Pharmaceutical traceability in Brazil

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Pharmaceutical traceability in Brazil
The Brazilian Drug Control System
SNCM
Brazilian Drug Control System – SNCM

Agenda

Legal basis
Objectives
Operational Dynamics
Computerized System
Brazilian Drug Control System – SNCM

Timeline

**Federal Law no. 11,903/2009**
Establishes the Brazilian Drug Control System

**Federal Law no. 13,410/2016**
Amends Law no. 11,903/2009

**Anvisa Resolution RDC 54/2013**
Amends RDC 59/2009

**Anvisa Resolution RDC 157/2017**
May 2017

**Anvisa Resolution RDC 59/2009**
Establishes Regulations for Federal Law no. 11,903/2009

**Normative Instruction 17**
- Drugs and Chain Members

**Normative Instruction 18**
- Excluded Drugs

**Normative Instruction 19**
- Technology
Brazilian Drug Control System – SNCM

PREVIOUS MODEL

CURRENT MODEL
The National Drug Control System of Brazil

Regulation Phase - 4 Months -

- Dec 2016

Actions Taken
- Regulation completed
- Preparation for experimental phase: selection of manufacturers and products
- Creation of committee to follow-up the experimental phase

Experimental Phase - 12 Months -

- Aug 2017

Actions Taken
- Implementation of experimental phase
- Selection of other manufacturers
- Database system Development (pilot)
- Adaptation of companies’ systems
- System testing and evaluation
- Creation of Management Committee as required by Law

Evaluation Phase - 8 Months -

- Aug 2018

Actions Foreseen
- System analysis, correction and validation
- Definition of implementation plan
- Revision of regulation (RDC and IN)
- Conclusion of the System

Implementation Phase - 36 Months -

- Apr 2019
- Apr 2022

Actions Foreseen
- Complete implementation of the System in Brazil
- Evaluation and monitoring of results
- Corrective actions
Brazilian Drug Control System – SNCM
Federal Law no. 13,410/2016

Distinct deadlines to communicate the event
Definition of the drugs to be included in SNCM
Database centralized in a Federal Government institution
Use of open communication protocols

Experimental and assessment phases
Implementation within three years
Identification and Data Capture

Secondary Packaging

The **RDC 157/2017** states that the GS1 DataMatrix bar code symbol should encode at least the following data that makes up the IUM (Unique Medicine Identification) in the following order:

I - **GTIN** - Global Trade Item Number  
II - ANVISA Medicine Registry Number  
III - Serial Number  
IV - Expiration Date  
V - Lot / Batch Number

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**IUM - Unique Medicines Identification**

- **GTIN**: (01)07898357410015  
- ANVISA’s Number: (713)3210987654321  
- Serial: (21)1234567890123  
- Expire Date: (17)150206  
- Lot Number: (10)123ABC
Identification and Data Capture

Tertiary Packaging

According to RDC157/2017 - Article 7. Every transport package containing at least one medicinal product included in the SNCM experimental 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.
Article 4-A. The Brazilian Drug Control System shall have a database centralized in a Federal Government institution, for storage and consultation on the movement of drugs under its responsibility.
Pilot project deadlines

I - up to one year: industry, importers, distribution and retail representatives chosen by the competent federal health surveillance institution may, on a experimental basis, receive and disseminate data on at least three drug batches;

II - up to eight months after phase I: results obtained during the experimental phase are object of assessment, correction, and validation report by ANVISA, through the Management Committee;

III - up to three years: full implementation of the Brazilian Drug Control System.
Objective of the Pilot Project

To validate the application of the Normative Instructions and its implementation guides:

- Traceability process
- System complexity
- Technological integrations and their operation
- Limitations
Brazilian Drug Control System – SNCM
Normative Instruction 17

Operational Dynamics – NI 17/2017

Pilot Project Participants:
Authorization holders (manufacturers or importers)
Distributors/ Wholesalers
Retailers
Hospitals
Other health establishments
Brazilian Drug Control System – SNCM
Computerized System

Computerized System

Construction

Publication

Validation

Assessment

01

02

03

04

Productive chain members
Computerized System

End-to-end traceability
Performance
Information exchange
UIM
Allow use of different system models already adopted by companies
Wrong flows, losses, undue commercialization...
Thank you!

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Contact

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