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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

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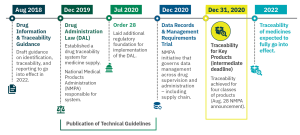
China Compliance:
Systems and Standards at a Glance

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 can set intermediate deadlines for specific medicines up 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.

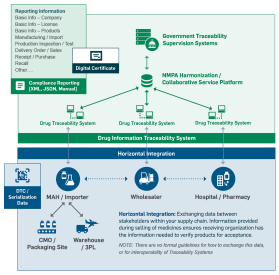
Intermediate deadline:
Special Product Categories
December 31, 2020

- Products of national drug centralized procurement
- Narcotic drugs
- Psychotropic drugs
- Blood products

Pharmaceutical Drugs

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 Hospitals/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

- Provide accurate information across the whole process of drug manufacturing and distribution to regulatory authorities.
- Retain drug traceability records and certificates for 5 years.

Serialization

- Apply a unique drug traceability code to the sales packaging unit at each level.
- File each drug traceability code to the 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.

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 complex management of master data ("basic information") and transaction data comprising approximately 15 – 40 individual data fields.

Master Data
Basic Information – Domestic Drug Manufacturer
Basic Information – Overseas Drug Manufacturer
Basic Information – Distributors
Basic Information – Drug Use Organizations (Pharmacy, Hospital)
Basic Information – Pharmaceutical Distribution Enterprises
Basic Information – Drug Manufacturing License
Basic Information – Drug Business/Operations License
Basic Information – Domestic Drug Products
Basic Information – Foreign Drug Products (Imported)

Traceability Data
Manufacturing Information – Domestic Drugs (locations, products, codes, etc.)
Drug Import Information (locations, products, codes, etc.)
Drug Production Self-Inspection and Test Information
Delivery Order / Sales Information
Receipt / Purchase Information
Drug Use (Hospital, etc.) Information
Retail Information of Drug Distributing Enterprise
Drug Recall Information
Temperature Information (not reported to Collaborative Service Platform)

SERIALIZATION AND ENCODING OPTIONS

The August 2019 amendment allows for two serialization options: the original China EDMC format and the GS1-compatible ISO/IEC 15459 format. The adoption of the GS1 standard reflects China's important role in the global pharmaceutical supply chain.

Format Options
- DEA/eCode standard (more frequent)
- ISO/IEC 15459 (GS1 compatible)

Composition
- Drug Identification Code
- Production Code
- Serial Number
- Check Bit

Carrier
- 1D barcode, 2D barcode, or RFID
- Network (cloud) – detailed information

Optional GS1 Information
- Lot Number
- Manufacturing Date
- Expiration Date

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—including Serialized Product Intelligence—as 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 technical 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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