COLLEGIATE BOARD RESOLUTION No. 973 OF 23 APRIL 2025

Amends Collegiate Board Resolution – RDC No. 471 of 23 February 2021, which establishes the criteria for prescribing, dispensing, monitoring, packaging, and labeling medicinal products based on substances classified as prescription antimicrobials, whether isolated 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, items III and IV, and Article 15, items III and IV of Law no. 9,782 of 26 January 1999, and Article 187, item VI, Paragraph 1 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 16 April 2021, and I, Acting Director-President, determine its publication.

Article 1. The summary of Collegiate Board Resolution – RDC No. 471 of 23 February 2021, published in the Federal Official Gazette No. 36 of 24 February 2021, Section 1, page 85, is in effect with the following alterations:

"Provides for the criteria for the prescription, dispensing, control, packaging, and labeling of medicinal products based on isolated or combined substances, for use under prescription and retention of the prescription, listed in the specific Normative Instruction." (NEW WORDING)

Article 2. Collegiate Board Resolution – RDC No. 471 of 23 February 2021, published in the Federal Official Gazette No. 36 of 24 February 2021, Section 1, page 85, is in effect with the following alterations:

"Article 1. This Resolution provides for the criteria for the prescription, dispensing, control, packaging, and labeling of medicinal products based on isolated or combined substances, for use under prescription and retention of the prescription, listed in the specific Normative Instruction.

Sole paragraph. This Resolution also applies to salts, ethers, esters, and isomers of the substances listed in the specific Normative Instruction." (NEW WORDING)

"Article 3. Municipal, state, and federal dispensing units, as well as pharmacies at hospitals or any other equivalent healthcare facilities, whether public or private, that do not sell medicinal products must maintain the specific prescription and dispensing control procedures already in place for medicinal products containing substances listed in the specific Normative Instruction, either isolated or in combination, in accordance with this Resolution." (NEW WORDING)

"Article 4. .....

"VIII – specific registration book: Document for manual recording of data of health interest authorized by the local health authority for medicinal products listed in the specific Normative

Instruction. Record-keeping must be performed by the pharmacist or under their supervision;" (NEW WORDING)

"Article 6. Prescriptions for medicinal products covered by this Resolution and described in the specific Normative Instruction must be made in a prescription pad reserved for the prescriber or healthcare facility. Therefore, there is no specific prescription template.

....." (NEW WORDING)

"Article 7. Prescriptions for medicinal products covered by this Resolution will be valid according to the timeframes established in the specific Normative Instruction." (NEW WORDING)

"Article 8.....

Sole paragraph. There is no limit to the number of items containing medicinal products covered by this Resolution prescribed through a prescription." (NEW WORDING)

"Article 10. .....

.....

Paragraph 3.....

II – the dispensed quantity of the medicinal product covered by this Resolution and the specific Normative Instruction;

....." (NEW WORDING)

"Article 11. Dispensing of the medicinal product included in the specific Normative Instruction must essentially meet the prescribed treatment, including through a commercial fractionable form, in accordance with Collegiate Board Resolution – RDC No. 80 of 2006, or any subsequent replacement." (NEW WORDING)

"Article 14. .....

Sole paragraph. In locations or regions without internet access, the local health surveillance agency may authorize the control of the recording of these medicinal products in a Specific Registration Book for each of the categories listed in the Normative Instruction linked to this Resolution, 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." (NEW WORDING)

"Article 15. Public pharmacies that dispense medicinal products for reimbursement, such as units of the Brazilian Popular Pharmacy Program, must record them using a Specific Registration Book for the categories listed in the specific Normative Instruction, which is the subject of this Resolution, or through a computerized system previously evaluated and approved by the local health surveillance agency, with a maximum period of seven (7) days for recording, counting from the date of dispensing." (NEW WORDING)

"Article 16. All establishments that use a Specific Registration Book for each of the categories listed in the Normative Instruction linked to this Resolution must comply with the deadlines established in the sole paragraph of Article 14 of this Resolution." (NEW WORDING)

"Article 17. Health and pharmaceutical epidemiological monitoring of the use of medicinal products covered by this Resolution and the specific Normative Instruction must be carried out

by the entities that comprise the Brazilian Health Surveillance System (SNVS, in Portuguese), with Anvisa being responsible for establishing implementation criteria." (NEW WORDING)

"Article 18. The package inserts and labels of medicinal products containing substances listed in the specific Normative Instruction, which is the subject of this Resolution, must contain, in capital letters, the phrase: "SOLD UNDER MEDICAL PRESCRIPTION – MAY ONLY BE SOLD WITH RETAINED PRESCRIPTION."

Sole paragraph. On secondary packaging labels, the phrase must be displayed within the red band, in accordance with Collegiate Board Resolution – RDC No. 768 of 12 December 2022." (NEW WORDING)

"Article 20. The deadlines for adapting the labels and package inserts of medicinal products covered by this Resolution will be established in the specific Normative Instruction, which is the subject of this regulation.

Sole paragraph. The medicinal products referred to in the caption of this article, including those with packaging with a red stripe, without the words "SALE UNDER MEDICAL PRESCRIPTION – MAY ONLY BE SOLD WITH RETAINED PRESCRIPTION", may be dispensed until the end of their validity period, upon presentation of a prescription, in accordance with this Resolution." (NEW WORDING)

"Article 21. Individuals are prohibited from returning, to drugstores and pharmacies, manufactured or compounded medicinal products containing substances listed in the specific Normative Instruction, which is the subject of this regulation.

....." (NEW WORDING)

"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 the substances, as well as medicinal products containing substances listed in the specific Normative Instruction, which is the subject of this regulation." (NEW WORDING)

Article 3. This Resolution shall come into effect 60 (sixty) days after the date of its publication.

Rômison Rodrigues Mota

Acting Director-President