Text of the Brazil
“PUBLIC CONSULTATION No. 747 OF NOVEMBER 12, 2019”

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Translated on November 15, 2019

PUBLIC CONSULTATION No. 747 OF NOVEMBER 12, 2019

The Collegiate Board of the National Health Surveillance Agency, in the use of the 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, III, §§ 1 and 3 of the Internal Rules approved by Resolution of the Collegiate Board - RDC No. 255, of December 10, 2018, resolves to submit for public consultation, for comments and suggestions from the general public, proposal for a standard act in the Annex, as resolved in the meeting held on November 5, 2019, and I, the Chief Executive Officer, have determined its publication.

Art. 1 The deadline of 45 (forty-five) days for the submission of comments and suggestions to the text of Normative Instruction -IN which establishes the deadlines for the beginning of data transmission and definitions for the implementation of the National Drug Control System, is established, as attachment.

Single paragraph. The term dealt with in this article shall begin seven (7) days after the date of publication of this Public Official Diary of the Union.

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 in a specific form, available at:
http://formsus.datasus.gov.br/site/formulario.php?id_aplicacao=51058.

§ 1. The contributions received are considered public and will be available to anyone interested through tools electronic form, in the “result” menu, including during the consultation process.

§ 2. At the end of the completion of the electronic form will be made available to the interested protocol number of the registration of their participation, being dispensed the postal or in-person protocol of documents in physical media with the Agency.

§ 3. In case of limited access by the citizen to informed resources, suggestions may be sent and received, in writing, during the consultation period, to the following address: National Surveillance Agency Sanitary / GGMON, SIA Section 5, Special Area 57, Brasília-DF, CEP 71.205-050.

§ 4. Exceptionally, international contributions may be sent in physical media to the following address: National Health Surveillance Agency / International Affairs Office - AINTE, SIA Section 5, Special Area 57, Brasília- DF, Zip Code 71.205-050.

Art. 3 After the deadline set in art. 1, the National Health Surveillance Agency will promote the analysis of contributions and, at the end, it will publish the result of the public consultation on the Agency's portal.

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

WILLIAM DIB
CEO

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Document electronically signed by **William Dib, CEO**, on 12/11/2019, at 17:24, according to Brasilia's official time, based on art. 6, § 1, of Decree No. 8,539, of October 8, 2015
hp: //www.planalto.gov.br/ccivil_03/_Ato2015-2018/2015/Decreto/D8539.htm.

The authority of this document can be found at h ps: //sei.anvisa.gov.br/auten city , informing the code Checker **0809666** and the CRC code **C0B6BB20** .

ATTACHMENT
PROPOSAL FOR PUBLIC CONSULTATION

Process #: 25351.048778 / 2012-10
Subject: Proposed Normative -IN Instruction setting deadlines for commencement of data transmission and definitions for implementation of the National Drug Control System

2017-2020 Regulatory Agenda: Not an Agenda Item
Responsible Area: General Management of Health Surveillance Product Monitoring - GGMON
Rapporteur Director: Antonio Barra Torres

NATIONAL HEALTH SURVEILLANCE AGENCY

NORMATIVE INSTRUCTION DRAFT – IN

NORMATIVE INSTRUCTION - IN Nº [Nº] , OF [DAY] OF [MONTH FOR EXTENSE] OF [YEAR]

It establishes the deadlines for the commencement of data transmission and definitions for the implementation of the National Drug Control

The Collegiate Board of the National Health Surveillance Agency, in the use of the 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, VI, §§ 1 and 3 of the Internal Regulations approved by Resolution of the Collegiate Board - RDC No. 255, of December 10, 2018, resolves to adopt the following Normative Instruction, as resolved at a meeting held on XX of XX of 201. .., and I, the Chief Executive, determine its publication

Art. 1 In compliance with the provisions of art. 2 of RDC Collegiate Board of Executive Officers Resolution 157, of May 11, 2017, amended by Resolution - RDC No. XX of XX of XXXX of 201X, the respective minimum limits of packagings of industrialized medicinal products and their Maximum time limits for commencement of movement data transmission to the National Drug Control System - SNCM:

I - at least 25% of the marketed production of each establishment by 1 October 2020;

II - at least 50% of the marketed production of each establishment until April 1, 2021;

III - at least 75% of the marketed production of each establishment until September 1, 2021; and

IV - 100% of the marketed production of each establishment until April 1, 2022;

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§ 1. As long as the medicinal products in accordance with the above items are moved, the other members of the chain shall commence the transmission of the receipt and subsequent movement of the packaging in its custody.

§ 2. Except as provided in Paragraph 1, the health services and the management bodies of the SUS, which shall have until April 28, 2022 to start transmission of drug movement data.

Art. 2 From the implementation of item I of art. 1, the transmission of the bookkeeping data of the object medicines Resolution of the Collegiate Board - RDC No. 22, of April 29, 2014, will be held for the SNCM.

Art. 3 The Normative Instruction - IN No. 19, of August 22, 2017, is effective with the following changes:

"Art. 2 The software systems used by members of the drug supply chain for the registration and SNCM event instance communication shall be developed or evolved to specifications defined by Anvisa." (NR)

....

"Art. 14 The management area of SNCM at Anvisa may adopt complementary configurations to those defined in this Instruction Standard, aimed at ensuring the solution's operation in different technological and operational contexts. "(NR)

Art. 4 The Normative Instructions - IN nº 17 and 18, of August 22, 2017, and nº 23, of March 15, 2018 are hereby revoked.

Art. 5 This Normative Instruction shall enter into force on the date of its publication.

WILLIAM DIB