Shanghai New Regulation on Medical Devices

Berlin, January 30

Zexia Huang, GS1 China

The global language of business

www.gs1.org

Contents

- About GS1 China
- About healthcare sector in China
- Shanghai new regulation on medical devices
- Implementation guideline for the Regulation: The application of GS1 ID & Barcode
- Q & A

China

GS1 China

Chenghai ZHANG, CEO

Mission

- To organize, coordinate, manage article numbering, bar coding and identification work for multi-sectors at national level
- To establish and maintain article numbering and identification system based on GS1 standards in China
- To promote and help to implement GS1 standards concerning bar code and RFID technologies and data exchanges in China

China

GS1 China in Number

- Neutral and non-profit organization
- Established in 1988
- Joined GS1 in 1991
- 46 branches
- Over 100,000 members so far

GS1 HUG

Healthcare Sector in China

Governors in Healthcare Sector

SFDA (State Food and Drug Administration)

- Main regulator of the industry on food, pharmaceuticals and medical devices

MoH (Ministry of Health)

- For demand side mainly via hospitals

NDRC (National Development and Reform Committee)

- To specify the maximum price for medical product

AQSIQ (General Administration of Quality Supervision, Inspection and Quarantine)

- SAC (Standards Administration of China): National Standards Body
- Type Approval for Medical Device and Conformity Assessment

Comparison of TOP Healthcare Companies in US, Japan, EU and China

Country	Number of TOP Companies	Total Sales Revenue
US	3	95%
Japan	5	80%
EU	3	65%
China	3	23%

(2006)

China's TOP 3:

Sinopharm

Shanghai Pharma

Jointown Group

GS1 HUG

Shanghai Regulation on Medical Devices

Why

Why

- To *strengthen management of production*, operation and usage of implants
- To *fight against illegal production*, sale and use of fake and bad quality medical devices
- To refrain from business *bribery linked* with purchasing and marketing

What, when

What

- *Shanghai FDA[2006] No. 751: Opinions on Further Strengthening Management on Implantable Medical Devices in Shanghai, issued on November 7, 2006*

When

- Effective as of January 1, 2007 for implants manufacturers and operators
- Effective as of April 1, 2007 for medical institutions

Shanghai Regulation - Article 1 – General

Article 1:

To build up product tracking and tracing system for implants.

- Enterprises in scope
  - Implant manufacturers, operators (wholesaler/distributor/dealers) and user units

- Products in scope

  Implants, and currently including:
  - Internally fixed implants for orthopedics
  - Artificial joint / lens / breast
  - Implantable cardiac pacemaker
  - Artificial heart valve
  - Stent / intervention devices in blood vessels and channels
  - Other metal or hyper molecular implant

Shanghai Regulation - Article 2 – Manufacturer

Article 2:

Be fully responsible for product quality and tracking and tracing after product launching onto market.

- To specify product tracking method and product code allocation rules in documentation
- To update tracking information in time and keep the accuracy of the information
- To record information of patient who receive an implant

Shanghai Regulation - Article 3 – Manufacturer

Article 3:

Implants on market should have unique ID for tracking and tracing and manufacturer should provide basic product information to their dealers and medical institutions.

The tracking information should include * :

- Product characteristics code
- Product tracing code
- Manufacturer name / place
- Product name / type/ expiry date / production date / quantity
- SFDA license No. / expiry date
- ……

*Strongly recommend to use bar code technologies.

Shanghai Regulation - Article 4 – Operator

Article 4:

Shall obtain *a License for Operation of Medical Device* and *relevant permit on business scope* and establish *tracking and tracing management system* for implants based on manufacturers requirements.

Shanghai Regulation - Article 5 – Medical Institution

Article 5:

Shall set up *Equipment & Devices Management Committee* to be responsible for the purchasing and usage of implants.

- Should not purchase or use the implants that can not be traced
- To establish qualified supplier database and implants database for tracking and tracing

Shanghai Regulation - Article 6 – Medical institution

Article 6:

Should establish *a prior notification system* and strengthen clinical usage of implants.

- Basic tracing information should be recoded on *the Operation Records* and *the Medical Record* just after operation
- Show implants list to patients or their dependents.
  - Product name
  - Product specification
  - Product characteristics number
  - Product tracing number
  - Quantity
  - Manufacturer name
  - Price

Shanghai Regulation - Article 7 & 8 – Manufacturer, Operator, Medical Institution

Article 7:

Shall adopt medical device adverse reporting *system.*

Article 8:

Shall establish their own patient/product tracking database and provide the patients and product tracking information to the local FDA and other government offices in the pre-defined format MONTHLY.

Shanghai Regulation - Article 9 & 10 – Healthcare Government

Article 9:

Shall set up an e-Platform for management and services of implants in Shanghai.

Article 10:

Shall monitor and inspect the manufacturing, management and usage of implants based on their own duties and the Laws.

Implementation Guideline for the Regulation: The Application of GS1 ID & Bar Code

A unique product ID =
GTIN-14 + Batch/Lot Number or Serial Number

A Unique Product ID Code	
Product Characteristics Code	Product Tracing Code
GTIN-14	Batch/Lot Number *or* Serial Number

- GTIN-14 is mandatory as a Product Characteristics Code

- A Batch/Lot number or serial number is mandatory as a Product Tracing Code

GTIN Allocation Rules in China

12,000 Chinese healthcare companies are using GTIN Allocation Rules

www.gs1.org/gtinrules

GTIN分配规则主页 >

GTIN分配规则主页
- GTIN分配原则概览
- 最佳应用
- 搜索GTIN 规则
- 免责声明
- 相关链接

中文 Change language

GTIN 分配规则

全球贸易项目代码，GTIN (Global Trade Item Number) 为任一交易产品（如在产品定价、定购、开发票等业务过程中）提供全球供应链标识代码解决方案。

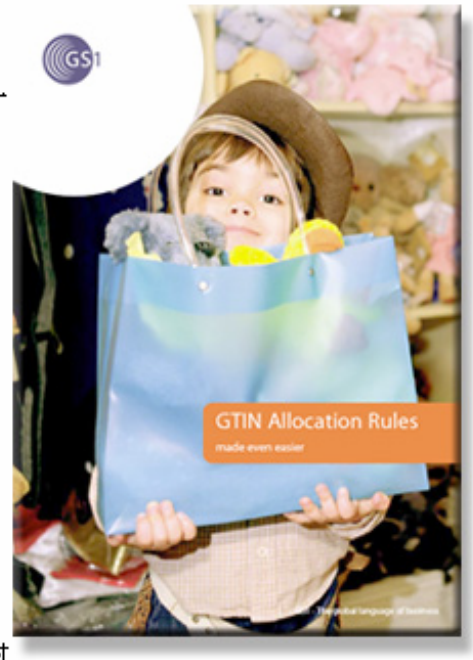
GTIN 是许多公司关键性业务（如POS扫描系统以及GDSN）的基础。 采用 相同的分配规则 ，会降低整个供应链成本。

本站点列出了涉及GTIN代码变化的常见的产品变更。

如需更多信息，请与 中国物品编码中心（GS1 China）联系。

查看GTIN 分配规则

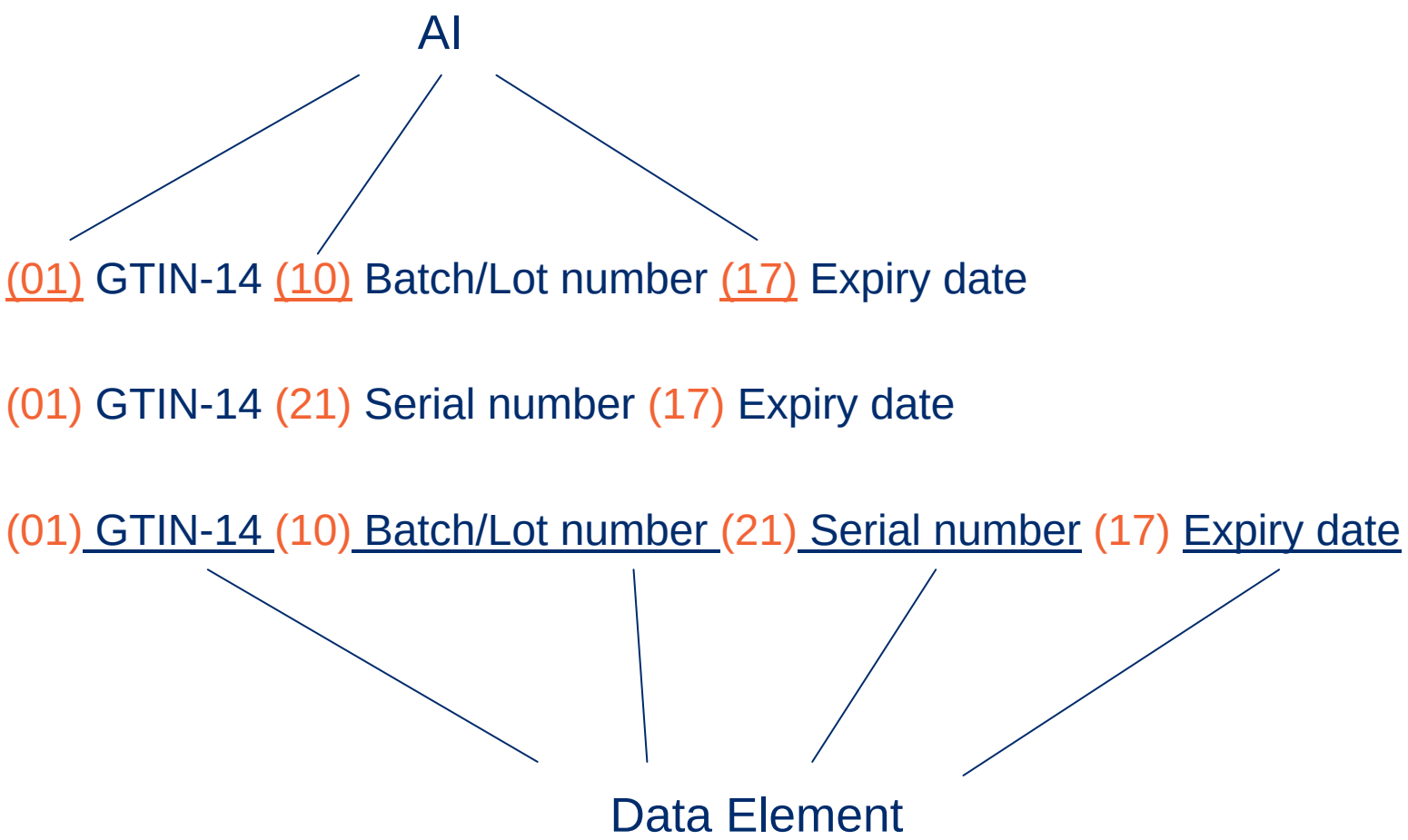
注: 所述目的是为了全球通用。仅当地方法律法规有其他强制要求时例外。



下载 GTIN 指导手册

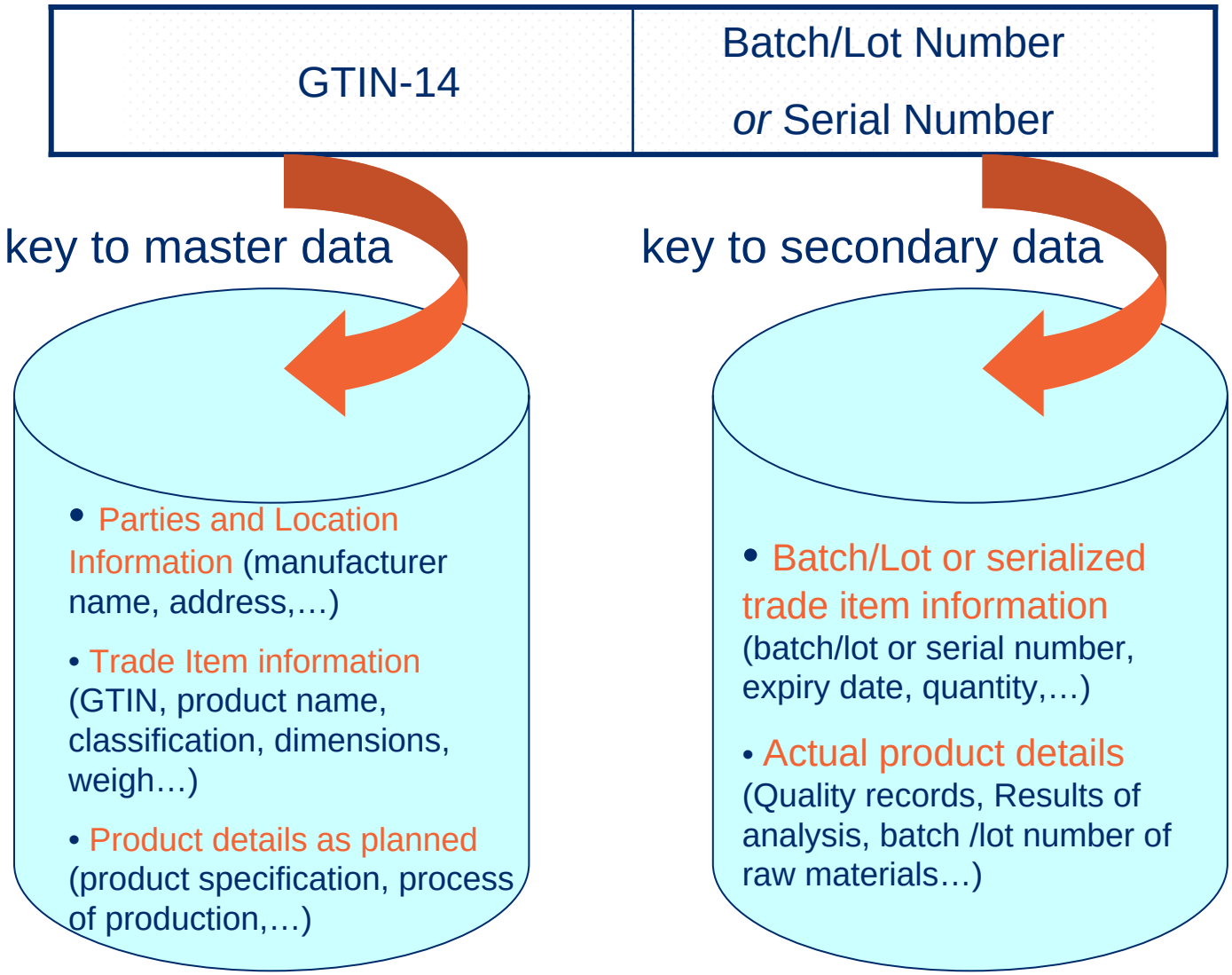
GS1 HUG

Examples



Note: Other AIs may be used.

A unique product ID is a key to product data pool



GS1-128 is mandatory for bar coding

EAN/UPC

GS1-128

For POS scanning

For tracking and tracing

From EAN/UPC to GS1-128

(from retailing to tracking and tracing through supply chain)

GS1 HUG

Solution for bar coding

All data represented in one GS1-128 symbol
☹Not recommended - Too long

Data represented in two GS1-128 symbols
☺For general use

GS1 HUG

Conclusion (1)

- Implants in Shanghai must have one unique code as a tracking indicator. GTIN and Batch/Lot number (or serial number) are mandatory.
- GS1-128 should be applied and is highly recommended to be printed in separate two lines.
- Manufacturer, operator and medical institution should build up tracking and tracing system.
- Manufacturer should update their own patient/product tracking database, and provide related information to the government regularly. Tracking methods shold be documented.

Conclusion (2)

- Manufacturer should provide the tracking information to their hospitals or dealers.
- The Regulation was put into practice as of Jan 1, 2007 in manufacturer and April 2007 in hospital in Shanghai.

Contact Information

- Shanghai FDA
  Tel: +86 (0)21 6385 5666
  www. shfda.gov.cn

- GS1 China Shanghai Office
  Contact person: CHEN Yong
  Tel: +86 (0)21 64370807 ext.210/211
  E-mail: cheny@cnsis.info
  www.cnsis.info

Contact details

Zexia Huang
GS1 China
T +32 (0)2 788 78 00
E zexia.huang@gs1.org
huangzx@gs1cn.org

The global language of business

www.gs1.org