Pharmaceutical Serialization and Traceability system in South Korea

Progress and Status of national pharmaceutical serialization system

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Health Insurance Review & Assessment Service (HIRA)
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About KPIS (Korea Pharmaceutical information service)

Manages Standard data carriers

Collection & Management of Pharmaceutical distribution information

The Serialization of all prescription drugs within an established system

An information hub for pharmaceutical logistics, the Korea Pharmaceutical Information Service
CONTENTS

• Pharmaceutical information Standardization in South Korea
  - KD code
  - Data Carrier Requirements
  - Classification by Drugs category
• National pharmaceutical Serialization system
• Traceability system
KD code (GTIN)

- National trade item numbering system

Within 30 days of MFDS approval, apply for KD Code at KPIS

Manufacturer, Importer

Assign code for pharmaceutical companies

Submit new drug application

Grant approval

Assign and notify KD Code (within 10 days) Develop and provide DB of products

Link drug information (on-line)

Product Code (Approval of MFDS) → Notify KD Code

KDC (KD code) EXAMPLE

<table>
<thead>
<tr>
<th>Digits</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>1</th>
</tr>
</thead>
<tbody>
<tr>
<td>Contents (GS1 prefix)</td>
<td>Company number</td>
<td>Item reference</td>
<td>Check digit</td>
<td></td>
</tr>
<tr>
<td>Examples</td>
<td>880</td>
<td>6400-6999</td>
<td>00011-9999</td>
<td>1-9</td>
</tr>
<tr>
<td></td>
<td>6200-6299</td>
<td>0500-0999</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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Data Carrier Requirements

- All drugs distributed in Korean market are required to have **Global Standard barcodes or RFID tags** which encode the **KD Code**.

<table>
<thead>
<tr>
<th>Principle</th>
<th>Barcode</th>
<th>RFID tag</th>
</tr>
</thead>
<tbody>
<tr>
<td>(01) 08806411057310</td>
<td><img src="image1" alt="Barcode Image" /></td>
<td><img src="image2" alt="RFID Tag Image" /></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Coding Structure</th>
<th>GTIN/ GS1 Application Identifiers</th>
<th>SGTIN-96 / SGTIN-198</th>
</tr>
</thead>
<tbody>
<tr>
<td>Company Usage Rate</td>
<td>96.5%</td>
<td>3.5% (*used by 16 companies)</td>
</tr>
</tbody>
</table>
## Classification by Drugs category

<table>
<thead>
<tr>
<th>Category</th>
<th>OTC drugs</th>
<th>ETC drugs (Prescription drugs)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Data</td>
<td>KDC(GTIN)</td>
<td>KDC (GTIN) + Expiration date/Batch number /Serial number*</td>
</tr>
<tr>
<td>Symbology</td>
<td>GS1-DataMatrix</td>
<td>GS1-DataMatrix</td>
</tr>
<tr>
<td></td>
<td>or EAN-13</td>
<td>or GS1-128</td>
</tr>
</tbody>
</table>

* GS1-DataMatrix

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CONTENTS

• Pharmaceutical Standardization in South Korea
• National pharmaceutical Serialization system
  - Introduction
  - Progress
  - Status
  - Data linkage
• Traceability system
Introduce of national PSS (Pharmaceutical Serialization System)

I. Serialization per smallest packing unit

II. Manage of data digitally including aggregation

III. Register data to KPIS upon shipment

IV. Real-time data linkage and Monitoring
Progress

<table>
<thead>
<tr>
<th>phase</th>
<th>I</th>
<th>II</th>
<th>III</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reporting system</td>
<td>Report at the time of shipping</td>
<td>Report at the time of shipping</td>
<td>Report at the time of shipping (※ Apply administrative measures when violated)</td>
</tr>
</tbody>
</table>

※ Base date for report is ‘the date of supply’
Status

Serialization on ETC drugs in 2016

- Average Rate 1/3: 85.7%
- Average Rate 2/3: 92.7%
- Average Rate 3/3: 95.5%

Registration of supply records with serial number

- Participation Rate(%) of pharmaceutical companies in 2016
  - Jul.: 96.5%
  - Aug.: 97.0%
  - Sep.: 98.1%
  - Oct.: 99.6%
  - Nov.: 98.1%
  - Dec.: 99.2%
Data linkage

Supplier

Manufacturer (importer) (Self-checkup)

Wholesaler A (Self-checkup)

Wholesaler B (Self-checkup)

Provider

Receiver

KPIS (Post-factum electronic checkup)

Real-time shipping report

Data linkage

Real-time shipping report

Data linkage

Data linkage

Direct transaction (Delivery)

Delivery

Delivery

Delivery
CONTENTS

• Pharmaceutical Standardization in Korea
• Pharmaceutical Serialization system
  • Traceability system
    - Utilization
    - Benefits of the pharmaceutical industry
    - AG data linkage service
    - Safety check service (Under plan)
Information Utilization

Establish D/W Information Center

Production & Import record

Supply record

Claims record of providers

Product information

Usage record

Information Utilization

Government
(National Assembly, MoA, MoIS, Statistics office)
- Healthcare policy and statistics management(OECD and etc.)

Audit and Investigative agency
(policeman, prosecutor’s office and tax office)
- Legal process

Healthcare researchers
- Research of healthcare industry

NHIF related agency
- Utilize for review and assessment
- Support benefit policy

Pharmaceutical company
- Develop drugs and identify market size

Wholesaler
- Utilize distribution information

Consumer & Media
- Comprehensive information including drug safety

Information provider

Production & Import record

Supply record

Claims record of providers

Product information

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Benefits of Pharmaceutical industry

**Manufacturer/Importer**
(approx. 460 companies)

- Prove a Product Authentication
- Protect company brand and reputation
- Efficient recall process

**Distributor**
(approx. 2,000 companies)

- Effective logistics management
- Easy to get data on the delivered medicine packages
- Easily detect drugs to be recalled

**Hospital/Pharmacy**

- Build trust with patients
- Eliminates counterfeit and illegal medicines
- Easy expiry data management
- Accurate inventory control
AG Data linkage service (On-going)

- Provide each serial number when AG (aggregation) barcode scanning
- Only when the supplier register of AG data on the package
Safety check service (Under plan)

• Drug information lookup through Mobile application software
Contact Information

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