RESOURCES

SIG Recap: Breaking Down China Importing and Recall Reporting Choreographies

The industry continues to monitor activity by China's regulatory agency, the National Medical Products Administration (NMPA), for news and technical guidance on its Collaborative Service Platform as well as for any signs of new interim compliance deadlines. In its two March sessions, TraceLink's China Special Interest Group (SIG) reviewed the expanded compliance requirements with respect to its legacy requirements and focused on how the new compliance regime might affect specific business scenarios, including requirements for imported products, recalled products, and temperature-controlled products.

Reinforcing the need for readiness

Although the exact date has not been announced, full traceability of medicines is expected to go into effect sometime in 2022. A critical milestone will be the availability of the NMPA Collaborative Service Platform for product registration and reporting. Once the system is "live," companies should expect an accelerated pace of testing and implementation of their serialization and reporting solutions and core capabilities:

Traceability Reporting

- Provide accurate information to regulatory authorities across the whole

process of drug manufacturing and distribution
- Retain drug traceability records and certificates for 5+ years

Serialization

- Apply a unique DTC (drug traceability code) to the sales packaging unit at each level
- File each drug traceability code to the NMPA Collaborative Service Platform prior to allocation and application
- Create aggregation relationships among the drug traceability codes at all levels

Supply Chain Data Exchange

- Provide traceability information to downstream enterprises or medical institutions for product verification and acceptance

The China SIG also regularly reviews and analyzes the significant “data gap” companies face as they transition from the 2015 reporting requirements to the 2019 reporting requirements. In all, TraceLink has identified as many as 15 additional system information sets—including master data and transactional data sets—as well as an estimated 35 data field-level gaps within those sets. It will be critical for companies to have their data prepared for testing as soon as the NMPA system is ready.

Breaking down three key business scenarios

A primary goal of the TraceLink SIG is breaking down different reporting choreographies and identifying the business entities and the roles they play in manufacturing, importing, distributing, and dispensing medicines. In March, the SIG looked at three important scenarios:

- **Production Outside China, Import, and Sell at Free Trade Zone.** The SIG looked at the basic reporting requirements for products entering China

and ultimately finding their way to the China Free Trade Zone. The roles of the manufacturer, customs warehouse, and importer in reporting were mapped out, as well as the Drug Self-Inspection and Test Information and Delivery Order/Sales Information reporting requirements.

- **Drug Recall Reporting.** An especially important—and complex—topic was understanding the reverse logistics of recalled products, how these transactions will be reported, and who is responsible for reporting them. Critical dependencies between the Marketing Authorization Holder (MAH) and the importer were also discussed.
- **Temperature Data Upload into the Collaborative Service Platform.** TraceLink and its customers have noted the absence of temperature data in reports to be submitted to the Collaborative Service Platform. Temperature data is a component of traceability datasets published by the NMPA and is required for daily reporting of cold chain products in storage and at warehouse receipt. This possible omission has been communicated to the NMPA and the SIG is awaiting confirmation as to whether this data will be added to the reporting requirements.

Setting priorities for 2021

TraceLink's Senior Director of Industry Marketing and Community, Allan Bowyer, continues to collect ideas from members of the China SIG on areas of key concern. Looking ahead to the second quarter, a poll of China SIG attendees revealed an extensive list of concerns and topics for upcoming sessions:

- Managing intermediate deadlines
- Product coding determination
- Transitioning between old and current traceability requirements
- Closing data gaps between the legacy reports and the current traceability reports
- Meeting the downstream data exchange requirement: Tencent, AliHealth, or other partner

- Aligning plans among Global, Affiliate, and (Supply Chain) Partner
- Mapping product importation flows (physical, informational, financial)

Stay informed with TraceLink’s China Special Interest Group

As 2021 unfolds, TraceLink’s China Special Interest Group will continue to monitor new developments throughout the year to ensure that our customers and their partners have the information and insight they need to ensure compliance and business continuity. Stay up to date on China’s compliance regulations with our weekly regulatory updates.

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The 2019 China Drug Administration Law introduced track and trace terms and agencies that you need to understand for your China compliance strategy.

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