OFFICIAL GAZETTE

Published on: 09/Oct/2020 | Edition: 195 | Section: 1 | Page: 110
Agency: Ministry of Health/ Brazilian Health Regulatory Agency/ Collegiate Board

COLLEGIATE BOARD RESOLUTION - RDC N. 430, DATED OCTOBER 8th, 2020

Provides for Good Practices of Distribution, Storage and Transportation of Medicines.

The Collegiate Board of the Brazilian Health Regulatory Agency, in the use of the powers conferred upon it by art. 15, III and IV, allied to art. 7, III and IV of Law no. 9,782, of January 26th, 1999, and art. 53, VI, paragraphs 1 and 3 of the Internal Regulations approved by Collegiate Board Resolution - RDC No. 255, of December 10th, 2018, hereby resolves to adopt the following Collegiate Board Resolution, as decided in a meeting held on October 7th, 2020, and I , Deputy Chief Executive Officer, hereby determine its publication.

CHAPTER I

PRELIMINARY PROVISIONS

Section I

Objective

Art. 1. This Resolution is intended to establish the requirements of Good Practices for Distribution, Storage and Transport of Medicines.

Section II

Scope

Art. 2. This Resolution applies to companies that carry out the activities of distribution, storage, or transportation of medicines and, where applicable, the storage and transportation of bulk products.

Sole paragraph. This Resolution does not apply to the activities of distribution, storage and transportation of raw materials, medicinal gases or labels and packaging.

Section III

Definitions

Art. 3. For the purposes of this Resolution, the following definitions are adopted:

I - storage: safe storage, handling, and conservation of medicines;

II - in-transit storage: a set of procedures, of a temporary nature, related to the transit of cargo, involving the activities of receiving, temporary custody, conservation, and safety of medicines;

III - Good Storage Practices (GSP): set of actions that ensure the quality of a medicine through adequate control during the storage process, as well as providing tools to protect the storage system against counterfeit, disapproved, illegally imported, stolen, damaged and/or tampered medicines;

IV - Good Distribution and Storage Practices (GDSP): a set of actions that ensure the quality of a medicine through adequate control during the distribution and storage process, as well as providing tools to protect the distribution system against counterfeit, disapproved, illegally imported, stolen, damaged and/or tampered medicines;

V - Good Transportation Practices (GTP): a set of actions that ensure the quality of a medicine through adequate control during transportation and in-transit storage, as well as providing tools to protect the transport system against stolen, damaged and/or tampered medicines;

VI - cold chain: process encompassed by the activities of storage, conservation, handling, distribution, and transportation of temperature-sensitive products;

VII - contamination: unwanted introduction of chemical or microbiological impurities, or foreign matter, in bulk product or finished product during the storage or transportation stages;

VIII - container: environment used for storage or transportation of products, which can be refrigerated and with controlled temperature;

IX - outsourcing contract: document mutually agreed and controlled between the parties, establishing the attributions and responsibilities of the contracting and contracted companies;

X - expiry date: deadline for the use of a medicine defined by the manufacturer, based on its respective stability tests, provided the established storage and transport conditions are maintained;

XI - distribution: a set of activities related to cargo handling that includes the supply, storage, and shipping of medicines, excluding direct supply to the public;

XII - distributor or wholesale trade: comprises the sale of medicines, in any quantity, carried out between legal entities or professionals for the exercise of their activities;

XIII - shipping: a set of procedures related to shipping for purposes of transporting medicines;

XIV - batch: defined quantity of product processed in one or more processes, the essential characteristic of which is homogeneity;

XV - cargo manifest: document containing a list of goods that constitute the loading of the ship, aircraft, and other transport vehicles;

XVI - thermolabile medicine: medicine whose maximum temperature specification is equal to or less than 8°C;

XVII - batch number: a defined combination of numbers and/or letters that uniquely identifies a batch on its labels, batch documentation, corresponding certificates of analysis, among others;

XVIII - logistic operator (OL): company with Operating Permit (AFE) and Special Permit (AE), when applicable, able to provide transportation and/or storage services;

XIX - standard operating procedure (SOP): written and authorized procedure that provides instructions for carrying out operations that are not necessarily specific to a given product or material, but of a general nature (for example, operation, maintenance and cleaning of equipment, qualification, cleaning of facilities and environmental control, sampling and inspection);

XX - recalled product: finished product, shipped and marketed, returned to the registration holder or distributor;

XXI - bulk product: any product that has gone through all production stages, except the packaging process; sterile products in their primary packaging are considered bulk products;

XXII - qualification: a set of actions performed to certify and document that any facilities, systems, and equipment are properly installed and/or working correctly and lead to the expected results;

XXIII - thermal qualification: documented verification that the equipment or the temperature-controlled area guarantees thermal homogeneity inside it;

XXIV - quarantine: temporary retention of finished products, physically isolated or by other means that prevent their use, pending a decision on their release, rejection or reprocessing;

XXV - receipt: a set of activities related to the arrival, check, and internalization of medicines stock;

XXVI - recall: an action aimed at the immediate and effective withdrawal from the market of a certain medicine batch, with sufficient evidence or proof of quality deviation, which may pose a health risk, or upon cancellation of registration, related to product safety and efficacy, to be implemented by the registration holder and its distributors;

XXVII - shipment or delivery: quantity of a given medicine supplied in response to a purchase order, a single shipment can include one or more volumes and materials belonging to more than one batch;

XXVIII - active control system: those with active temperature and/or humidity control, capable of adjusting themselves to variations in external temperature, such as refrigerated containers for air and sea transportation and refrigerated trucks;

XXIX - passive control system: those without active temperature and/or humidity control, such as thermally insulated containers, made of polystyrene or polyurethane, with refrigerant material. They are not able to adjust themselves to external temperature variations, and their capacity is determined through studies and temperature and humidity forecasts for the route in question;

XXX - transporter: company that carries out the transport of medicines, from the sender to a certain recipient, and is able to carry out additional in-transit storage;

XXXI - return: return to the supplier of medicines that were fiscally incorporated into the customer's stock and, thus, entered the customer's custody chain. These drugs, when returned to their origin, are delivered with a tax or corresponding document, different from the shipping document.

CHAPTER II

GENERAL PROVISIONS

Art. 4. All parties involved in the production, storage, distribution, and transportation must be responsible for the quality and safety of medicines.

Sole paragraph. Shared responsibility includes recall actions, regardless of whether it was motivated by the health authority, the registration holder, the distributor, or the logistics operator.

Art. 5. The GSP, GDSP and GDP principles must also be observed in reverse logistics, when medicines are being returned or collected from the market.

Art. 6. Distribution companies must supply medicines only to companies licensed and authorized by the competent health authority for the activities of distributing or dispensing medicines.

Sole paragraph. The supply of radiopharmaceuticals must be carried out by institutions licensed by the Health Authority, the National Nuclear Energy Commission (CNEN) and other competent authorities.

Art. 7. The purchase of medicines from distribution companies that are not the registration holder is allowed, provided that cargo traceability is guaranteed through the National Medicines Control System - SNCM.

Sole paragraph. In case of non-applicability of the SNCM, traceability must be guaranteed through documentary proof that the origin is lawful and authentic by the supplier distributor.

Art. 8. Facilities that carry out the activities of distribution, storage or transportation of medicines must have a quality management system capable of documenting, verifying, and

ensuring the specific requirements for each process that has an impact on the quality of the products.

CHAPTER III

DISTRIBUTION, STORAGE AND TRANSPORTATION

Section I

Organization and Administration

Art. 9. The organizational structure of the company must be described in an organization chart.

Sole paragraph. The responsibilities of all personnel must be indicated in the job descriptions.

Section II

Personnel

Art. 10. The company must have an appropriate number of employees with appropriate qualifications, ensuring that the responsibilities assigned individually are not as extensive as to present risks to product quality.

Art. 11. Requirements related to the health, hygiene and clothing of personnel must be established, according to the activities to be carried out.

Art. 12. The system for training employees whose duties have an impact on the Quality Management System must be described.

Paragraph 1. The employees referred to in the caput of this article must receive initial and periodic training, according to the complexity of the activity and compatible with the training action carried out.

Paragraph 2. The records that allow the trainee to be identified, date of execution and workload, as well as the strategy used, the subjects covered, and the efficacy evaluation must be kept.

Paragraph 3. Relevant training requirements to each job position, expressed in the policies, programs, procedures and forms, must be defined.

Art. 13. It is forbidden to smoke, eat, drink (with the exception of drinking water, which must be available in a specific sector), chew, keep plants, food, personal medicines, personal objects or any object foreign to the sector, in the storage, in-transit storage, receipt and shipping areas.

Section III

Quality Management System

Art. 14. The Quality Management System must cover all aspects that influence the quality of the medicines or services provided.

Art. 15. The processes that impact on the quality of medicines or services provided must be mapped.

Sole paragraph. The processes identified in the mapping must be preceded and governed by standard operating procedures, with duly generation of records.

Art. 16. The actions of the Quality Management System are the responsibility of the entire company and must be exercised by all its members.

Art. 17. Divergences in relation to the requirements expressed by the Quality Management System must be interpreted and treated as non-compliances.

Art. 18. The area responsible for the Quality Management System must have hierarchical autonomy and the necessary resources to exercise the following functions:

I - guarantee the implementation and maintenance of a quality system;

II - coordinate documental management;

III - elaborate, review and formally approve the standard operating procedures;

IV - adopt and maintain a self-inspections program;

V - adopt and maintain initial and periodic training programs;

VI - supervise recall activities, including recall simulations;

VII - receive and investigate complaints;

VIII - manage returned products;

IX - implement a system for change control and management;

X - verify and guarantee the legal requirements for health license operation permit of the members of the drug distribution chain when exercising the distribution activity;

XI - manage the qualification and calibration of equipment and instruments;

XII - record, investigate and adopt corrective and preventive actions for identified non-compliances;

XIII - manage waste;

XIV - guarantee the integrity and traceability of medicines and data related to commercial transactions;

XV - implement a pest management program with safe agents, regularized with the competent agencies and that do not pose a risk of contamination to stored products;

XVI - carry out the communications provided to health agencies according to models established and published by them and communicate to the business partners and competent police authorities in case of theft and identification of counterfeit or adulterated products; and

XVII - ensure the adequate destination for counterfeit products.

Subsection I

Documentation

Art. 19. The management and control of quality documents must provide guidelines for the preparation, review, approval, distribution and control, training, codification, storage, and obsolescence of documents in physical or electronic format.

Art. 20. Standard operating procedures must be followed and available at their respective workplaces.

Art. 21. Standard operating procedures must be kept up to date so that they correspond to routine practice.

Art. 22. Standard operating procedures must be understandable to employees and must be unambiguous.

Art. 23. Manual or electronic records must be readily recoverable and must be stored using security measures against any unauthorized modification, damage, deterioration or loss.

Paragraph 1. The correction of a recorded data must be performed by justifying the need for change, preserving the possibility of reading the originally recorded data.

Paragraph 2. Backups must be maintained for records generated or stored in electronic format.

Art. 24. Standard operating procedures, as well as manual or electronic records, must be maintained for at least 5 (five) years after their obsolescence.

Sole paragraph. Access to these documents must be restricted to persons delegated by the Quality Management System.

Subsection II

Complaints

Art. 25. An attendance service must be established and disclosed to customers to receive complaints.

Art. 26. Complaints related to the quality, authenticity, legality, or integrity of medicines or those related to adverse events must be recorded and investigated.

Paragraph 1. The responsibility for the investigation extends proportionally to the participation of each member of the chain in the cause of the deviation.

Paragraph 2. The investigation must classify the complaints as valid or not valid, confirming or discarding the related non-compliances.

Paragraph 3. It is up to the investigation to define the root cause of the problem, assess the impacts to customers and, if necessary, suggest recall to the manufacturer or the registration holder.

Paragraph 4. The investigation should consider the possibility that other batches of the medicine have been affected by the same root cause.

Paragraph 5. Corrective actions must be defined, implemented, and monitored for situations where the recurrence of non-compliance poses a risk to the patient.

Art. 27. Complaints related to quality deviations must be recorded separately from those related to distribution, storage, or transportation activities.

Sole paragraph. Complaints related to quality deviations must be submitted to the manufacturer or registration holder for investigation, and the results of this must be added to the initial registration.

Subsection III

Recall

Art. 28. The recall must comply with the provisions of this Resolution, with no prejudice to the provisions given in Collegiate Board Resolution - RDC No. 55 of March 17th, 2005 and its updates.

Art. 29. The registration holder is responsible for coordinating the recall.

Sole paragraph. Participation in the recall by the distributor, storage company or logistics operator extends proportionally to the contribution of each one on the distribution map and to the root cause of the recall.

Art. 30. The distribution maps must be readily recoverable for a time consistent with the validity of the medicines distributed.

Paragraph 1. The registration data related to the companies included in the distribution map must be updated and contain the minimum information required for postal, telephone and e-mail contact.

Paragraph 2. A reconciliation simulation must be carried out between the units distributed and located at the customers, once a year for the worst case of the distribution chain, in order to test the effectiveness of the recall and correct possible failures.

Art. 31. The registration holder must be consulted in advance about the recall when it is made by another company in the distribution chain.

Art. 32. At the end of the recall, the efficacy assessment of the communications issued and the degree of recovery of the units distributed must be reported.

Art. 33. All customers and the competent health authorities, from all countries to which a given medicine has been distributed, must be notified immediately when the need to recall a given batch is identified.

Sole paragraph. The person responsible for the recall must keep records of the notifications and their receipts.

Subsection IV

Returns

Art. 34. Before a returned medicine is reintegrated into marketable stock, at least the following factors must be recorded and weighted by the quality management system:

I - the reason for return;

II - the storage and transportation conditions employed by the buyer;

III - the integrity of the original secondary packaging; and

IV - the expiry date.

Art. 35. Failure to ensure that the returned medicine remains within its quality standards should result in the rejection of reintegration.

Art. 36. Medicines object to theft or other misappropriation, even if recovered, must be rejected.

Paragraph 1. The medicines described in the caput, whose custody chain has been interrupted by theft or other misappropriation and that do not present damage or violation of the shipping box and security devices present at the time of the event and that can be concluded as appropriate from the point of view of quality, safety and efficacy through a risk analysis carried out under the distributor's responsibility, can be reintegrated into the commercial stock.

Paragraph 2. The provisions of the previous paragraph do not apply to thermolabile medicines.

Subsection V

Self-inspections

Art. 37. Processes with an impact on Quality must be self-inspected according to the frequency established and justified by the company.

Art. 38. Self-inspections must be conducted by a professional not hierarchically linked to the inspected process or department.

Sole paragraph. The professionals referred to in the caput must be trained specifically for the self-inspection activity.

Art. 39. Self-inspections must be compiled in reports with the following minimum information:

I - identification of the inspection team;

II - period;

III - non-compliances identified;

IV - corrective and preventive actions listed and their respective deadlines for completion and implementation;

V - actions to monitor the adoption and the efficacy of corrective and preventive actions; and

VI - evaluation and agreement of the heads of each affected department and of the maximum hierarchical position of the company.

Subsection VI

Qualifications and Validations

Art. 40. Computerized equipment and systems must be qualified and validated before use or after any change considered significant.

Sole paragraph. Risk analysis can be used as a tool to waive the need for qualification and validation of equipment that does not have a significant contribution to quality.

Art. 41. There must be a preventive maintenance program for equipment with an impact on quality.

Section IV

Storage Facilities

Art. 42. The exercise of the activity of storing medicines requires, at least:

I - area for receiving and shipping medicines separately from each other;

II - general medicine storage area;

III - returned medicines storage area or site;

IV - disapproved, expired, recalled, suspected of counterfeit or falsified medicines storage area or site;

V - area or site for the storage of medicines subject to the special control regime, when applicable;

VI - quarantined medicine storage area or site, when applicable;

VII - radionuclides medicines storage area, when applicable;

VIII - cleaning material storage area;

IX - administration area; and

X - canteens area, if any, and changing rooms, toilets, and washbasins area, without direct communication with the storage areas.

Paragraph 1. Alternation of hours, delimitation of the common area, color coding or other procedures to reduce the risk of exchanges should be adopted when the separation required in item I is not possible.

Paragraph 2. Any storage areas must have restricted access, however, the areas or locations indicated by items III, IV, V and VII must be separated from the others and must have differentiated access control.

Paragraph 3. The replacement of the physical quarantine described in item VI by a qualified computerized system is possible.

Paragraph 4. The areas mentioned must protect the products from the weather and animals.

Art. 43. The storage areas must have equipment and instruments necessary to control and monitor the required temperature and humidity.

Paragraph 1. The monitoring must be carried out by instruments positioned according to the thermal qualification study of the area.

Paragraph 2. The reading of the instruments, if performed intermittently, must correspond to the periods of greatest criticality.

Paragraph 3. Monitoring must be recorded, and records must be maintained, for at least two years after their generation.

Paragraph 4. The instruments must be calibrated before their first use and at defined intervals and justified by the instrument performance and the measurement sensitivity.

Art. 44. The facilities must be of a size compatible with the volume of the operations carried out.

Art. 45. The facilities must have smooth surfaces, without cracks and without the release of dust, in order to facilitate cleaning and avoid contaminants.

Art. 46. The facilities must be cleaned with the aid of equipment and cleaning agents approved for this purpose.

Sole paragraph. Cleaning operations referred to in the caput must be recorded.

Art. 47. The facilities must be provided with adequate lighting in order to allow all operations to be carried out accurately and safely.

Art. 48. Maintenance areas, if any, should be separated from storage areas.

Sole paragraph. Repairs, maintenance, and calibrations carried out must not compromise the medicine quality.

Section V

Storage

Art. 49. Damaged medicines must be removed from usable stocks and stored separately as disapproved.

Art. 50. The storage conditions of the medicines must follow the specifications of the registration holder.

Art. 51. Medicines must not be placed directly on the floor or against the walls, they must keep a minimum distance from the roof and must not be directly exposed to sunlight.

Art. 52. Pallets must be of a material that allows cleaning and does not constitute a source of contamination, such as treated wood, aluminum, or plastic materials.

Art. 53. The storage must obey a logical address that avoids exchanges and provides the unequivocal location of the stored quantities.

Art. 54. Storage must comply with the load setting established for the medicine.

Sole paragraph. The provision also applies during transportation, in-transport storage or when held by logistic operators.

Art. 55. Periodic stock inventories must be done.

Sole paragraph. Discrepancies in the inventory should be recorded and investigated to ensure that no mixing, incorrect billing, or theft has occurred.

Section VI

Receiving and Shipping

Art. 56. Each receipt operation must check and record:

I - the applicable transportation and storage conditions, including special requirements for temperature, humidity, or exposure to light;

II - batch numbers, expiry date, and quantities received against orders placed and invoices received; and

III - the load integrity.

Art. 57. Loads that do not meet the receipt requirements must be returned upon receipt or quarantined pending their availability by the quality assurance.

Art. 58. The fractionation of medicines from their transport packaging must not violate the secondary packaging.

Sole paragraph. The fractionation operation must be carried out according to separation orders specific to the quantity to be fractioned and must have a specific record, which must be checked at the end.

Art. 59. Electronic files related to the shipping must include at least the following information:

I - shipping or receipt date;

II - corporate name, address and CNPJ of the carrier;

III - the driver's full name and identification document;

IV - corporate name, address and CNPJ of the recipient;

V - medicines description, including name and dosage form;

VI - quantity, batch numbers and expiry date;

VII - applicable transport and storage conditions, including the identification of the vehicle responsible for transport and the serial number of the instrument used to monitor environmental conditions, when applicable;

VIII - unique number to allow the identification of the delivery order; and

IX - invoice number.

Art. 60. The invoices issued must contain the batch numbers and data on the origin of the transacted medicines.

Art. 61. The ordering of cargo in vehicles or containers must be carried out in order to avoid damage to medicines.

Sole paragraph. Vehicles and containers must be loaded carefully and systematically and, where applicable, follow the "first in, last out" sequence.

Art. 62. Delivery schedules and routes must be established according to local needs and conditions.

Section VII

Transportation and In-Transit Storage

Art. 63. The following are obligations of the parties contracting medicines transportation:

I - carriers qualification;

II - to provide guidance and technical assistance for cases of accidents involving medicines under transport, together with the Technical Responsible of the contracted company.

Art. 64. The following are obligations of companies that transport medicines:

I – to have the transported cargo manifest with the forecast for unloading on board of the transport vehicle;

II - to monitor the transport conditions related to temperature, packaging, storage, and humidity specifications of the medicine using calibrated instruments;

III - to apply the passive or active temperature and humidity control systems that are necessary to maintain the conditions required by the health registration or other applicable specifications;

IV - to provide the contracting Party with all data related to storage conditions during transportation, as well as during in-transit storage;

V - to provide restricted access to medicines; and

VI - to receive and deliver medicines only to companies duly authorized and licensed for the related activities.

Paragraph 1. The control provided for in item III can be eliminated when using transport conditions qualified for the route.

Paragraph 2. The mandatory temperature and humidity monitoring provided for in item II can be waived when the maximum transportation time is proven in the records to be less than 8 (eight) hours, this is carried out at the final point of medicine dispensing and when thermal packs that have qualification in line with the transport time and conditions are used.

Art. 65. The transport systems used must have mechanisms that provide evidence of unauthorized access.

Sole paragraph. Transport companies or logistical operators are prohibited when, in the activity of transporters, there is violation of the transported cargo.

Art. 66. Guidelines regarding storage facilities, storage, receipt, and shipping provided for in this regulation, also apply to in-transit storage.

Art. 67. Vehicles, equipment and containers must not expose medicines to conditions that may affect their stability and the integrity of their packaging or generate contamination of any kind.

Art. 68. Vehicles and containers must be properly maintained and cleaned.

Art. 69. Recalled or returned medicines, as well as those suspected of counterfeiting, must be clearly and safely identified and, whenever possible, mechanisms that allow segregation during transportation should be used.

Art. 70. Shared transportation with other product categories is only possible when risks are analyzed, mitigated, and concluded as acceptable.

Art. 71. In case of accident or theft of radiopharmaceuticals, CNEN must be communicated.

Section VIII

Outsourcing

Art. 72. Outsourcing of the activities regulated by this standard must be preceded by the approval of the contract by the quality management system.

Paragraph 1. The approval referred to in the caput of this article results from the qualification of the contracted service provider.

Paragraph 2. The supplier qualification must be guided by the verification of specific requirements and must be recorded.

Paragraph 3. The maintenance of the provider's status as qualified must be periodically reassessed by means of indicators established for this purpose.

Art. 73. The contract between the contracting and contracted companies must establish the responsibilities of each party.

Sole paragraph. The contract referred to in the caput of this article must provide that subcontracting depends on prior assessment and approval by the original contracting Party.

Art. 74. The contracting Party must provide the contracted Party with all the information necessary to carry out the contracted operations correctly, in accordance with the medicine registration and any other legal requirements.

Art. 75. The contracting Party and the contracted Party must be able to meet the applicable legal and regulatory requirements.

Art. 76. The contracted Party must have adequate facilities and qualified personnel, to satisfactorily perform the service requested by the contracting Party.

Section IX

Thermolabile Medicines

Art. 77. Exposure to room temperature should be minimized during receipt and shipping of thermolabile medicines, including, if necessary, the adoption of refrigerated areas next to the receipt and shipping sites.

Sole paragraph. The total exposure time of thermolabile medicines to room temperature, during the operations referred to in the caput of this article, must be recorded.

Art. 78. The storage of thermolabile medicines must be done according to the recommendations of the registration holder in a medium that can be thermally qualified.

Art. 79. The equipment involved in the storage of thermolabile medicines must have, in addition to the primary source of electrical energy, an alternative source capable of effecting the immediate supply of energy, in the event of failure of the primary source.

Art. 80. Contingency plans must be drawn up to protect thermolabile medicines in the event of a power failure or storage equipment failure.

Art. 81. Emergency cooling alternatives, such as liquid nitrogen or dry ice, may be acceptable, as long as the storage conditions established by the registration holder are maintained.

Sole paragraph. When these alternatives are adopted, precautions to avoid temperature excursions below the minimum value specified should be adopted.

Art. 82. In the impossibility of adopting a barrier system for thermolabile medicines storage sites, the stock movement must be planned in advance to reduce temperature variations.

Art. 83. The transport of thermolabile medicines must be carried out in a medium that can be thermally qualified.

Art. 84. Temperature monitoring and control during storage and transportation must be carried out.

Art. 85. The disposition and assembly of loads for transportation must be guided by the registration holder to distributors, carriers and logistical operators and must be based on qualification studies of the cold chain.

Sole paragraph. The disposition of the loads must avoid the direct exposure of the medicines to refrigerating agents used to keep the temperature.

CHAPTER IV

FINAL PROVISIONS

Art. 86. Failure to comply with the provisions contained in this Resolution constitutes a health violation, under the terms of Law no. 6,437, of August 20th, 1977, with no prejudice to the applicable civil, administrative, and penal responsibilities.

Art. 87. The following are hereby revoked:

I - Collegiate Board Resolution - RDC No. 304, dated September 17th, 2019, published on the Official Gazette of September 18th, 2019; and

II - Collegiate Board Resolution - RDC No. 360, dated March 27th, 2020, published on the Official Gazette of March 31st, 2020.

Art. 88. The following are hereby restored:

I – Ordinance No. 802, dated October 8th, 1998, published on the Official Gazette of October 9th, 1998; and

II - Collegiate Board Resolution - RDC No. 320, dated November 22nd, 2002, published on the Official Gazette of November 25th, 2002.

Paragraph 1. The rights of third parties are protected in the period between March 16th, 2020 and the date immediately before the date of publication of this Resolution, provided that they have acted in good faith and provided that their activities have been carried out in accordance with the Collegiate Board Resolution - RDC No. 304, of September 17th, 2019.

Paragraph 2. The normative acts listed in items I and II of this article will be automatically revoked, as from the date of entry into force of this Resolution.

Art. 89. A period of 1 (one) year from the date of entry into force of this Resolution is established for the application of the set of actions that will be necessary for the implementation of the requirement in items II and III of art. 64.

Paragraph 1. During the term set out in the caput of this article, companies that are part of the distribution chain must generate temperature and humidity mapping studies that will support the active or passive control measures that will be applied to the transportation systems.

Paragraph 2. During the term set out in the caput of this article, all data produced do not generate, due to their transitory nature, additional obligations to companies with regard to the control of temperature and humidity conditions and, therefore, are not considered, even when outside their acceptance range, violations of the requirements of this standard, as long as the medicines quality is preserved.

Paragraph 3. The transience provided for in the caput of this article also applies to in-transit storage, as this activity is intrinsic and inseparable from transportation.

Art. 90. This Resolution takes effect on March 16th, 2021.

Sole paragraph. Arts. 7 and 87 and items I and II and Paragraph 1 of art. 88 are exceptions for the provisions of the caput of this article, which are effective immediately on the date of publication of this Resolution.

ANTONIO BARRA TORRES