

The Global Language of Business

Implementation reality – vaccines pilot in China

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Vaccine regulatory policy of China



- On Nov. 11, 2018, the State Administration for Market Regulation released the draft of the Vaccine Administration Law to the public to solicit their opinions.
- The draft is around vaccine administration legislation, puts emphasize on its characteristics, and intensifies its risk management, full control, strict supervision, and social co-governance, to effectively assure a safe, effective, and normative vaccination.
- On Jan. 4, 2019, the draft was deliberated on the 7th meeting of the 13th National People's Congress Standing Committee and then released to the public on the Congress's official website.







Article 10 of Vaccine Administration Law

- **The State** applies an information-oriented vaccine traceability system.
- The drug regulatory and public health departments under the State Council are responsible for setting vaccine traceability norms and standards, building national information-oriented vaccine traceability collaboration platform, and integrating all information during vaccine production, circulation, and use.
- **Manufacturers** should build an information-oriented vaccine traceability system which connects to the national platform to implement traceability and identification of minimum vaccine packages during their production, circulation, and use.
- **Disease prevention and control institutions and vaccination units** should take records of vaccine circulation and use according to law, and provide the traceability information following relevant standards.





Other relevant documents

- Vaccine Circulation and Vaccination Control Ordinance (2016)
- Criterion of Vaccination (2016)
- Immunization planning—child immunization program and instructions (2016)
- Pharmaceutical trading quality management practices
- > The State Council's guidance on accelerating the construction of important product traceability system
- > The State Food and Drug Administration's guidance on promoting food and drug production operators to improve the traceability system
- Guidance on promoting the construction of important product informatization and traceability system
- > The notice of the construction of modern supply chain system in the circulation field in 2018



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Introduction: Backgrounds





- Last year, a Chinese vaccination firm, Changchun Changsheng, had falsified production data for its rabies vaccine. The scandal sparked a huge outcry in China.
- President Xi Jinping called for improving the long-term oversight mechanism for vaccine production, and firmly upholding the bottom line of public safety and safeguarding people's health.
- Good manufacturing and regulatory practices should be designed to prevent problems in the process of ensuring quality vaccines.



Introduction: Backgrounds





- Till now, a large amount of paperwork has been involved in the vaccine supply chain and logistics.
- Frontline vaccination workers have to deal with 17 normative worksheets for both national and local archives.



Introduction





- Traceability on single-dose level
- Adoption of GS1 specifications
- Establishing a human–vaccine association
- Cross-platform deployment
- Adoption of blockchain technology

Every dose of vaccine and every participant can be traced back. The safety of information can be guaranteed.



Introduction







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| | | Intelligent vaccination | | |
|---|---|---|---|--|
| Blockchain | GS1 | platform | IoT | Others (VVM, AI, etc.) |
| Allow sharing, use, and statistical analysis of vaccine and health data, and secure the data with encryption. | Allow a traceable management during vaccine's manufacturing, transportation, warehousing, vaccination, and follow-up health assessment. | Allow integrating information resources such as vaccine, children, parents. | Allow implementing vaccine traceability in an IoT system. | More techniques are supposed to be implemented in vaccine traceability system, e.g., VVM label and AI. |





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Recommendation

Bar codes are recommended on all packaging levels used by manufacturers, with the exception of primary packaging, and should conform to GS1 standards and associated specifications. Bar code data should include the Global Trade Item Number (GTIN), lot number, and expiry date.





31 March 2015



Either GS1-128 or DataMatrix code can be used according to the package it is displayed on. The coding structure is shown as follows:

| Application identifier | Title | Content | String format |
|------------------------|---------------|----------------|---------------|
| 01 | GTIN | 12017161991004 | n14 |
| 17 | Expiry date | 191201 | n6 |
| 10 | Batch/Lot | 12345 | an…20 |
| 21 | Serial number | 1234567892 | an…20 |



GS1-128



DataMatrix





- Codes are assigned under GS1 rules.
- Vaccine information is included in the package.
- Match GS1 codes with China Electronic Drug Monitoring Codes (EDMC) in different ways.
- Storage procedures are recorded by scanning codes on the product.

















During the transition period, GS1 code can be assigned:

- **1.** during the circulation process, and
- 2. at the user end.

However, the assigning and labeling of GS1 codes will eventually become manufacturers' duty. Otherwise the ultimate full-circulation traceability will not be completed.







Temperature monitoring using IoT technology



Passive/active thermal labels

Passive/active thermal labels perform well in storage scenarios







Integrative overall solution

Solutions cover scenarios including chips, labels, devices, and platforms for quick interventions.



Industry-leading technology

Devices are high-band, high-precision, and with long service life and adjustable read/write distance, and support a variety of scenarios.











Supporting techniques: Blockchain



Whole-process monitoring



Blockchain technology can help in recording and tracking information from each part of the circulation. Regulatory pressure can consequently be decreased.

Decentralization

Distributed storage system build with blockchain technology will realize the decentralization of the data, to protect the data from being deleted or falsified.



GS1 + IoT + Blockchain



Smart contract and blockchain technique can together assure the security of both the information and the product. Effectiveness of the vaccine will be guaranteed. Blockchain technique can also be implemented in medical insurance, health industry, and ecological communities.



Security assurance

Other possible applications



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Zhoushan (pilot city):

- Location Zhejiang province, China
- Area

- 22,200 km²
- Population 1,121,261







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Monitor all the information during

vaccine circulation

Integrate different monitoring methods



Collect information about the children and their parents.

Implement an alert mechanism





How the temperature changes in each doze?

Who is in charge of the vaccination?

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Convenient vaccination service

- Vaccination booking service
- Health course programs
- Increase participation of the parents
- Online payment













Multi-function system and its application









Vaccine management form

Current inventory status

Inventory changes
in the jurisdiction in
a certain timeMonthly statistical
data of the usage of the jurisdiction in a
the vaccine and
syringe







Advantages of the platform in vaccine industry

- 1 Smooth matching and recognition of GS1 codes
- 2 Low system maintenance cost





Thank you!



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