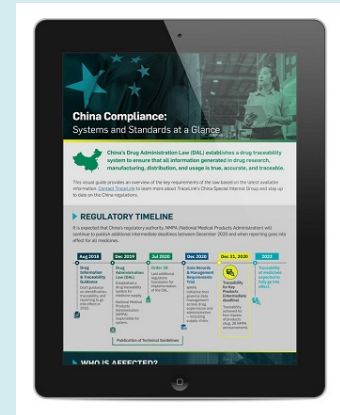




RESOURCES

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China Compliance: Systems and Standards at a Glance



China is quickly ramping up its regulatory infrastructure and setting intermediate deadlines—and you need to be ready. This visual guide provides an overview of the key features of China’s Drug Administration Law so you can begin your 2021 serialization and compliance planning now.

Topics include:

- The latest regulatory timeline, including the December deadline for 4 medicine classes
- China’s 3-tier reporting system and the importance of “horizontal integration” with downstream partners
- Master data and traceability data requirements
- Key differences between China EDMC and GS1-compatible identifiers

China Compliance: Systems and Standards at a Glance

China's Drug Administration Law (DAL) establishes a drug traceability system to ensure that all information generated in drug research, manufacturing, distribution, and usage is true, accurate, and traceable.

This visual guide provides an overview of the key requirements of the law based on the latest available information. Contact TraceLink to learn more about TraceLink's China Special Interest Group and stay up to date on the China regulations.

REGULATORY TIMELINE

It is expected that China's regulatory authority, NMPA (National Medical Products Administration) will continue to publish additional intermediate deadlines between December 2020 and when reporting goes into effect for all medicines.



WHO IS AFFECTED?



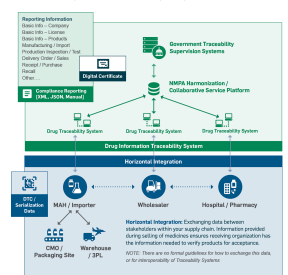
WHAT MEDICINES WILL BE AFFECTED BY THE 2022 DEADLINE?

The China government is aiming for full traceability of all pharmaceutical drugs by 2022. While the NMPA has not published a detailed list, they have set an intermediate deadline of December 31, 2020 for four classes of medicines. NMPA set an intermediate deadline for specific medicines until 2022. In the previous version of the Law, all products from the National Essential Drugs List and the Provincial Essential Drugs List were included from the beginning.



REPORTING AND COMPLIANCE CHOREOGRAPHY

Report requirements vary based on whether the company is acting as an MAH, Wholesaler, or Dispenser.



- Marketing Authorization Holders (MAHs)/Importers, Wholesalers, and Hospital/Pharmacies are responsible for reporting company and transaction data to a central system.
- A digital certificate is required for reporting to the NMPA HSP/CSP.
- Serialization and aggregation are required at each packaging level and horizontal information exchange between partners will be required.

STAKEHOLDER RESPONSIBILITIES



REPORTING REQUIREMENTS: MANUFACTURERS AND DISTRIBUTORS

Specific compliance reporting requirements depend on the role of the company or organization: manufacturer, distributor, or hospital. Individual reports will require complete management of master data ("basic information") and transaction data comprising approximately 15–40 individual data fields.

Master Data	Traceability Data
Basic Information: Domestic Drug Manufacturer	Manufacturing Information: Domestic Drug (location, products, etc.)
Basic Information: Domestic Drug Manufacturer	Drug Import Information (location, products, etc.)
Basic Information: Distributors	Drug Production Information and Test Information
Basic Information: Drug Distribution Pharmacy/Hospital	Delivery Order (basic information)
Basic Information: Pharmaceutical Distributor/Enterprise	Reverse Purchase Information
Basic Information: Drug Manufacturing License	Drug Use (Hospital, etc.) Information
Basic Information: Drug Business/Operation License	Real-time information of Drug Distributing Enterprise
Basic Information: Domestic Drug Product	Drug Batch Information
Basic Information: Foreign Drug Products Imported	Temperature Information (not reported to Collaborative Service Platform)

SERIALIZATION AND ENCODING OPTIONS

The August 2019 annex specifies allows for two validation options: the original China GS1 format and the GS1 intermediate GS128 1D barcode format. The addition of the GS1 standard reflects China's important role in the global pharmaceutical supply chain.

Format Options	Composition
• GS1 DataMatrix (2D barcode)	• Drug Identification Code (DIC)
• GS1 DataMatrix (2D barcode)	• Product Code
• GS1 DataMatrix (2D barcode)	• Serial Number
• GS1 DataMatrix (2D barcode)	• Check Digit
Carrier	Optional GS1 Information
• 2D barcode	• Expiration Date
• 2D barcode or RFID	
• 2D barcode or RFID	

The Most Proven Track and Trace Solution Worldwide

TraceLink's proven compliance and serialization platform supports global planning and scalable deployment across the enterprise and ensures operational excellence through TraceLink's suite of network applications—enabling Serialized Product Performance—well as access to expert training and automated validation tools.

- 700+ customers across the global supply chain.
- A team of experts dedicated to helping customers meet China regulatory and hospital requirements since 2013, including a China Compliance Solution for the original law.
- More than 16.5 billion serial numbers commissioned worldwide.
- A trusted compliance solution partner for customers across nearly 50 countries—more than any other provider.
- Purpose-built compliance solutions that incorporate market-specific business logic, reporting workflows, and user controls.

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