Pharmaceutical Serialization and Traceability System in South Korea

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• Introduction of KPIS in South Korea
• Standardization of pharmaceutical information
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Purpose of Establishment

- Korea Pharmaceutical Information Service was established in order to collect, investigation, research and provide drug distribution data which encompasses production, import, and consumption of drugs. (Oct. 2007)
Main Functions

**Standardization of Pharmaceutical information**
- Assign and announce standard code
- Manage barcode & RFID tag
- Assign ATC code

**Collection and management of Pharmaceutical distribution data**
- Information on production and import of drugs.
- Information on supply of drugs.

**Utilization of Pharmaceutical distribution data**
- Policy making
- Review & Assessment
- R&D

KPIS (Korea Pharmaceutical Information Service)
Korea Drug Code (KD code) : GTIN-13 system

- KD code: Unique numbers assigned to each drug for identification
  - Each digit represents country code (3 digits), company number (4 digits), Item reference (5 digits), check digit (1 digit).

<table>
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<tr>
<th>Digits</th>
<th>Contents</th>
<th>GS1 prefix</th>
<th>Company number</th>
<th>Item reference</th>
<th>Check digit</th>
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<td></td>
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<td>Package unit</td>
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<td>0001-9999</td>
<td>1-9</td>
</tr>
</tbody>
</table>

EDI claim code
Standardization of drug code

Process of Assigning KD code

- **Manufacturer, Importer**
  - Assign code for pharmaceutical companies
  - Within 30 days of MFDS approval, Apply for KD Code at KPIS

- **Ministry of Food and Drug Safety (MFDS)**
  - Grant approval

- **Korea Pharmaceutical Information Service (KPIS)**
  - Submit new drug application
  - Assign and notify KD Code (within 10 days)
  - Developed and provide DB of products
  - Link drug information (on-line)

Within 30 days of MFDS approval, Apply for KD Code at KPIS
Standardization of drug code

Application of KD code

- KD code is assigned to all the drugs distributed in Korea
- All drugs distributed in Korea should be applied with a barcode or a RFID tag which holds the KD code.
- KD code is used when distributors report production, import and distribution to KPIS
Global Standard Barcode System

Major Progress

2000: Introduction of mandatory marking of barcode on drugs

2008: Introduction of the global standard barcode system regulations (GTIN-13, GS1-128 system)

2013: Mandatory marking of KD code, expiration date, and batch number on ETC drug’s barcode

2015: Mandatory marking of serial number on ETC drugs - OTC drugs may be marked as GTIN-13 system, but it can also be marked as GS1-128 system.
Global Standard Barcode System

Barcode marking system

- **The rule that marks barcodes of ETC(Ethical) drugs.**
  - ETC drugs must follow the GS1-128 system
  - Using the Application Identifier, (01) KD code, (17)expire date, (10)batch number, (21) serial number should be marked.

  (01) KD code(GTIN-13) : 8806411123459
  (10) Lot/batch number : A12345
  (17) Expiration date : 181231
  (21) Serial number : B123456789

※ Serialization is not mandatory for OTCs and prescription drugs such as fluids
Barcode marking system

- **The rule that marks barcodes of OTC (Over the counter) drugs.**
  - OTC drugs may be marked only with a KD code using a barcode according to the GTIN-13 system.

- OTC drugs can also be marked according to GS1-128 system.
  - (01) KD code, (17) expire date, (10) batch number, (21) serial number

Global Standard Barcode System
National Pharmaceutical Serialization System

Definition

- Pharmaceutical serialization system enables to track and trace the passage of drugs from production, import, distribution and consumption by identifying a unique serial number on each drug packages.

Objective

- Prevent counterfeit/illegal drugs from entering supply chain
- Faster hazardous drug recall process
- Make the distribution process transparent
- Ensuring the safety of drugs to the people
Major progress

- **2011**: A general revision of the Guideline on the Use and Management of Barcodes and RFID Tags for Drug (MOHW Notification 2011-58)

- **2016**: Mandatory to report serial number on ETC drugs for manufacturers and importers (report at the time of shipping)

- **2017**: Mandatory to report serial number on ETC drugs for wholesalers (report at the time of shipping)

- **2018**: Mandatory to report serial number on ETC drugs for all distributors (report at the time of shipping)
  - OTC drugs may be reported by the end of the next month
National Pharmaceutical Serialization System

Serial number-based Track and Trace System

1. Supply

2. Supply

3. Supply

Health Insurance Review & Assessment Service (KPIs)

Manufacter/Importer

Serial numbers 001 ~ 005

Wholesaler A

Wholesaler B

Pharmacy

Supply data (serial number) reporting (at shipment)

Supply data (serial number) reporting (at shipment)

Supply data (serial number) reporting (at shipment)
National Pharmaceutical Serialization System

Implementation of NPSS

- **(who should report)** All suppliers of drugs (manufacturer/importer, wholesaler)
- **(what should be reported)** GTIN(KD code), **Serialization number**, Expiration date, Lot. number, Supply amount, Unit price, etc.
- **(When to report)** Transaction Data of **ETC drugs**, should be reported “at the time of shipping”
  - Data of OTC drugs can be reported by “the end of next month” of transaction
- **(How to report)** Report through the KPIS Web Portal
  - KPIS ESB Agent file upload, File upload through web portal, Direct input on the web portal
Linkage of drug distribution

1. Delivery from Manufacturer/Importer to KPIS
2. Real-time shipping report from Manufacturer/Importer to KPIS and delivery to Wholesaler A
3. Data linkage from KPIS to Wholesaler A
4. Real-time shipping report from Wholesaler A to Provider
5. Delivery from Wholesaler A to Provider
6. Delivery from Provider to Receiver
Utilization of pharmaceutical distribution information

**Produce**
- Pharmaceuticals

**Supply**
- Wholesalers

**Distribute**
- Providers

**KPIS**
- Policy
- Statistics
- Claims Review
- Reimbursement
- Healthcare support
- Marketing
- Media

**HIRA system**

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