National Health Surveillance Agency

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Public Consultation No. 311 of February 15, 2017
D.O.U, 2/16/2017

The Collegiate Board of the National Sanitary Surveillance Agency, in the use of the attributions granted by art. 15, III and IV allied to art. 7, III, and IV, of Law No. 9,782, of January 26, 1999, art. 53, III, §§ 1 and 3 of the Internal Regulations approved in accordance with Annex I of the Resolution of the Collegiate Board of Directors - RDC No. 61, of February 3, 2016, resolves to submit to the public consultation for comments and suggestions from the general public , A proposal for a normative act in the Annex, as resolved at a meeting held on February 14, 2017, and I, the Chief Executive Officer, determine its publication.

Art. 1 The deadline of 30 (thirty) days, from the date of publication of this Public Consultation in the Official Gazette of the Union, is hereby established to send comments and suggestions to the text of the proposed revision of the Resolution of the Collegiate Board of Directors - 54 of December 10, 2013, which provides for the implementation of the National Drug Control System and the mechanisms and procedures for tracking medications in the pharmaceutical chain and provides other measures, as per Annex.

Art. 2 The proposal for a normative act will be available in full on Anvisa's website and suggestions should be sent electronically by filling out a specific form, available at: http://formsus.datasus.gov.br/site /formulario.php?id_aplicacao=30286

Paragraph 1 The contributions received are considered public and will be available to any interested party through tools contained in the electronic form in the "result" menu, including during the consultation process.

§2. Upon completion of the electronic form, the interested party will be given the protocol number of the registration of his / her participation, being dispensed the postal or physical protocol of physical documents with the Agency.

Paragraph 3. In case of limitation of access of the citizen to computerized resources, it will be allowed to send and receive suggestions in writing, in physical environment, during the consultation period, to the following address: National Sanitary Surveillance Agency / Institutional Management Direction - DIGES, SIA section 5, Special Area 57, Brasília-DF, CEP 71.205-050.

§4º Exceptionally, international contributions may be sent in physical form to the following address: National Agency of Sanitary Surveillance / Advice of International Affairs (AINTE), SIA section 5, Special Area 57, Brasília-DF, CEP 71.205-050.

Article 3. After the deadline stipulated in art. 1, the National Health Surveillance Agency shall promote the analysis of contributions and, at the end, publish the result of the public consultation on the Agency's website.

Single paragraph. The Agency may, as necessary and for reasons of convenience and opportunity, liaise with bodies and entities involved with the matter, as well as those who have expressed interest in the matter, to subsidize subsequent technical discussions and the final deliberation of the Board of Directors.

JARBAS BARBOSA DA SILVA JR

PROPOSAL IN PUBLIC CONSULTATION

Process nº: 25351.048778 / 2012-10
Subject: Proposal to revise the Resolution of the Collegiate Board of Directors - RDC No. 54 of December 10, 2013, which provides for the implementation of the National Drug Control System and the mechanisms and procedures for tracking drugs in the pharmaceutical chain and gives Other measures
Regulatory Agenda Not Agenda Theme
Procedural Regime: Common
Responsible area: DIGES
Rapporteur: Jarbas Barbosa da Silva Jr.

RESOLUTION OF THE BOARD OF DIRECTORS - RDC N ° XX, OF XX OF XXXXXXXX OF 2017

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

The Collegiate Board of the National Health Surveillance Agency, in the use of the Art. 7, III and IV, 15, III and IV of Law No. 9,782, of January 26, 1999, confer on Art. 53, V, Paragraph 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 the provisions of Law No. 11,903, of 14 January 2009, as amended by Law No. 13,410 of December 28, 2016, resolves to adopt the following Resolution of the Collegiate Board of Directors, as resolved at a meeting held on March 20, 2017, and I, the Chief Executive Officer, determine its publication :

CHAPTER I

OF THE INITIAL PROVISIONS

Art. 1 It is established, within the scope of the National Drug Control System (SNCM), instituted by Law No. 11,903, of January 14, 2009, the mechanisms and procedures for drug tracking, throughout the national territory.

Single paragraph. Until the end of the period of implementation and evaluation of the experimental phase provided for in Article 5 of said law, this regulation is mandatory for members of the chain of Movement of medicines that participate in it.

Art. 2 - The provisions of In this standard to all medicinal products registered with the National Health Surveillance (Anvisa).

Paragraph 1 The following categories of medicines are excluded from the caput of this article:

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

II - radiopharmaceuticals;

III - Prescription drugs;

IV - Medicines belonging to Programs of the Ministry of Health, Free distribution and individualized control of delivery;

V - Specific drugs, Herbal and energized;

VI - free samples.

§ 2º. Normative Instruction will be published with the listing of the Programs of the Ministry of Health and their respective medicines, included in items I and IV of paragraph 1 of this regulation.

CHAPTER II DEFINITIONS

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

I. Drug screening: A set of mechanisms and procedures that allow tracing the history, current location or the last known destination of drugs.

II. Event instance communication: electronic transmission of the event instance registered by the member of the drug handling chain.

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

IV. Event Instance: Information related to a drug unit or transport packaging unit that describes the context in which an operation of SNCM's interest occurred.

V. Members of the drug movement chain: responsible for the registration and communication of instances of events, which are: manufacturers, importers, distributors, wholesalers, retailers, hospitals, health establishments, storers, traders and dispensers of medicines.

VI. Members of the SNCM: members of the chain of movement of medicines or transporters.

VII. 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 medicine;

VIII. Serial code: individual code, contained in IUM, only for display, consisting of 1 to 20 alphanumeric characters..

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

X. Transport packaging: packaging used for the transport of medicinal products packaged in their commercial packaging.

XI. Global Trade Item Number (GTIN): An internationally recognized, fourteen-digit, international trade item identifier.

XII. Record holder: Manufacturer or importer, responsible for the registration of the medicinal product for human use regulated by ANVISA.

XIII. Distributor: member of the drug handling chain that stores the drug as an intermediate in any position in the chain between the record holder and the dispenser.

XIV. 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.

CHAPTER III

OF THE IDENTIFICATION OF MEDICINES

Art. 4 The two-dimensional bar code is the technology for capturing, storing and communicating the instances of events necessary for drug tracing within the SNCM.

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

Article 5. The holder of the registration of medicines is responsible for the generation and DataMatrix on commercial packaging containing the Unique Drug Identifier (IUM) data.

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

I – GTIN Of the presentation;

II – Registration number of the drug presentation with Anvisa;

III – Serial code, up to 20 digits;

IV – Expiration date

V – Production batch.

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

Art. 7 All transport packaging, from the event of dispatch of the registration holder, must have a unique code of its own, allowing the relation with the IUM of the medicines contained therein.

CHAPTER IV

THE IDENTIFICATION OF SNCM MEMBERS

Art. 8 SNCM members shall be identified by their CNPJ, when recording the events.

§ 1 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) or others that are applicable.

CHAPTER V

LABELING

Art. 9 The registry holders shall include the serial code and the two-dimensional code (DataMatrix), on the commercial packaging of the medicines, in addition to the information required by RDC 71/2009 and its updates.

§ 1 The provision in the caput must ensure reading by mechanisms of electronic data capture and the human eye, throughout the chain of movement of medicines and within the period of validity of the product.

§ 2 The procedure set forth in this article will be considered a notification changeable labeling, with immediate implementation, without prior approval.

Art. 10 Imported medicines may have the Datamatrix and serial code impressions made by the manufacturer in their country of origin or by the holder of the registration in Brazil.

Single paragraph. The registry holder shall notify Anvisa, in the process of consent of the license Their option of individual identification provided for in the caput.

CHAPTER VI

STANDARDS OF STORAGE AND COMMUNICATION OF EVENT BODIES

Article 11 Each member of the drug handling chain shall electronically store and transmit data corresponding to instances of events occurring with the drug under his or her custody.

Art. 12 The members of the chain of movement of medicines shall keep the register Of the events for a period of one (1) year after the expiration of the period of validity of the product.

Single paragraph. The records referred to in the caput should be the same as those
SNCM, being forbidden to change any information.

Art. 13 Communication of instances of events to SNCM shall comply with the following Deadlines:
I – Within 3 (three) days for registrants;
II – Within 5 (five) days for distributors;
III – Within 7 (seven) days for dispensers.

§1º. The communication of instances of events will be carried out respecting the order Chronological record of the event.

§2º The member of the drug handling chain shall promptly rectify 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 chain of movement of medicines shall communicate to the Centralized data, the data corresponding to the instances of events related to the Medication, through open communication protocols.

Art.15 Os Systems used by members of the chain of Ensure the confidentiality, integrity, availability and authenticity of the data.

Chapter VII
OF FINAL PROVISIONS

Art. 16 For purposes of complying with Subsection II of the Sole Paragraph of Article 5 of Law no. 11,903 / 2009 will be instituted in a normative act of the Management Committee with representation of the Members of SNCM and coordinated by Anvisa.

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

Art. 18 Resolution RDC n. 54 of December 10, 2013, published in the DOU of November 11, 2013 and Resolution RDC No. 114 of September 29, 2016, published in the Dou 's 30 whisper bro.' S.

Article 19 This Resolution shall enter into force on the date of its publication.

JARBAS BARBOSA DA SILVA JR.

CEO