COLLEGIATE BOARD RESOLUTION – RDC NO. 430 OF 8 OCTOBER 2020

Provides for the Good Practices of Distribution, Storage, and Transportation of Medicinal Products.

The Collegiate Board of Directors of the Brazilian Health Regulatory Agency, in the use of the attributions vested in it under Article 15, items III and IV, and Article 7, items III and IV of Law no. 9,782 of 26 January 1999, and item V, paragraphs 1 and 3 of Article 53 of the Internal Regulation approved by Collegiate Board Resolution – RDC no. 255 of 10 December 2018, adopts the following Collegiate Board Resolution, as decided upon in a meeting held on 7 October 2020, and I, Deputy Director-President, determine its publication.

CHAPTER I

INITIAL PROVISIONS

SECTION I

OBJECTIVE

Article 1. This Resolution has the objective of establishing the requirements of Good Practices of Distribution, Storage, and Transportation of Medicinal Products.

SECTION II

SCOPE

Article 2. This Resolution applies to companies that perform the activities of distribution, storage, or transportation of medicinal products and, where appropriate, storage and transportation of bulk products.

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

SECTION III

DEFINITIONS

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

I – storage: safe storage, handling, and conservation of medicinal products;

II – transit storage: set of temporary procedures related to cargo transit, involving the activities of receipt, temporary storage, conservation, and safety of medicinal products;

III – Good Storage Practices (GSP): set of actions that ensure the quality of a medicinal product through proper control during the storage process, and provide tools to protect the storage system against counterfeit, rejected, illegally imported, stolen, damaged, and/ or tampered medicinal products;

IV – Good Distribution and Storage Practices (GDSP): set of actions that ensure the quality of a medicinal product through proper control during the distribution and storage process, and provide tools to protect the distribution system against counterfeit, rejected, illegally imported, stolen, damaged, and/ or tampered medicinal products;

V – Good Transportation Practices (GTP): set of actions that ensure the quality of a medicinal product through proper control during transportation and transit storage, and provide tools to protect the transportation system against stolen, damaged, and/ or tampered medicinal products;

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

VII – contamination: undesirable introduction of chemical or microbiological impurities or foreign matter into a bulk product or finished product during storage or transportation steps;

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: limit date for the use of a medicinal product as defined by the manufacturer, based on its respective stability tests, while maintaining the storage and transportation conditions established;

XI – distribution: set of activities related to cargo handling that includes supply, storage, and shipment of medicinal products, excluding direct supply to the public;

XII – wholesale distributor or trade: comprises the trade of medicinal products, in any quantity, carried out among legal entities or professionals for the exercise of their activities;

XIII – expedition: set of procedures related to the shipment for the purpose of transportation of medicinal products;

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 represent the loading of the ship, aircraft, and other transportation vehicles;

XVI – thermolabile medicinal product: a medicinal product whose maximum temperature specification is equal to or lower than 8°C;

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

XVIII – logistics operator (LO): company holding Operating Authorization (OA) and Special Authorization (SA), when applicable, qualified to provide transportation and/ or storage services;

XIX – Standard Operating Procedure (SOP): authorized written procedure providing instructions for performing operations not necessarily specific to a given product or material, but of a general nature (e.g., operation, maintenance, and cleaning of equipment, qualification, cleaning of facilities and environmental control, sampling, and inspection);

XX – returned product: finished product, shipped and marketed, returned to the marketing authorization holder or distributor;

XXI – bulk product: any product that has gone through all production stages, not including the packaging process; sterile products in their primary packaging are considered as bulk products;

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

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

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

XXV – receipt: set of activities related to arrival, conference, and internalization in stock of medicinal products;

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

XXVII – shipment or delivery: quantity of a given medicinal product supplied in response to a purchase order, and a single shipment may include one or more volumes and materials belonging to more than one batch;

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

XXIX – passive control system: system without active temperature and/ or humidity control, such as thermally insulated containers made of polystyrene or polyurethane, with refrigerant material. They are unable to adjust themselves to external temperature variations, and their capacity is determined by temperature and humidity studies and forecasts for the concerned route.

XXX – carrier: company that performs the transportation of medicinal products, from the sender to a given recipient, and may additionally perform the transit storage.

CHAPTER II

GENERAL PROVISIONS

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

Sole paragraph. Shared responsibility includes recall actions, regardless of whether they are motivated by the health authority, the marketing authorization holder, the distributor, or the logistics operator.

Article 5. The principles of GSP, GDSP and GTP must also be observed in reverse logistics when the medicinal products are being returned or recalled from the market.

Article 6. The distributing companies must supply medicinal products only to companies licensed and authorized by the competent health authority for activities of distribution or dispensing of medicinal products.

Sole paragraph. The supply of radiopharmaceuticals must be performed by institutions licensed by the Health Authority, the Brazilian Nuclear Energy Commission (*Comissão Nacional de Energia Nuclear* – CNEN, in Portuguese), and other competent authorities.

Article 7. The acquisition of medicinal products from distributing companies other than the marketing authorization holders is permitted, provided that the cargo is traceable through the Brazilian Drug Control System (*Sistema Nacional de Controle de Medicamentos* – SNCM, in Portuguese).

Sole paragraph. Where the SNCM is not applicable, traceability must be ensured upon documentary evidence by the supplying distributor that the origin is lawful and authentic.

Article 8. The establishments that carry out the activities of distribution, storage, or transportation of medicinal products must have a quality management system capable of documenting, verifying, and ensuring the requirements specific to each process that impact on the quality of the products.

CHAPTER III

DISTRIBUTION, STORAGE, AND TRANSPORTATION

Section I

Organization and Management

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

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

Section II

Staff

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

Article 11. Requirements related to the health, hygiene, and clothing of the staff must be established, according to the activities to be performed.

Article 12. The system to train employees whose duties have an impact on the Quality Management System must be described.

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

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

Paragraph 3. The training requirements relevant to each job position, expressed by policies, programs, procedures, and forms, must be defined.

Article 13. It is forbidden to smoke, eat, drink (except drinking water, which must be available in a specific sector), chew, keep plants, food, personal medicinal products, personal objects, or any foreign object to the sector in the storage, transit storage, receipt, and shipment areas.

Section III

Quality Management System

Article 14. The Quality Management System must cover all aspects that influence the quality of medicinal products or the services provided.

Article 15. The processes that impact the quality of medicinal products or services provided must be mapped.

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

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

Article 17. Disagreements regarding the requirements expressed by the Quality Management System must be interpreted and treated as nonconformities.

Article 18. The area responsible for the Quality Management System must have hierarchical autonomy and resources necessary to perform the following duties:

I – ensure the implementation and maintenance of a quality system;

II – coordinate documental management;

III – formally develop, review, and approve standard operating procedures;

IV – adopt and maintain a self-inspection program;

V – adopt and maintain initial and periodic training programs;

VI – supervise recall activities, including recall simulations;

VII – receive and investigate complaints;

VIII – manage the returned products;

IX – implement a system for alteration control and management;

X – verify and ensure the legal requirements of health license and operating authorization of the members of the distribution chain of medicinal products when performing distribution activities;

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

XII – register, investigate, and adopt corrective and preventive actions for the nonconformities identified;

XIII – manage waste;

XIV – ensure the integrity and traceability of medicinal products and business transaction data;

XV – implement a pest management program with safe agents, regularized with the competent authorities, and offering no risk of contamination to stored products;

XVI – perform the communications expected to the health authorities according to models established and disclosed by them, and communicate to business partners and competent law enforcement authorities when theft and identification of counterfeit or tampered products occur; and

XVII – ensure appropriate disposal of counterfeit products.

Subsection I

Documentation

Article 19. The management and control of quality documents must have the guidelines for development, review, approval, distribution and control, training, coding, storage, and obsolescence of documents in physical or electronic format.

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

Article 21. Standard operating procedures must be kept up to date to correspond to routine practice.

Article 22. Standard operating procedures must be understandable to employees and must not be ambiguous.

Article 23. The records, either manual or electronic, must be readily retrievable, and must be stored using safety measures against any unauthorized alteration, damage, deterioration, or loss.

Paragraph 1. Correction of recorded data must be performed by justifying the need for alteration, preserving the possibility of reading the data originally recorded.

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

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

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

Subsection II

Complaints

Article 25. A customer service must be established and disclosed to clients to receive complaints.

Article 26. Complaints related to quality, authenticity, legality, or integrity of medicinal products or those related to adverse events must be registered and investigated.

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

Paragraph 2. The investigation must classify the complaints as well-founded or not, confirming or discarding the related nonconformities.

Paragraph 3. The investigation is responsible for defining the root cause of the problem, assessing the impacts on clients, and suggesting the recall, if necessary, to the manufacturer or the marketing authorization holder.

Paragraph 4. The investigation must consider the possibility that other batches of the medicinal product have been affected by the same root cause.

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

Article 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 passed on to the manufacturer or the marketing authorization holder for investigation, and the results must be added to the initial record.

Subsection III

Recall

Article 28. The recall must comply with the provisions of this Resolution, without prejudice to the provisions given in Collegiate Board Resolution – RDC No. 55 of 17 March 2005 and its updates.

Article 29. The marketing authorization holder is responsible for coordinating the recall.

Sole paragraph. Participation in the recall by the distributor, storing company, or logistics operator extends in proportion to their individual contribution to the distribution map and the root cause of the recall.

Article 30. The distribution maps must be readily retrievable for a time consistent with the validity of the medicinal products distributed.

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

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

Article 31. The marketing authorization holder must be previously consulted about the recall when it is performed by another company in the distribution chain.

Article 32. At the end of the recall, the assessment of the efficacy of the communications issued and the degree of recovery of the distributed units must be recorded in a report.

Article 33. All clients and the competent health authorities, of all countries to which a given medicinal product has been distributed, must be notified immediately when the necessity of recall of a certain batch has been found.

Sole paragraph. The entity responsible for the recall must keep records of notifications and their proof of receipt.

Subsection IV

Returns

Article 34. Before a returned medicinal product is reintegrated to the marketable stock, at least the following factors must be recorded and considered by the quality management system:

I – reason for the return;

II – storage and transportation conditions employed by the buyer;

III – integrity of the original secondary packaging; and

IV – expiry date.

Article 35. Failure to ensure that the returned medicinal product remains within its quality standards must result in rejection of reintegration.

Article 36. Medicinal products object of theft, robbery, or other misappropriation, even if recovered, must be rejected.

Paragraph 1. The medicinal products referred to in the caption of this article that have their custody chain interrupted by theft, robbery, or other misappropriation and that do not present damage or violation of shipment box and security devices present at the moment of the event, and that can be considered adequate regarding quality, safety, and efficacy through risk assessment carried out under the distributor’s responsibility, may be reintegrated to the marketable stock.

Paragraph 2. The provisions in Paragraph 1 above are not applicable to thermolabile medicinal products.

Subsection V

Self-Inspections

Article 37. Processes with impact on Quality must be self-inspected as often as established and justified by the company.

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

Sole paragraph. The professionals referred to in the caption of this article must be trained specifically for the self-inspection activity.

Article 39. Self-inspections must be compiled in reports with at least the following information:

I – identification of the inspector team;

II – period;

III – nonconformities identified;

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

V – follow-up actions for the adoption and monitoring of the efficacy of corrective and preventive actions; and

VI – assessment and agreement by the heads of each department affected and the maximum hierarchical position of the company.

Subsection VI

Qualifications and Validations

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

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

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

Section IV

Storage Facilities

Article 42. The conduction of medicinal product storage activity requires, at least:

I – area for receipt and shipment of medicinal products separated from each other;

II – general medicinal product storage area;

III – storage area or place for returned medicinal products;

IV – storage area or place for rejected, expired, recalled, suspected counterfeit, or counterfeit medicinal products;

V – storage area or place for medicinal products subject to special control regimen, when applicable;

VI – storage area or place for quarantined medicinal products, when applicable;

VII – storage area for radionuclide medicinal products, when applicable;

VIII – storage area for cleaning materials;

IX – administration area; and

X – area for canteens or refectories, when existing, and changing rooms, toilets, and sinks, without direct communication with the storage areas.

Paragraph 1. The alternation of times, delimitation of the common area, color coding, or other procedures to reduce the risk of exchange must 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 places indicated in items III, IV, V, and VII must be separated from the others and must have different access control.

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

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

Article 43. The storage areas must have equipment and instruments necessary for the control and monitoring of the required temperature and humidity.

Paragraph 1. Monitoring must be performed by instruments positioned in accordance with the thermal qualification study of the area.

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

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

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

Article 44. The facilities must have a size compatible with the volume of the operations carried out.

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

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

Sole paragraph. The cleaning operations referred to in the caption of this article must be recorded.

Article 47. The facilities must be equipped with adequate lighting to allow all operations to be carried out with accuracy and safety.

Article 48. Areas intended for maintenance, if any, must be separated from storage areas.

Sole paragraph. Repairs, maintenance, and calibrations performed must not compromise the quality of medicinal products.

Section V

Storage

Article 49. Damaged medicinal products must be removed from usable stocks and stored separately as rejected medicinal products.

Article 50. The storage conditions for medicinal products must follow the specifications of the marketing authorization holder.

Article 51. Medicinal products must not be placed directly on the floor or against the walls, they must be kept at a minimum distance from the roof, and must not be under direct sunlight.

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

Article 53. The storage must observe a logical addressing that avoids exchanges and provides unambiguous location of the stored quantities.

Article 54. The storage must comply with the cargo configuration established for the medicinal product.

Sole paragraph. The provisions also apply during transportation, storage in transportation, or when stored by logistics operators

Article 55. Periodic stock inventories must be performed.

Sole paragraph. Inventory discrepancies must be recorded and investigated to ensure that no mixtures, incorrect billings, or thefts occurred.

Section VI

Receipt and Shipping

Article 56. Each receipt operation must verify and record:

I – applicable transportation and storage conditions, including special temperature, humidity, or light exposure requirements;

II – batch numbers, expiry date, and quantities received against the orders made and invoices received; and

III – cargo integrity.

Article 57. Cargos that do not comply with receipt requirements must be returned upon receipt or be quarantined while awaiting their disposal by quality assurance.

Article 58. The fractionation of medicinal products from their transportation packaging must not violate the secondary packaging.

Sole paragraph. The fractionation operation must be performed according to separation orders specific to the quantity to be fractioned and must have a specific record with a final check.

Article 59. Shipment-related electronic files must include at least the following information:

I – date of shipment or receipt;

II – carrier's business name, address, and CNPJ [Corporate Taxpayer Registry];

III – driver's full name and identification document;

IV – recipient's business name, address, and CNPJ;

V – description of the medicinal products, including name and dosage form;

VI – quantity, batch numbers, and expiry date;

VII – applicable transportation and storage conditions, including identification of the vehicle used for transportation and 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.

Article 60. The invoices issued must contain the batch numbers and data regarding origin of the traded medicinal products.

Article 61. The ordering of cargo in vehicles or containers must be performed in such a way as to avoid damage to the medicinal products.

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

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

Section VII

Transportation and Transit Storage

Article 63. The obligations of the contractors of the medicinal products transportation services are the following:

I – qualify the carriers;

II – provide guidance and technical assistance in case of accidents involving medicinal products under transportation, together with the Technical Responsible officer of the contracted company.

Article 64. The obligations of the companies performing the transportation of medicinal products are the following:

I – have the cargo manifesto carried with the predicted landing on board the carrier vehicle;

II – monitor the transportation conditions related to the specifications of temperature, packaging, storage, and humidity of the medicinal product using calibrated instruments;

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

IV – provide the contractor with all data relating to storage conditions during transportation, as well as during transit storage;

V – provide restricted access to medicinal products; and

VI – receive and deliver medicinal products only to companies duly authorized and licensed for the related activities.

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

Paragraph 2. The obligatoriness of temperature and humidity monitoring provided for in item II may be exempted, when the maximum transportation time is proven in the records to be less than 8 (eight) hours, and this is performed at the end point of dispensing the medicinal product to the patient, and qualified thermal packaging is used, compatible with transportation time and conditions.

Article 65. The transportation systems used must have mechanisms that provide evidence of unauthorized access.

Sole paragraph. Carriers or logistic operators are forbidden, when performing the activity of carrier, to violate the cargo transported.

Article 66. The guidelines regarding storage facilities, storage, and receipt and shipping provided for in this Resolution also apply to transit storage.

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

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

Article 69. Medicinal products recalled or returned, as well as those suspected of counterfeit, must be clearly and securely identified and, where possible, mechanisms that allow segregation during transportation must be used.

Article 70. Transportation shared with other product categories is only possible when the risks are analyzed, mitigated, and concluded as acceptable.

Article 71. In the event of an accident, robbery, or theft of radiopharmaceuticals, CNEN must be notified.

Section VIII

Outsourcing

Article 72. The outsourcing of the activities regulated in this Resolution must be preceded by the approval of the contract by the quality management system.

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

Paragraph 2. The qualification of the supplier must be based on the verification of specific requirements and must be registered.

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

Article 73. The contract between the contractor and the contracted party must establish the responsibilities of each party.

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

Article 74. The contractor must provide the contracted party with all information necessary to carry out the contracted operations correctly, in accordance with the medicinal product marketing authorization and any other legal requirements.

Article 75. The contractor and the contracted party must be able to meet the legal and regulatory requirements that apply to them.

Article 76. The contracted party must have adequate facilities and qualified personnel to satisfactorily perform the service requested by the contractor.

Section IX

Thermolabile Medicinal Products

Article 77. Exposure to room temperature during receipt and shipment of thermolabile medicinal products must be minimized, including, if necessary, the adoption of refrigerated areas close to receiving and shipping spaces.

Sole paragraph. The total exposure time of thermolabile medicinal products at room temperature during the operations referred to in the caption of this article must be recorded.

Article 78. The storage of thermolabile medicinal products must be done in accordance with the recommendations of the marketing authorization holder in an environment that is thermally eligible.

Article 79. The equipment involved in the storage of thermolabile medicinal products must have, in addition to the primary source of electric energy, an alternative source capable of executing the immediate supply of energy, in case of failures of the primary source.

Article 80. Contingency plans must be developed to protect thermolabile medicinal products in the event of power failure or failure of storage equipment.

Article 81. Emergency cooling alternatives, such as liquid nitrogen or dry ice, may be acceptable as long as the conservation conditions established by the marketing authorization holder are maintained.

Sole paragraph. When adopting these alternatives, precautions to avoid temperature deviations below the minimum values specified must be taken.

Article 82. If adopting a barrier system for storage places of thermolabile medicinal products is impossible, the stock movement must be planned in advance to minimize temperature variations as much as possible.

Article 83. The transportation of thermolabile medicinal products must be done in a thermally qualifiable environment.

Article 84. Temperature monitoring and control during storage and transportation must be performed.

Article 85. The disposition and assembly of cargos for transportation must be directed by the marketing authorization holder to distributors, transporters, and logistics operators and must be based on cold chain qualification studies.

Sole paragraph. The arrangement of loads must prevent direct exposure of the medicinal products to refrigerants used for temperature conservation.

CHAPTER IV

FINAL PROVISIONS

Article 86. Failure to comply with the provisions contained in this Resolution constitutes a health infraction, pursuant to Law No. 6,437, of 20 August 1977, without prejudice to the applicable civil, administrative, and criminal liabilities.

Article 87. The following are hereby revoked:

I – Collegiate Board Resolution – RDC no. 304 of 17 September 2019, published in the Federal Official Gazette of 18 September 2019; and

II – Collegiate Board Resolution – RDC no. 360 of 27 March 2020, published in the Federal Official Gazette of 31 March 2020.

Article 88. The following are hereby restored:

I – Administrative Rule no. 802 of 8 October 1998, published in the Federal Official Gazette of 9 October 1998; and

II – Collegiate Board Resolution – RDC no. 320 of 22 November 2002, published in the Federal Official Gazette of 25 November 2002.

Paragraph 1. The rights of third parties are hereby safeguarded, in the period between 16 March 2020 and the date immediately before the date this Resolution in published, as long as they have acted in good faith, and provided that their activities have been carried out in accordance with Collegiate Board Resolution – RDC no. 304 of 17 September 2019.

Paragraph 2. As from the date this Resolution enters into force, the normative acts referred to in items I and II of this article shall be revoked.

Article 89. A period of 1 (one) year after the date this Resolution enters into force is hereby established, for the enforcement of the set of actions that will be necessary for the implementation of the provisions in items II and III of Article 64.

Paragraph 1. During the period established in the caption of this article, distribution chain companies must generate temperature and humidity mapping studies, which shall base the active or passive control measurements that shall be applied to transportation systems.

Paragraph 2. During the period established in the caption of this article, all data produced do not generate additional obligations to the companies regarding the control of temperature and humidity conditions, due to the provisional nature given; therefore, such data are no considered as infractions of the requirements in this Resolution, even when they are out of their acceptance range, as long as the quality of the medicinal products is preserved.

Paragraph 3. The period provided for in the caption of this article also applies to transit storage, because such activity is intrinsic to and inseparable from transportation.

Article 90. This Resolution shall enter into force on 16 March 2021.

Sole paragraph. Articles 7 and 87, as well as items I and II and Paragraph 1 of Article 88 are exempted from the provisions in the caption of this article, and they shall be immediately effective on the date this Resolution is published.

ANTÔNIO BARRA TORRES