



Pharmaceutical Serialization and Traceability System in South Korea

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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

Standardization of drug code



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).

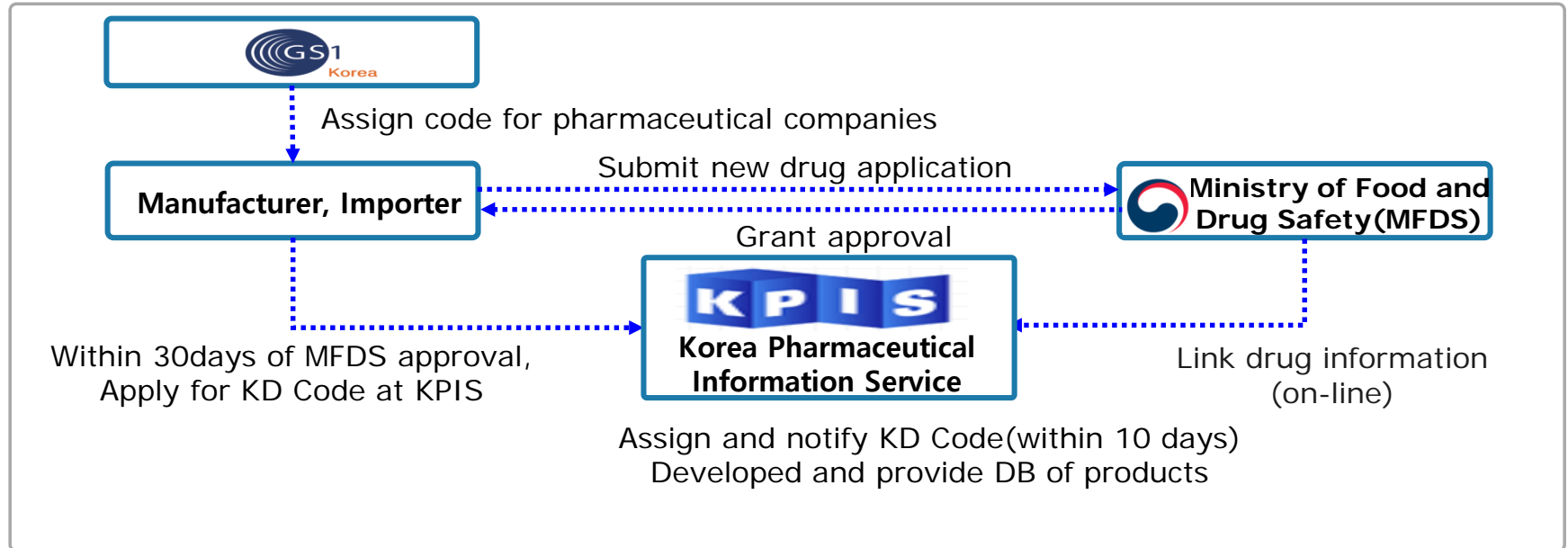
Digits	3	4	5	1	
Contents	GS1 prefix	Company number	Item reference	Check digit	
Examples	880	6400-6999 6200-6299 0500-0999	Product code including content 0001-9999	Package unit 1-9	0-9

EDI claim code
EDI claim code

Standardization of drug code



Process of Assigning KD code



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.



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

(01)08806411123459(10)A12345



(17)181231 (21)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 marked only a KD code using a barcode according to 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)

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

National Pharmaceutical Serialization System



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)

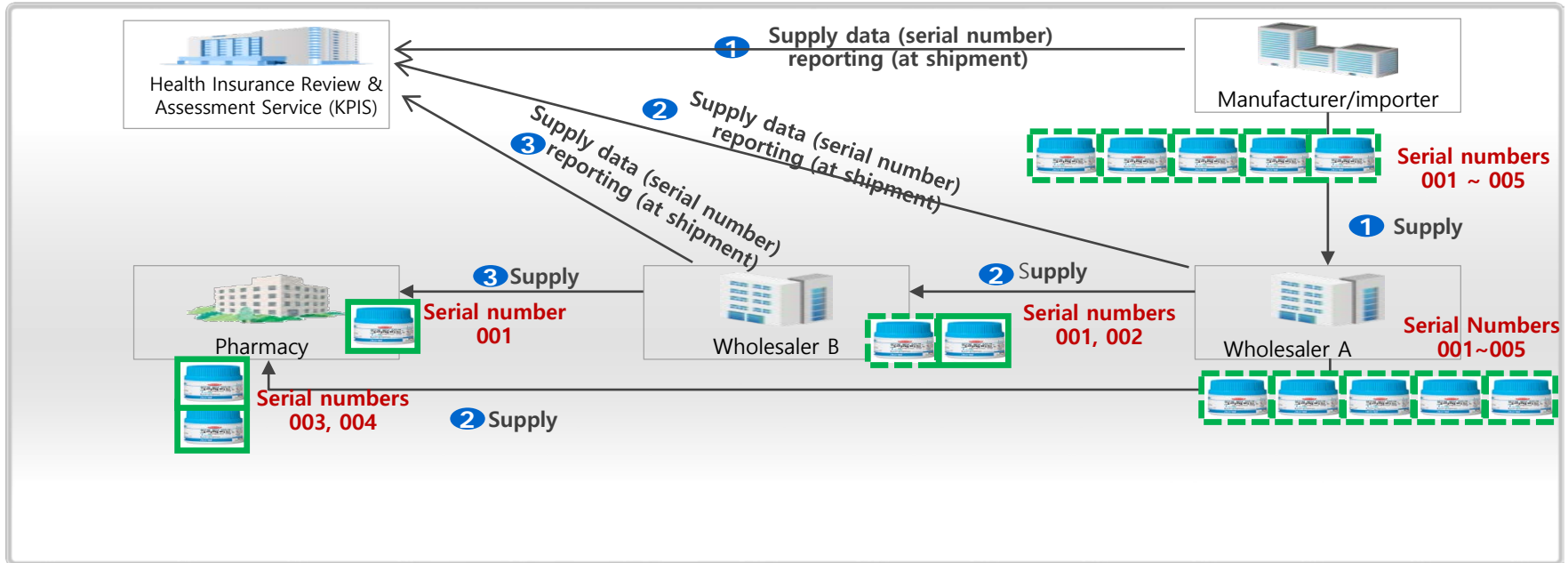
2018

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





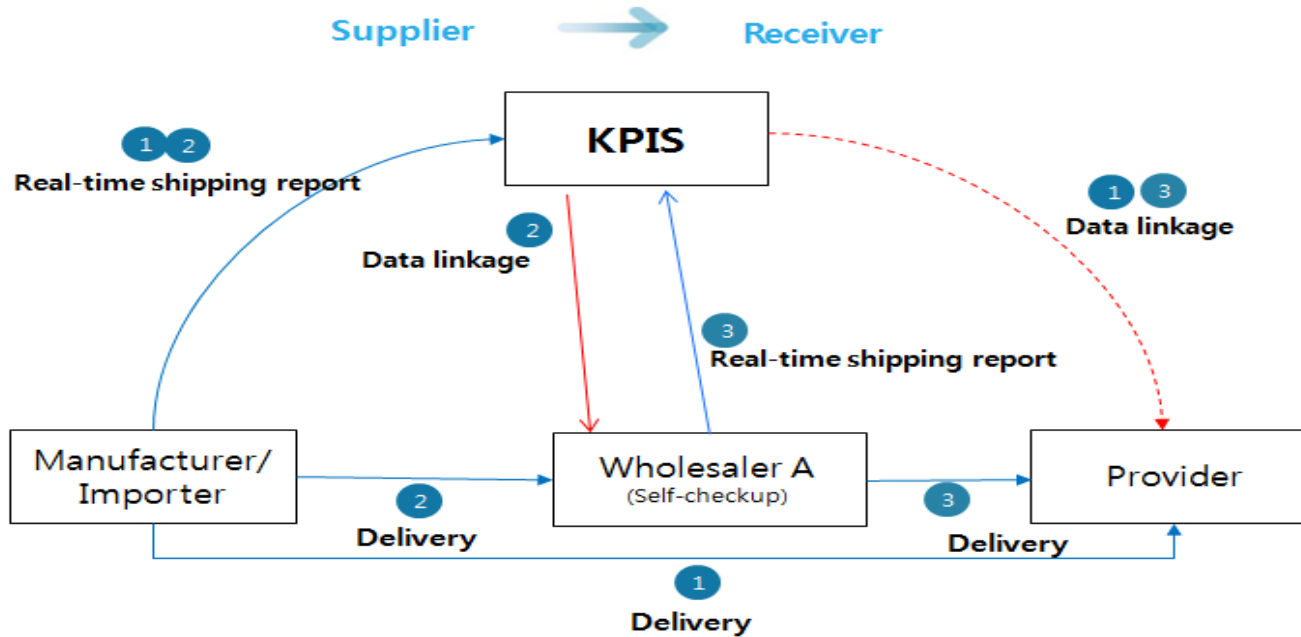
Implementation of NPSS

- **(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

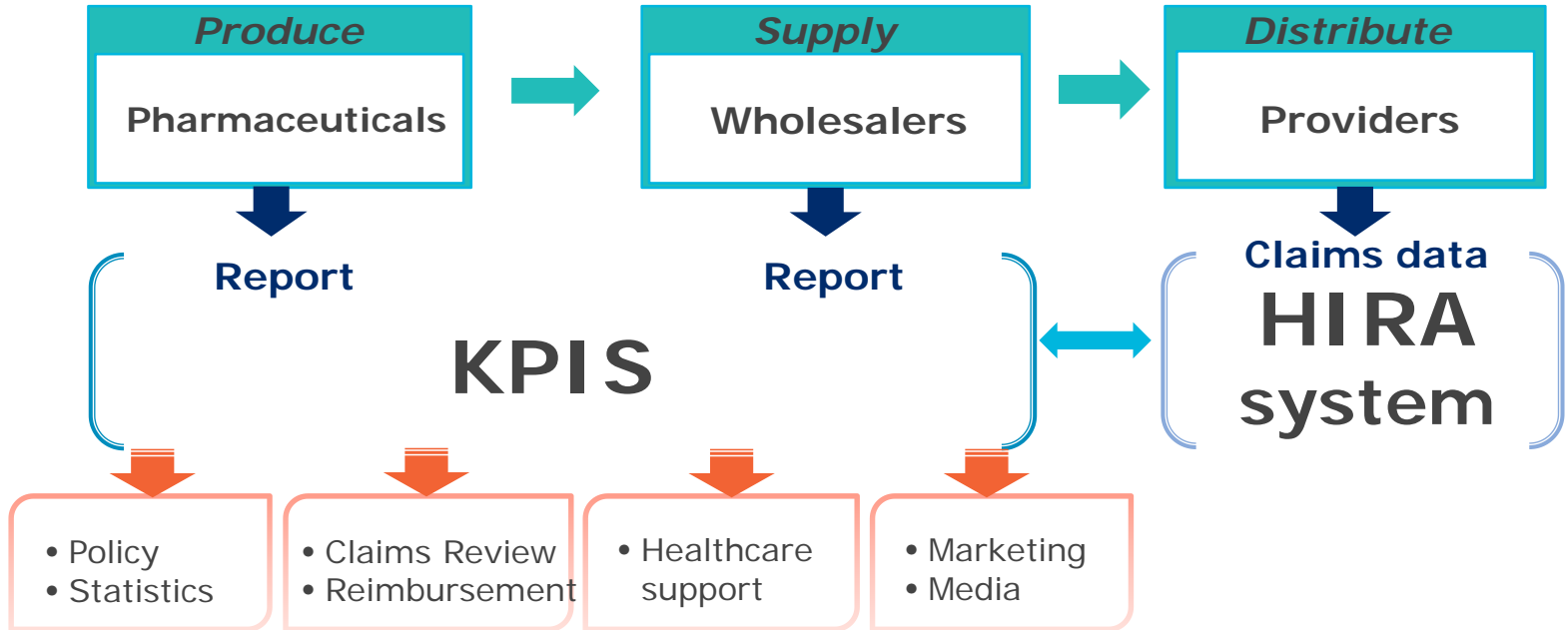
National Pharmaceutical Serialization System



Linkage of drug distribution



Utilization of pharmaceutical distribution information



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