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Your ANVISA Implementation Plan: Quick Start Guide

December 18 Update: *ANVISA continues to modify its Normative Instruction and certain requirements, deadlines, and terminology may have changed since this article was originally published. Updated information will be published as soon as it becomes available.*

With the 2022 ANVISA readiness deadline now less than 18 months away, ANVISA is in the final stages of finalizing its Normative Instruction and is expected to confirm its requirement that companies file their serialization implementation plans before the end of 2020. This guide represents the latest information as of the most recent meeting of the ANVISA directorship on November 5th.

While the Normative Instruction has not yet been formally released, it is expected that Marketing Authorization Holders (MAHs) will be required to submit a serialization implementation plan as early as December 31, 2020 via the government reporting system (SNCM) portal. In doing so, companies are signaling to ANVISA their commitment to meeting the country's track and trace requirements by February 2022.

Implementation plans must be submitted through the ANVISA portal.

Prior to the final release of the Normative Instruction, ANVISA has launched a test environment where companies can preview the web portal that they must use to

submit their serialization and reporting implementation plans and register their master data:

- A valid digital certificate is required to access the portal. Individual user logins are not supported.
- Companies can track the progress of their implementation plan through a dashboard and progress chart.
- The portal will provide Portuguese, Spanish, and English language support.
- New plans can be added.
- There will be a section for companies to register serialized products that are not subject to SNCM traceability reporting.

The ANVISA web portal provides a highly structured, step-by-step process for entering company data and updating the progress of each serialization activity. Based on the final Normative Instruction, the implementation plan must include the expected dates for the beginning and end of the following steps:

- Process mapping
- Approval of the acquisition plan by management
- Acquisition and installation of equipment
- Packaging validation and updating of the elements of the pharmaceutical quality management system
- Integration with SNCM and logistic processes

High-level information categories include:

- General company data
    - Production plants
    - Total number of production lines: internal and contract manufacturing
    - Distribution centers
    - SKUs in production
    - SKUs to be serialized
    - Serialization lines for each plant

- Implementation details for each activity, including:
    - Start date
    - Number of days to complete
    - % completion

ANVISA has added a new metadata requirement.

ANVISA has released the technical guidelines, including a new metadata requirement and related web services and tools. This metadata links to the product's ANVISA registration number to enhance the oversight and control capabilities of the SNCM system. Metadata can be uploaded and queried using an automated web service or by using a web interface to upload data manually using a CSV file. The required metadata includes:

- GTIN (Global Trade Item Number)
- Anatomical Therapeutic Chemical (ATC) Classification
    - ATC/WHO (World Health Organization)
    - ATC/DDD (Defined Daily Dose)
    - ATC/EphMRA (European Pharmaceutical Market Research Association)
- Portaria 344/98 Regulatory Classification / Prescription Type
- Commercialization Start Date
- Commercialization End Date (optional)
- Commercialization End Reason (optional)

ANVISA will begin automatic track and trace notifications in April 2022.

At the September 2020 SETRM conference, ANVISA noted that they will not be notifying companies of serialization or reporting issues until April 2022, when the track and trace law goes into effect. ANVISA also pointed out that there are no interdependencies between product serialization systems and the SNCM system

that prevent companies from developing and registering their implementation plans and working with partners on horizontal data integration. To help companies prepare, ANVISA has created a new microsite and has published its technical guidelines for connecting and reporting to the SNCM system. In addition, they have provided a test environment to start simulating event reporting.

Start your Brazil implementation plan with TraceLink.

TraceLink's local Brazil team is ready to help you prepare your Brazil serialization implementation plan and stay on track to meet the final April 2022 deadline. As the world's leading provider of proven track and trace solutions, TraceLink can help your company develop and implement a successful serialization plan for Brazil. Contact TraceLink to learn more about becoming a TraceLink customer and joining our Brazil Special Interest Group.

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