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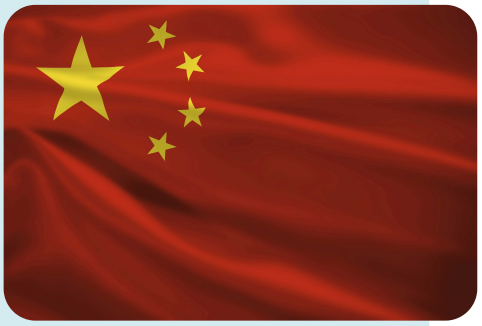
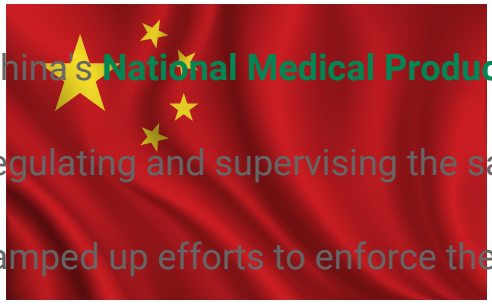
Pharmaceutical Track-and-Trace Regulatory Update: China Speeds Up Efforts to Implement Full Traceability Requirements



The Chinese government's effort to implement comprehensive pharmaceutical track-and-trace requirements is picking up momentum as long-awaited regulations go into effect and development continues on the country's digital traceability monitoring system.



China's **National Medical Products Administration (NMPA)**, which is responsible for regulating and supervising the safety of drugs, medical devices, and cosmetics, has also ramped up efforts to enforce the country's Online Drug Sales regulations and put a new requirement into effect that is designed to empower patients and consumers with more information about medicines and other non-prescription products they use.

The best way for TraceLink customers to keep up with the latest news and developments in China's serialization and track-and-trace laws is to join **TraceLink's China Special Interest Group**. The group meets regularly to review the latest updates

and announcements from the Chinese government, gain a better understanding of China's traceability laws and regulations, and discuss the best ways to ensure continuous regulatory compliance in the region. The China Special Interest Group has seen significant engagement from members across the pharmaceutical supply chain. Key metrics include:

- **95** companies represented at China Special Interest Group meetings in the last year.
- **155** current members
- **13** China Special Interest Group meetings held in the last year.

"Implementing medicines traceability in China is one component of the country’s long-term ambition to become a recognized world leader in the pharmaceutical industry by bolstering quality and establishing global standards," said Allan Bowyer, Senior Director of Industry and Community at TraceLink. "The NMPA has imposed intermediate requirements designed to prepare the entire supply chain for full traceability. One example of this is a new requirement for manufacturers to apply a unique identifier to medicines packs, either with the legacy Electronic Drug Monitoring Code (EDMC) barcodes or by using the worldwide GS1 standard. This requirement went into effect in June 2023."

New serialization and traceability requirements

In addition to the mandate requiring unique identifiers, the NMPA has introduced more requirements and updated pharma supply chain stakeholders on the development of the country's drug traceability system.

Earlier this year, the NMPA announced a requirement for full traceability of the Botulinum Type A injectable. The mandate states that serialized data for Botulinum Type A must be exchanged across the end-to-end supply chain using a third-party traceability system. The requirement went into effect in late February.

In April, the NMPA announced the construction of the Collaborative Service Platform, the middle tier of the country’s overall traceability architecture, which serves as a conduit between manufacturers’ traceability systems and the NMPA's provincial monitoring systems.

Additionally, China has begun to enforce existing regulations. In June, the NMPA announced enforcement actions against four companies that were found to be in violation of the country's Online Drug Sales regulations. The cases involved the sale of drugs online without proper licenses, the sale of prescription drugs without a prescription, and the sale of prohibited drugs. The government imposed fines and confiscated illegal proceeds in each case.

The NMPA has implemented a new requirement for pharmaceutical companies to provide product information to patients and consumers via a product pack barcode scan. Patients and consumers can now scan product packs with their mobile devices to find information about the manufacturer, expiration date, traceability data, contraindications, and much more.

Patients and consumers can gain access to this information by visiting a website or calling a toll free number and providing the product code. Patients can also use a mobile app to set up automatic alerts that remind them when it's time to take medications.

Learn more in TraceLink's China Special Interest Group

TraceLink continuously monitors new, emerging, and existing serialization and track-and-trace regulations in countries around the world. The **TraceLink China Compliance solution** ensures that TraceLink customers are in continuous compliance with China's track-and-trace requirements as regulations evolve over time.

To keep up with the latest developments in China serialization and track-and-trace regulations, TraceLink customers should join our **China Special Interest Group**. Meetings are held virtually via Zoom on a monthly basis.

One of the key ongoing discussion topics in the China Special Interest Group is how to manage the transition from the old product coding scheme to the globally-accepted GS1

standard. Additional upcoming topics to be covered include:

- Meeting 2023 Serialization and Consumer Query Requirements
- NMPA Platform and Infrastructure Development
- Ensuring Compliance with China's 2019 Drug Administration Law
- China Legal and Regulatory Updates and Intermediate Traceability Deadlines
- NMPA Technical Guidelines and Stakeholder Reporting Responsibilities
- Product Coding Strategies and Long-Term Planning
- Transitioning to China's Current Traceability Requirements

"We know full track and trace is inevitable in China, and the effort is picking up speed, but there has been a slow rollout of the regulations and uncertain deadlines in the past," Bowyer said. "In this uncertain environment, TraceLink's China Special Interest Group allows members to exchange ideas, approaches, and best practices for China traceability."

TraceLink Customers: Join our China Special Interest Group today!

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