Text of the Brazil Anvisa
"RESOLUTION OF THE COLLEGIATE BOARD - RDC No. 319, NOVEMBER 12, 2019"

as translated by Google Translate

Ministry of Health - MS
National Health Surveillance Agency – ANVISA

RESOLUTION OF THE COLLEGIATE BOARD - RDC No. 319, NOVEMBER 12, 2019

(Published in DOU No. 220 of November 13, 2019)

Provides for the implementation phase of the National Control System Medicines

The Collegiate Board of the National Health Surveillance Agency, in the use of attributions 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 Regulations approved by Resolution of the Collegiate Board - RDC No. 255, of December 10, 2018, resolves adopt the following Resolution of the Collegiate Board, as resolved at a meeting November 5, 2019, and I, the Chief Executive Officer, determine its Publication.

Art. 1 This Resolution provides for the implementation phase of the National System of Drug Control - SNCM.

Art. 2 The Resolution of the Collegiate Board of Directors No. 157, of May 11, 2017, is now effective with the following changes:

"Art. 2º Anvisa will publish Normative Instruction with the listing of medicines and members of the supply chain to which the provisions of this standard apply, as well as the respective deadlines and conditions for sending the data of movement of medicines. "(NR)

"Art. 7º Every medicine transport package subject to the SNCM must have its own unique identifier code that allows the relation with the IUM of the medicines contained in it.

Sole paragraph: The transport package identifier code defined in the above Article shall be generated from the record holder shipping event instance. "(NR)

“Art. 9th ....
....

§ 2. Modifications necessary to comply with the provisions of this Article shall be deemed to be notifiable, as soon as they are implemented, without prior approval by the Agency for release to the market." (NR)

“Art. 10 ....
....

II - manufacturer in the national territory, only the holder of the registration with manufacturing activity; and

III - registration holder with AFE or AE to import and who does not have AFE or AE to manufacture, outsourcing the serialization step to the CBPF drug manufacturing company, minimally to the secondary packaging line.

§ 1. The serialization activity provided for in item III of the **current article** is solely to print the information relating to the IUM and its Datamatrix on the sealed commercial packaging of finished imported medicines.

§ 2. The serialization provided for in item III of the **current article** should be duly formalized in an outsourcing contract between the registration holder and the contracted manufacturing company.

§ 3. The serialization provided for in item III of the **current article** shall be performed according to conditions approved in the registration of the medicine or biological product and made explicit in the outsourcing contract." (NR)

“Art. 13 ....
....
....
....

§ 1. The member of the drug supply chain shall record and report a rectifying event instance on any event instances that it has reported in error to the SNCM as soon as it identifies or becomes aware of this fact.

§ 2. The deadlines provided for in this article may be extended by reasoned justification sent to the management area of SNCM at Anvisa." (NR)

“Art. 14 ....

Single paragraph. Chain members shall ensure compliance with the content of transmitted data by implementing and transmitting corrective action information as soon as there are irregularities or health warnings related to the products or chain members with whom they relate." (NR)

"Art. 19 The health authority shall apply health risk management methodology information from the SNCM, to direct control activities, considering criteria related to:

I - class and risk classification of the drug;

II - type of movement;

III - history of thefts, thefts and falsifications of the drug;

IV - relevance and criticality of medication in health policies and programs public;

V - laboratory analysis results;

VI - national and international health alerts;

VII - company compliance history; and

VIII - random sampling.

Single paragraph. The criteria set out in this article are not listed in order of application and may be used individually or in combination, subject to the health risk involved. "(NR)

Art. 3 This Resolution shall enter into force on the date of its publication.

WILLIAM DIB
CEO