COLLEGIATE BOARD RESOLUTION RDC No. 471 OF 23 FEBRUARY 2021

Provides for the criteria for prescribing, dispensing, controlling, packaging, and labeling medications based on substances classified as prescription antimicrobials, whether alone or in combination, as listed in a specific Normative Instruction.

The Collegiate Board of Directors of the Brazilian Health Regulatory Agency, in the use of the attributions vested in it under Article 7, item III, and Article 15, items III and IV of Law no. 9,782 of 26 January 1999, and Article 53, item VI, Paragraphs 1 and 3 of the Internal Regulation approved by Collegiate Board Resolution – RDC no. 585 of 10 December 2021, adopts the following Collegiate Board Resolution, as decided upon in a meeting held on 23 February 2021, and I, Director-President, determine its publication.

CHAPTER I
SCOPE AND DEFINITIONS

Article 1. This Resolution establishes the criteria for prescribing, dispensing, controlling, packaging, and labeling medications based on substances classified as prescription antimicrobials, whether alone or in combination, listed in a specific Normative Instruction.

Sole paragraph. This Resolution also applies to salts, ethers, esters, and isomers of the antimicrobial substances listed in the Normative Instruction.

Article 2. Private pharmacies and drugstores, as well as public municipal, state, and federal dispensing units that provide medicinal products for reimbursement, such as units of the Brazilian Popular Pharmacy Program, must dispense medications containing the substances listed in the Normative Instruction, whether alone or in combination, by retaining the prescription and recording it in accordance with this Resolution.

Article 3. Municipal, state, and federal dispensing units, as well as pharmacies at hospitals or any other equivalent public or private healthcare facilities that do not sell medications, must maintain specific prescription and dispensing control procedures already in place for medicinal products containing antimicrobial substances.

Article 4. For the purposes of this Resolution, the following definitions are adopted:

I – antimicrobial: a substance that prevents the proliferation of infectious agents or microorganisms or that kills infectious agents to prevent the spread of infection;

II – concentration: concentration is the ratio between the quantity or mass of a substance and the total volume of the medium in which that compound is found;

III – quality deviation: departure from the quality parameters defined and approved in the medicinal product registration;

IV – dispensing: the act of a pharmacist providing one or more medications to a patient, usually in response to a prescription prepared by a licensed professional. In this act, the pharmacist informs and guides the patient on the proper use of the medication. Important elements of this guidance include, among others, an emphasis on adherence to the dosage regimen, the influence of foods, interactions with other medications, recognition of potential adverse reactions, and product storage conditions;

V – dose: total amount of medication administered to the patient at one time;

VI – bookkeeping: manual or computerized recording procedure for the movement (entry, exit, loss and transfer) of medicinal products subject to health control and defined by current legislation, as well as other data of health interest;

VII – pharmacoepidemiology: studies the use and effects of medicinal products in the general population;

VIII – antimicrobial registration book: a document authorized by the local health authority for manual recording of data of health interest. Record-keeping must be performed by the pharmacist or under their supervision;

IX – pharmacoepidemiological monitoring: systematic monitoring of pharmacoepidemiological indicators related to medication consumption in populations to support public health intervention measures, including health education and changes in current legislation. This monitoring consists of three basic components:

a) data collection;
b) regular analysis of data; and
c) wide and periodic dissemination of data.

X – health monitoring: systematic monitoring of operational indicators related to company accreditation in the system, prescription retention, bookkeeping, electronic file submission, and data management system efficiency to support, among other health surveillance tools, health inspections. This monitoring consists of three basic components:

a) data collection;
b) regular analysis of data; and
c) wide and periodic dissemination of data.

XI – dosage: includes a description of the medication's dosage, the intervals between administrations, and the duration of treatment. Not to be confused with "dose” – the total amount of a medication administered at one time;

XII – prescription: a document of a health nature, standardized and mandatory, through which legally qualified professionals, within the scope of their competences, prescribe prescription medicinal products to patients, to be dispensed by a pharmacist or under their supervision in pharmacies and drugstores or in other health establishments, duly authorized to dispense medicinal products;

XIII – Brazilian Controlled Products Management System (SNGPC, in Portuguese): computerized instrument for capturing and processing data on the production, trade, and use of substances or medicinal products; and

XIV – prolonged treatment: medicinal therapy to be used for a period longer than thirty days.

CHAPTER II

PRESCRIBING

Article 5. Prescribing medicinal products covered by this Resolution must be carried out by legally qualified professionals.

CHAPTER III

PRESCRIPTION

Article 6. Antimicrobial medication prescriptions must be written on a prescription pad that is exclusive to the prescriber or healthcare facility. Therefore, there is no specific prescription template.

Sole paragraph. The prescription must be written legibly, without erasures, in two copies, and contain the following mandatory information:

I – patient identification: full name, age, and gender;

II – name of the medication or substance prescribed under the Brazilian Common Name (DCB, in Portuguese), dose or concentration, pharmaceutical form, dosage, and quantity (in Arabic numerals);

III – identification of the issuer: name of the professional with their registration with the Regional Council or name of the institution, full address, telephone number, signature, and graphic marking (stamp); and

IV – date of issue.

Article 7. Antimicrobial prescriptions are valid throughout the Brazilian territory for 10 (ten) days from the date of issue.

Article 8. The prescription may contain prescriptions for other categories of medications, provided they are not subject to special control.

Sole paragraph. There is no limit to the number of items containing antimicrobial medications prescribed per prescription.

Article 9. In situations of prolonged treatment, the prescription may be used for subsequent purchases within a period of 90 (ninety) days from the date of issue.

Paragraph 1. In the situation described in the caption of this article, the prescription must indicate continuous use, with the quantity to be used every 30 (thirty) days.

Paragraph 2. In the case of treatments related to Ministry of Health programs that require periods different from those mentioned in the caption of this article, the prescription and dispensing must comply with the program guidelines.

CHAPTER IV

DISPENSATION AND RETENTION OF PRESCRIPTION

Article 10. Dispensing in public and private pharmacies and drugstores will be carried out by retaining the 2nd (second) copy of the prescription, and the 1st (first) copy must be returned to the patient.

Paragraph 1. Pharmacists may not accept prescriptions after the expiration date established under this Resolution.

Paragraph 2. Prescriptions may only be dispensed by the pharmacist when presented legibly and without erasures.

Paragraph 3. At the time of dispensing, the following information must be recorded on both copies of the prescription:

I – the date of dispensing;

II – the quantity of the antimicrobial dispensed;

III – the batch number of the medication dispensed; and

IV – the pharmacist's signature, attesting to the service, on the back of the prescription.

Article 11. The dispensing of antimicrobials must essentially comply with the prescribed treatment, including through a fractionable commercial presentation, in accordance with Collegiate Board Resolution – RDC No. 80 of 2006, or its successor.

Article 12. This Resolution does not prohibit or restrict remote sales, and, therefore, Good Pharmaceutical Practices in Pharmacies and Drugstores, established in Collegiate Board Resolution – RDC No. 44 of 17 August 2009, must be observed.

Article 13. The prescription must be filled only once and cannot be used for subsequent purchases, except in the situations provided for in Article 8 of this regulation.

Sole paragraph. Each time the prescription is filled within the prescribed period, the procedure set forth in Paragraph 3 of Article 10 of this Resolution must be followed.

CHAPTER V

BOOKKEEPING AND MONITORING

Article 14. The accreditation and recording of the purchase and sale transactions of the medications covered by this Resolution must be carried out in the Brazilian Controlled Products Management System (SNGPC, in Portuguese), as established in Collegiate Board Resolution – RDC No. 22 of 29 April 2014.

Sole paragraph. In locations or regions without internet access, the local health surveillance authority may authorize the control of the recording of these medications in a Specific Antimicrobial Registration Book or through a previously evaluated and approved computerized

system, with a maximum period of seven (7) days for recording, counting from the date of dispensing.

Article 15. Public pharmacies that dispense medications for reimbursement, such as units of the Brazilian Popular Pharmacy Program, must record such information using a Specific Antimicrobial Registration Book or a computerized system previously evaluated and approved by the local health surveillance authority. They must comply with a maximum period of seven (7) days for recordkeeping, counting from the date of dispensing.

Article 16. All establishments that use a Specific Antimicrobial Registration Book must comply with the deadlines established in the sole paragraph of Article 14 of this Resolution.

Article 17. Sanitary and pharmaco-epidemiological monitoring of antimicrobial consumption must be carried out by the entities that comprise the Brazilian Health Surveillance System, with Anvisa being responsible for establishing the criteria for implementation.

CHAPTER VI

PACKAGING, LABELING, PACKAGE INSERT, AND FREE SAMPLES

Article 18. The package inserts and labels of medications containing antimicrobial substances listed in a specific Normative Instruction must contain, in capital letters, the phrase: "SOLD UNDER MEDICAL PRESCRIPTION – MAY ONLY BE SOLD WITH RETENTION OF PRESCRIPTION."

Sole paragraph. On secondary packaging labels, the phrase must be displayed within the red band, in accordance with Collegiate Board Resolution – RDC No. 71 of 23 December 2009.

Article 19. The manufacture and distribution of free samples will be permitted provided that the requirements defined in Collegiate Board Resolution – RDC No. 60 of 26 November 2009 are met.

Article 20. The adequacy of the labels and package inserts of medications containing antimicrobial substances from the list contained in the Normative Instruction must comply with the deadlines established in Collegiate Board Resolution – RDC No. 71 of 2009 and Collegiate Board Resolution – RDC No. 47 of 2009.

Sole Paragraph. Pharmacies and drugstores may dispense antimicrobial-based medicines that are in packaging with red stripes, which are not yet adequate, provided that they are manufactured within the timeframes established in the caption of this article.

CHAPTER VII

FINAL PROVISIONS

Article 21. The return, by individuals, of manufactured or compounded antimicrobial medicinal products to drugstores and pharmacies is prohibited.

Paragraph 1. The provisions of the caption of this article are exempt from returns due to deviations in quality or quantity that make them unsuitable or inadequate for consumption, or due to disparity with the indications contained in the container, packaging, labeling, or advertising message, which must be evaluated and documented by the pharmacist.

Paragraph 2. If the return is deemed appropriate, the pharmacist may not reinstate the medicinal product to the marketable stock under any circumstances and must immediately notify the competent health authority, providing the product's identification data, in order to allow for the relevant health actions.

Article 22. Establishments must keep available to health authorities, for a period of 2 (two) years, documentation regarding the purchase, sale, transfer, loss, and return of antimicrobial substances, as well as medicinal products containing them.

Article 23. The Brazilian Health Surveillance System, in addition to ensuring compliance with this regulation, is responsible for ensuring uniformity of actions according to the principles and standards of regionalization and hierarchization of the Unified Health System.

Article 24. The competent technical department of Anvisa shall be responsible for adopting measures or procedures for cases not covered by this Resolution.

Article 25. Failure to comply with the provisions of this Resolution constitutes a health violation, under Law No. 6,437 of 20 August 1977, without prejudice to applicable civil, administrative, and criminal liabilities.

Article 26. The following are hereby revoked:

I – Collegiate Board Resolution – RDC No. 20 of 5 May 2011;

II – Collegiate Board Resolution – RDC No. 68 of 28 November 2014; and

III – Collegiate Board Resolution – RDC No. 174 of 15 September 2017.

Article 27. This Resolution shall come into effect on the date of its publication.

ANTONIO BARRA TORRES

Director-President