Shanghai New Regulation on Medical Devices

Berlin, January 30
Zexia Huang, GS1 China
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
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

Chenghai ZHANG, CEO
• Neutral and non-profit organization

• Established in 1988

• Joined GS1 in 1991

• 46 branches

• Over 100,000 members so far
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

<table>
<thead>
<tr>
<th>Country</th>
<th>Number of TOP Companies</th>
<th>Total Sales Revenue</th>
</tr>
</thead>
<tbody>
<tr>
<td>US</td>
<td>3</td>
<td>95%</td>
</tr>
<tr>
<td>Japan</td>
<td>5</td>
<td>80%</td>
</tr>
<tr>
<td>EU</td>
<td>3</td>
<td>65%</td>
</tr>
<tr>
<td>China</td>
<td>3</td>
<td>23%</td>
</tr>
</tbody>
</table>

(2006)

**China’s TOP 3:**

- Sinopharm
- Shanghai Pharma
- Jointown Group
Shanghai Regulation on Medical Devices
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

• *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
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
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
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.
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.
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
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.
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

<table>
<thead>
<tr>
<th>Product Characteristics Code</th>
<th>Product Tracing Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>GTIN-14</td>
<td>Batch/Lot Number</td>
</tr>
<tr>
<td></td>
<td>or Serial Number</td>
</tr>
</tbody>
</table>

- **GTIN-14** is mandatory as a Product Characteristics Code

- **A Batch/Lot number or serial number** is mandatory as a Product Tracing Code
12,000 Chinese healthcare companies are using GTIN Allocation Rules

www.gs1.org/gtinrules

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。
Examples

AI

(01) GTIN-14 (10) Batch/Lot number (17) Expiry date

(01) GTIN-14 (21) Serial number (17) Expiry date

(01) GTIN-14 (10) Batch/Lot number (21) Serial number (17) Expiry date

Data Element

Note: Other AIs may be used.
A unique product ID is a key to product data pool

<table>
<thead>
<tr>
<th>GTIN-14</th>
<th>Batch/Lot Number or Serial Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>key to master data</td>
<td>key to secondary data</td>
</tr>
</tbody>
</table>

- **Parties and Location Information** (manufacturer name, address, …)
- **Trade Item information** (GTIN, product name, classification, dimensions, weigh…)
- **Product details as planned** (product specification, process of production, …)

- **Batch/Lot or serialized trade item information** (batch/lot or serial number, expiry date, quantity, …)
- **Actual product details** (Quality records, Results of analysis, batch /lot number of raw materials, …)
GS1-128 is mandatory for bar coding

EAN/UPC

For POS scanning

GS1-128

For tracking and tracing

From EAN/UPC to GS1-128
(from retailing to tracking and tracing through supply chain)
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

For retrieving master data

For retrieving secondary data
• 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 should 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

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www.gs1.org