



Pharmaceutical traceability in Brazil

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Pharmaceutical traceability in Brazil

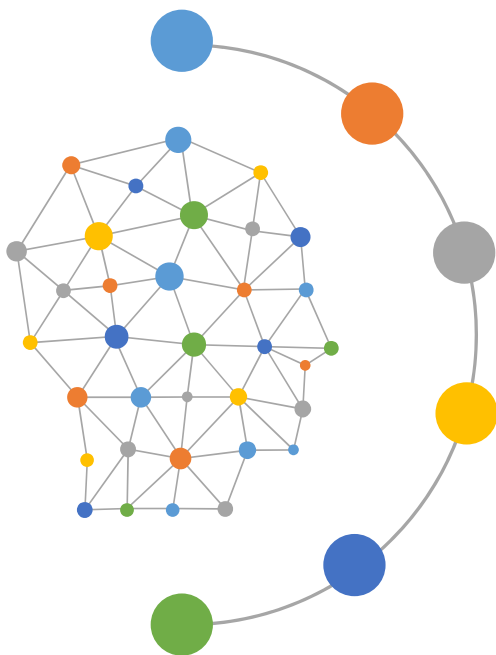
The Brazilian Drug Control System

SNCM



Brazilian Drug Control System – SNCM

Agenda

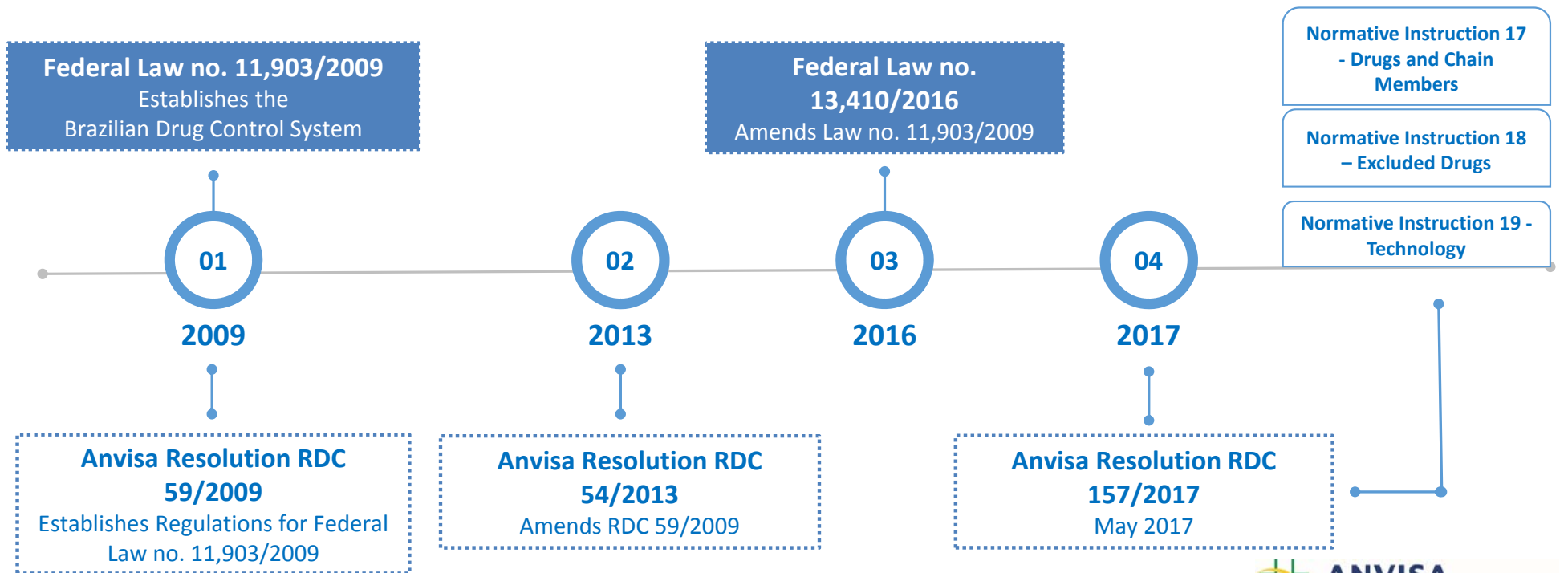


Legal basis
Objectives
Operational Dynamics
Computerized System



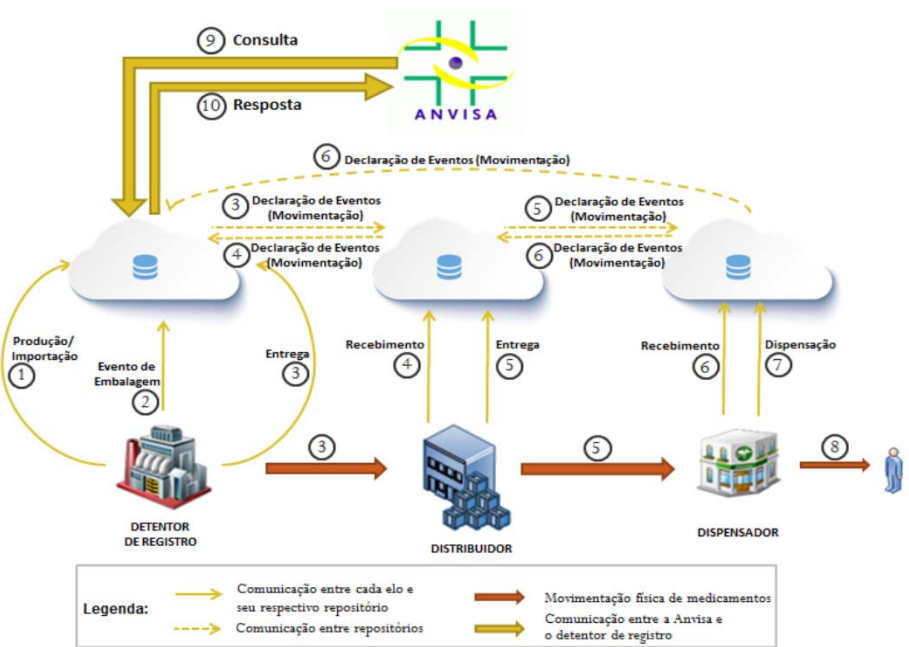
Brazilian Drug Control System – SNCM

Timeline

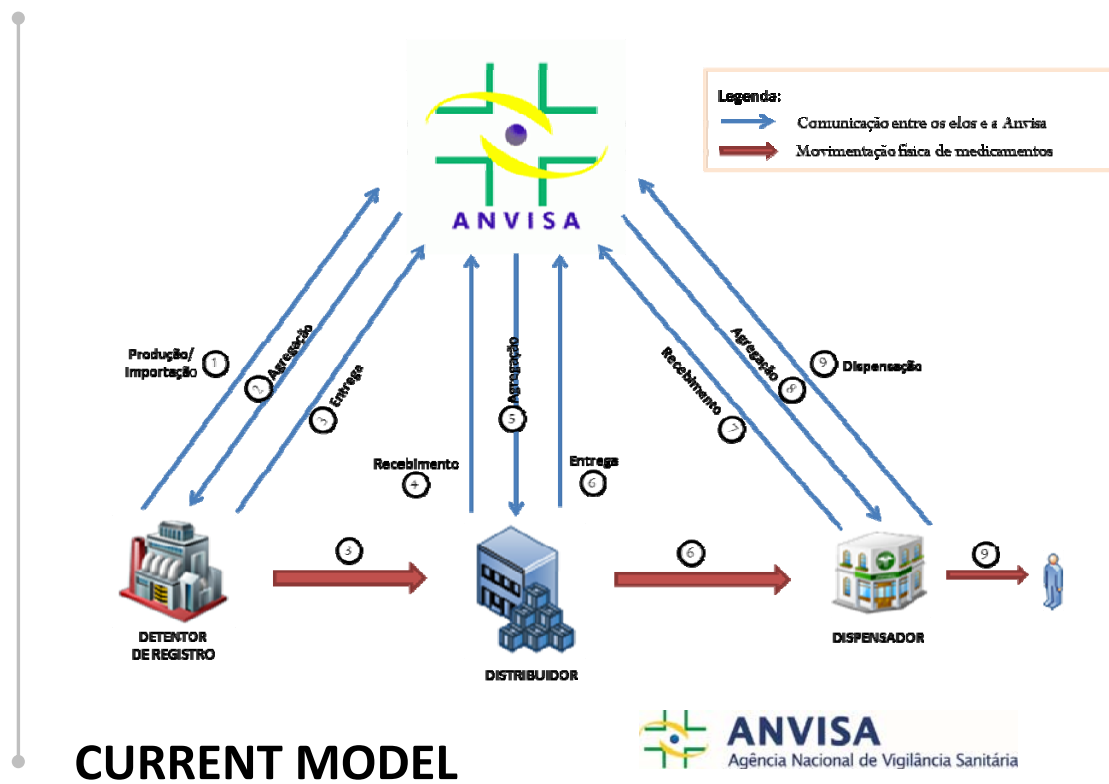




Brazilian Drug Control System – SNCM



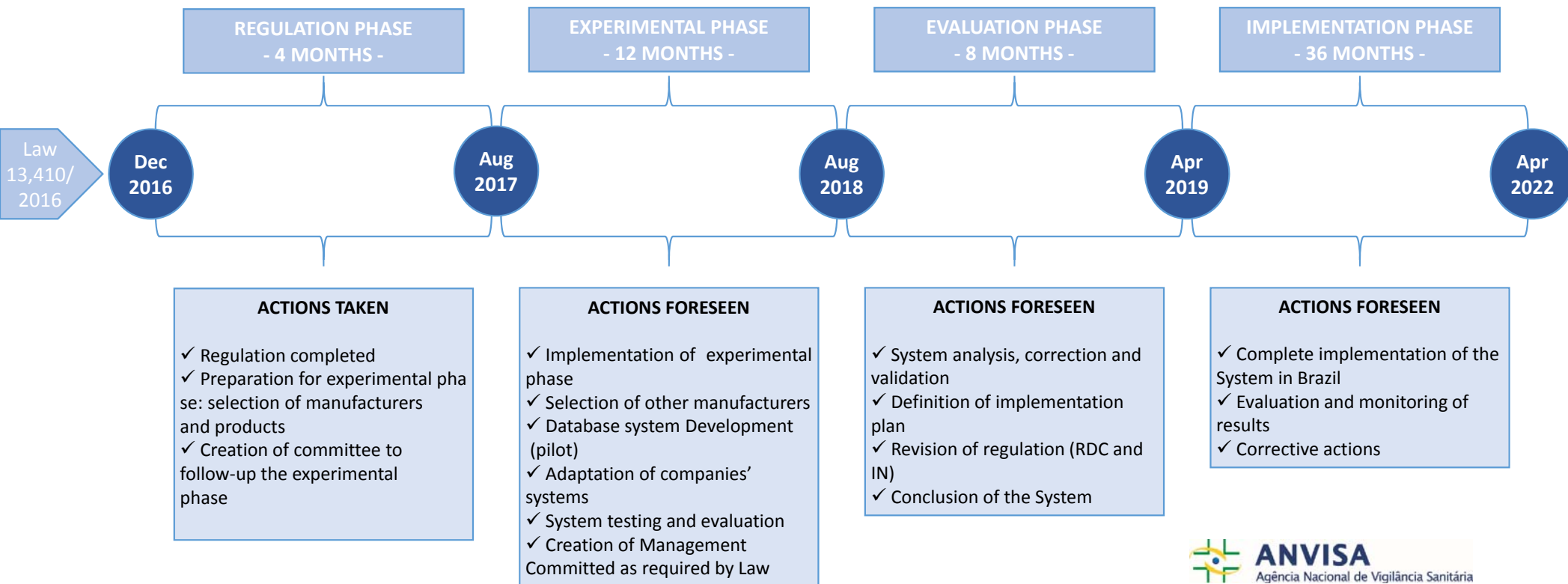
PREVIOUS MODEL



CURRENT MODEL



The National Drug Control System of Brazil





Brazilian Drug Control System – SNCM

Federal Law no. 13,410/2016





Brazilian Drug Control System – SNCM
Identification and Data Capture

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



IUM - Unique Medicines Identification

GTIN: (01)07898357410015

ANVISA's Number: (713)3210987654321

Serial: (21)1234567890123

Expire Date: (17)150206

Lot Number: (10)123ABC



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Identification and Data Capture

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.



Brazilian Drug Control System – SNCM
Data Storage

Data Storage

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.





Brazilian Drug Control System – SNCM

Pilot Project deadlines

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 Comittee**;

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



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Objective of the Pilot Project

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

Productive chain members

Assessment





Brazilian Drug Control System – SNCM
Computerized System

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!

Bianca Zimon

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Contact

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