do not present UTI, but vaginal infections;

- the patient complains of discomfort in the urethra or knows that she suffers from urethritis, after unprotected sexual intercourse or irritating substances;

- the patient suffers from sexually transmitted diseases;

- the patient complains of symptoms due to vaginal atrophy following menopause (for example: vaginal itching/burning sensation);
- the patient is immunosuppressed (for example: radiotherapy, chemotherapy, systemic corticosteroids, etc.).

If the patient shows up to the pharmacy with the following key symptoms:

- dysuria (pain, stinging, itching, burning sensation when urinating);

- nocturia and has not had it in the past (the need to urinate at night);

- cloudy urine at first glance, which may be accompanied by other symptoms, such as:

- urgent need to urinate;

- increased frequency of urination;

- visible haematuria (red urine);

- suprapubic pain/sensitivity;

- sensation of incomplete emptying of the bladder,

the pharmacist recommends, in agreement with the patient, the steps to follow, depending on the severity of the symptoms:

- for patients with mild symptoms, the pharmacist may recommend analgesics, anti-inflammatories, antispasmodics, urinary antiseptics and self-care:

• for female patients who do not show any key symptom or additional symptom, it is unlikely that they have a UTI; self-care and products addressing the specified symptoms are recommended;
• for patients who present 1 key symptom, referral to a family physician or medical specialist is also recommended, as the existence of a UTI is possible, as is any other diagnosis;
• examples of self-care measures that the pharmacist may recommend to patients:

- hydration: while the symptoms persist, it is recommended to drink more fluids, at least 1.5 liters daily (normally, 2-3 liters of fluids should be consumed, approximately 8-12 cups per day). This promotes proper hydration, more dilute urine and the elimination of bacteria through urine;

- urination: frequent urination and complete emptying of the bladder each time is recommended. Strict adherence to feminine hygiene rules after urination is recommended, with the correct direction of wiping being urethra-anus;
- warm compress: applying a heat source (e.g., electric heating pad) to the lower abdomen is recommended to help relieve pain and discomfort;
- avoiding irritants: limiting or avoiding caffeinated, alcoholic, and carbonated beverages is recommended, as they can irritate the bladder;
- rest: sufficient rest is recommended (7 - 9 hours per day, depending on age; in children and adolescents 8 - 12 hours/day) to allow the body to recover from the infection;

- for patients with moderate-severe symptoms, if the patient declares the

impossibility of contacting medical service in a timely manner, the pharmacist may recommend the following types of antibiotic treatment:

First-line antimicrobial therapy:

• Nitrofurantoin 50 mg every 6 hours or 100 mg every 6-12 hours.

Caution is advised for renal insufficiency if the patient has recent test results (if glomerular filtration rate GFR < 45 ml/min/1.73 m^2, caution is recommended and it is contraindicated if glomerular filtration rate GFR < 30 ml/min/1.73 m^2).

Alternatives:

• Amoxicillin + clavulanic acid 500 + 125 mg every 8 hours;

• Amoxicillin + clavulanic acid 875 + 125 mg every 12 hours.

If the patient is allergic to penicillins, it is recommended:

• Sulfamethoxazole + trimethoprim 800 mg + 160 mg every 12 hours.

Although the pharmacist may recommend the antibiotic dose for 48 hours, the duration of administration necessary for the effectiveness of the above-mentioned medicinal products is longer (5 - 7 days), this aspect being important to specify to the patients, in order to contact the physician in order to continue the treatment based on medical prescription.

WARNING!

• Advise patients who wish to have a urine test to collect the sample before taking the antibiotic.

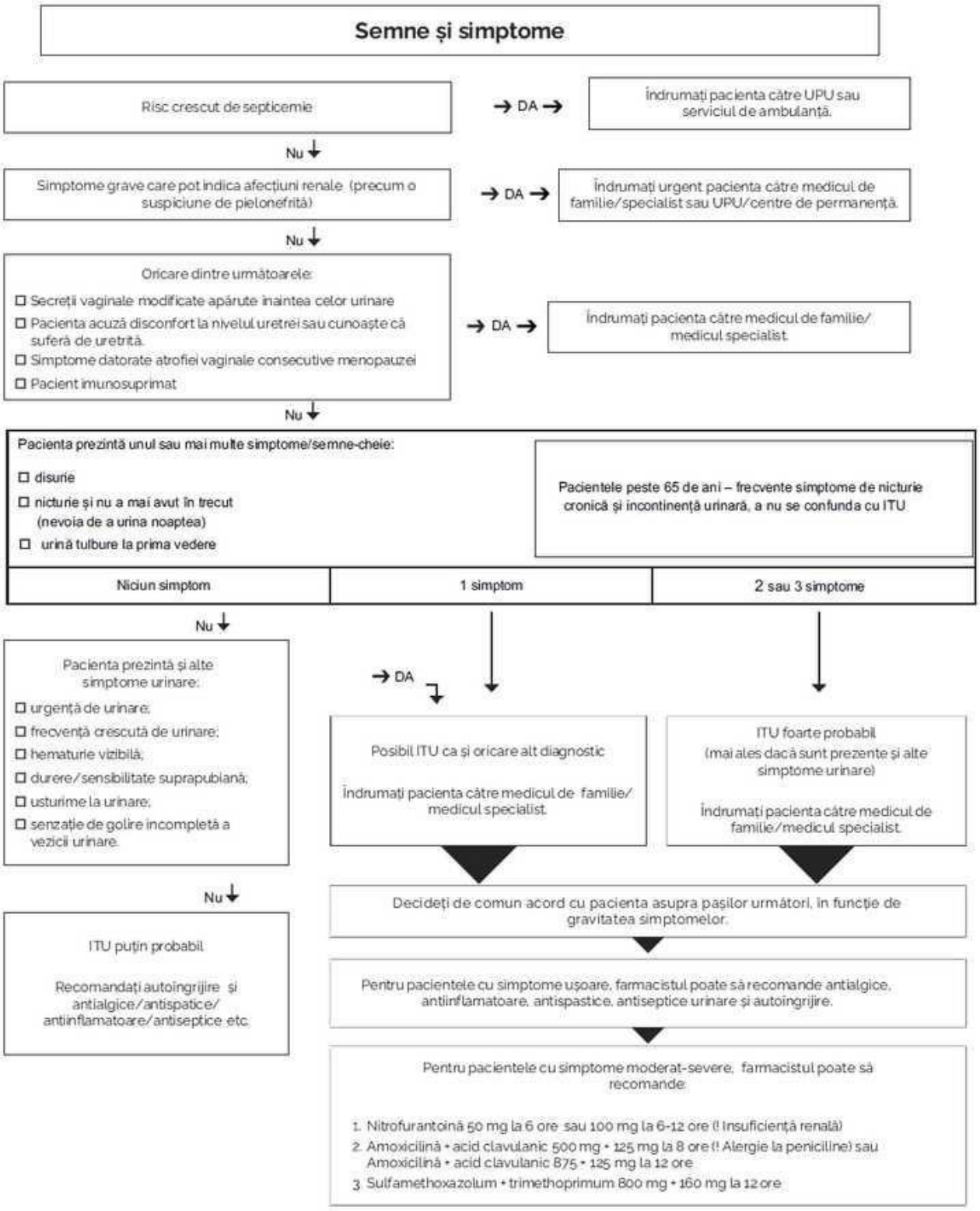
• For all patients: if symptoms worsen rapidly or do not improve within 48 hours with the recommended treatment, the pharmacist will refer the patient to their family physician or medical specialist.

• Patients over 65 years of age frequently have symptoms of nocturia and urinary incontinence, which should not be confused with UTI.

**) Pyelonephritis is a severe infection of the upper urinary tract, characterised by appearance of an inflammatory process in one or both kidneys, which can sometimes be life-threatening.*

Decision-making scheme for suspected uncomplicated urinary tract infection*)

**) The scheme is reproduced in facsimile.*



Pharmaceutical assistance sheet - counselling and dispensing of the antibiotic dose in case of suspected uncomplicated urinary tract infection, in community pharmacy

Date: .....

I take it upon myself to declare that all data and information communicated to the

pharmacist are complete, correct and fully correspond to reality.

Patient's signature:

.....

Patient's full name

.....

.....

Contact data

.....

.....

The patient stated that she was over 16 years old. |¯| Yes

Symptoms described by the patient (list):

.....

.....

.....

.....

.....

.....

.....

.....

The pharmacist referred the patient to the family physician/medical specialist/emergency admission units (UPU)/ambulance service/permanence centers, following a discussion with the patient which resulted in the following:

- pregnancy or suspected pregnancy;

- urinary catheter;

- serious symptoms that may indicate kidney disease (such as suspected pyelonephritis);

- ongoing medicinal product treatment for other conditions:

- immunosuppressants (including systemic corticosteroids);

- anticancer medicinal products;

- antibiotic treatment in the last 3 months with nitrofurantoin, amoxicillin + clavulanic acid or sulfamethoxazole + trimethoprim (whatever the condition being treated);

- treatment for UTI with any antibiotic in the last 3 months;

- recurrent UTI (2 episodes in the last 6 months or 3 episodes in the last 12 months).

Other information provided by the patient:

- other health conditions previously diagnosed by a medical specialist/family physician (for example: kidney disease)

.....

.....

.....

- known allergies to medicinal products: |¯| No |¯| Yes)*

If Yes, please list (especially allergies to antibiotics that may be recommended in this case):

.....

.....

The pharmacist recommended the following:

- medicinal products with analgesic, anti-inflammatory, antiseptic, antispasmodic action;
- self-care measures;
- antimicrobial medication in a 48-hour dose, according to the Pharmacist's Guide and the specifications of Order of the Minister of Health no. 63/2024 on the regulation of the methodology for monitoring the prescription and dispensing at national level of medicinal products in the category of antibiotics and antimycotics for systemic use, as further amended and supplemented.

|¯| *Yes*)*

|¯| *No*

**) When checking Yes, the following statement is completed by the patient, as well as the pharmaceutical assistance sheet, in emergency situations, according to the CFR Procedure for the emergency dispensing of Rx medicinal products in community pharmacies:*

STATEMENT

Under the sanctions applied to the act of misrepresentation of facts mentioned in Law 286/2009 on the Criminal code, as further amended and supplemented, I, the undersigned,.....,
residing in ....., street …… no. ...., building number ...., stairway number ....., appartment number ...., county/sector.....,
identity card series no. ....., personal numeric code (CNP)……., I take it upon myself to declare that I did not pick up the maximum 48-hour dose of medication ……..from another pharmaceutical unit, during this treatment.

Date .....

Patient/patient's relative signature .....

I hereby agree with the above

Signature

.....

B. Acute throat pain

1.To whom is it addressed?

Antibiotic counselling and prescription for 48 hours, as appropriate, for acute sore throat, is addressed to adults and children over 5 years of age who present symptoms specific to streptococcal (bacterial) pharyngitis detailed in this guideline and scored by the FeverPAIN score, namely:

- fever (over 38° C measured axillary at home);

- presence of pus in the throat;

- severe inflammation of the tonsils;

- symptoms which persist for less than 3 days;

- no cough or coryza (cold symptoms).

2.Patient exemption criteria

When a patient with suspected acute sore throat shows up to the pharmacy, if the following signs and symptoms are identified, it is mandatory to refer the patient to the emergency admission unit/ambulance service or other types of medical assistance (family physician, medical specialist, permanence centers, etc.):

- patient-reported symptoms that may indicate suspected epiglottitis - dysphagia, dysphonia, hypersalivation, agitation;

- stridor (noisy, shrill breathing);

- patient-reported symptoms that may indicate suspected viral or bacterial infection, which may also present with a rash (e.g., scarlet fever), or patient-reported symptoms that may indicate parapharyngeal abscess or infectious mononucleosis (see details below);

- immunosuppressed patient (e.g., radiotherapy, chemotherapy, systemic corticosteroids, etc.). In neither case will the patient's throat be examined.

3.Counselling the patient with acute sore throat in community pharmacy

If the patient does not fall into one of the situations described in point 2, for which a medical consultation is mandatory, the pharmacist will apply the FeverPAIN Score, which will award 1 point for each key symptom reported by the patient from the following:

- fever (above 38° C measured axillary at home);

- presence of pus in the throat;

- severe inflammation of the tonsils;

- symptoms which persist for less than 3 days;

- no cough or coryza (cold symptoms).

The pharmacist will decide in agreement with the patient on the steps to follow, depending on the score obtained and the severity of the symptoms:

- In all cases, if the symptoms do not improve within 3 - 5 days or if the symptoms worsen rapidly, the pharmacist will refer the patient to a family physician or medical specialist.

- In all situations, the pharmacist will consider recommending OTC

symptomatic treatment (painkillers, anti-inflammatories, local anaesthetics or antiseptics, etc.), dietary supplements or other health products, as well as self-care measures.

• Self-care tips for sore throat which the pharmacist can recommend to patients:

- gargle with warm salt water: 1/2 teaspoon of salt in a glass of warm water, 3-4 times a day (not recommended for children);

- increased fluid intake, 2 to 3 liters per day (approximately 8-12 cups or more), unless restricted by a medical condition (e.g. cardiovascular or kidney disease). Recommended fluids: water, warm herbal teas, (chicken, vegetable) soups, diluted fruit juices or electrolyte solutions, especially if fever is present;

- consumption of cold or soft foods, avoiding alcohol and caffeine, which can dehydrate;

- avoiding smoking or places where people smoke or with strong odours or dry air;

- ice cubes or lozenges can be used to soothe a sore throat (do not give to small children due to the risk of choking);

- sufficient rest (7 - 9 hours per day, depending on age; in children and adolescents 8 - 12 hours/day) and vocal rest.

OTC medication:

- paracetamol or non-steroidal anti-inflammatory medicinal products (if there are no contraindications or allergies);

- lozenges/sprays with local anaesthetics, anti-inflammatories or antiseptics.

- In all cases, the pharmacist will take into account in his/her recommendations the severity of the symptoms and how they are perceived by the patient, including the impact on the quality of life and daily activities, and each case will be treated individually and specifically.

- In the case of a score of 0 or 1, the administration of an antibiotic is not necessary. In the case of a score of 2 or 3, the administration of an antibiotic does not shorten the duration of symptoms and it is unlikely that complications will occur even if antimicrobial therapy is not administered.

• For patients with a score of 4 or 5, the pharmacist recommends:

• for patients with minor symptoms, symptomatic treatment and self-care measures will be considered as first-line treatment;

• for patients with severe symptoms, the pharmacist may recommend the following types of antibiotic treatment, in doses for 48 hours:

First-choice antimicrobial treatment:

- Amoxicillin

• children weighing < 40 kg (suspension SmPC):

- for children with swallowing difficulties, consider the dispensing of the oral suspension form;

- 40 - 90 mg/kg/day in 2 doses.

• adults, adolescents and children weighing > 40 kg (SmPC tablets):

- 500 mg every 8 hours or 750 mg to 1 g every 12 hours;

- for severe infections - 750 mg to 1 g every 8 hours, for 10 days.

- Phenoxymethylpenicillin (to be administered on an empty stomach)

• children < 12 years (SmPC suspension): 10 - 15 mg/kg/dose every 8 hours, without exceeding the adult dose;

• children > 6 years (SmPC tablets): 500,000 IU mg (312.5 mg) every 8 - 12 hours, without exceeding the adult dose;

• adults, adolescents and children > 12 years (SmPC tablets);

• adolescents (> 40 kg) and adults (> 60 kg): 1,000,000 IU (625 mg) every 8 hours;

• adults, obese patients and the elderly: 1,500,000 IU (937.5 mg) every 8 hours.

Alternatives (especially for patients who declare being allergic to penicillins, but have not had life-threatening reactions, for example, an anaphylactic shock):

- cephalexin

• children and adolescents (5 - 12 years): 25 - 50 mg/kg/day, in divided doses every 12 hours, without exceeding the adult dose;

• adults, adolescents and the elderly with normal renal function: 250 mg every 6 hours or 500 mg every 12 hours. Although the pharmacist can recommend a dose of antibiotic sufficient for 48 hours of treatment, the recommended duration of treatment for the medicinal products listed above is longer and it is important to clarify to patients the need to contact their physician for continued treatment based on a medical prescription.

Temperature limits depending on the measurement site:

Temperature	*Normal range (° C)*	*Fever (° C)*
Rectal	*36.6 - 38*	*> 38*
Oral	*35.5 - 37.5*	*> 37.6*
Axillary	*34.7 - 37.3*	*> 38*
Tympanic	*35.7 - 37.7*	*> 37.8*

Detailing the cases in which the pharmacist, based on the symptoms presented by the patient, may exempt the patient from being dispensed the antibiotic dose and refer the patient to a healthcare provider:

- symptoms reported by the patient indicating possible epiglottitis:

- sudden and severe onset of sore throat and fever;

Detailing the cases in which the pharmacist, based on the symptoms presented by the patient, may exclude the patient from dispensing the antibiotic dose and

refer the patient to a healthcare provider:

- symptoms reported by the patient indicating possible epiglottitis:

- sudden and severe onset of sore throat and fever;

- difficulty breathing, which may improve when the patient leans forward (especially in young children);

- hoarse voice (especially in young children);

- inspiratory stridor (a high-pitched sound when breathing in) (especially in young children);

- pain and difficulty swallowing (especially in older children and adults);

- drooling (especially in older children and adults);

- irritability and agitation;

- patient-reported symptoms indicating a suspected bacterial infection, which may also manifest as a rash (possibly scarlet fever):

- fever (may also be present with a sore throat);

- swollen lymph nodes in the neck (may also appear because of a sore throat);

- tongue coated with a white coating that later develops into a red tongue ("raspberry tongue");

- red cheeks (may be less visible on darker skin);

- pink-red rash that feels like sandpaper (on darker skin, the rash may be less visible, but its rough texture should be obvious);

- bright red skin in the folds of the armpit, elbow, and groin;

- patient-reported symptoms indicating a possible parapharyngeal abscess:

• fever;

• sore throat;

• trismus (inability to open the mouth);

• hoarse voice;

• displaced uvula (noticed and reported by the patient);

• enlarged and displaced tonsil (noticed and reported by the patient);

• swelling of the peritonsillar region (noticed and reported by the patient);

- symptoms reported by the patient that indicate a possible infectious mononucleosis (especially in adolescents and young adults):

• very high body temperature;

• severe sore throat;

• swollen lymph nodes (on any part of the neck);

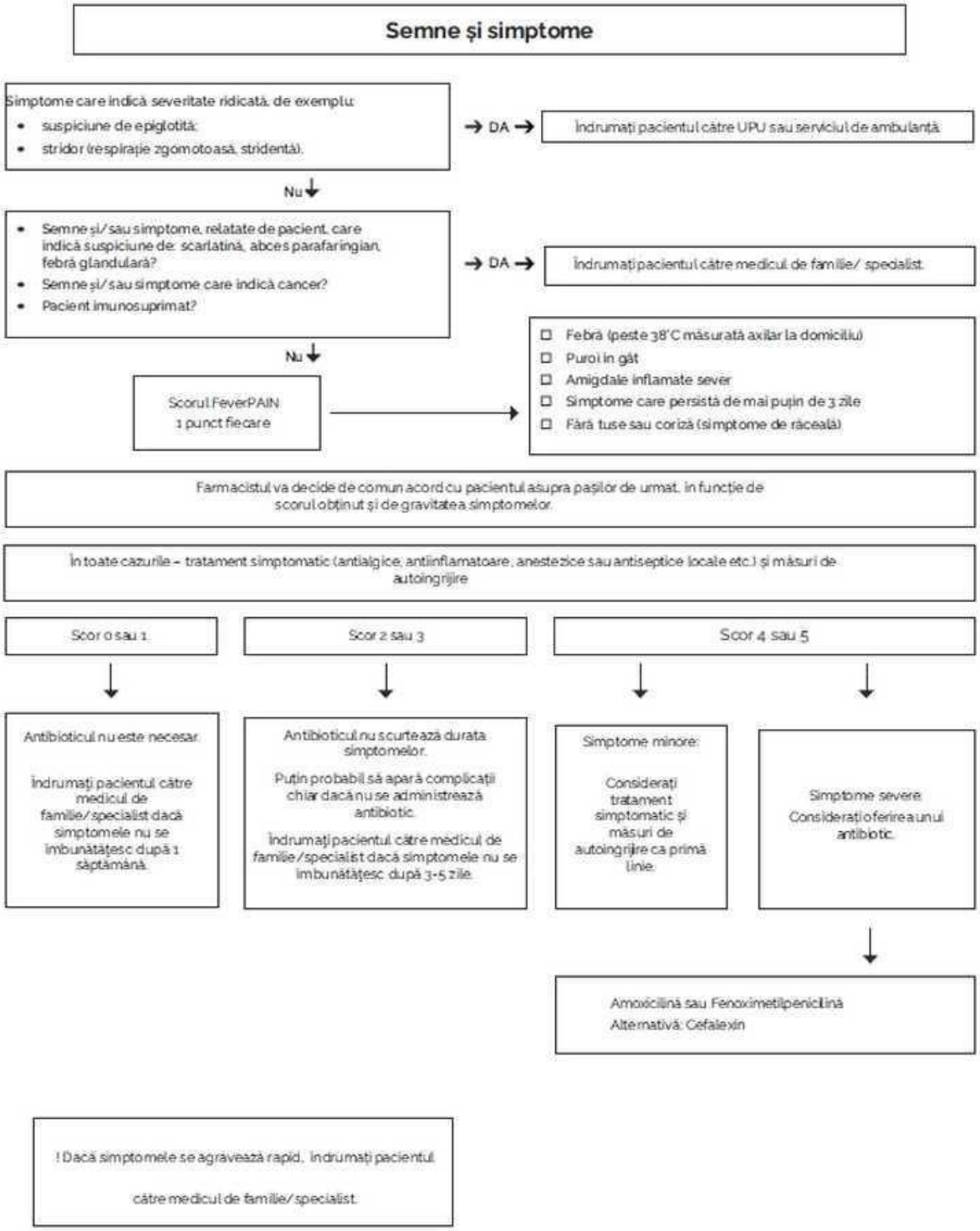
• extreme fatigue or exhaustion;

• tonsillitis that does not improve.

The exemption criteria for acute throat pain refer to conditions which may require antibiotic treatment, but that require the healthcare team's intervention at a different level.

Decision-making scheme *) - Acute throat pain

**) The scheme is reproduced in facsimile.*



Pharmaceutical assistance sheet - counselling and dispensing of a 48-hour dose of antibiotic, as appropriate, for acute sore throat, in the community pharmacy

Date .....

I take it upon myself to declare that all data and information communicated to the pharmacist are complete, correct and fully correspond to reality.

Patient's signature

.....

Symptoms described by the patient (list):

.....

.....

The pharmacist referred the patient to the family physician/medical specialist/emergency admission units (UPU)/ambulance service/permanence centers, following a discussion with the patient, which resulted in the following:

- pregnancy or suspected pregnancy;

- patient-reported symptoms that may indicate suspected epiglottitis - dysphagia, dysphonia, hypersalivation, agitation;

- patient-reported symptoms that may indicate a suspected viral infection, which may also manifest as a rash (e.g., scarlet fever), or patient-reported symptoms that may indicate parapharyngeal abscess or infectious mononucleosis;

- ongoing medicinal product treatment for other conditions:

- immunosuppressants (including systemic corticosteroids);

- anticancer medicinal products;

- recurrent sore throat/tonsillitis: 7 or more significant episodes in the last 12 months or 5 or more episodes in each of the last two years or 3 or more in each of the last three years.

Other information provided by the patient:

• other health conditions previously diagnosed by a medical specialist/family physician (e.g. kidney disease):

.....

.....known allergies to medicinal products: |¯| No |¯| Yes)*

.....

.....

If Yes, please list (especially allergies to antibiotics that may be recommended in this case):

.....

.....

The pharmacist recommended the following:

- symptomatic treatment (OTC medications with analgesic, anti-inflammatory, antiseptic, antispasmodic action, dietary supplements, etc.);

- self-care measures

antimicrobial medication in a 48-hour dose in accordance with the Pharmacist's Guideline and the provisions of Order of the Minister of Health no. 63/2024 on the regulation of the methodology for monitoring the prescription and dispense at national level of medicinal products in the category

of antibiotics and antimycotics for systemic use, as further amended and supplemented.

-

|¯| *Yes*)*

|¯| *No*

**) When checking Yes, the following statement is completed by the patient, as well as the pharmaceutical assistance sheet, in emergency situations, according to the CFR Procedure for the emergency dispensing of Rx medicinal products in community pharmacies:*

STATEMENT

Under the sanctions applied to the act of misrepresentation of facts mentioned in Law 286/2009 on the Criminal code, as further amended and supplemented, I, the undersigned, ..., residing in ....., street ..... no. ..., building number ....., stairway number ....., appartment number ....., county/sector....., identity card series no. ....., personal numeric code (CNP)....., I take it upon myself to declare that I did not pick up the maximum 48-hour dose of medication ……from another pharmaceutical unit, during this treatment.

Date .....

Patient/patient's relative signature .....

I hereby agree with the above

Signature

.....

C. Dental abscess

1. To whom is it addressed? Antibiotic counselling and prescription for 48 hours, as appropriate, for suspected dental abscess is addressed to adults and children over 12 years of age (especially those with signs that may indicate a systemically disseminated infection, as well as patients with uncontrolled diabetes mellitus).

2.Patient exemption criteria:

- The patient is undergoing dental surgery or has a severe complication following such treatment.

- The patient wants antibiotic treatment only to reduce inflammation or to treat dental pain (which may be a result of a dental procedure) or will undergo a dental procedure.

- Pregnancy

- Immunosuppressed patient (e.g. radiotherapy, chemotherapy, systemic corticosteroids, etc.).

The pharmacist can apply these exemption criteria only to the extent that the information is presented completely and correctly by the patient, and it is possible that these exemption criteria cannot be applied in all cases.

3.Counselling the patient with suspected dental abscess in the community pharmacy

It is important to note and remember that most infections and dental pain can be treated without antibiotics, by removing the cause and draining the infection with a specific dental procedure (e.g., tooth extraction).

Likewise, antibiotics:

- do not prevent severe complications and cannot replace necessary surgical treatment;

- should not be used before a dental procedure, only to reduce inflammation or to treat dental pain, unless indicated by the dentist;

- should not be used before dental procedures to prevent postoperative infections, unless indicated by the dentist.

When a patient with suspected dental abscess shows up to the pharmacy, if one of the following aspects is identified, the pharmacist will refer the patient to the dentist:

- The patient is undergoing dental surgery or has a severe complication following such treatment.

- The patient wants antibiotic treatment only to reduce the discomfort caused by inflammation or to treat dental pain (which may be a result of a dental procedure) or will undergo a dental procedure.

- Pregnancy

- Immunosuppressed patient (e.g. radiotherapy, chemotherapy, systemic corticosteroids, etc.).

As far as these patients are concerned, the pharmacist may recommend symptomatic, anti-inflammatory and/or analgesic treatment.

If the patient shows up to the pharmacy with the following symptoms and signs:

- toothache which can be localised, acute, severe and persistent, which can radiate to the ear, jaw or neck;
- tooth sensitivity (for example when chewing) and swelling of the cheek in the region of the affected tooth; untreated, the infection can spread and cause signs of cellulitis around the eye or neck, fever, tachycardia and adenopathy may occur.

The pharmacist will decide in agreement with the patient on the steps to follow, depending on the severity of the symptoms:

- In all situations, the pharmacist may consider recommending a symptomatic, anti-inflammatory and/or analgesic treatment, for example:

• Ibuprofen 200 - 400 mg every 6 - 8 h (max. 2.4 g/day).

• Paracetamol 500 - 1,000 mg every 4 - 6 h, max. 4 g/day (if liver failure or cirrhosis, max. 2 g/day).

- The pharmacist may recommend the following self-care and hygiene measures to the patient:

• compliance with oral hygiene rules even during the episode of dental pain; if

the affected area does not tolerate contact with the toothbrush, toothpaste can be applied to the finger to sanitize the painful area;

• to reduce local pain, soothing gels for the gums can be used or ice packs can be applied to the affected area;

• after each meal, it is recommended to rinse the oral cavity with mouthwash or salt water to ensure proper hygiene.

- The pharmacist may recommend the following types of antibiotic treatment (always accompanied by the recommendation of a dental consultation), in a dose for 48 hours, for patients with:

• severe dental infections;

• patients with uncontrolled diabetes mellitus (higher risk of complications). First-choice antimicrobial treatment:

- Amoxicillin 500 mg every 8 h per os;

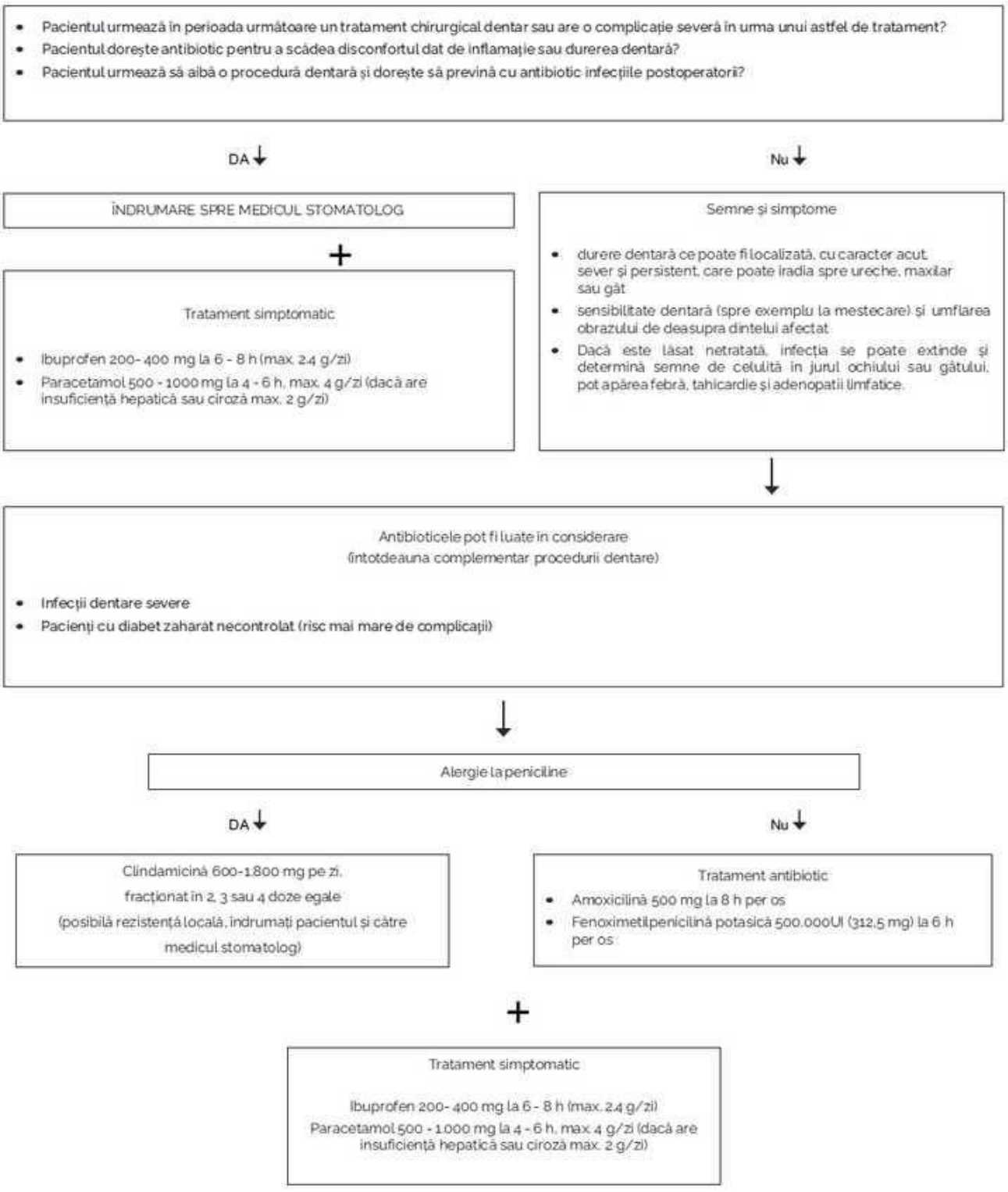
- Phenoxymethylpenicillin potassium 500,000 IU (312.5 mg) every 6 h per os. In case of allergy to penicillins:

- Clindamycin 600 - 1,800 mg per day, divided into 2, 3 or 4 equal doses (possible local resistance, refer the patient to the dentist as well).

Although the pharmacist can recommend a dose of antibiotic sufficient for 48 hours of treatment, the recommended duration of treatment for the abovementioned medicinal products is between 3 and 5 days, depending on the physician's assessment, and it is important to specify to patients to contact their doctor for continued treatment based on medical prescription.

Decision-making scheme *) - Suspicion of dental abscess

**) The scheme is reproduced in facsimile.*



Pharmaceutical assistance sheet - counselling and dispensing of a 48-hour dose of antibiotics, as appropriate, for suspected dental abscess, in the community pharmacy

Date .....

I take it upon myself to declare that all data and information communicated to the pharmacist are complete, correct and fully correspond to reality.

Patient's signature:

.....

Patient's full name

.....

Contact data

.....

The Patient/Patient's relative stated that the patient is over 12 years of age. |¯| Yes

Symptoms and signs described by the patient (list):

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The pharmacist referred the patient to the dentist, following a discussion with the patient, which revealed the following:

- pregnancy or suspected pregnancy;

- ongoing dental surgery or severe complication following such treatment;

- tooth inflammation or pain (which may be due to an ongoing dental procedure); or scheduled to have a dental procedure;

- immunosuppressed patient (e.g. radiotherapy, chemotherapy, systemic corticosteroids, etc.). Other information provided by the patient:

- other health conditions previously diagnosed by a specialist/family doctor (e.g. kidney disease)

.....
.....
.....
.....

known allergies to medicinal products: |¯| No |¯| Yes)*

If Yes, please list (especially allergies to antibiotics that may be recommended in this case):

.....
.....

The pharmacist recommended the following:

• *symptomatic treatment (OTC medications with analgesic, anti-inflammatory*

action, etc. or other health products);

- *self-care measures*
- *antimicrobial medication in a 48-hour dose in accordance with the Pharmacist's Guideline and the provisions of Order of the Minister of Health no. 63/2024 on the regulation of the methodology for monitoring the prescription and dispense at national level of medicinal products in the category of antibiotics and antimycotics for systemic use, as further amended and supplemented*

|¯| *Da*)*

|¯| *Nu*

**) When checking Yes, the following statement is completed by the patient, as well as the Pharmaceutical assistance sheet, in emergency situations, according to the CFR Procedure for the emergency dispensing of Rx medicinal products in community pharmacies:*

STATEMENT

Under the sanctions applied to the act of misrepresentation of facts mentioned in Law 286/2009 on the Criminal code, as further amended and supplemented, I, the undersigned,....., residing in ....., street ..... no. ....., bl , stairway number ....., appartment number ....., county/sector ....., identity card series no. ....., personal numeric code (CNP)……., I take it upon myself to declare that I did not pick up the maximum 48-hour dose of medication…… from another pharmaceutical unit during this treatment.

Date .....

Patient/patient's relative signature .....

I hereby agree with the above

Signature

.....

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- *The Summary of Product Characteristics of Sumetrolim 400 mg/80 mg*