Automated English Translation of Brazil RDC-157-2017 using Google Translate

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May 19, 2017

Note that this version of RDC-157 is intended to guide the 3-lot pilot to take place in 2017. Article 19 below states:

"After the deadline for evaluating the pilot phase, as per item II, single paragraph, Art. 5 of Law 13.410 / 2016, a new normative act will be published for the full implementation of the SNCM."

NATIONAL HEALTH SURVEILLANCE AGENCY

BOARD OF DIRECTORS

RESOLUTION OF THE BOARD OF DIRECTORS - RDC N ° 157, OF MAY 11, 2017

Provides for the implementation of the National Drug Control System and the mechanisms and procedures for drug tracking and other measures.

The Collegiate Board of the National Sanitary Surveillance Agency, in the use of the attribution conferred by art. 15, III and IV, together with 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 Regulations approved in accordance with Annex I Resolution of the Collegiate Board of Directors - RDC nº 61, of February 3, 2016, and also, in view of the provisions of Law No. 11,903, of December 14, January 2009, as amended by Law No. 13,410, dated December 28, 2016, resolves to adopt the following Resolution of the Collegiate Board of Directors, as resolved at a meeting held on April 25, 2017, and I, the Chief Executive Officer, determine its publication:

CHAPTER I
OF THE INITIAL PROVISIONS

Art. 1. The mechanisms and procedures for drug tracing, established by Law No. 11,903, dated January 14, 2009, are established within the scope of the National Drug Control System (SNCM), by means of capture technology, Storage and electronic transmission of data, throughout the pharmaceutical chain in the national territory.

Art. 2. The provisions of this standard shall apply to all drugs and members of the pharma supply chain that participate in the pilot phase provided for in Article 5 of said law.

§ 1. It will be published Normative Instruction with the list of medicines and members of the pharma supply chain that will be part of the pilot phase.

§ 2. The following categories of drugs are excluded from the pilot phase:

I - sera and vaccines that are part of the National Immunization Program;

II - radiopharmaceuticals;

III - prescription-free medicines;

IV - medicines belonging to Ministry of Health Programs, free distribution and individualized control of delivery;

V - specific medicines, phytotherapeutic and energized;

VI - free samples;

VII - injectable contrast media;

VIII - medicinal gases.

§ 3. It will be published Normative Instruction with the listing of the Programs of the Ministry of Health and their respective medicines included in items I and IV of § 1 of this article.

CHAPTER II
OF DEFINITIONS

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

I. Pharma supply chain: flow of origin to the consumption of medicines covering the manufacturing, import, distribution, transportation, storage and dispensing stages, as well as other types of movement provided by health controls.

II. Code serial: individual code, contained in IUM, unique per presentation, composed of 1 to 20 alphanumeric characters.

III. Event instance registration communication: electronic transmission, to the central database, of the event instance registered by the member of the drug handling chain.

IV. Registration holder: manufacturer or importer, responsible for the registration of the medicinal product for human use regulated by ANVISA.

V. Dispenser: establishment responsible for providing, remunerated or free, of medicines to the consumer or patient, which are: pharmacy, drugstore, hospital, health unit and health establishment.

VI. Distributor: member of the pharma supply chain that stores the drug as an intermediary in any position in the chain between the registration holder and the dispenser.

VII. Commercial packaging: secondary packaging, including multiple, hospital or secondary packaging for fractionation, or primary packaging when the product is not applied to the dispenser in secondary packaging.

VIII. Packaging: packaging used for the transport of medicaments packaged in their commercial packaging.

IX. Unique Medication Identifier - IUM: a series of numeric, alphanumeric or special characters, created through identification and coding standards, allowing the individualized, exclusive and unambiguous identification of each commercial packaging of the medicinal product;

X. Instance event: information related to a commercial drug packaging or transport packaging unit describing the context in which an operation of interest to the SNCM occurred.

XI. SNCM members: members of the pharma supply chain or carriers.

XII. Members of the pharma supply chain: responsible for registering instances of events and their communication to the centralized database, which are: manufacturers, importers, distributors, wholesalers, retailers, hospitals, health establishments, warehouses, merchants and Dispensers.

XIII. Global Trade Item Number (GTIN): Internationally recognized standard identifier of trade item with fourteen digits.

XIV. Trace of drugs: a set of mechanisms and procedures that allow to trace the history, the current custody or the last known destination of medicines;

XV. Event Instance Record: Store the event instance in the database of the member of the pharma supply chain itself.

XVI. Serialization: generation and inclusion of DataMatrix as well as the inscription of the serial code in the commercial packaging of the medicine.

CHAPTER III
OF DATA CAPTURE TECHNOLOGY

Art. 4. The two-dimensional bar code is the technology for the capture and storage of instances of events necessary for drug tracing within the SNCM.

Single paragraph. The two-dimensional code standard adopted is DataMatrix, as specified in ISO / IEC 16022: 2006 and its updates.

Art. 5. The holder of the drug registration is responsible for the management of all the data that make up the Unique Drug Identifier (IUM).

Art. 6. The IUM shall contain the following data, in the following order:

I - Presentation GTIN;

II - Registration number of the presentation of the drug with Anvisa;

III - Serial code, up to 20 digits;

IV - Expiry date;

V - Manufacturing lot.

Single paragraph. It is forbidden to repeat the serial code between units of the same drug presentation.

Art. 7. Every transport package containing at least one medicinal product included in the SNCM pilot phase, from the registration holder's dispatch event instance, must have a unique identifier code that allows the relationship with the IUM of the medicinal products contained therein.

CHAPTER IV
THE IDENTIFICATION OF SNCM MEMBERS

Art. 8. The members of SNCM will be identified by their CNPJ, when registering the instances of events.

Single paragraph. Those who do not have their own CNPJ will be identified by the existing registration mechanisms, such as the National Register of Health Establishments (CNES).

CHAPTER V
OF LABELING

Art. 9. The commercial packaging of medicines included in the scope of SNCM must contain the DataMatrix and the serial code registration, in addition to comply fully with the provisions of Resolution of the Collegiate Board of Directors-RDC No. 71, of December 22, 2009, or standard that To replace it.

§ 1. The provisions in this regulation must ensure reading by electronic data capture mechanisms and must be legibly inscribed to the human eye, throughout the pharma supply chain and within the validity of the product.

§ 2. The modifications necessary to comply with the provisions of this article shall be considered notifiable labeling changes, with immediate implementation, without the need for prior approval.

Art. 10. The serialization of medicines may be performed by the following members of the system:

I - manufacturer in his country of origin, in the case of imported products;

II - manufacturer in national territory, only the record holder with manufacturing activity.

CHAPTER VI
STANDARDS FOR STORAGE AND COMMUNICATION OF EVENT BODIES

Art. 11. Each member of the pharma supply chain shall electronically record and communicate data corresponding to instances of events occurring with the drug under his or her custody.

Art. 12. The members of the pharma supply chain shall keep the registration of the instances of events for a minimum period of one (1) year after the expiration of the period of validity of the medicine.

§ 1. The records referred to in this regulation shall be the same as those communicated to SNCM, and any information shall be altered.

§ 2. The member of the pharm supply chain shall be able to retransmit, at the request of Anvisa, instances of events already communicated to SNCM

Art. 13. The communication of registration of instances of events to the SNCM will be carried out respecting the chronological order of the registration of the instances of events, obeying the following terms:

I - Within three (3) business days for the record holders;

II - Within 5 (five) business days for distributors;

III - Within 7 (seven) business days for dispensers.

Single paragraph. The member of the pharma supply chain will record and report a rectification event instance on any instances of events that have reported errors to SNCM as soon as they identify or become aware of this fact.

Art. 14. The member of the pharma supply chain will register in their information systems and communicate to the centralized bank the data corresponding to the instances of events related to the drug, through open communication protocols.

Art. 15. The electronic systems used by the members of the pharma supply chain must guarantee the confidentiality, integrity, availability and authenticity of the data.

CHAPTER VII
OF FINAL PROVISIONS

Art. 16. For the purposes of complying with Subsection II of the Sole Paragraph of Article 5 of Law 11,903 / 2009, the Management Committee with representation of the members of SNCM and coordinated by Anvisa shall be instituted in a normative act.

Art. 17. The technological specifications necessary for the operation of SNCM shall be published by means of a Normative Instruction, within four months of the publication of this standard.

Art. 18. Cases of proven impossibility of complying with the provisions established in this regulation, by the members of the pharma supply chain, do not constitute sanitary infraction and must be communicated to Anvisa.

Art. 19. After the deadline for evaluating the pilot phase, as per item II, single paragraph, Art. 5 of Law 13.410 / 2016, a new normative act will be published for the full implementation of the SNCM.

Art. 20. The Resolution of the Collegiate Board of Directors (RDC) n ° 54, of December 10, 2013, published in the Official Gazette of December 11, 2013, and Resolution of the Collegiate Board of Directors - RDC No. 114, dated September 29, 2016, Published in the DOU of September 30, 2016, are revoked.

Art. 21. This Resolution shall enter into force on the date of its publication.

JARBAS BARBOSA DA SILVA JR.
Director-President