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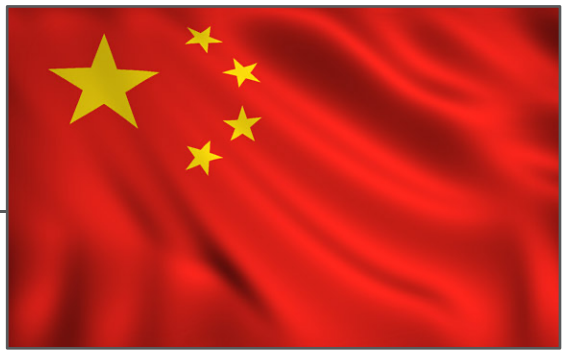
China Electronic Drug Supervision System



Regulatory Update

August 2020

Regulatory Agency	China National Medical Products Administration (NMPA)
Regulation Name or System Name	The regulations formerly known as the 12th Five-Year Plan of National Drug Safety, based on the Guidance for Drug Electronic Supervision Technology developed by State Bureau, the system was known as "Electronic Drug Supervision System". This system is suspended (terminated) as of February 2016. The remainder of this document explains our best estimate of what may be in place as of the date of this document revision, based on translated documents we have been able to obtain. The reader should be especially cautious when making decisions about compliance in China. Do not use our summary as your only source for information when making those decisions. On August 23, 2019 the State Drug Administration posted three new draft guidance documents for comments by stakeholders. The final version of the implementation guide was published on October 31, 2018. In September of 2019 the NMPA published four document specifying "datasets" for manufacturers, distributors, dispensers and "consumer inquiry". A fifth document was also published with technical requirements for data exchange. On March 11, 2020, the NMPA published five new documents containing the basic datasets for their drug traceability system for supply chain participants, and the basic technical requirements for data exchange. On July 2, 2020 the NMPA announced a traceability pilot, to begin on December 1, 2020. The contents of this Systech Regulatory Update are our best interpretation of these draft and final documents. The system is called "National Drug Regulatory Information Standard"
Compliance Dates	"Key products such as vaccines, narcotic drugs, psychotropic drugs, pharmaceutical precursor chemicals, blood products, etc. should take the lead in establishing a drug information traceability system; basic drugs, medical insurance reimbursement drugs and other products that consumers are generally concerned about **as soon as possible** to establish a drug information traceability system." In December 2019 the China National Medical Products Administration (NMPA) announced that "…*vaccine information traceability systems should be established through*

	the country to achieve traceability of the entire process of all marketed vaccines and ensure that the smallest packaging unit of the vaccine is traceable and verifiable…" **by March 31, 2020**. No implementation details are known.
Applies to	"…Marketing authorization holders, drug manufacturers, pharmaceutical operating units to establish the drug traceability systems and drug supervision and management departments of supervision and inspection. It does NOT apply to the production and operation of Chinese herbal medicines, raw materials and special packaging preparations".

Unit-level Packaging ("units of sale")

Barcode Symbology	"One-dimensional barcode, two-dimensional barcode or RFID tag, etc. can be selected as the carrier of the drug traceability code according to the actual needs. Drug traceability codes shall be recognized by equipment and the human naked eyes."
Barcode Contents	The Drug Traceability Code (DTC) is a China-specific 20-character code, or any code that "…complies with the coding rules of relevant international standards prescribed by the International Organization for Standardization (ISO) (e.g. Standards for ISO/IEC 15459 Series)." The DTC should be associated with: • Name of the drug listing license holder • Name of the drug manufacturer • Generic name of the drug • Drug approval number • Drug standard code • Dosage form • Formulation specification • Packaging specification • Date of manufacture • Batch • Expiration date And it should contain a serial number and a check digit
Serial Number Randomization	Not specified
Serial Number Reuse	None
Human Readable Expiry Date Format	Not specified
Barcode Data Encoding	Not specified
Product Code notes	See "Barcode Contents"
Free Samples must be marked?	Not specified
Stickering after manufacturing allowed?	Not specified

Homogeneous Cases

Barcode Symbology	Not specified
Barcode Contents	Appears to be the same as units

Logistics Units

Logistics Units Must be Serialized?	Not specified

Data Capture

Unit-to-Case Aggregation Capture?	Yes

Data Exchange

Send Unit Data to Government Repository?	Probably
Send Unit Data to Third-Party Repository?	No
Send Unit Data to Trading Partner?	Yes
Send Aggregation Data to Government Repository?	Probably
Send Aggregation Data to Third-Party Repository?	No
Send Aggregation Data to Trading Partner?	Probably

Authentication

Who Offers Data Repository for Authentication?	Provinces
Manufacturers Must Register Shipments in Repository?	Probably
Downstream Trading Partners Must Authenticate on Receipt?	Yes
Downstream Trading Partners Must Authenticate on Shipment?	Apparently not

Government Reporting

Manufacturer Activity Reported?	yes
Downstream Trading Partner Activity Reported?	Yes

Challenges

- Documents from the CFDA, NMPA and the State Drug Administration are difficult to obtain and translate accurately so information can be late and/or incomplete.
- The latest draft documents do not seem to have much in common with the documents that were published sparsely over the previous three years, raising the appearance of drifting priorities and requirements.
- The first traceability deadline of the new decade has passed (vaccine traceability) with no detailed requirements, making it seemingly impossible to meet. Vaccine manufacturers should check directly with the NMPA to get their detailed requirements.

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About Systech

Systech provides digital product authentication and traceability solutions to combat counterfeiting, prevent diversion and meet regulatory compliance. Built on decades of experience as the leader in pharmaceutical serialization, our comprehensive brand protection suite delivers the real-time insight, actionable product data, digital connectivity and consumer engagement functionality needed to fight supply chain threats.

Global brands across industries rely on us to keep their products authentic, safe and connected—from manufacturing to the consumer's hands. Together we are revolutionizing brand protection!

Regulatory Questions?

Contact us at info@systechone.com or visit us online here.