PROPOSAL UNDER PUBLIC CONSULTATION

Process no: 25351.048778/2012-10
Subject: Proposal for the review of Collegiate Board of Directors Resolution – RDC no. 54 of December 10th, 2013, that provides for the implementation of the National System of Medicine Control and the mechanisms and procedures to track medicines throughout the pharmaceutical products chain and other provisions.
Regulatory Agenda is not included in the Agenda
Processing Regime: Regular
Responsible area: DIGES
Speaker: Jarbas Barbosa da Silva Jr.

COLLEGIATE BOARD OF DIRECTORS' RESOLUTION – RDC No. XX, OF XXXXXXXX XXth, 2017

Provides for the implementation of the National System of Medicine Control and the mechanisms and procedures to track medicines and other provisions.

The Collegiate Board of Directors of the National Agency of Sanitary Surveillance, in the use of the attributions vested in it by Art. 7, items III and IV, 15, items III and IV and the Law no. 9.782, of January 26th, 1999, art. 53, item V, §§ 1 and 3 of the Internal Regulation approved under the terms of the Annex I of the Collegiate Board of Directors' Resolution – RDC no. 61, of February 3rd, 2016, along with the provisions of the Law no. 11.903, of January 14th, 2009, altered by the Law no. 13.410, of December 28th, 2016, resolves to adopt the following Collegiate Board of Director's Resolution, as per the deliberations carried out in a meeting held on xx xxth, 2017, and I, the Managing Director, determine its publication:

CHAPTER I
INITIAL PROVISIONS

Art. 1 Establishes the mechanisms and procedures to track medicines throughout the national territory, within the arch of the National System of Medicines Control (SNCM), instituted by the Law no. 11.903, of January 14th, 2009.

Sole paragraph. This regulation is mandatory for all parties participating in the movement chain of medicines up to the final deadline of implementation and evaluation of the experimental phase as provided for in the Art. 5 of the abovementioned Law.

Art. 2 The provisions of this norm are applicable to all medicines registered at the National Agency of Sanitary Surveillance (Anvisa).

§ 1 The following categories of medicines are exceptions of the main section of this article:

I. Sera and vaccines from the National Immunization Program;
II. Radiology drugs;
III. OTC medicines;
IV. Medicines belonging to Ministry of Health's programs that are free and have an individualized delivery control;
V. Specific medicines, phytotherapic compounds, and dynamized drugs;
VI. Free samples.

§ 2. A Normative Instruction will be published with the list of the Ministry of Health's Programs and its respective medicines as defined in items I and IV of the first paragraph of this norm.

CHAPTER II
DEFINITIONS

Art. 3 The following definitions will be used for the purpose of this Resolution:

I. Tracking of medicines: set of mechanisms and procedures that allow outlining the record, current location, or last known destination of medicines.

II. Communication of event: electronic transmission of an event instance registered by a member of the movement chain of medicines.

III. Movement chain of medicines: flow from the origin up to the consumption of medicines encompassing all phases from manufacturing to importation, distribution, transport, storage, dispensing, and administration, as well as all other types of movement as foreseen by the sanitary controls.

IV. Event instance: information related with a medicine unit or transport package that describes the context in which a given operation of interest for the SNCM took place.

V. Members of the medicine movement chain: all those that are responsible for the registration and communication of event instances, including manufacturers, importers, distributors, wholesalers, retailers, hospitals, health establishments, storage, merchants, and dispensers of the medicine.

VI. SNCM participants: members of the movement chain of medicines or carriers.

VII. Unique Medicine Identifier – IUM: a series of numeric, alphanumeric, or special characters, created through identification and codification patterns that allow the individualized exclusive and unequivocal identification of each commercial package of the medicine;

VIII. Serial code: individual code contained in the IUM, unique for each presentation, comprised of 1 to 20 alphanumeric characters.

IX. Commercial package: secondary package, including multiple, hospital or secondary package for fractioned medicines, or the primary package when the medicine is not shipped to the dispenser in a secondary package.

X. Transport package: package used for the transportation of medicines packaged in their commercial packages.

XI. Global Trade Item Number (GTIN): internationally recognized standard identifier of a commercial item, with fourteen digits.

XII. Registration holder: manufacturer or importer, responsible for the registration of the medicine for human use as regulated by ANVISA.

XIII. Distributor: member of the medicine movement chain that stores the medicine as an intermediary in any position of the chain between the registration holder and the dispenser.

XIV. Dispenser: establishment responsible for the paid or free supply of medicines to the consumer or patient including: pharmacy, drugstore, hospital, health unit, or health establishment.

CHAPTER III
IDENTIFICATION OF MEDICINES

Art. 4 The two-dimensional bar code is the technology to capture, store and communicate event instances that are necessary to track medicines in the scope of the SNCM.

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

Art. 5 The medicine registration holder is responsible for the generation and inclusion of the DataMatrix on the commercial packages, containing the data of the Unique Medicine Identifier (IUM).

Art. 6 The IUM must contain the following data, in the order as shown below:

I. GTIN of the presentation;
II. Registration number of the presentation of the medicine at ANVISA;
III. Serial code with up to 20 digits;
IV. Expiration date;
V. Manufacturing lot.

Sole paragraph. The repetition of the serial code between the units of one single medicine presentation is prohibited.

Art. 7 Every transport package must have a unique identifier code beginning at the shipping event of the registration holder that allows the correlation with an IUM of the medicines contained in it.

CHAPTER IV
IDENTIFICATION OF THE SNCM PARTICIPANTS

Art. 8 The participants of the SNCM will be identified by its CNPJ (business tax payer number) upon registration of the events.

§ 1 Those who do not have their own CNPJ will be identified through the current record mechanisms, namely the Cadastro Nacional de Estabelecimentos de Saúde (CNES) [National Registration of Health Care Establishments] or others that are applicable.

CHAPTER V
LABELING

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

§ 1 The provision in the main section must ensure reading through data electronic capture mechanisms and the human eye, throughout the entire movement chain of medicines within the expiration date of the product.

§ 2 The procedure foreseen in this article will be considered a change of the labeling requiring notification, with immediate implementation, without the need of previous approval.

Art. 10 The imported medicines can have the DataMatrix and serial code impressions made either from the manufacturer in their country of origin or the registration holder in Brazil.

Sole paragraph. The registration holder will notify Anvisa, in the approval process of the importation process, regarding their individual identification option as foreseen in the main section.

CHAPTER VI
STORAGE STANDARDS AND COMMUNICATION OF EVENT INSTANCES

Art. 11 Each member of the movement chain of medicines must store and electronically transmit the corresponding data of the event instances that took place while the medicine was in their custody.

Art. 12 The members of the movement chain of medicines must keep the event record over the period of 1 (one) year after the product's expiration date.

Sole paragraph. The records mentioned in the main section must be the same as informed to the SNCM, and changing information is prohibited.

Art. 13 The communication of event instances to the SNCM must abide to the following timeline:

I. Up to 3 (three) days for registration holders;
II. Up to 5 (five) days for distributors;
III. Up to 7 (seven) days for dispensers.

§1. The communication of event instances will be made respecting the chronological order of the event record.

§2 The member of the movement chain of medicines will promptly rectify any event instances that have been communicated with errors to the SNCM as soon as these are identified or they become aware of the fact.

Art. 14 The member of the movement chain of medicines will communicate to the centralized data bank the data corresponding to the event instances relative to the medicine, by opening communication records.

Art.15 The electronic systems used by the members of the movement chain of medicines must ensure the secrecy, integrity, availability, and authenticity of the data.

CHAPTER VII
FINAL PROVISIONS

Art. 16 For compliance purposes of the Item II of the sole paragraph of the Art. 5 of the Law no. 11.903/2009 a Managing Committee will be instituted in a proper normative act with representation of the members of the SNCM and coordinated by Anvisa.

Art. 17 The technological specifications necessary for the operationalization of the SNCM will be published through a Normative Instruction within four months of the publication of this norm.

Art. 18 The Resolution-RDC no. 54, of December 10th, 2013, published in the DOU (Official Gazette) of November 11th, 2013 and the Resolution-RDC no. 114, of September 29th, 2016 published in the DOU of September 30th, 2016 are hereby revoked.

Art. 19 This Resolution enters into force on the date of its publication.

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Managing Director

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