TraceLink Brazil Community: Action Less Risky than Wait-and-See Approach



Key Takeaways from the May 6 and May 20 Brazil Special Interest Group sessions

- The Covid-19 pandemic continues to preoccupy the Brazil healthcare system. ANVISA appears to be working on the next draft of the Normative Instruction, but there is no announced date to publish.
- To avoid being caught in a time crunch, a growing number of members are moving forward with preparations despite the absence of the final Normative Instruction.
- Members cite partner onboarding and system integration as a major concern in meeting the deadline.
- Companies are analyzing past compliance challenges to determine how they can mitigate risk.

Work on the Normative Instruction continues, but discussions are on hold

The most recent draft of the Normative Instruction for industry compliance with Brazil's track and trace regulations was communicated by ANVISA on March 12. On May 14, several major industry associations in Brazil—representing manufacturers, wholesalers, and dispensers—followed up on their initial March request to suspend discussions related to the government reporting system, SNCM. As of May 20,

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ANVISA has not yet responded to the second communication.

While public discussions of the Normative Instruction have been suspended, it appears that work on the draft is continuing, led by two of the five-member board of ANVISA commissioners (DICOL). There has been no announcement of the next release date.

See the March Brazil SIG recap for an overview of the March 12 draft.

The focus is now on "What can we do today?"

While the Normative Instruction is in flux, April 2022 is still the deadline established by law and has not changed. As companies begin to assess the risk of waiting for a final "go-ahead" signal from ANVISA and having to implement a functioning solution in an increasingly narrow timeframe, questions and discussions are now focusing on actions that can begin immediately.

In the May 6 session, TraceLink Global PMO Manager Greg Firestone led a discussion on four key area of concern that companies can address now to lay the groundwork for a successful Brazil compliance solution:

- **Data readiness:** Mapping out and finalizing multiple manufacturing use cases; collecting or generating master data; and ensuring staff is trained and "serialization ready"
- **Internal lines and distribution centers:** Reviewing Brazil use cases with line management system (LMS) vendors; ensuring warehouse management software and hardware are updated
- **Partner readiness:** Reaching out to contract manufacturers and third-party logistics providers to review use cases, transaction processes, and data requirements
- **Downstream connectivity:** Ensuring that partners are already on the TraceLink Network or providing new partner information to the TraceLink Network Success Team team for onboarding

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Partner onboarding and system integration is a key concern

In the May 20 session, TraceLink Global Manager for Network Success, Adam Reczkowski, responded to customer concerns about partner onboarding raised in the May 6 meeting. With horizontal integration a looming challenge for companies doing business in Brazil, Adam stressed the advantage of the Integrate Once, Interoperate with Everyone™ approach enabled by the TraceLink Network, versus having to build and maintain individual point-to-point connections with each partner.

Adam reviewed how members can take advantage of the no-cost partner onboarding services provided by TraceLink:

- Submit a list of trade partners for an analysis of their current onboarding status and to determine if additional action is required
- Provide TraceLink with new trading partner company details:
  - Name, address, DUNS number, and Brazil tax ID number (CNPJ)
- Review timelines, your data requirements, and transactions with 3PL partners:
  - If 3PL is on the TraceLink Network, you can begin onboarding to establish connectivity
  - If 3PL is not on the TraceLink Network, they can begin getting connected to TraceLink's network

What are the risks of further delay?

Brazil has been a particularly challenging market in terms of planning and designing a compliance solution. Understandably, some members have chosen to minimize the risk of taking the wrong path by waiting for ANVISA to finalize the Normative Instruction. However, a growing number of members are looking past the ANVISA delays and considering the broader set of issues experienced in other markets as the basis of their overall risk evaluation, including:

- Equipment delays as LMS vendors scramble to support upgrades and new LMS

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installs
- Delays with trade partner readiness
- Delays and changes in final guidelines and specifications

With fewer than 100 working days until the beginning of the Implementation Phase, the TraceLink Brazil Community appears to be looking at the factors that are within their control and moving ahead with their plans rather than taking a “wait-and-see” approach to Brazil compliance.

Stay informed with TraceLink’s Brazil Special Interest Group

TraceLink's Brazil Special Interest Group will continue to be the dedicated space for TraceLink customers to share interpretations of regulatory requirements; discuss the business challenges they create and how fellow members are meeting them; and get updates on TraceLink’s track and trace solutions. TraceLink’s Brazil SIG meets every two weeks on Thursdays, with upcoming meetings on June 3 and June 17. To join the TraceLink Community, visit the TraceLink communication preference center:

- Select “Join the TraceLink Community” checkbox
- Once the new options appear, select the “Brazil” check box
- Scroll to the bottom of the page and select the “Update Communication Preference” box to submit your request

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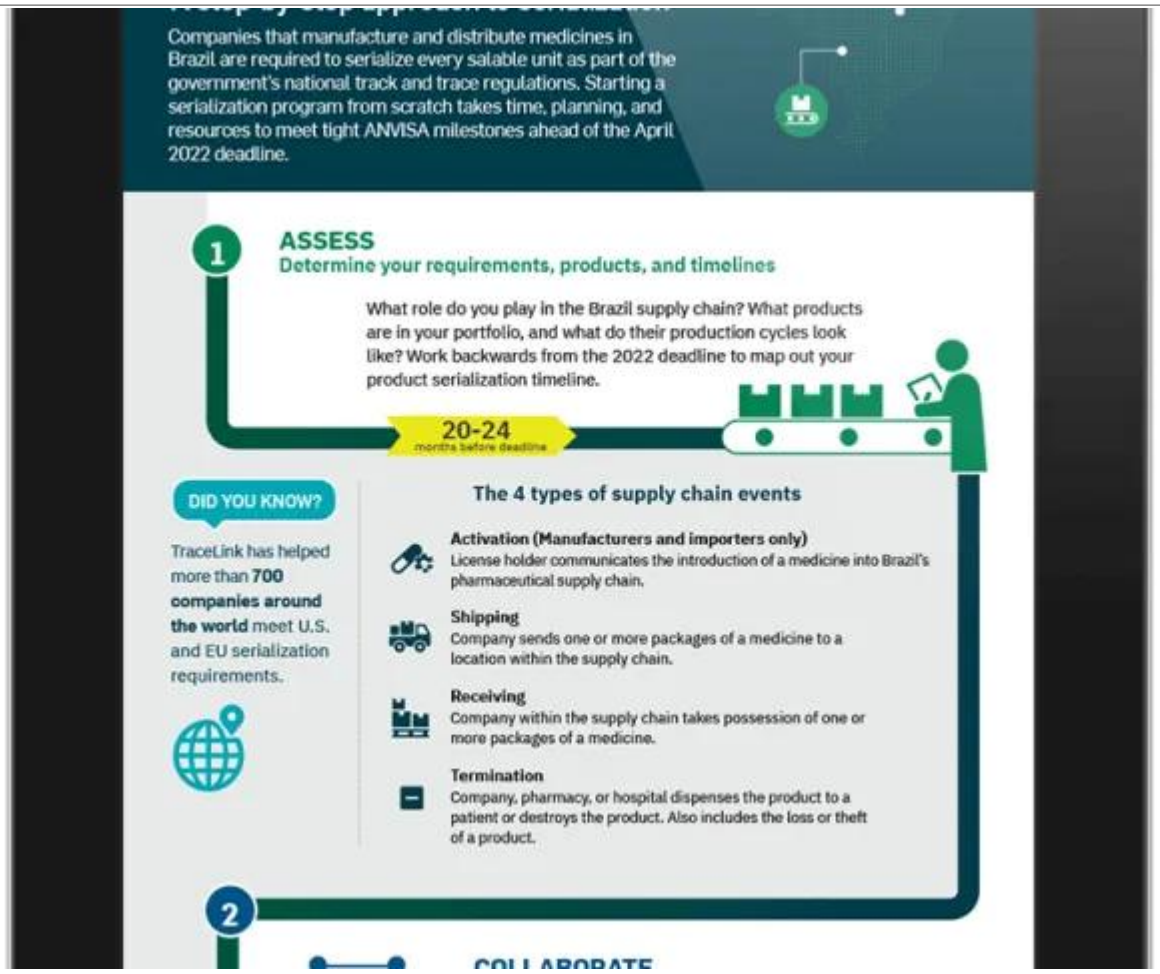
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