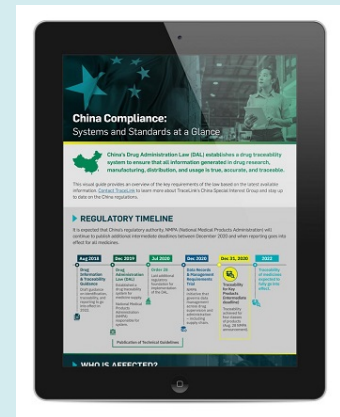




RESOURCES

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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

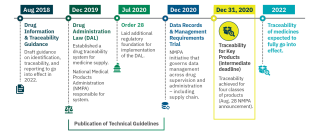
China Compliance: Systems and Standards at a Glance

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.



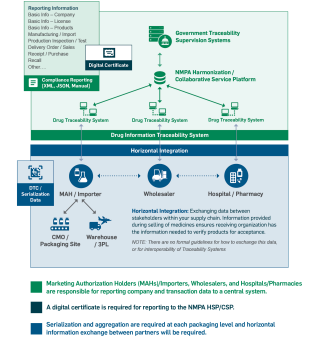
WHAT MEDICINES WILL BE AFFECTED BY THE 2022 DEADLINE?

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.

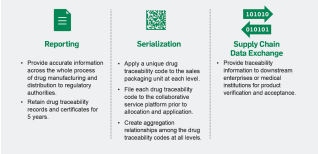


REPORTING AND COMPLIANCE CHOREOGRAPHY

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



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 Locations, products, etc.
Basic Information: Overseas Drug Manufacturer	Drug Import Information (location, products, etc.)
Basic Information: Distributors	Drug Production Information and Test Information
Basic Information: Drug Distributors/Pharmacy/Hospital	Delivery Order (Sales Information)
Basic Information: Pharmaceutical Distributor-Wholesaler	Reverse Purchase Information
Basic Information: Drug Manufacturing License	Drug Use Hospital, etc. Information
Basic Information: Drug Business/Operation License	Basic Information of Drug Distribution Enterprise
Basic Information: Domestic Drug Products	Drug Retail Information
Basic Information: Foreign Drug Products Imported	Temperature Information (not reported to Collaborative Service Platform)

SERIALIZATION AND ENCODING OPTIONS

The August 2019 announcement allows for two-level division across the original GS1 (EAN) format and the GS1 international (GS1 2489) format. The addition of the GS1 standard reflects China's important role in the global pharmaceutical supply chain.



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