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Brazil SIG Analyzes New Draft of ANVISA Normative Instruction, Industry Reaction

Key Takeaways from the March Brazil Special Interest Group meetings

- A new draft of the Normative Instruction was communicated by ANVISA on March 12 but it has not yet been approved by the agency's directorship (DICOL). The draft incorporated industry feedback from the previous version.
- The April 2022 compliance deadline, set by law, remains in place. The latest Normative Instruction defines an Implementation Phase leading up to April 2022, and an Operational Phase from April 2022 onwards.
- In the Implementation Phase, manufacturers and importers must report based on a percentage of commercial batches. In the Operational Phase, the criteria for manufacturers shifts to a production-line basis.
- Contract manufacturers (CMOs) will have SNCM reporting requirements as a "reporting entity."
- ANVISA has clarified the conditions under which a product is "activated" when it enters the supply chain.
- The SNCM system is scheduled to become available in June for reporting under the "assisted implementation" phase. Companies are expected to achieve 5% of batches reports by October, 2021 and 10% by the April 2022 deadline.

Notable provisions from the latest Normative Instruction draft

- Although it has yet to be finalized and approved, a revised draft of the "directional playbook" for industry compliance with Brazil's track & trace regulations was communicated by ANVISA on March 12. The new draft of the Normative Instruction offers several key provisions that were reviewed by TraceLink's Brazil Special Interest Group (SIG):
- While Marketing Authorization Holders (MAHs) remain subject to the April 2022 serialization and reporting deadline, certain downstream entities may have additional time before they must be in compliance.
- ANVISA is recommending that companies prioritize certain product classes for serialization and traceability.
- The SNCM system will be available in June 2021, and companies should submit and update their implementation and operational plans beginning in July. It is expected that the system will be able to process full track and trace reporting, including anomaly detection and response, within the October-November timeframe.
- The Implementation Phase will run from October 2021 to April 2022, with companies expected to report 10% of its product batches from November 2021 through April 2022.
- The Operational phase replaces the Implementation phase in April 2022. Companies will be required to report 30% of their packaging lines beginning in April 2022; 70% by April 2023; and 100% by April 2024. Note that importers are required to follow these same percentage milestones on a batch basis.

According to TraceLink's Brazil Director, Luca Gabrielli, the SNCM system used for the implementation phase will be replaced with an operational system hosted in a government facility, as required by law, in April 2022. He also noted that data uploaded to the implementation system will NOT be migrated to the operational system once it goes live in April 2022.

Assessing industry concerns and ANVISA response

In March, an open letter was published by an association representing the Brazil pharmaceutical industry, requesting that ANVISA suspend its industry directives due to the impact of the COVID-19 pandemic on the industry's ability to focus on serialization and SNCM reporting. While ANVISA continues to take industry concerns into account in establishing phased milestones for regulatory compliance, the fact remains that ANVISA does not have the authority to change the law. ANVISA also notes that, while the instructions for connecting to SNCM have not been finalized, companies have known about the general serialization requirement since 2016.

Answering questions about "Product Activation"

A common question among SIG attendees centers around product activation: When, exactly, does ANVISA consider a product to be subject to reporting and tracking in the supply chain? Based on his discussions with ANVISA, Luca Gabrielli offered several insights:

- Activation indicates that a product is entering the Brazil supply chain.
- An activation event can only be reported AFTER a product has been "quality released" and is "fit for distribution in the Brazil market" according to Brazil pharmaceutical standards and regulations.
- Activation must take place prior to the initial shipment of a product after it is quality released. If a product is manufactured by a CMO but the CMO does not perform the quality release prior to shipping to a warehouse, the product is not considered to be activated.
- Products that are manufactured outside of Brazil must be activated by an MAH that is registered with a Brazil tax ID number (CNPJ) and that has obtained the necessary digital certificate for reporting.

Contract manufacturers (CMOs) may be considered "reporting

entities”

ANVISA continues to examine use cases that are being raised by industry representatives and solution providers such as TraceLink. For example, ANVISA has indicated that contract manufacturing or packaging organizations (CMOs/CPOs) may, under certain circumstances, be responsible for reporting serialization events, for example, if a CMO conducts a “quality release” prior to shipping a product. While details have yet to be finalized, it is assumed that the CMO/CPO will be required to have a CNPJ and digital certificate as the first shipment after activation indicates which tax ID has reporting responsibilities.

Questions and concerns: Upcoming TraceLink Brazil SIG topics

As we enter the second quarter of 2021, the path forward in Brazil remains fluid. TraceLink’s Senior Director of Industry Marketing and Community, Allan Bowyer, continues to collect ideas from members of the Brazil SIG on areas of key concern. Future topics under consideration include:

- Understanding how to meet the reporting deadlines under the Implementation Phase and after the Operational Phase begins in April 2022
- Fleshing out use cases, especially around importation, and how TraceLink’s Brazil solution will address them
- Clarification on the requirements of CMOs and use cases in which they would need to connect to the SNCM
- Differences between the current staging SNCM system and the final version in 2022.
- Understanding the requirements for horizontal data exchange and options available

Upcoming meetings of the ANVISA directors (DICOL) are scheduled for April 7, 14, and 28. TraceLink’s local Brazil team is monitoring the situation closely and will continue to update the Brazil SIG. TraceLink’s Brazil SIG meets every two weeks on Thursdays, with upcoming meetings April 8 and 22. Contact TraceLink to learn

more about joining TraceLink Community discussions.

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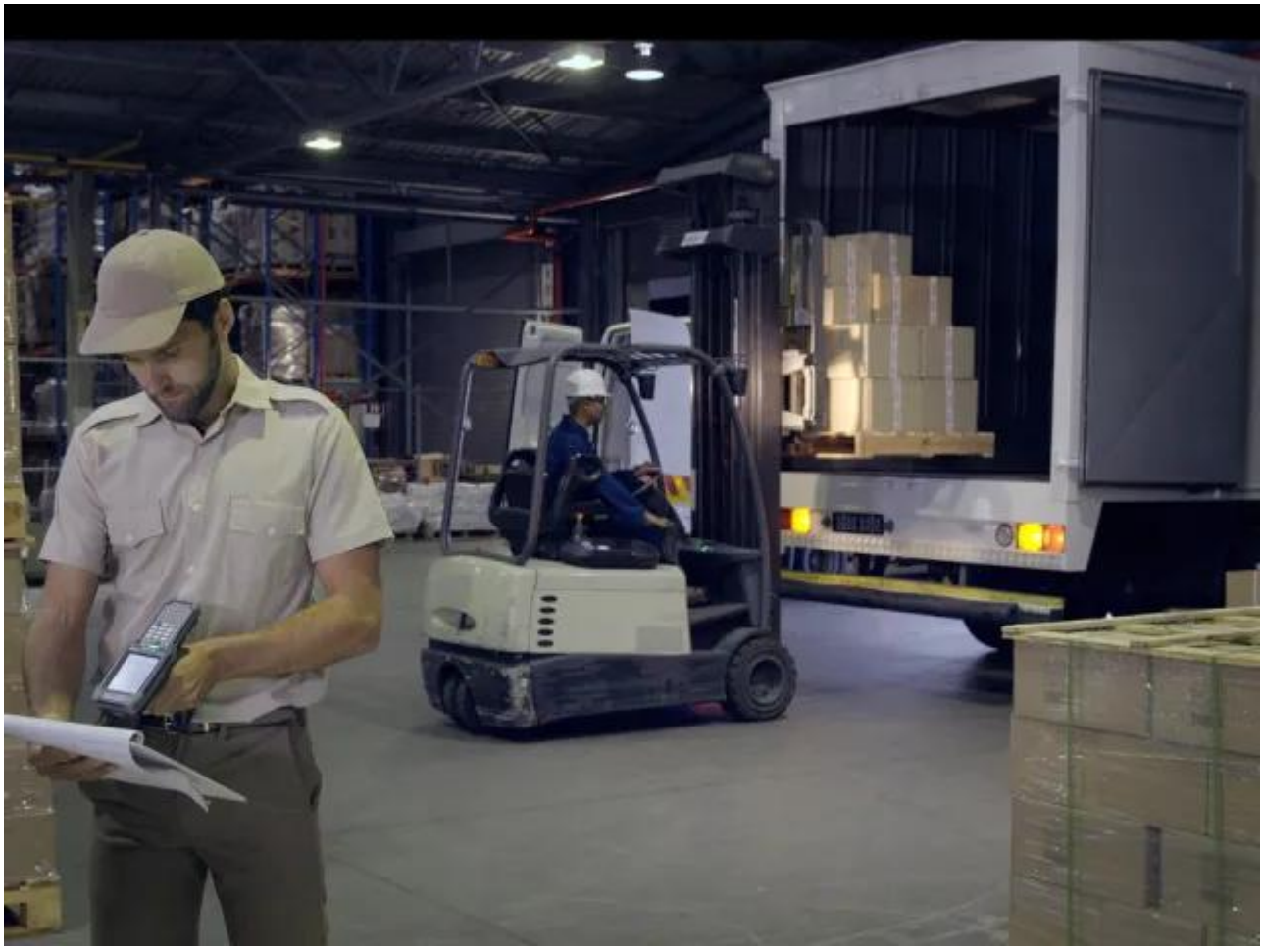

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