Ministry of Health - MS
National Agency of Sanitary Surveillance - ANVISA

RESOLUTION OF THE BOARD OF DIRECTORS - RDC Nº 234, OF JUNE 20, 2018

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It deals with the outsourcing of production, quality control analysis, transport and storage of medicines and biologicals, and gives other measures.

The Collegiate Board of the National Sanitary Surveillance Agency, in the use of attribution conferred by art. 15, III and IV allied to art. 7, III, and IV, of Law No. 9,782, of January 26, 1999, and to art. 53, V, §§ 1 and 3 of the Internal Rules of Procedure pursuant to Annex I of the Resolution of the Collegiate Board of Directors - RDC n ° 61, of February 3 2016, resolves to adopt the following Resolution of the Collegiate Board, as deliberated at a meeting held on June 12, 2018, and I, the Chief Executive Officer Substitute, I determine its publication.

CHAPTER I

OF THE INITIAL PROVISIONS

Section I

goal

Art. 1 This Resolution establishes rules for the outsourcing of stages of production, analyzes of quality control, transportation and storage of medicines and biological products.

Section II

Scope

Article 2 This Resolution applies to manufacturers, packers, importers, distributors, logistics operators, conveyors, warehouses and laboratories of quality control of medicines and biological products.

Article 3. This Resolution also applies to the outsourcing of control quality of pharmaceutical inputs, by manufacturers of medicines and products with a view to their approval for use in production.

Section III

Definitions

Art. 4 For the purpose of this Resolution, the following definitions are adopted:

I - storage: storage, handling and storage of medicines and products according to Good Practice;

II - quality control: a set of measures to verify quality medicinal products, biological products and pharmaceutical supplies, with a view to verify whether they meet the criteria of activity, purity, efficacy and safety;

III - outsourcing contract: document mutually agreed between the Companies Contractor and contractor setting out the contractual responsibilities and responsibilities of each of the parties, regarding the outsourcing of production stages, quality control, transportation and storage of medicines and products biological;

IV - in-process control: checks carried out during the production of medicinal products and biologicals, in order to monitor and, if necessary, adjust the manufacturing process in order to ensure that the product is in compliance with the specifications. Control of the environment, as well as equipment, can be considered part of the process control;

V - registration holder: legal entity holding the registration of a medicinal product or biological product before Anvisa and, therefore, holder of rights and responsibilities products;

VI - Contracted Company: company that performs the outsourced service, jointly and severally responsible for the technical, operational and legal aspects inherent activities being outsourced;

VII - Contracting Company: company that contracts services of third parties, responsible for all technical, operational and legal aspects related to the medicinal product or biological product and the activities subject to outsourcing;

VIII - manufacturer: holder of the Enterprise Operation Permit (AFE) and Special Authorization (EA), where applicable, for the manufacturing activity of according to the requirements of the current health legislation;

IX - importer: holding company of Business Operation Authorization (AFE) and / or Special Authorization (AE) for import activity of medicines,

holder of the drug registration in Brazil;

X - logistic operator (OL): company holding an Operating Permit (AFE) and Special Authorization (AE), when applicable, able to provide the services of transport and / or storage;

XI - production: all operations involved in the preparation of a given medicine or biological product, from the receipt of the materials of the warehouse, through processing and packaging, until the finished product is obtained;

XII - Outsourcing: provision of services, by contracted company, in activities production, quality control, transport or storage of biological products.

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CHAPTER II

TERMINATION AGREEMENT

Art. 5 The Contracts of Outsourcing of Production, Quality Control, Transportation or Storage shall comply with the following provisions, as appropriate:

I - be clearly defined, agreed upon and controlled, in order to avoid interpretations that could result in a product, process or unsatisfactory quality;

II - to define the specific responsibilities and attributions of the Companies Contractor and Contractor, with special emphasis on those related to Good Practices;

III - define as changes in process, in equipment, methodologies and specifications will be managed by the Contracting and Contracted Companies;

IV - to clearly establish how the designated person of the Contracting release each batch of the product for sale or issue the certificate of analysis, exercises its full responsibility and ensures that each lot has been manufactured and verified in accordance with the registration requirements;

V - ensure that the Contractor Company informs the Contracting any potential risk to the quality, safety or effectiveness of the biological product or product being outsourced;

VI - allow the Company to perform audits in accordance with the of the contracted company involved in the contract, with a view to verifying the compliance with applicable Good Practices;

VII - be signed by the legal representatives of the Contracting Companies and Contracted.

Article 6. The Outsourcing Contract shall provide for the maintenance and storage of of the records relating to the activities carried out, observing the principles of Good Practices.

Paragraph 1 - The Outsourcing Contract must be filed with the Companies Contractor for at least 5 (five) years, counted from the end of validity.

Paragraph 2. The other documents related to outsourced activities must be available both in the Contracting Company and in the Contracted Company, at any time, for verification by the competent health authorities for at least one period of five (5) years.

CHAPTER III

TERMS AND CONDITIONS FOR THE

Art. 7 The Contracted Company shall be jointly and severally liable to the authorities with the Contracting Company, for the technical, and legal aspects inherent to the activity being outsourced.

Art. 8 The Contracting Company shall provide to the Contracted Company all the information necessary for the operations being outsourced to be carried out according to the registration of the medicinal product or the biological product, as well any other regulatory requirement.

Art. 9 The Contracting Company is responsible for auditing and evaluating the qualification and performance of the Contracted Company, approve the activities provided for in the Outsourcing and ensure that applicable Good Practices standards are followed during the term of the contractual relationship.

Article 10. The responsibility for the release of the final product is the holder of the registration, regardless of whether some stage of your production or quality control has been made by third parties, and the Contracted Company is responsible for the object of the Outsourcing Agreement.

Article 11. The Contracted Company must have facilities, equipment, knowledge and qualified personnel to perform services, in accordance with the terms of the contract, as well as the requirements established by the sanitary legislation in force.

Article 12. The Contracted Company may subcontract, in whole or in part, the object of the Contract provided that the prior evaluation and approval of the Contracting Company takes place.

Paragraph 1 - The Subcontracted Company must comply with sanitary legislation and be jointly and severally responsible to the health authorities, together with the Contracting Contractor, for the technical, operational and legal aspects inherent in the activity outsourcing.

Paragraph 2. Contracts between the Contracted Company and the Subcontracted Company shall ensure that all product and process information is available, in the same way as between the Contracting and Contracting Companies.

Paragraph 3. In the event of subcontracting, the contract shall allow the Company Contractor to audit the premises and activities of both the Contracted Company and the Subcontracted.

CHAPTER IV

OF THE PRODUCTION STAGE TERMINATION

Art. 13. In cases of Outsourcing of production stages, the Contracted Company must hold a Sanitary License, AFE and, where applicable, AE, for the activity of "making".

§ 1º The Contracted Company must comply with Good Manufacturing Practices.

Paragraph 2. It is allowed to outsource the packaging stage with contracted companies that are holders of AFE and, where applicable, AE, for the activity of "packing".

Paragraph 3. In the event of outsourcing referred to in paragraph 2 of this article, the company must comply with all Good Manufacturing Practices applicable.

Art. 14. The establishment of the Contracted Company must have a structure required to carry out in-process control tests of production.

Single paragraph. It is forbidden to outsource control activities in the process of dissociated from production.

Art. 15. The outsourced production stages shall be carried out in accordance with the approved in the registration of the medicinal product or the biological product.

Article 16. The Contracting and Contracted Companies shall keep available for, in the

minimum, five (5) years or one (1) year after the expiration of the term of validity of the medicinal product or biological product, whichever period is longer, the raw data generated during the production process by the Contracted Company, and to present them to the competent authority when requested.

CHAPTER V

OF THE TERMINATION OF QUALITY CONTROL

Art. 17. The Contracted Company to carry out the activity of Control of Quality must be qualified by the Contracting Company, which is responsible for evaluating the competence of the contractor.

Single paragraph. In the qualification process, the Contracting Company must ensure meeting the requirements of good laboratory practice by the Contracted Company, the which can be demonstrated by:

I - qualification with the Brazilian Network of Analytical Laboratories in Health (REBLAS) for the contracted tests;

II - compliance with the provisions of Resolution RDC No. 11 of February 16, 2012 and its subsequent updates;

III - Certification of Good Manufacturing Practices, when it is a company manufacturer of medicines or biological products;

IV - accreditation according to ISO 17025 for the tests contracted;
or

V - proof of compliance with Good Laboratory Practices, as internationally recognized guidelines.

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Article 18. The Contractor and Contractor Companies shall keep available for, in minimum, five (5) years or one (1) year after the expiration of the term of validity of the medicinal product or biological product, whichever period is longer, the raw data generated during the Quality Control analyzes carried out by the Contracted Company, as well as how to present them to the competent health authority on request.

Art. 19. The final approval for release of the product must be given by the person designated by the Contracting Company, in accordance with the principles of Good And with the requirements of the registry as specified in the contract.

CHAPTER VI

OF THE STORAGE TERMINATION

Art. 20. In cases of Outsourcing of Storage, the Contracted Company must hold a Sanitary License, AFE and, where applicable, AE, for the activity to "store".

Art. 21. The Contracted Company must comply with Good Storage Practices.

Article 22. Only those batches of medicinal product or biological product that have been released by the Registration Holder may be Hired company.

§1. Lots of medicament or biological product in quarantine can only be to the Contracted Company when, in both companies, computerized management of integrated materials or having an interface between Yes.

§ 2 The computerized materials management systems, as well as the interface that makes the communication between the systems of the Contracting and Contracted Companies must be validated, in order to comply with the provisions of paragraph 1 of this article.

CHAPTER VII

OF THE TRANSPORTATION TERMINATION

Art. 23. In cases of Transportation Outsourcing, the Contracted Company shall be sanitary license holder, AFE and, where applicable, AE, for the activity of "carry".

Single paragraph. The carrier undertaking the storage of medicines or biological products must be Sanitary License holder, AFE and, when applicable, EA, for the "store" activity.

Art. 24. The Contracted Company must comply with Good Transportation Practices and, when applicable, Storage.

CHAPTER VIII

TWO LOGISTIC OPERATORS

Article 25. Contracted Companies called Logistics Operators shall be holders of Sanitary License, AFE and, where applicable, AE, for the activities of "Store" and "carry", according to the activities that are carried out.

Article 26. Logistical operators shall comply with the provisions of the legislation Good Practices that are applicable to the activities they carry out.

CHAPTER IX

OF FINAL PROVISIONS

Art. 27. As of the date of publication of this Resolution, they will not be received by Anvisa petitions of "Outsourcing Notification" of production steps, analysis of quality control and storage of medicines and biological products.

Single paragraph. The contracts whose petitions for "Outsourcing Notification" been filed at Anvisa until the date of publication of this Resolution will be considered valid and the provisions established by this standard must be complied with.

Art. 28. Outsourcing activities may be started provided that provisions established by current legislation, in particular those relating to the compliance with the corresponding Good Practices and the registration and post-registration of medicines and biologicals.

Paragraph 1 The contracting and contracting companies are responsible for the execution of the observing the technical, operational and legal aspects inherent to the activities of the object of outsourcing.

§2 In cases of outsourcing of production steps and control analysis of quality must be complied with the provisions of the current registration and post-registration of medicinal products and biological products related to the regularization of manufacturing and local quality control.

Art. 29. Failure to comply with the provisions of this Resolution constitutes a breach of health, under the terms of Law No. 6.437 of August 20, 1977, without prejudice to the civil, administrative and penal liabilities.

Article 30. Art. 9th of the Resolution of the Collegiate Board of Directors - RDC No. 10, of March 21 2011, which provides for the quality assurance of imported medicines and provides other provisions, shall read as follows:

.....

"Art. 9 The importer is responsible for the complete in Brazil, in accordance with the registration of the medicinal product in the

Anvisa, for each cargo received, lot by lot, of all imported medicines. "

(NR)

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Art. 31. Paragraph VIII of art. 10 of the Resolution of the Collegiate Board of Directors - RDC No. 10, 2011 is now in force with the following wording:

"Art. 10 .....

VIII - all the full analyzes shall be carried out in accordance with the registration of the medicinal product, of at least two lots per year, in the up to eight charges / year of each drug. For imports less than or equal to eight year of each drug received, all complete, of at least two lots every two years. "(NR)

..... (I.e.

Art. 32. This standard incorporates MERCOSUR / GMC / RES. No. 50/02 "Contracting outsourcing services for pharmaceutical products within the scope of Mercosur "to the national legal system of Brazil.

Art. 33. Art. 52 of the Resolution of the Collegiate Board of Directors - RDC n ° 17, of April 16, 2010; the sole paragraph of art. 8 and the sole paragraph of art. 9th Resolution of the RDC Collegiate Board No. 10, of 2011, and the Board Resolution Collegiate - RDC nº 25, of March 29, 2007.

Art. 34. This Resolution shall enter into force on the date of its publication.

FERNANDO MENDES GARCIA NETO