RESOURCES

TraceLink Brazil Community: ANVISA Approval Sets Aggressive Timeline in Motion

Key Takeaways from the August 2021 Brazil Special Interest Group sessions

- On August 20, ANVISA approved the Normative Instruction, which confirms the April 28, 2022 deadline for manufacturers, wholesalers, and dispensers to serialize products and report events for those products entering commercialization on or after the deadline.

- Approval of the Normative Instruction is expected to facilitate discussions with ANVISA on clarifying questions on multiple reporting use cases, including imported products.

- Tracelink has developed a survey for its customers to use to assess the readiness of third-party logistics providers (3PLs) that they plan to authorize as proxies for reporting to SNCM, ANVISA's traceability system.

Approval of Normative Instruction confirms April deadline

With its approval of the Normative Instruction on August 20, Brazil's Health Regulatory Agency, ANVISA, is sending a clear message that it expects all segments—manufacturers, importers, distributors, and dispensers—to comply with the April 28, 2022 deadline. ANVISA has reiterated that the agency does not have the authority to change the date as it is written into the law.

TraceLink's Brazil Director, Luca Gabrielli, noted that ANVISA has acknowledged the complexity of implementing the serialization and track and trace capabilities but has reiterated that, as a regulatory body, it's bound by the existing law that defines April 28, 2022 as the date by which products must be serialized and reporting to SNCM must begin.

The impact on manufacturers and importers

Luca Gabrielli summarized the key provisions from the approved Normative Instruction:

- All supply members must meet the requirements of the SNCM, including wholesalers and dispensers. As a result, manufacturers' downstream partners will require serialization and aggregation information for received shipments in order to fulfill their reporting obligations.

- The ANVISA registry holder (manufacturer or importer) is required to provide product master data to the SNCM for current products licensed in Brazil. Master data for new products must be provided as they are launched.

- The date by which products must be serialized before they can enter the Brazil market is April 28, 2022.

- The date after which events must be reported to the SNCM is April 28, 2022.

- Manufacturers must submit a Serialization Plan within 30 days of the SNCM system becoming available that outlines how they will implement serialization and reporting for Brazil products.

- Manufacturers and Importers are expected to adapt their Brazil compliance solution as ANVISA continues to develop the SNCM system and reporting processes.

In response to member questions around reporting requirements, Luca Gabrielli pointed out that the reporting requirement applies only to products serialized after April 28, 2022 and that, with the approval of the Normative Instruction, ANVISA is expected to provide more clarification around requirements for a number of

unaddressed business use cases, such as reporting on imported products.

Finally, Luca Gabrielli noted that ANVISA can impose penalties on companies that are not in compliance, including fines; shutting down a production or distribution facility; and initiating an audit of the manufacturer.

Assessing 3PL readiness: Questions manufacturers and importers should ask

In his presentation, TraceLink project manager Greg Firestone noted that some companies may choose to designate a third-party logistics provider (3PL) as a proxy for reporting to SNCM. TraceLink is providing an assessment to its customers to ensure that a 3PL has the capabilities and infrastructure to keep the delegating company compliant. The survey covers 5 key areas:

- Data Management
- Validation
- Proxy Reporting Capabilities
- Horizontal Data Exchange
- Disaster Recovery/Business Continuity

Greg Firestone also pointed out that TraceLink compliance customers can—and should—be configuring their core Serialized Operations Manager application with Brazil product and partner master data to be ready when the Brazil Compliance module is released in September.

Stay informed with TraceLink's Brazil Special Interest Group and Product Innovation Forum

TraceLink's Brazil Special Interest Group will soon convert to a Product Innovation Forum where TraceLink customers can discuss business requirements and get updates on TraceLink's Brazil Compliance and Serialized Traceability solutions for horizontal data exchange. TraceLink's Brazil Community meets every two weeks on Thursdays. Join the TraceLink Community.

Brazil
Contact Us
Learn more about Brazil compliance solutions from TraceLink.

More Brazil Compliance Resources

Brazil: ANVISA Normative Instruction Spurs Industry Action Ahead of April 2022 Deadline

See key provisions of the ANVISA Normative Instruction and what manufacturers and importers must do to meet the April 2022 deadline.

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Brazil Deadline: Final Normative Instruction Means All Segments Must Comply by April 2022

With only 8 months before the deadline, learn why manufacturers need to start their Brazil compliance projects now.

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Horizontal Integration in Brazil: The Key to Compliance, Business Continuity, and Operational Efficiency

Download this infographic to learn why horizontal integration in Brazil is the key to compliance, business continuity, and operational efficiency.
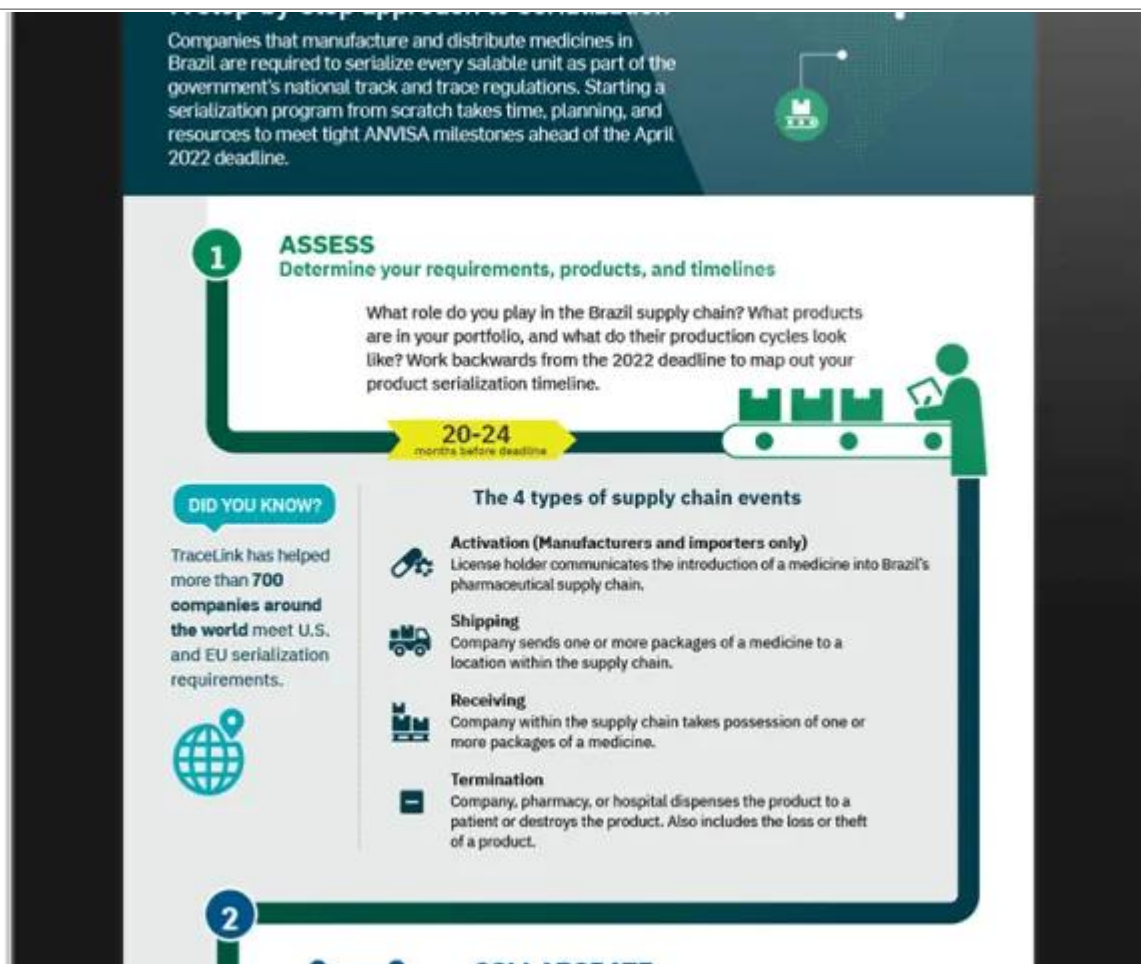
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5 Risk Factors of Using Your LMS Provider to Meet Brazil Compliance Requirements

Learn why Line Management System (LMS) vendors can't compare to TraceLink's enterprise-level data management capabilities for Level 4 - Level 5 serialization.

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Companies that manufacture and distribute medicines in Brazil are required to serialize every salable unit as part of the government's national track and trace regulations. Starting a serialization program from scratch takes time, planning, and resources to meet tight ANVISA milestones ahead of the April 2022 deadline.

1 ASSESS
Determine your requirements, products, and timelines

What role do you play in the Brazil supply chain? What products are in your portfolio, and what do their production cycles look like? Work backwards from the 2022 deadline to map out your product serialization timeline.

20-24 months before deadline

DID YOU KNOW?
TraceLink has helped more than **700** companies around the world meet U.S. and EU serialization requirements.

The 4 types of supply chain events

Activation (Manufacturers and importers only)
License holder communicates the introduction of a medicine into Brazil's pharmaceutical supply chain.

Shipping
Company sends one or more packages of a medicine to a location within the supply chain.

Receiving
Company within the supply chain takes possession of one or more packages of a medicine.

Termination
Company, pharmacy, or hospital dispenses the product to a patient or destroys the product. Also includes the loss or theft of a product.

2 COLLABORATE

Brazil Compliance: A Step-by-Step Approach to Serialization

Begin your Brazil serialization journey and see why you need to start today to meet the April 2022 ANVISA deadline. Download the infographic.
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2016 Global Drug Supply, Safety and Traceability Report

See how 331 life sciences companies are faring with DSCSA lot-level requirements and serialization readiness.

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