The Global Language of Business

From Manufacturer to Patient

- GS1 Pilot in China

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Agenda

- **Pilot Background**
  - PSM Research on Drug Traceability System
  - Policy Changes
- **Pilot Introduction**
  - Governance Structure
  - Pilot Principles
  - Current Status
- **Next step**
- **Summary**

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Partnership for Safe Medicine (PSM)

Established in Nov2012 by 13 members associations, cover the whole drug supply chain from manufacturers, distributors, pharmacies, hospitals,

- Supported by Government
- Public Needs
- Social Responsibility
- Reference International Best practice

PSM Research on Drug Traceability System

Background :

- China electronic bar code system failed to reach patients and was suspended by CFDA in Feb 2016
- The publication of a series of document on drug trace and track from CFDA and State Council in 2016 with no implementation details

Purpose:

- Explore elements of an efficient and effective China drug traceability system
- Provide recommendation to policy makers
- Explore solutions to stakeholders in the whole supply chain: manufacturers, distributors, pharmacies, hospitals

PSM Research on Drug Traceability System

Key Milestones:

- *Kick off meeting*: Sept 2016, participated by PSM member associations and CFDA（now NMPA)
- *Field visits and interview*: over *50* field visits and interview over *1000* peoples
- *International symposium*: two international symposiums in Nov 2016 and Dec 2017, experts/regulators from US, EU, Argentina，APEC and etc. presented international best practices
- *Survey*: distributed over 1000 questionnaire and collected 860 responses, including 421 responses from hospitals, 200 from pharmacies, 108 from manufacturers, and 131 from distributors
- *Report:* was presented and submitted to **5** ministries in Dec 2017

PSM Research on Drug Traceability System

Key findings:

China Drug Traceability System using China e-code

- Reduced management efficiency of the supply chain
  - Apply China e-code prior to manufacturer of each batch
  - Not compatible with logistic platforms
- Not aligned with domestic and international practice using GS1
- Failed to achieve regulatory objectives of ensuring patient safety
  - Low scan rate (<5%) of China e-code at pharmacy and CDC and almost zero at medical institutions
  - Lose of traceability during the supply chain
- Caused concern of the security of the database
  - Ownership of the data
  - Security of the database

PSM Research on Drug Traceability System

Conclusions:

An efficient and effective drug trace and track system:

- Must reach to the patients in the end
- Shall direct integrate into global logistics system and help enterprises/institutions to improve supply chain management efficiency
- Shall refer international best practice and adopting global standards

Key recommendations:

- **To adopt GS1 standards**
- **To conduct a pilot to demonstrate proof of concept of an alternative drug traceability system in China that uses GS1 global standards**

Policy Changes

2016.1	**State Council:** *Opinions for Accelerating Establishment of Important Product Trace and track system (document 95)* - Important products include pharmaceuticals
2016.2	**CFDA (now NMPA):** *Notice on Suspending the Implementation of National Electronic Supervision Code" (Document 40)*
2016.7	**CFDA (now NMPA):** *Decision of Modifying the "Management Specification for Drug Supply Quality" (Document 28)* – Delete electronic bar code requirements – Require manufacturer/distributor to establish/maintain trace and track system
2016.9	**CFDA(now NMPA):** *Opinions for Further Perfecting Drug Trace and Track System (Document 122)* – Enterprises' responsibility to establish drug traceability system – Encourage to use IT technology – Encourage 3rd party service provider – Encourage industry association to establish platform – Do not mandate specific 3rd party service provider – Cover drug, medical device, cosmetics, raw materials and excipients

Policy Changes

2017.10

Ministry of Commerce, Ministry of Industry and Information, Ministry of Public Security, Ministry of Agriculture Ministry、General Administration of Quality Supervision, Inspection and Quarantine 、CFDA: *Opinion about promoting information technology on Important Product Trace and track system (Ministry of Commerce document 523)*

- Till 2020, preliminary establish a nation-wide, cooperative trace and track system on important products, harmonize trace and track standards and system
- Implement enterprise responsibility on drug trace and track system, step-wised realization of a full trace and track system from manufacture to distribution to usage
- Promote harmonization toward international standards

2017.12

Ministry of Commerce and Ministry of Finance: *Notice on construction of modern supply chain system, （Document 337）*

- Supply chain system construction should starting from GS1 global trade item number…
- Linkage of different package level and use information technology

Policy Changes

2018.2

CFDA (now NMPA) *Solicitation of Public Opinions on Rules of Medical Device Unique Identifier (UDI) (Draft for Comments, 1st version)*

2018.9

State Administration for Market Regulation: *Solicitation of Public Opinions on Rules of Medical Device Unique Identifier (UDI) (Draft for Comments, 2nd version)*

- Refer US FDA, IMDRF regulation and guidance
- Refer international standards
- Encourage issue agency to adopt international standards

2018.9

NMPA: *Solicitation of Public Opinions on Guidance for the Construction of Drug Traceability Information System (Draft for Comments)*

- Step-wised implementation of drug serialization and full traceability, starting from essential drugs and drug in the reimbursement list, and expand to all drugs by 2022
- General Rules for Drug Traceability Code
- Drug Traceability Information System Construction Guidelines

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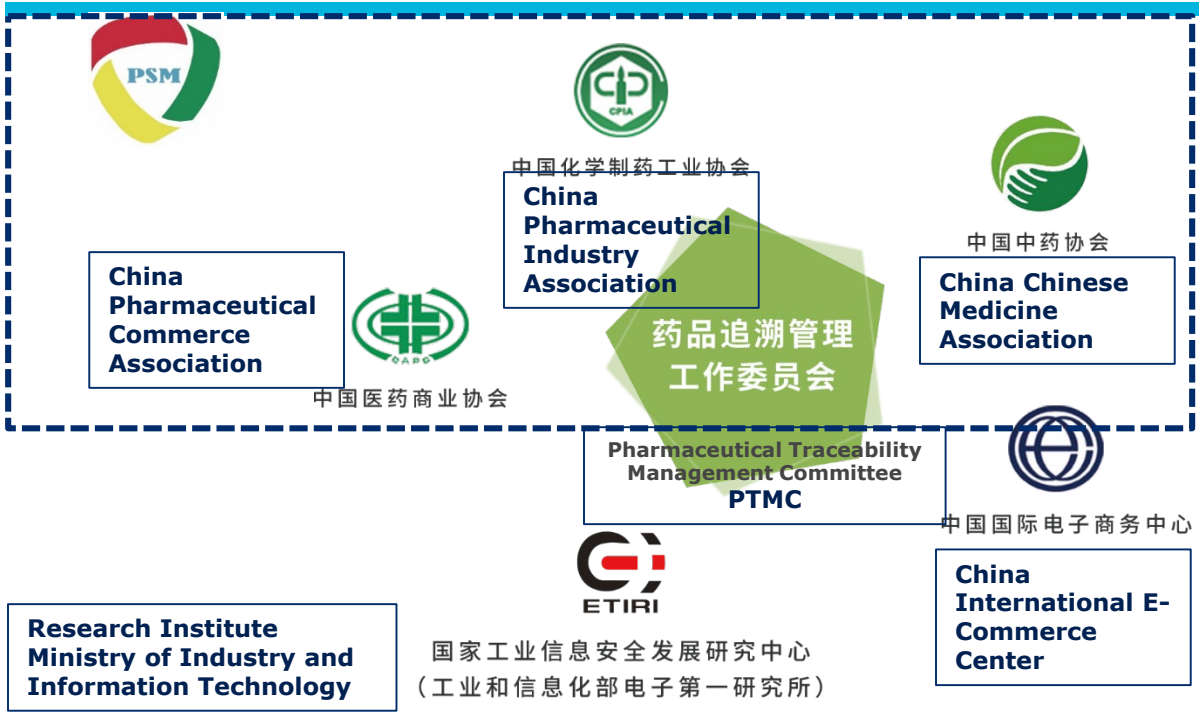
Governance Structure



Sponsors

- Ministry of Commerce
- Ministry of Industry and Information Technology
- Ministry of Labor and Social Security (now National Medical Security Bureau)
- National Health & Family Planning (now National Health Commission, NHC)
- China Food & Drug Administration (now National Medicinal Products Administration)
- State Administration of Traditional Chinese Medicine of the People's Republic of China (Report to NHC)
- Standardization Administration of the People's Republic of China
- State Council Deeping Healthcare System Reform Office

Pilot Principles

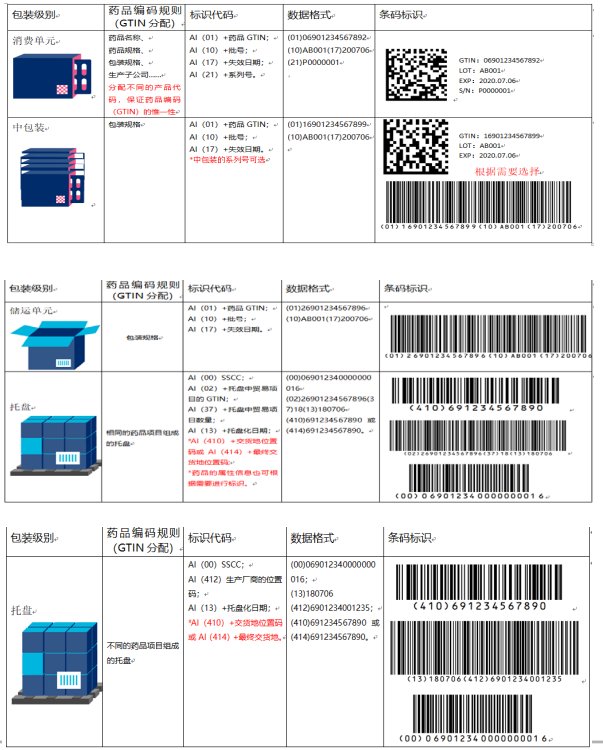
1. The GS1 global system of standards will be used. Product will be identified with a GS1 2D Data Matrix that includes the four standard data elements—GTIN, batch, expiry, and serial number
2. The pilot is voluntary, stakeholder-developed and –managed under the support of Pharmaceutical Traceability Management Committee (PTMC) ; NMPA and other government agencies shall be informed in advance and throughout the pilot and their support/supervision will be sought
3. The pilot will be open to all willing participants who align with the pilot's objectives and principles
   ① *There will be no fees for participating in the proof of concept – every party will cover their costs*
   ② *Participation of local Chinese manufacturers will be sought*
   ③ *One single traceability solution will not be selected through the pilot. Solution providers that agree to these principles may offer solutions.*
4. A drug traceability system that uses the GS1 global system of standards should be phased in after the GS1 2D barcode is implemented on the packaging of the chosen drugs

Pilot Principles

5. Manufacturers will generate their own serial numbers, conforming to GS1 standards and
   according to industry best practice
6. The GS1 Data Matrix will be affixed to the saleable unit and full homogenous cases
7. Manufacturers will aggregate saleable units to cases
8. Manufacturers will select the drugs/GTINs they will include in the pilot
9. Wholesalers and hospitals/pharmacies will scan and verify the serialized
   product
   - *Verification may be phased in, with wholesalers verifying first, hospitals and retail pharmacies later when capabilities are established.*
10. Traceability model will need to be defined and refined
11. Interoperability should be ensured between all data platforms developing in China.

Current Status

- Kick off meeting was held in May 2018, so far 3 F2F meetings were held
- Agreed on pilot governance structure and principles
- Participants confirmed:
  - Three domestic manufacturers
  - Two MNCs
  - Two 3PLs
- GS1 implementation standards finalized
- Joint comments on the NMPA draft guidance being developing



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Next Step

1. Provide comments on draft guidance to relevant government agencies and advocate policy change
2. Recruit pilot participants from manufacturers, distributors, Pharmacies and hospitals
3. Align with all participants and key stakeholders on duration, objectives and measurement criteria for the pilot
4. Explore traceability solutions
5. GS1 training and education to all stakeholders

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Summary

An efficient and effective drug trace and track system

- Must reach to the patients and increase patient safety
- Shall drive supply chain efficient
- Shall adopt global standards

A single global standards provides huge cost savings and patient safety benefits

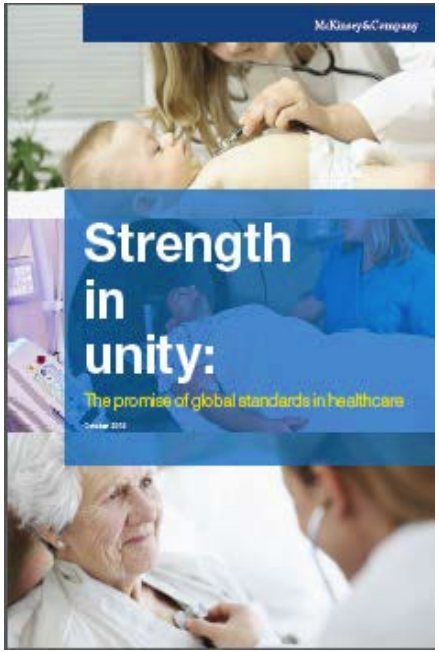
"Implementing **global standards** across the entire healthcare supply chain **could save 22,000-43,000 lives** and avert 0.7 million to 1.4 million patient disabilities"

•"Rolling out such standards-based systems globally **could prevent tens of billions of dollars' worth of counterfeit drugs** from entering the legitimate supply chain"

•[We] "estimate that **healthcare cost could be reduced by $40 billion-$100 billion globally**" from the implementation of global standards

•"Adopting **a single set of global standards** will cost significantly less than two" (between 10-25% less cost to stakeholders)

McKinsey report "Strength in unity: The promise of global standards in healthcare"
http://www.gs1.org/healthcare/mckinsey



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