



The Global Language of Business

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Pharmaceutical Serialization in Korea

Pharmaceutical serialization policy & national traceability system

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Definition and Objectives



Definition

- Pharmaceutical serialization system
- It 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

Objectives

- Prevent counterfeit/illegal drugs from entering supply chain
- Make the distribution process transparent
- Contribute to national health

Legal grounds



The Pharmaceutical Affairs Act Article 47-2

② Where a person who has obtained product licenses of drugs, an importer, or a drug wholesaler has supplied medical institutions, pharmacies, and drug wholesalers with drugs, he/she shall submit details of such **supply** to the Korea Pharmaceutical Information Service, as prescribed by Ordinance of the Ministry of Health and Welfare

Enforcement Rule of the pharmaceutical Affairs Act Article 45

(Drug supply record report, etc.) If a person who has obtained a product license, importer, or wholesaler supplies **finished drugs (including narcotics, ultra-narcotics, and psychotropic drugs, but excluding high pressure medical gases)** to medical institutions, pharmacies, wholesalers, and non-pharmacy sellers of selected OTC (convenient store), **the supply record shall be reported to KPIS at shipping** through digital medium (such as diskette CD), or through the Internet. Provided, **the following items are allowed to report by the end of next month.**

1. OTC: Form 24 of Annex

2. Prescription drugs allowed to opt out from serialization under the Notification of the Minister of health and Welfare: Form 24-2 of Annex

MoHW Notification

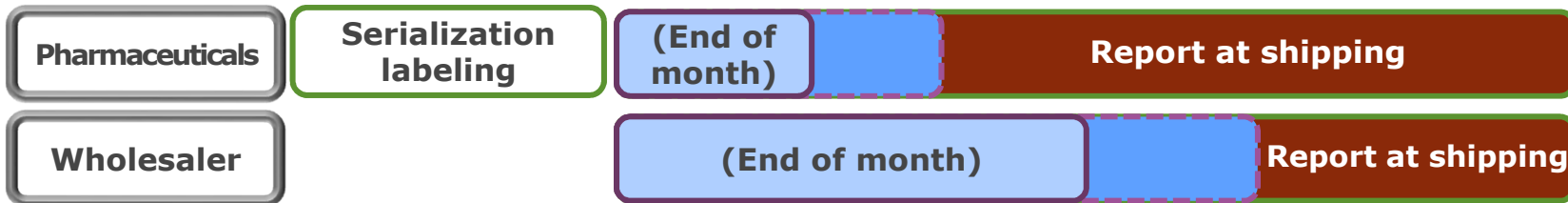
Guideline on the Use and Management of Barcode and RFID Tags for Drug

The history of drug transaction data management



| Year | Contents | |
|----------------------------|--|--|
| 2007 | Established KPIS | |
| 2008 | Assigning barcodes (KD codes) to the drugs Started the transaction report (Quarterly) | |
| 2012 | Mandated expiration date and lot number (Designated drugs) | Monthly Report by the end of the next month (Designated /Prescription drugs, OTC drugs) |
| 2013 | Mandated expiration date and lot number (Prescription drugs) | |
| 2015 | Mandated serial number (Designated /Prescription drugs) | |
| 2016 | Mandated serial number data reporting | Report at the time of shipping (Designated /Prescription drugs) |
| Second half of 2016 | KPIS web site (www.kpis.or.kr) being integrated into data management system (biz.kpis.or.kr) is under way. After that, OTC drugs report submission to "biz.kpis.or.kr" obligatorily (expiration data and lot number can be omitted) | |

Time of system implementation



| | Phase I | Phase II | Phase III |
|-------------------------|--|--------------------------------|---|
| Reporting system | Report at the time of shipping Allowed to report by the end of next month | Report at the time of shipping | Report at the time of shipping (※ Apply administrative measures when violated) |
| Pharmaceuticals | Jan. 2016 – Jun. 2016 | From Jul. 2016 | From Jan. 2017 |
| Wholesaler | Jan. 2016 – Jun. 2017 | From Jul. 2017 | From Jan. 2018 |

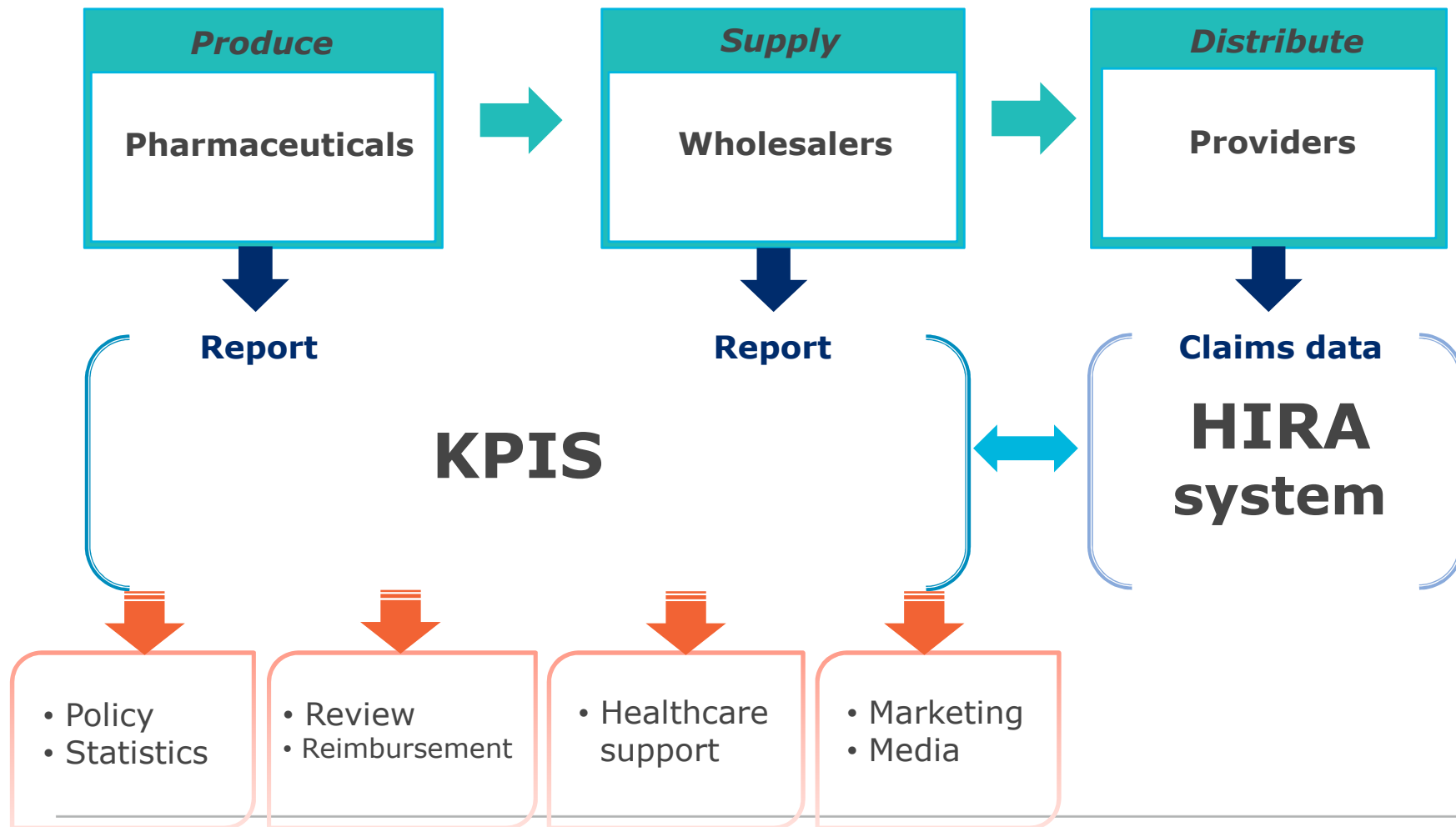
※ Base date for report is 'the date of supply'

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- The process of pharmaceutical serialization
 - Flow of drug distribution information collection
 - Pharmaceutical serialization and data reporting
 - Report process of drug transaction records
 - Report form and time reporting
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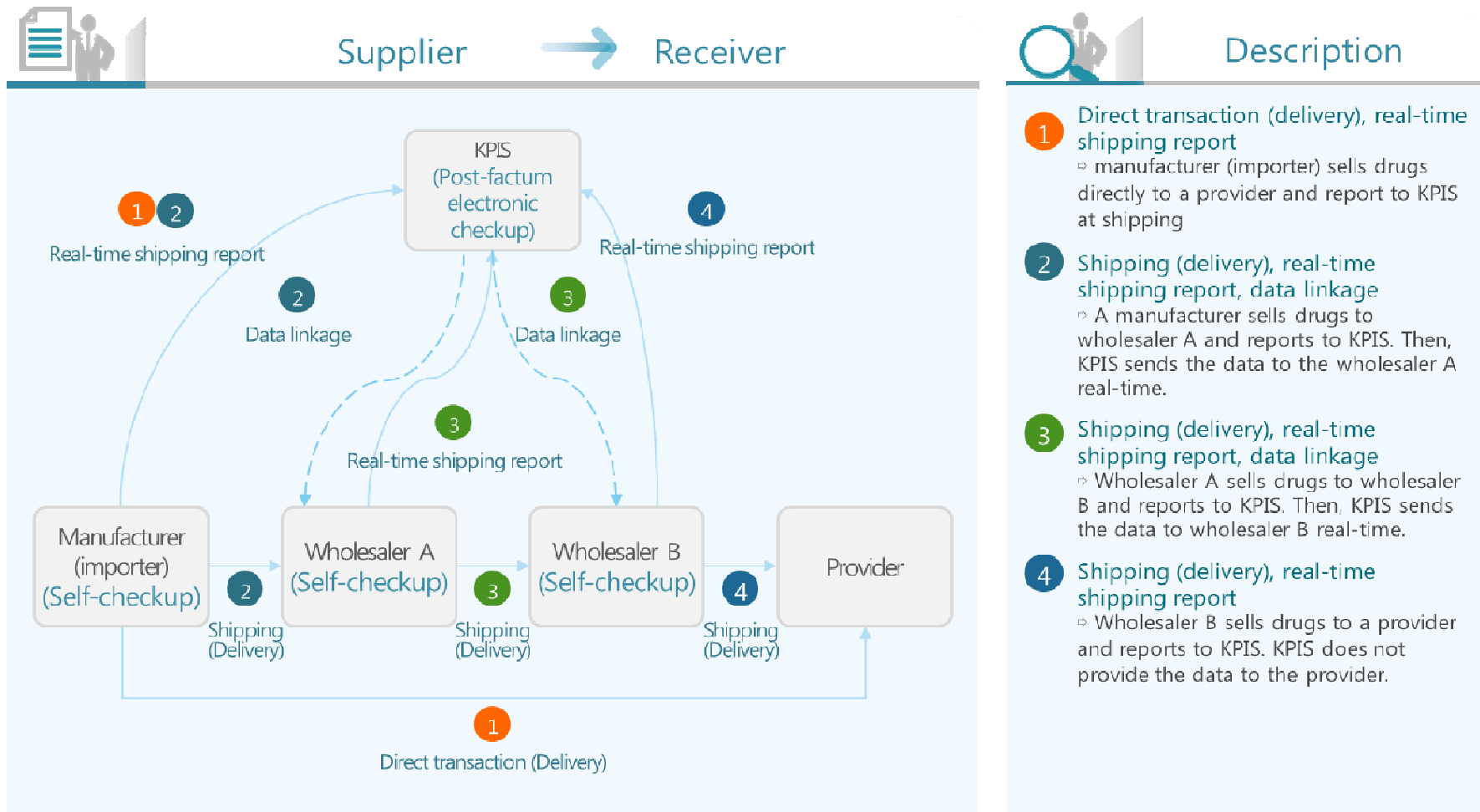
Flow of drug distribution information collection



Pharmaceutical serialization and data reporting



Report process of drug transaction records



Report form and time reporting



| Type | Form | | Time of reporting | |
|---|--------------------|------------------|-------------------------|--------------------------|
| | Form 24-2 of Annex | Form 24 of Annex | At the time of shipping | By the end of next month |
| Prescription drugs | Mandatory | Not allowed | Mandatory | Not allowed |
| Prescription drugs that are allowed to opt out* | Mandatory | Not allowed | Allowed | Mandatory |
| OTC | Allowed | Mandatory | Allowed | Mandatory |

* [Table 1-2 of Annex] Prescription drugs allowed to opt out from serialization in GS1-128 code. (regarding Article 5 paragraph 3)

1. Fluids, 2. Artificial perfusates, 3. Cleaning and disinfecting solvents of medical devices, 4. Contrast medium

* Searchable on 'KPIS website-Barcode-Code mapping'

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 - Barcode
 - GS1 codes
 - Application of KD code

Barcode



All drugs distributed in Korean market should have Global Standard barcodes or RFID tags which encode the Korea Drug code.

Barcode

- Represents drug information with numbers or letters using KD code
- Read by a scanner

RFID tag

- Vicinity-read radio frequency identification recognition technology that can read and record tagged data with reader, tag, and antenna without physical contact
- in use by 11 pharmaceutical companies

◆ Ratio of barcodes / RFID tags use in 2015
- Barcodes: 2.13 billion (96%), RFID tags: 96 million (4%)

GS1 codes



| | GTIN | GS1 Application Identifiers |
|-----------|--------------------------|--|
| Symbology | EAN-13 or GS1-DataMatrix | GS1-128 or GS1-Datamatrix |
| Data | KD code | KD code + Expiration Date + Lot No. + Serial No. |



EAN-13



GS1-DataMatrix



GS1-128

Application of KD code



Current status of assigning KD codes to drugs

(As of late Dec. 2015)

| Pharmaceuticals | Number of Items | Number of KD codes |
|-----------------|-----------------|--------------------|
| 590 | 49,503 | 140,760 |

Application of KD codes

- Drugs have barcodes or RFID tags which encode the KD code
- KD codes are utilized as item codes for reimbursement claims (9 digits)
- KPIS collects the performance of production and import, and the transaction data

Thank you



Contact Information



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