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MINISTRY OF HEALTH & WELFARE

Guideline for Pharmaceutical Serialization System

[The first edition]

Nov. 2015

HIRA
HEALTH INSURANCE REVIEW & ASSESSMENT SERVICE

KPIS Korea Pharmaceutical Information Service

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Guideline for **Pharmaceutical Serialization System**

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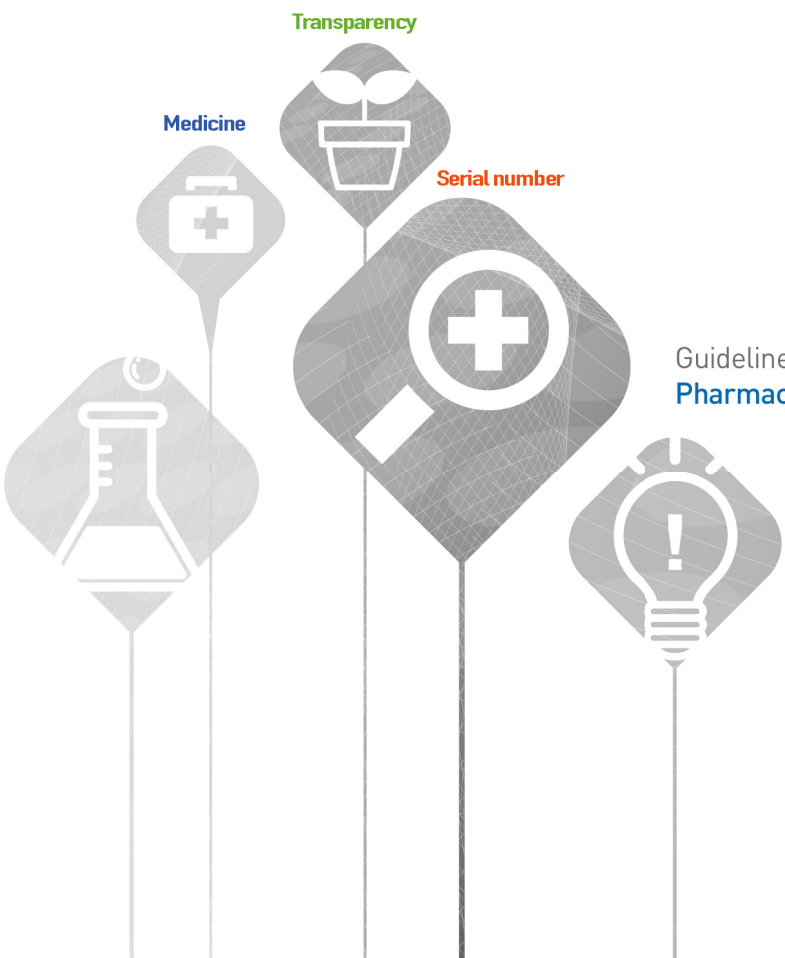
I Introduction

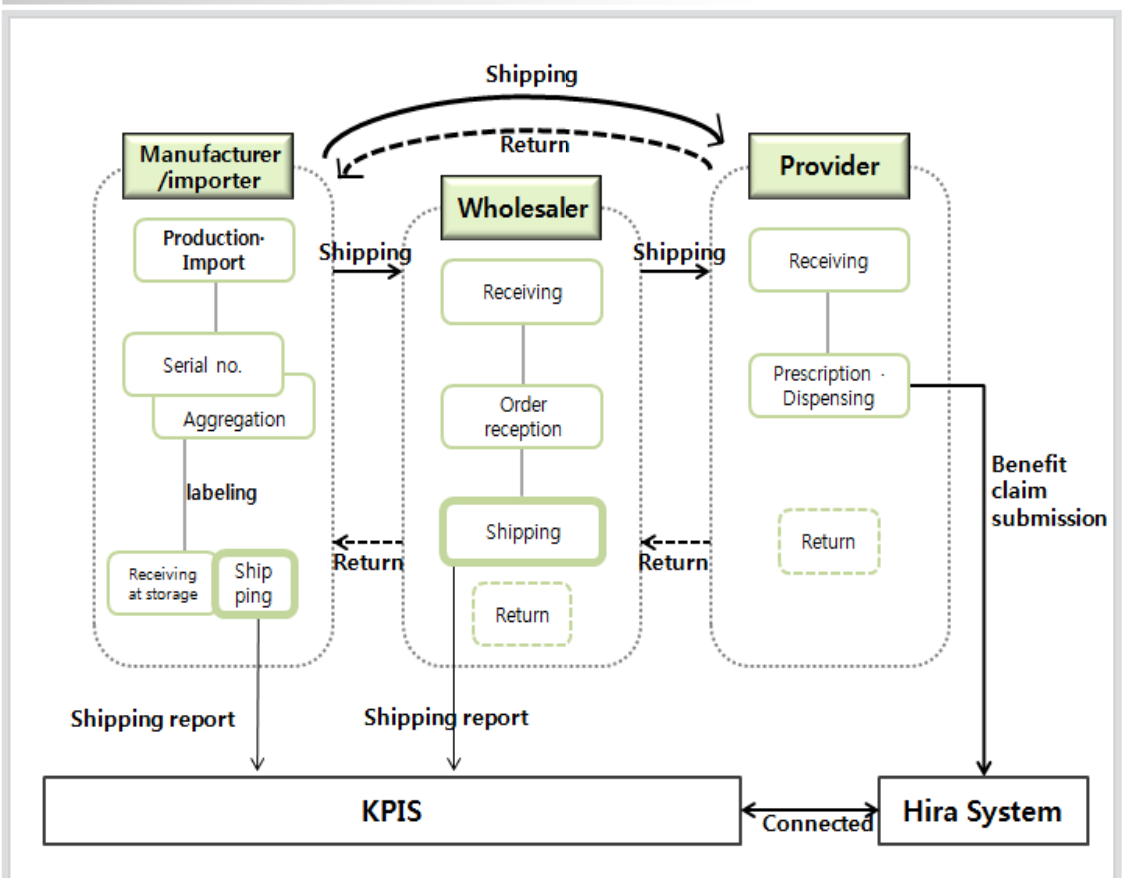


Guideline for
Pharmaceutical Serialization System

1-1. Definition and objective

- **National** 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.
- Therefore, it can prevent counterfeit/illegal drugs from entering supply chain, and drugs with issues can be withdrawn from the market before consumption, which will create a safer pharmaceutical environment.
- The distribution route will be more clearly identified on each transaction, which will make the distribution process transparent and prevent unlawful practices.

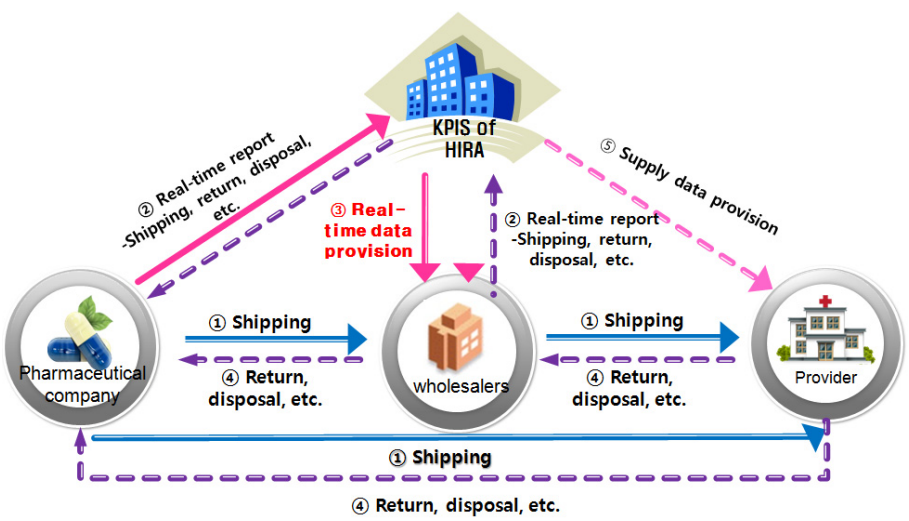
Flow of drug distribution after implementing serialization system



1-2. Main contents

- Pharmaceutical serialization system consists of two parts: i) assigning a serial number on each drug package. ii) capturing and reporting the transaction data which include serial numbers.
- Manufacturer/importer assigns serial numbers on drugs and reports the transaction data as the drugs are shipped out.
- When wholesalers ship out drugs, they must report to KPIS about the transaction data including serial numbers.

assigning a serial number on each drug package.	capturing and reporting the transaction data which include serial numbers.
2015	2016



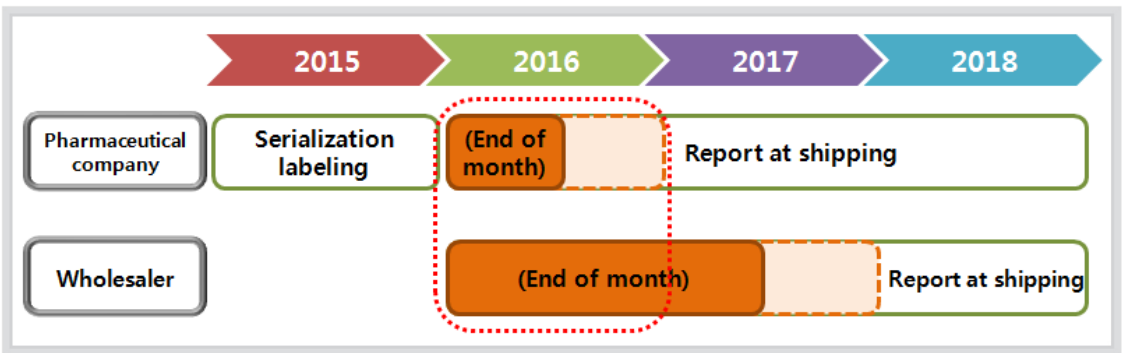
• Pharmaceutical serialization system enables a systematic management of drug traceability with the data reported to KPIS.

〈Work flow chart〉

① Shipping: When the supplier ships drugs out
② Realtime reporting: The supplier reports to KPIS on transaction details including shipping, return, and disposal on a realtime basis
③ Realtime data sharing: The reported shipping data are shared with the receiver on a realtime basis (including API service, etc.)
④ Return, disposal, etc.: Supplier reports to KPIS when it receives return/disposal data
⑤ Transaction data sharing: Send drug transaction data to the provider through Providers' Portal

Time of system implementation

The drug serial no. information report is enforced from January 1, 2016. Grace periods are allowed by June 2016 for pharmaceutical companies, and by June 2017 for wholesalers, where they are allowed to "report monthly by the end of the next month" of the transaction.



〈 Phased enforcement plan 〉

	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 companies	Jan. 2016 – Jun. 2016 (6 months)	From Jul. 2016 (6 months)	From Jan. 2017
Wholesalers	Jan. 2016 – Jun. 2017 (18 months)	From Jul. 2017 (6 months)	From Jan. 2018

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

※ 「Enforcement Regulation of the Pharmaceutical Affairs Act」 Notification of revision of Article 45 (Executive order made by the Minister of Health and Welfare, No. 363, Nov. 11, 2015)

- From Jan. 1, 2016, for all finished drugs, the transation record must be reported "at the time shipping". Provided, drugs listed below are allowed to report by the end of next month.
  1. Over-the-counter drug: Form 24 of Annex
  2. Prescription drugs allowed to opt out from serialization according to the Notification of the Minister of Health and Welfare: Form 24-2 of Annex
- (Supplementary provision) Exception law for drug transaction record reporting: It is allowed to report "by the end of next month of transaction" by Jun. 30, 2016 for manufacturers and importers, and by Jun. 30, 2017 for wholesalers.

I Introduction

Implementation target

- (WHO MUST REPORT) All suppliers of drugs (manufacturer/importer, wholesaler)
- (WHAT SHOULD BE REPORTED) All finished drugs may be serialized. It is mandatory for designated drugs and prescription drugs to have serial numbers in GS1-128 code.

> * Designated drugs: Narcotics and psychotropic drugs, inflammable/explosive drugs, biopharmaceuticals (Enforcement Regulation on the Safety of Pharmaceuticals, etc., Table 6 of Annex)
> * Prescription drugs: A drug that is not an OTC (Pharmaceutical Affairs Act, Article 2 Subparagraph 10)

- Exceptions: Serialization is not mandatory for **OTCs** and prescription drugs listed in Table 1-2 of Annex of Guideline on the Use and Management of Barcodes and RFID Tags for Drug (e.g. fluids, etc.).

> * [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

Data reporting

- (WHEN TO REPORT) Transaction Data of designated drugs and prescription drugs, should be reported "at the time of shipping".
  - Data of OTC and non-serialized prescription drugs can be reported by "the end of next month" of transaction.

- (REPORTING FORMAT) Transaction data of all finished drugs (prescription drugs/OTC) should be reported using Form 24-2 of Annex (Expiration date, lot number and serial number, etc.).
  - OTC drugs transaction data report can use Form 24 of Annex. Prescription drugs without serialization should use Form 24-2 of Annex, and include each drug' "expiration date and lot number" data, leaving serial number blank.

〈 Report form and Time of 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 drug	Mandatory	Not allowed	Mandatory	Not allowed
Prescription drugs that are allowed to opt out (Listed in Table 1–2 of annex)	Mandatory	Not allowed	Allowed	Mandatory
OTC	Allowed	Mandatory	Allowed	Mandatory

<Forms of Annex>

■ Enforcement Regulation of the Pharmaceutical Affairs Act [Form 24–2 of Annex]

Receipt Number	Receipt Date	Issued Date

① Sequence No.	② Supplier type	③ Contract type	④ Supply class	⑤ Supply type	Receiver			⑨ KD Code Name (Product Name)	⑩ KD Code (Product Code)	⑪ Package Total Unit (Standard)	⑫ Supply Qty.	⑬ Supply date	⑭ Supplied Amount (KRW inc. VAT)	⑮ Unit Price (inc. VAT)	⑯ Receipt No. (Subject of re-report)	⑰ Return Code (Subject of re-report)	⑱ Lot no.	⑲ Expiration Date	⑳ Serial No.	㉑ Aggregation code	㉒ RFID tag Code	㉓ Note
					⑥ Name	⑦ Business Registration No.	⑧ Provider code															

■ Enforcement Regulation of the Pharmaceutical Affairs Act [Form 24 of Annex]

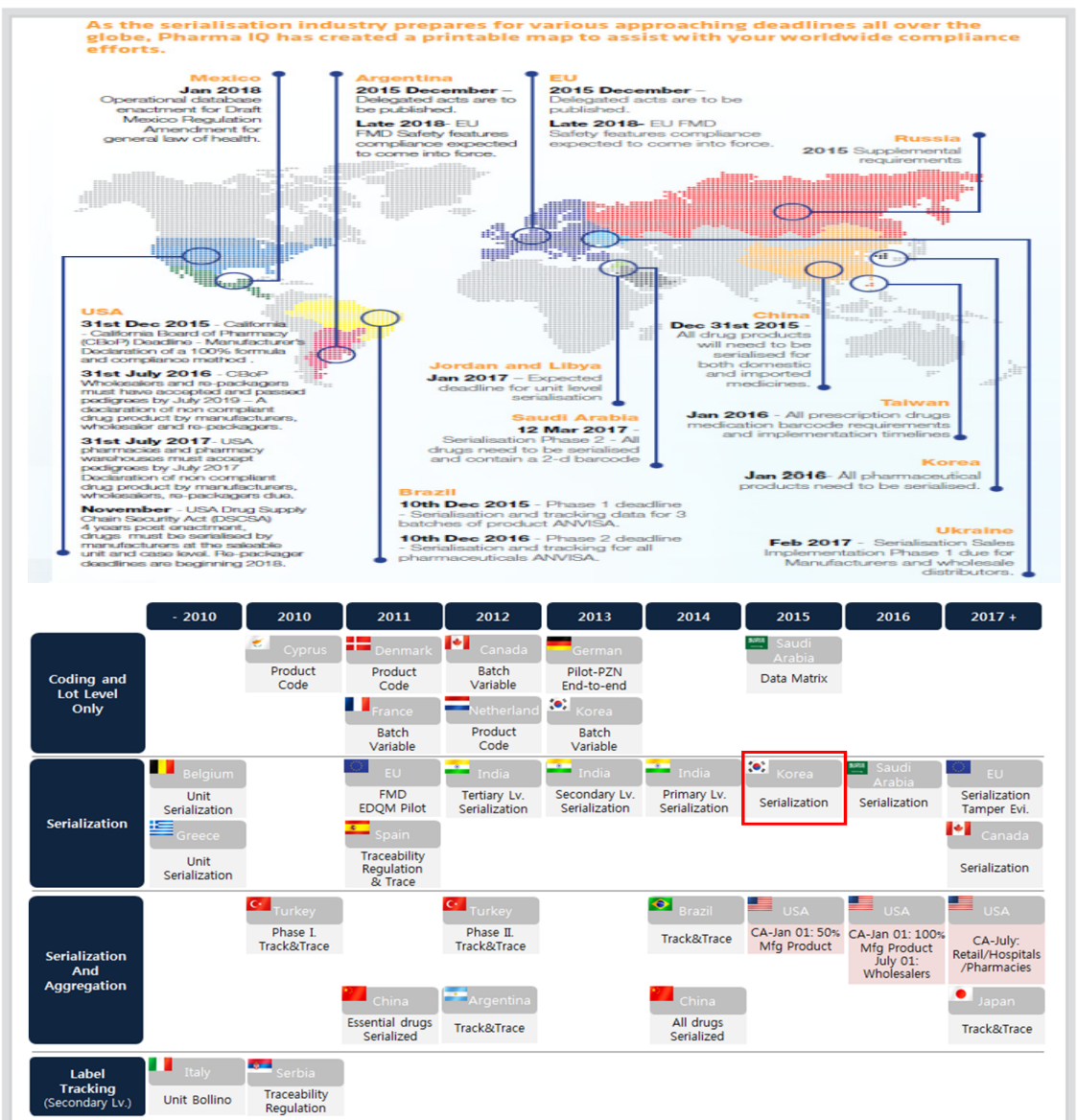
Receipt Number	Receipt Date	Issued Date

① Sequence No.	② Supplier type	③ Contract type	④ Supply class	⑤ Supply type	Receiver			⑨ KD Code Name (Product Name)	⑩ KD Code (Product Code)	⑪ Package Total Unit (Standard)	⑫ Supply Qty.	⑬ Supply date	⑭ Supplied Amount (KRW inc. VAT)	⑮ Unit Price (inc. VAT)	⑯ Note
					⑥ Name	⑦ Business Registration No.	⑧ Provider code								

1-3. Overseas examples

- There are countries that have already introduced to enforced the serial no. system (Turkey, China and India etc) for the purpose of patient safety and preventing leak of insurance finances through the prevention of illegal and counterfeit drugs while the United States and EU area also planning to introduce the system starting the year 2017.

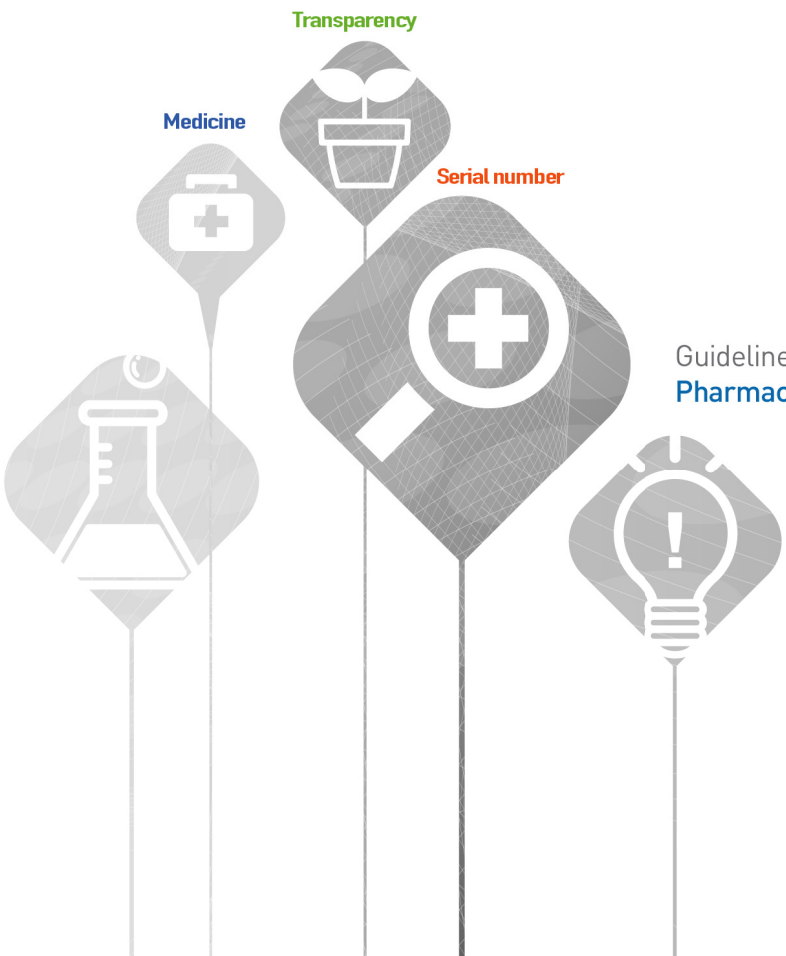
〈 Plans to adopt drug serialization system 〉



Ⅱ Implementation situation

2-1. Current status

2-2. Implementation process overview



Guideline for
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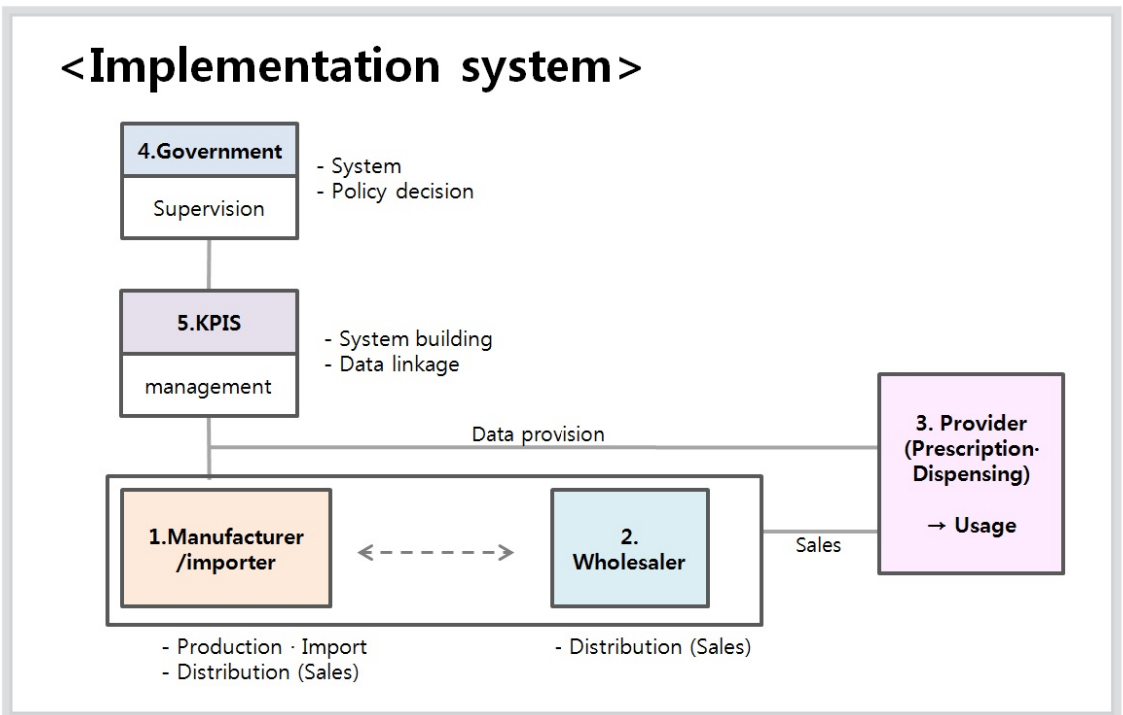
2-1. Current status

By year

	2008	2012	2013	2015	Jan. 2016
Main progress	Started transaction report (Quarterly report)	Mandated expiration data/lot number (Designated drugs)	Mandated expiration data/lot number (Prescription drugs)	Mandated serial number (Designated/ prescription drugs)	Mandated Serial number data reporting
		Monthly Report by the end of next month (Designated/prescription drugs, OTC)			Report at the time of shipping (Designated/prescription drugs)

<table>
<tr><th>Time</th><th>Contents</th></tr>
<tr><td>May 2011</td><td>
◐ A general revision of the Guideline on the Use and Management of Barcodes and RFID Tags for Drug (MOHW Notification 2011-58)
– Added the selective use of RFID tag in addition to barcode, encoding rule, pharmaceutical serialization regulation– Encoding expiration date and lot number in GS1 Barcodes became mandatory for designated drugs in 2012 and for prescription drugs in 2013. Encoding serial number became mandatory for prescription/designated drugs from Jan. 1, 2015.
– Published “Barcode Manual on Pharmaceuticals”
<table>
<tr><th>Year</th><th>Designated drugs</th><th>Prescription drugs</th></tr>
<tr><td>2012</td><td>Mandated expiration date and Lot No.</td><td></td></tr>
<tr><td>2013</td><td></td><td>Mandated expiration date and Lot No.</td></tr>
<tr><td>2015</td><td>Mandated serial numbers</td><td>Label serial numbers</td></tr>
<tr><td colspan="3">※Designated drugs: Narcotics, psychotropic drugs and biopharmaceuticals</td></tr>
</table>
</td></tr>
<tr><td>May 2014</td><td>◐ Added General principles on serialization and use of aggregation, etc., to “Barcode Manual on Pharmaceuticals” supplementation, and press release on serialization.</td></tr>
<tr><td>Aug. 2014</td><td>◐ Announced the adoption of Pharmaceutical Serialization System for safe use and transparent distribution of drugs (Division of Pharmaceutical Policy, MOHW)
– Pharmaceutical serialization implementation plan
– Draft reporting format and data utilization system structure
※ Considering the circumstances, 30% of prescription drugs were required to submit implementation plan, and the serial numbers to be labeled by Dec. 31, 2015.</td></tr>
<tr><td>May 2015</td><td>◐ 「Guideline on the Use and Management of Barcodes and RFID Tags for Drug」 MOHW Notification 2015-74, revised (May 14, 2015)</td></tr>
<tr><td>Nov. 2015</td><td>◐ Notification of revision of Article 45 (Drug transaction transaction record report, etc.) of the Enforcement Regulation of the Pharmaceutical Affairs Act (Nov. 11, 2015)
– For all finished drugs, the transaction record shall be reported "at the time of shipping" (using the new template, Form 24-2 of Annex). Yet, OTC (Form 24 of Annex) and serialization-exempted prescription drugs (Form 24-2 of Annex) may report by the end of next month of transaction.</td></tr>
</table>

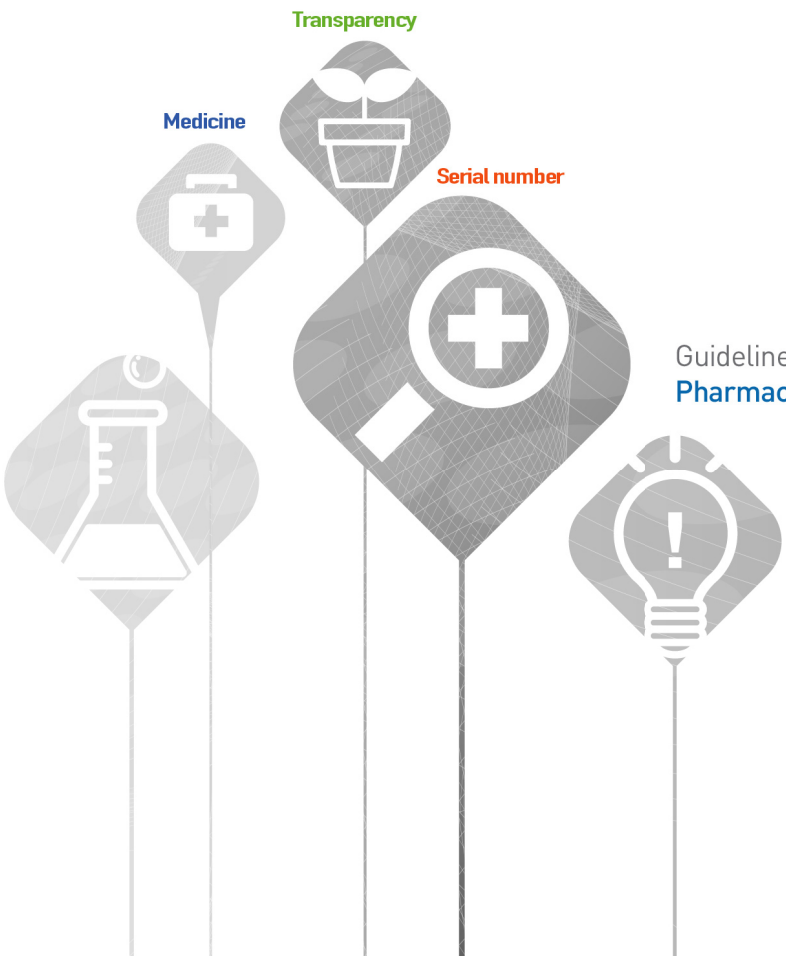
2-2. Implementation process overview



1. Manufacturer/Importer – Product serialization using GS1 standards – Report the drug transaction records	**4. Ministry of Health and Welfare (Division of Pharmaceutical Policy)** – Supervise the pharmaceutical serialization system
2. Wholesaler – Report the drug transaction records	**5. KPIS of HIRA** – Collect and manage the drug supply chain transaction data – provide standard barcoding and serialization guidance for industry – Operate the national pharmaceutical serialization system
3. Providers (ex. Hospital and pharmacy) – Safeguard public health by promoting safe use of drugs	

Ⅲ Implementation details

3–1. Assigning pharmaceutical serial number
3–2. Aggregation
3–3. Transaction record reporting including serial number data



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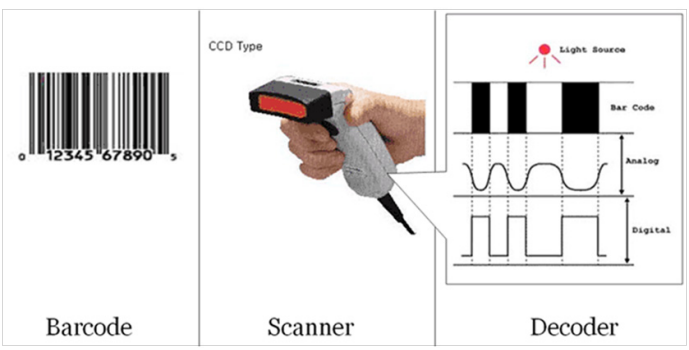
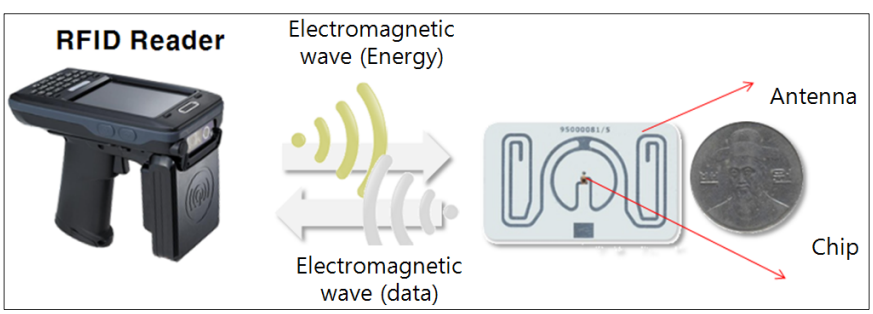
Pharmaceutical Serialization System

[Barcode symbol and RFID tag]

- **Barcode symbol**: Consisting of margin, HRI (Human Readable Interpretation) and black and white bar, barcode represents data relating to the object to which is attached. The data encoded in the barcodes can be read by optical scanners.



- **RFID tag** : RFID tag consists of a chip and antenna and the chip stores data. Pharmaceutical RFID tag does not have an independent energy source like a battery. The RFID reader emits radio wave to transmit the data. Unlike barcodes, RFID tag can be read at a distance by a reader



Ⅲ Implementation details

3-1. Assigning pharmaceutical serial number

Subject of serialization in barcode and RFID tag

- Drugs that are agreed to be serialized according to the 2015 serialization implementation plan submitted by manufacturer/importer, and manufactured/imported drugs that are subjects of serialization from 2016.

※ Drugs that can opt out from serialization: Rare disease drugs imported by the Korea Orphan Drug Center, radiopharmaceutical products that require radiation shielding, blood product under Article 2 Subparagraph 8 of the Blood Management Act, empty capsules

※ Excluded items from barcode and RFID tag system: High pressure medical gases, raw material medicine intended to be used at manufacturer, medicinal herbs, drugs for clinical trials

Encoding serial numbers

- GTIN-13 structure

  – International product ID, that uniquely identifies drugs

〈Example of GTIN-13 structure〉

Digits (13)	3	4	5		1
Content	GS1 prefix	Company number	Item reference		Check digit*
			Product code including content	Package unit	
Sample no.	880	6400-6999 6200-6299 0500-0999	0001-9999	1-9	0-9

* Check digit: Calculated by a formula, verification number is set in order to prevent misreading of barcode and improve confidency.

〈 EAN-13 〉

(01)08806411123459

〈 GS1-DataMatrix 〉

(01): Application Identifier
0: Leading '0' is added before the KD code (GTIN-13) to make the KD code (GTIN-13) a 14 digit number
8806411123459: KD code (GTIN-13)

GS1-128 coding scheme

- Consisting of GS1 Application Identifier (AI) and applicable data, it holds the set of data that should be included in designated/prescription drug barcode.
- Data type varies according to AI rules
  - Fixed length data (KD code (GTIN-13), expiration date) and variable length data (lot number, serial number)
  - Numeric data (KD code, expiration data), alphanumeric data (lot number, serial number)

〈Example of GS1-128 coding scheme〉

Digits	2	14	2	6	2	20 and below	2	20 and below
Content	AI GTIN	GTIN	AI expiration date	YYMMDD	AI lot no.	LOR/Batch No.	AI serial no.	Serial no.
Sample no.	(01)	08806411123459	(17)	101231	(10)	Q12345	(21)	A213291199

※ If a company wants to encode additional data, they should be encoded after the essential data set (KD code, expiration date, lot number, serial number)

< GS1-128 barcode >

(10)Q12345(21)A213291199

(01)08806411123459(17)101231

< GS1-DataMatrix >

Comparison of GTIN-13 and GS1-128

Coding system	GTIN-13 system	GS1-128 system
Data	KD code	KD code, Lot No. Expiration Date, Serial No.
Display method	Starting character-KD code	Staring character-AI-Data ...
Formula for interpretation	]E08806411123459]d201088064111234591710123 1...	]C1010880641112345917101231...]d201088064111234591710123 1...
Symbol	EAN-13 GS1-Datamatrix	GS1-128 barcode GS1-Datamatrix

Human Readable Interpretation (HRI)

- HRI is the readable text of the barcode data in the form of characters.
- It is allowed for GS1-Datamatrix to exclude HRI if there is not enough space.
- RFID tag could label the HRI of KD code and serial number.

Labeling method of pharmaceutical RFID tag

- ISO 18000-6C, 900MHz, passive RFID tag
- Recommended tags: Approved by state-authorized test authority on operating test in high temperature, operating test in low temperature, high temperature & mumid test, temperature change test, etc., and given performance test records for tag RF/Protocol standardization test and interoperability test.
- Must be readable in 1 meter distance at least from a product.

- RFID tag should not disturb the use or storage of the drug.
- RFID tag should be attached to paper box, film, plastic & glass packing materials in a fixed manner, so the tag recognition is not disturbed in the distribution process.
- Data standard
  - Data type SGTIN[1]-96, SGTIN-198

	Header	Filter	Partition	GS1 Company prefix	Item reference	Serial no
	8	3	3	24	20	38
Beat value/ Digits	00110000 (Fixed value)	Standard filter value	101	7 digits	6 digits	Max 274.8 billion

<KD code>	Classification	GS1 prefix	Company#	Indicator	Item reference
	Digits	3	4	1	5

〈 SGTIN-96 〉

1) SGTIN (Serial Global Trade Item Number): Product identifier (GTIN) which include serial number

	Header	Filter	Partition	GS1 Company prefix	Item reference	Serial no
	8	3	3	24	20	140
Beat value/ Digits	00110110 (Fixed value)	Standard filter value	101	7 digits	6 digits	Max 20 digits

<KD code>	Classification	GS1 prefix	Company#	Indicator	Item reference
	Digits	3	4	1	5

〈 SGTIN-198 〉

Utilization of RFID tag

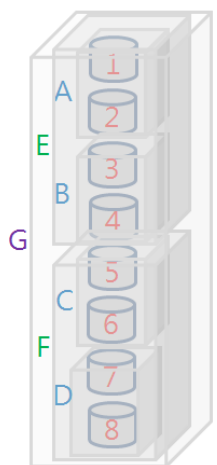
- RFID tag includes only GTIN and serial number. Therefore, **a separately managed DB** should include lot number and expiration date.
- According to Article 6 Paragraph 2 of the Guideline on the Use and Management of Barcodes and RFID Tags for Drug, pharmaceutical companies that have drugs with RFID tag should report to KPIS on KD code (RFID tag code), lot number for serialization, and expiration date.
- On the request of the company, KPIS provides lot number and expiry date data of the products, through KPIS ESB Agent and web portal.

3-2. Aggregation

Definition

- Aggregation is a packaging and logistics functionality which is used to create parent–child relationship throughout packaging hierarchy levels.
- In order to find G in the example below, one should look for the serial no. (1,2,3,4,5,6,7,8) of the standard code (8806411123459).

Aggregation data sample



KD code	Serial no.	Primary Aggregation	Secondary Aggregation	Tertiary Aggregation
8806411123459	1	A	E	G
8806411123459	2	A	E	G
8806411123459	3	B	E	G
8806411123459	4	B	E	G
8806411123459	5	C	F	G
8806411123459	6	C	F	G
8806411123459	7	D	F	G
8806411123459	8	D	F	G

※ Assignment method of A ~ G: SSCC, GTIN-14 + Serial

〈 Aggregation and KD code unit classification 〉

How to create aggregation code

- Using (GTIN–14) + Serial Number
  - GTIN–14 has a 14–digit data structure. The leftmost digits (1 to 8) are used to define packaging hierarchy of a product with the same Item Reference.
    ※ 0 and 9 are excluded in logistics identifier for logistics code.
  - Assign a unique serial number to a logistic unit (no longer than 20 digits)

〈GS1-128 coding sample using logistics code (GTIN-14) and serial no. 〉

Digits (13)	2	1	7		5	1	2	No longer than 20
			3	4				
Content	AI	Indicator digit	GS1 Prefix	Company#	Item reference	Check Digit	AI	Serial no.
Sample no.	(01)	1 (1~8)	880	6411	12345	6	(21)	7

〈 GS1-128 barcode 〉

〈 GS1-DataMatrix 〉

SSCC (Serial Shipping Container Code)

- Serial Shipping Container Code is a unique 18 digit number that can be used by companies to identify a logistic unit, which can be any combination of trade items packaged together for storage and/ or transport purposes; for example a case, pallet or parcel.

〈Example of SSCC structure〉

Digits (13)	2	1	7		9	1
			3	4		
Content	AI	Extension digit	GS1 prefix	Company number	Serial no.	Check no.*
Sample no.	(00)	0 (0~9)	880	6411	123456789	7

〈 GS1-128 barcode 〉

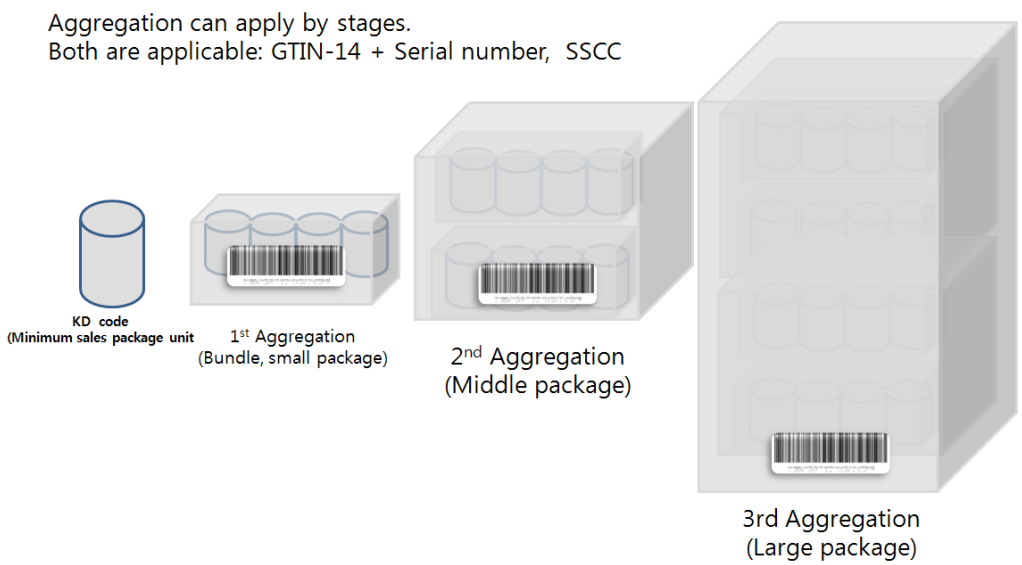
〈 GS1-DataMatrix 〉

Recommended unit for pharmaceutical aggregation

1) Small package (bundle): 5~10 units

2) Middle package: 25~100 units (5 ~ 10 units of small packages)

3) Large package: 125~1000 units (25 ~ 100 units of small packages, 5 ~ 10 units of middle packages)



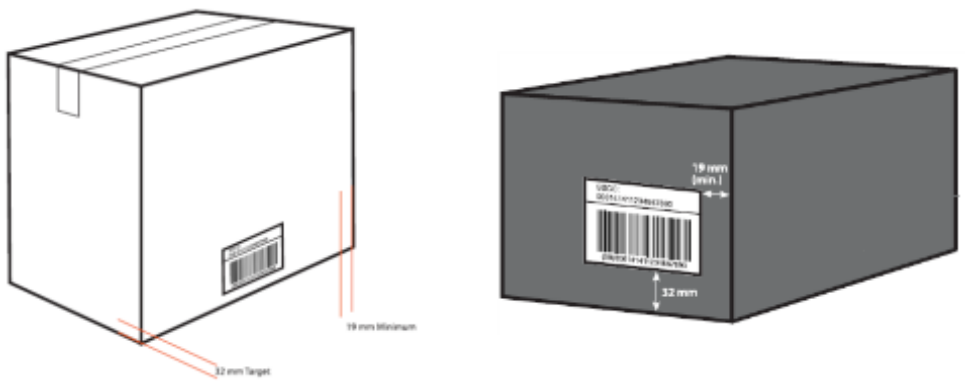
〈 Pharmaceutical aggregation units 〉

1) General principle (GS1 standard applied)

A) Should be labeled in the Easy-to-find location

B) It is recommended to place the barcord label at least 32 mm above from the bottom and 19 mm away from the edge.

2) Example

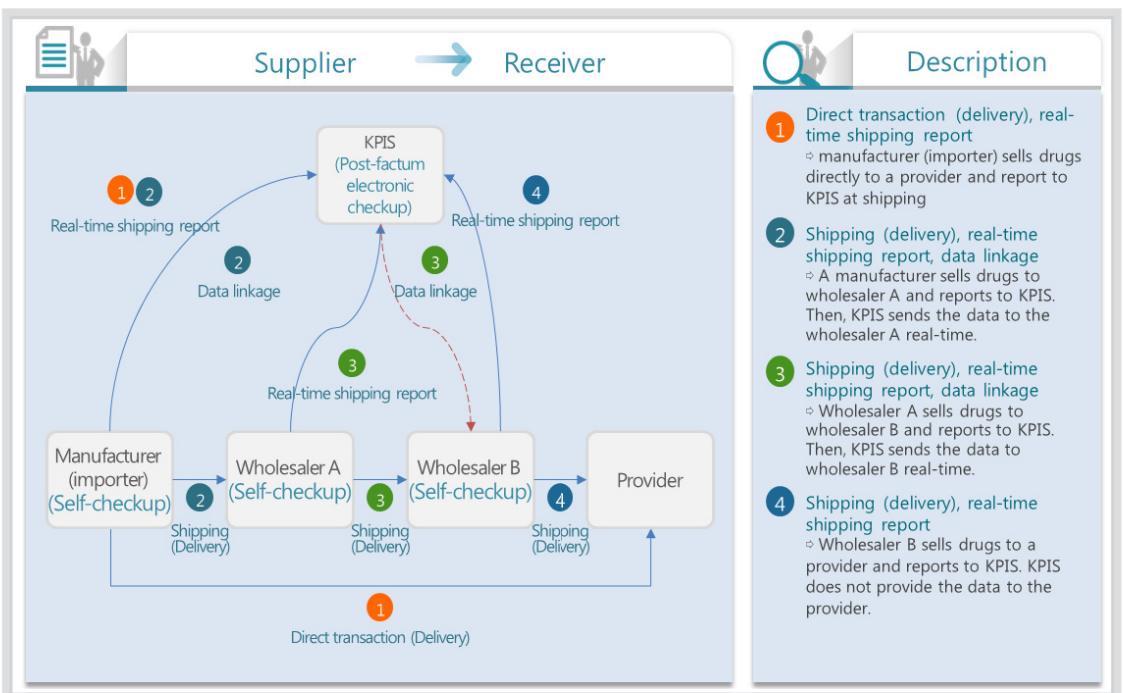


〈Barcode label example〉

3-3. transaction record reporting including serial number data

Definition of transaction record reporting

According to Article 47–2 Paragraph 2 of the Pharmaceutical Affairs Act, and Article 45 (Drug transaction record report, etc.) of the Enforcement Regulation of the Pharmaceutical Affairs Act, when persons who obtained permission for drug items, drug importers or pharmaceutical wholesalers supply finished drugs (including narcotics, ultra–narcotics and psychotropic drugs) to healthcare providers, pharmacies, wholesalers or convenient store, the transaction transaction records shall be reported to KPIS in the provided form.



Reporting method

General principle

– Reporting method
- KPIS ESB Agent file upload (file type: CSV)
- File upload through web portal (file type: CSV, Xls, Xlsx)
- Direct input on the web portal

※ Transaction record report shall be based on "date of supply "

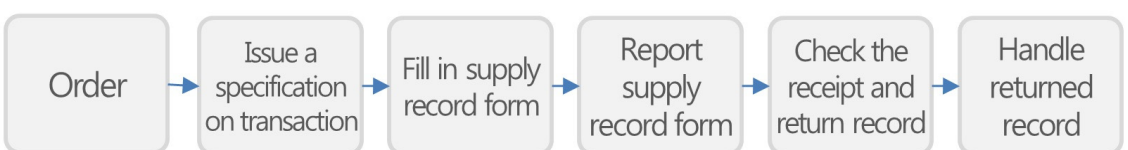
* "Date of supply" of transaction transaction record form is based on the date of "specification on transaction". But if the "specification on transaction" date and actual supply date do not match due to circumstances, note the "actual supply date" in the "Note" section.

Example) Date of specification on transaction (Oct. 1, 2015), Actual supply date (Nov. 1, 2015, Dec. 1, 2015) Divided delivery
– 1st report : Supply date (20151001), Note (ZC/20151101)
– 2nd report : Supply date (20151001), Note (ZC/20151201)

– Reporting template

Form no.	Name of the form	Description
S01	**Transaction** record reporting file	Supplier to KPIS
R01	**Transaction** record notification file	KPIS to suppliers
R02	Receipt	Receipt for file submission
R03	Return record notification file	Return info sent to the supplier
S04	RFID tag data request	RFID tag code, serial number
R04	RFID tag data notification	To check lot number and expiration date

※ Returned record must be processed

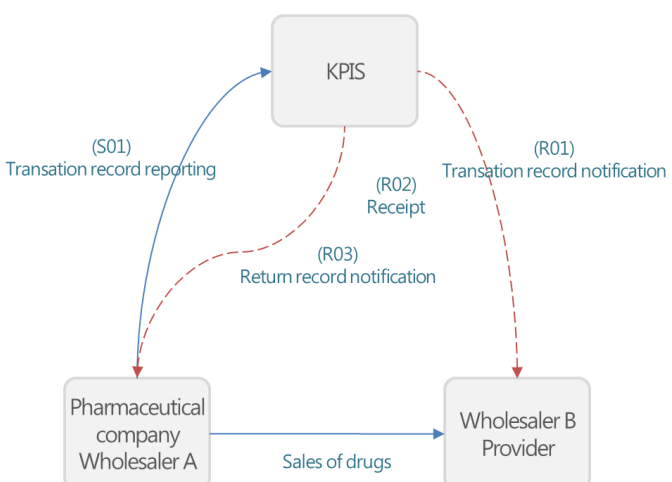


〈 Product shipping and report process〉

Shipping report

- When a supplier (seller) sells drugs to a receiver (buyer)
- Who should report: Supplier (seller)
- How to report: KPIS ESB Agent, file upload through web portal, direct input on the web portal
- When to report: At shipping, at the end of next month of supply
- Supply class: 1 (Shipping)

Type	Template	Time of report
Finished drugs	Form 24-2 of Annex	At shipping (in principle)
Prescription drugs	Form 24-2 of Annex	At shipping
Prescription drugs allowed to opt out from serialization	Form 24-2 of Annex	At the end of next month
OTC	Form 24 of Annex	At the end of next month



1. Transaction record reporting (shipping)
   - Supplier reports to KPIS on shipping data
2. Receipt and return record
   - Send the receipt for record submission and return record data

   ※ Return data should be checked and processed
3. Notify submitted records
   - KPIS sends the supply data to the buyer
4. Transaction of drugs
   - Delivery of purchased drugs

Transaction record reporting (shipping)

* Supplier sends the transaction data to KPIS "at the time of shipping", then the shipping data is sent to the buyer through "data linkage". (Data linkage with providers will be implemented later on)

Return reporting

– Reasons of return

* Elapsed or impending expiration date, damaged products (including defective products), excessive inventory (stagnant sales, stop order at hospitals), withdrawal (voluntary recall), hazardous drug withdrawal at the order of MFDS, etc.

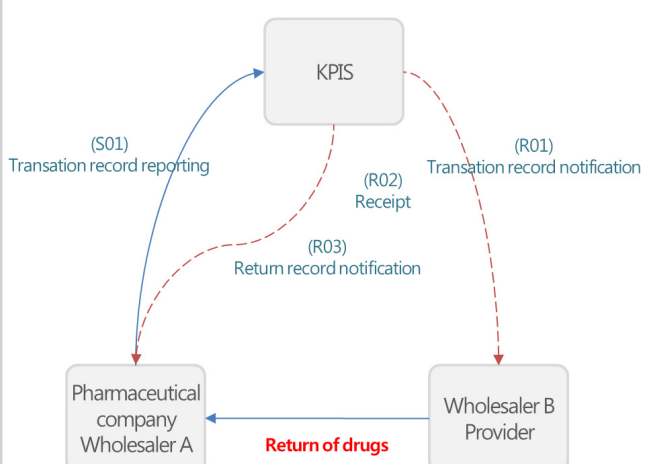
– Who should report: Supplier (seller)

– How to report: KPIS ESB Agent, file upload through web portal, direct input on the web portal

– When to report: At the end of next month of supply

– Supply class: 2 (Return)

Type	Template	Time of report
Prescription drugs (including prescription drugs allowed to opt out from serialization)	Form 24–2 of Annex	At the end of next month
OTC	Form 24 of Annex	At the end of next month



1 Drug return
– Delivery of drugs

2 Transaction record reporting (Return)
– Receiver of the return reports to KPIS on the return data

3 Receipt and return record
– Send the receipt for record submission and return record data
※ Return data should be checked and processed.

4 Transaction record notification
– KPIS sends the return record to the returned drug sender

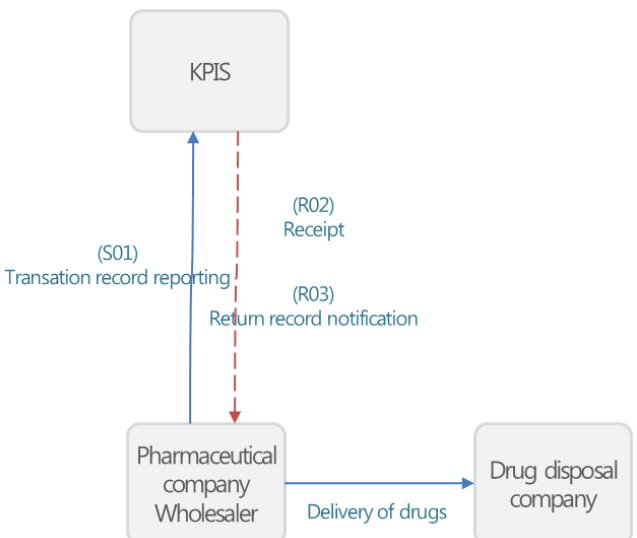
Return reporting

* When a drug manufacturer/supplier receives a return/disposal request, the manufacturer/supplier is responsible for return/disposal report. The buyer that requested return will receive the data through data linkage.

Disposal reporting (After return reporting)

- When the supplier (pharmaceutical company/wholesaler) discards drug inventory
  * Elapsed expiration date, damaged products, policy-motivated return (for disposal), withdrawal for disposal, stop order disposal, faulty products, etc.
- Who should report: Supplier (seller)
- How to report: KPIS ESB Agent, file upload through web portal, direct input on the web portal
- When to report: At the end of next month of supply
- Supply class: 3 (Disposal)

Type	Template	Time of report
Prescription drugs (including prescription drugs allowed to opt out from serialization)	Form 24-2 of Annex	At the end of next month
OTC	Form 24 of Annex	At the end of next month



1 Drug disposal
- Send the drugs to medication disposal company

2 Transaction record reporting (Disposal)
- The company that is going to discard the drugs report to KPIS

3 Receipt and return record
- Send the receipt for record submission and return record data

※ Return data should be checked and processed.

Disposal reporting

Error correction

– When there is a need for error correction in the **submitted shipping reports**

– Who should report: the company that made shipping report

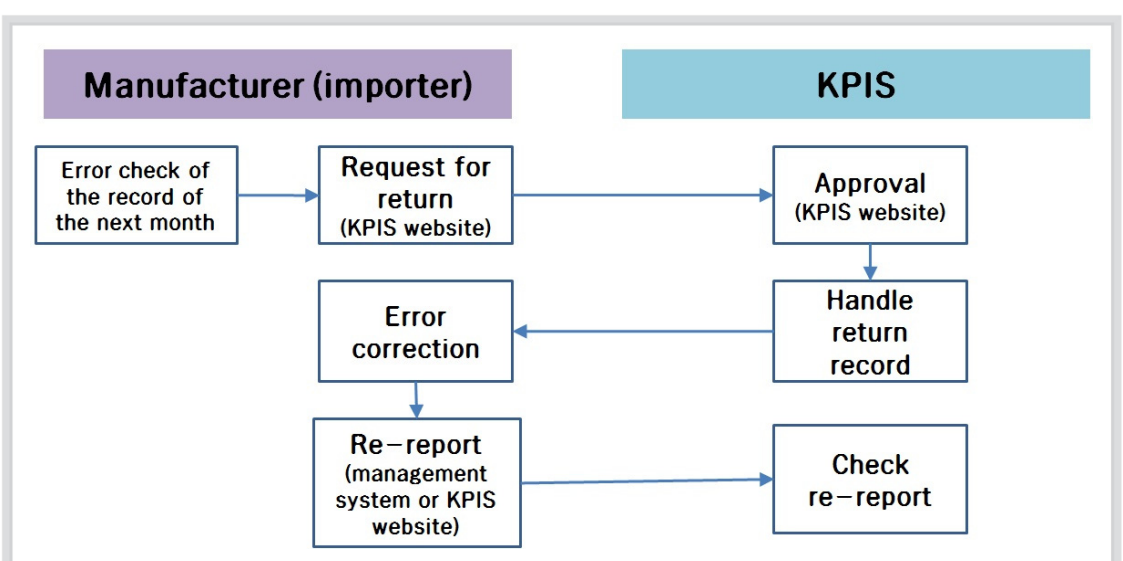
– How to report: KPIS ESB Agent, file upload through web portal, direct input on the web portal

– When to report: The error correction should be done "immediately" as "reporting at shipping" means **"before the products are received by the buyer"**

- **Error correction** of the already submitted transaction record is allowed until **"before the closing of reporting by the end of next month"**
- If the **"reporting by the end of next month was closed",** error correction is possible through web portal only after obtaining **an approval** of KPIS staff.

– Supply class: 4 (Error correction)

Type	Template	Time of report
Prescription drugs (including prescription drugs allowed to opt out from serialization)	Form 24–2 of Annex	At the end of next month
OTC	Form 24 of Annex	At the end of next month



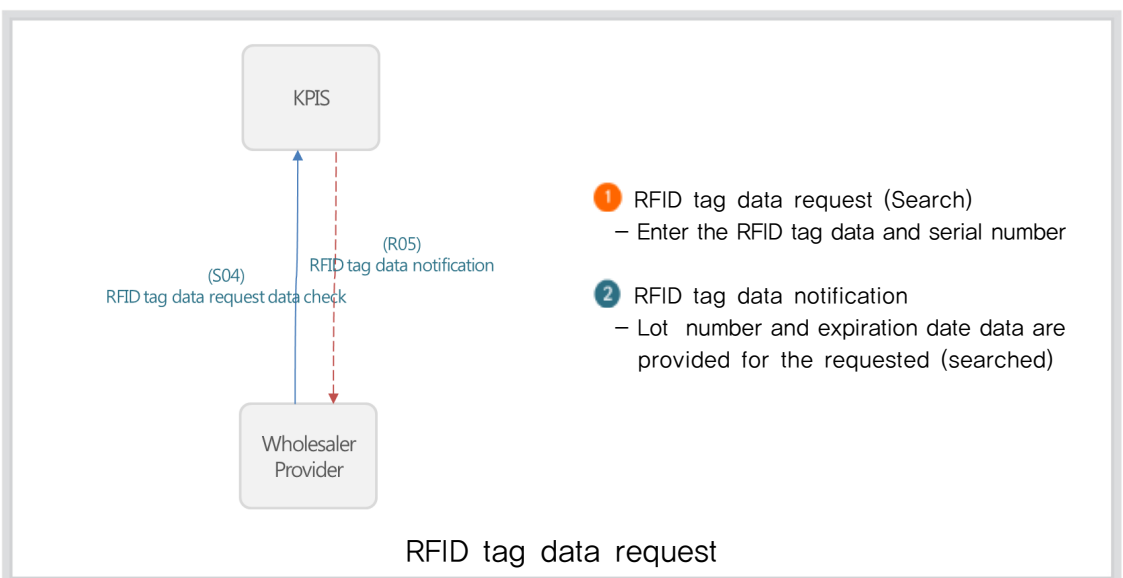
Cancellation reporting

- When there was no actual transaction under a supply report submitted to KPIS, or when the drugs are returned before a tax invoice was issued.
  * If the tax invoice was issued, take the case as return.
- Who should report: the company that made shipping report
- How to report: KPIS ESB Agent, file upload through web portal, direct input on the web portal
- When to report: At the end of the next month
- Supply class: 5 (Cancellation)

Type	Template	Time of report
Prescription drugs (including prescription drugs allowed to opt out from serialization)	Form 24–2 of Annex	At the end of next month
OTC	Form 24 of Annex	At the end of next month

RFID tag data request

- Searching large amount of products (file upload): Scan RFID tag with a reader and complete RFID tag data request form (S04) → Check and notify RFID data search result (R04)
- Searching single product: Scan RFID tag with a reader and enter the data in the drug search screen → Check RFID data search result



RFID tag data request

Return code and error code

Type		Description
Data return for failing field check and electronic check		When a reason for return was found in the transaction record reporting process, it is returned by sequence number unit with a return code in ⑰.
Return request		When there was an error in the record after the submission, the sender should request return, and person in charge check and return the record by sequence number unit.
Error code		The entire file is rejected when there is a duplication of receipt number, correction/cancellation/return receipt number/sequence number error.
Process and report method	Easy process for return	Report (Cancellation of Report) ※ For Transaction record, only the codes (DC, DH, FH, FI and DE) that can be excluded from checkup is allowed.
	Re-report	Submitting the file with applicable supply class (shipping, return, disposal) after error correction
	File modification	When there is an error code, correct the errors in the file and submit

Transaction record report template (Master/Sub)

- In the new template for transaction record reporting "Form 24–2 of Annex", "Master template" is for the existing transaction record details (reporting form by the end of next month) such as KD code unit supply quantity and amount, and "Sub template" is for serial number, aggregation, and RFID tag.

- All prescription drugs (including prescription drugs allowed to opt out from serialization) should use the Form 24–2 of Annex (Master + Sub). For prescription drugs allowed to opt out from serialization, it is allowed to not submit "Sub" template while "Master" template is mandatory.

- In case the supplier wants to "report at shipping" using serial number for OTC, it is allowed to use Form 24–2 of Annex. In that case, the space for expiration date and lot number can be left empty.

〈New〉 Form 24–2 of Annex
(Article 45 of the Enforcement Regulation of the Pharmaceutical Affairs Act)

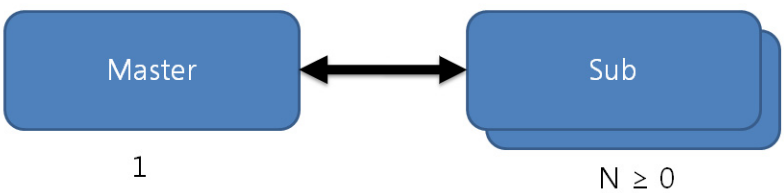
Template type	Report contents	Report item	Drug type		
			Prescription drug	Prescription drugs allowed to opt out from serialization	OTC
"Master template"	Product info.	Sequence no., KD code, package total unit (standard), lot number, expiration date, etc.	○	○	○ (expiration date and lot number can be omitted)
"Sub template"	Serial no. info.	Sequence no, serial no., aggregation, RFID tag code, etc.	○	–	–

Composition of Master and Sub template

Electronic form

Template for data linkage between KPIS and supplier (manufacturer importer wholesaler)

Elements



❖ When there is no serial number, only "Master" template is mandatory
- Drugs produced and imported before 2015 (Drugs in inventory, etc.)
- Prescription drugs allowed to opt out from serialization

Master template

①		②	③	④	⑤	⑥	⑦	⑧	⑨	⑩	⑪	⑫	⑬	⑭	⑮	⑯	⑰	⑱	⑲	⑳
Sequence no.	Business registration no.	Supplier type	Contract type	Supply class	Supply type	Receiver			KD code name	KD code	Package total unit (standard)	Supply quantity	Supply date	Supplied amount (including VAT)	Unit price (including VAT)	Receipt no.	Return code	Lot no.	Expiration date	Note
						Name	Business registration no.	Provider code												

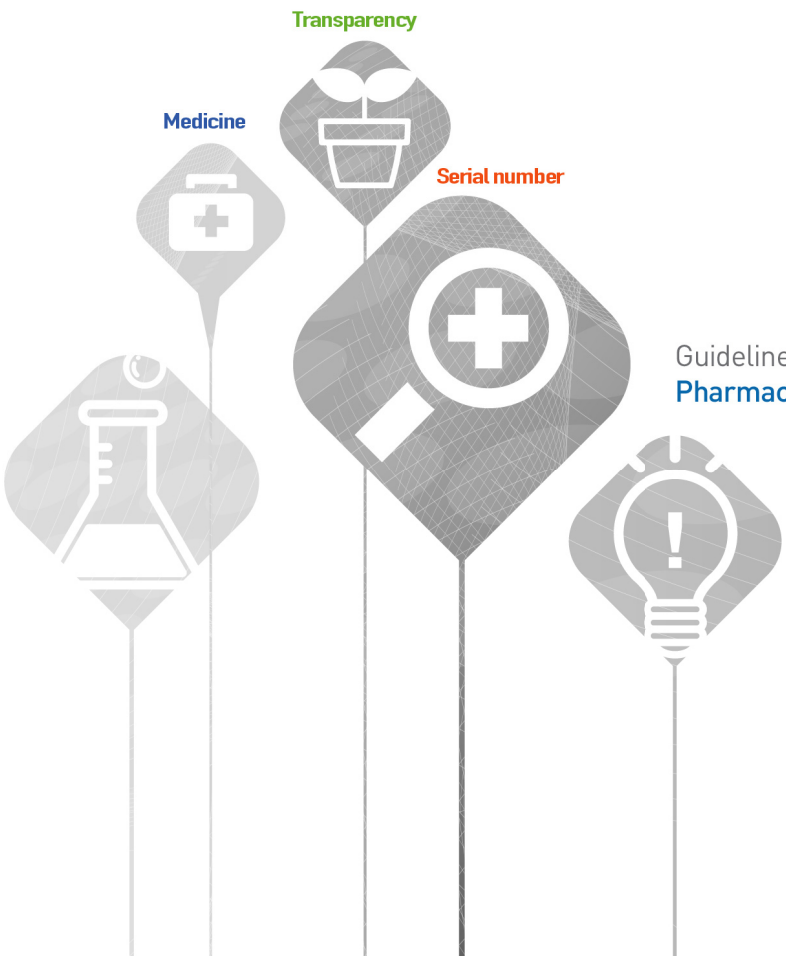
Sub template

①	⑳	㉑	㉒	㉓
Sequence no.	Serial no.	Aggregation code	RFID tag code	Note

⑳ Serial no.: Must be unique in a KD code unit
㉑ Aggregation code: Must be unique in a box unit (Primary/secondary/tertiary)

Ⅳ Regulations

4-1. Relevant laws



Guideline for
Pharmaceutical Serialization System

4-1. Relevant laws

1 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. 〈Revision on Nov. 11, 2015〉

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

Additional Clauses Article 1 (Enforcement date) This regulation shall take effect on January 1st 2016.
Article 2 (Exemption law for drug supply data reporting) Provided the revision of Article 45, the drug license holders and importers are allowed to report by the end of the next month of supply until June 30th 2016, and drug wholesalers until June 30th 2017.

2 GUIDELINE

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

[MoHW Notification No. 2015-74, May 14th 2015, Partial revision]
[Enforced May 14th 2015]

Article 5 (Type of Bar code and configuration etc.)

① When marking drugs with bar codes according to Paragraph 1 Article 3 of the Standards on Labeling Subject of Barcodes and RFID Tags for Drug, codes GTIN-13 or GS1-128 among the GS1 international standard code system should be used .

② Despite Clause 1 above, for prescription drugs (excluding radioactive drugs, orphan drugs and cell therapy drugs) as defined in Paragraph 10 Article 2 of the Pharmaceutical Affairs Act, or drugs designated under Appendix 6 Article 2 Paragraph B of the Regulation on Safety of Drugs, Etc., the GS1-128 code from the international standard code system described in Clause 1 should be used. However, when a GS1-128 code is used on an external container or packaging, only the GTIN-13 code may be used for an inside container or packaging that comes into direct contact with the drugs. 〈revised Apr 18, 2013〉

③ In spite of Clause 1 and 2, drugs included in Appendix 1-2 are allowed to omit serial number in GS1-128 code.

④ According to the Enforcement rule of the Pharmaceutical Affairs Act, the president of KPIS shall build a database with the submitted information, and can provide the data to the receiver mentioned in the Attachment template of the Enforcement rule of the Pharmaceutical Affairs Act.

⑤ Drug bar codes shall be configured as provided in Appendix 2.

⑥ In marking drug bar codes under Clause 1, the print size, color and location shall be as provided in Appendix 3.

⑦ When marking bar codes for the logistical management of drugs, the standard drug code may be expressed using the GTIN-14, GS1-128 codes or SSCC applied GS1-128 codes of the GS1 code system. The configuration shall be as provided in Appendix 4.

Article 6 (RFID tag configuration system, etc.) ① When attaching RFID tags to drugs pursuant to Article 3 Paragraph 1 of the MFDS notified Standards on Labeling Subject of Barcodes and RFID Tags for Drug, SGTIN-96 or SGTIN-198 of the GS1 code system shall be used. However, when an RFID tag is used, the GTIN-13 code may be used in either the direct-contact or external container or packaging.

② So as to allow for the efficient management of logistics and inventory, the trade name of the holder of product registration, importers or wholesalers that attach RFID tags according to the Clause 1 above to drugs shall notify the president of the KPIS of the expiration date and the lot number that correspond to the serial numbers prior to shipping of the products.

③ The president of KPIS shall build a database with the information obtained according to Clause 2, and may provide such information to receivers listed in the attachment templates of the Enforcement rule of the Pharmaceutical Affairs Act.

④ The configuration of RFID tags for drugs shall be as provided in Appendix 5.

⑤ The criteria for selection and method of affixation for the RFID tags for drugs shall be as provided in Appendix 6.

[Table 1-2 of Annex]

Items that are allowed to omit serial number in GS1-128 code
(Regarding Paragraph 3 of Article 5)

1. Items that meet all conditions below (Fluids)
   a. Size: Larger than 20㎖
   b. Routes of Administration: Vein, artery
   c. Dosage form: Liquid
   d. Style of Packing: bottle, bag, vial, and similar forms of packing

2. Items that meet all conditions below (Artificial perfusates)
   a. Medicinal effect classification: Artificial kidney perfusates (341), Other Artificial perfusates (349)
      ※ All artificial kidney perfusates are excluded from serialization regardless of size and dosage form. Other artificial perfusates shall meet the condition of b and c below in order to be excluded form serialization.
   b. Size: Larger than 20㎖
   c. Dosage form: Liquid

3. Items that meet all conditions below (Cleaning and disinfecting solvents of medical devices)
   a. Medicinal effect classification: Medicine for public health (730)
   b. Size: Larger than 20㎖
   c. Dosage form: Liquid

4. Items that meet all conditions below (Contrast medium)
   a. Medicinal effect classification: Xray contrast medium and MRI contrast medium among Xray contrast mediums (721), ultrasound contrast medium among other diagnostic drugs (729)
      ※ Medicinal effect classification follows 「Regulation on Codes for Classification of Medicinal Products and Other Products」 (Established rule of the Ministry of Food and Drug Safety)

V FAQ

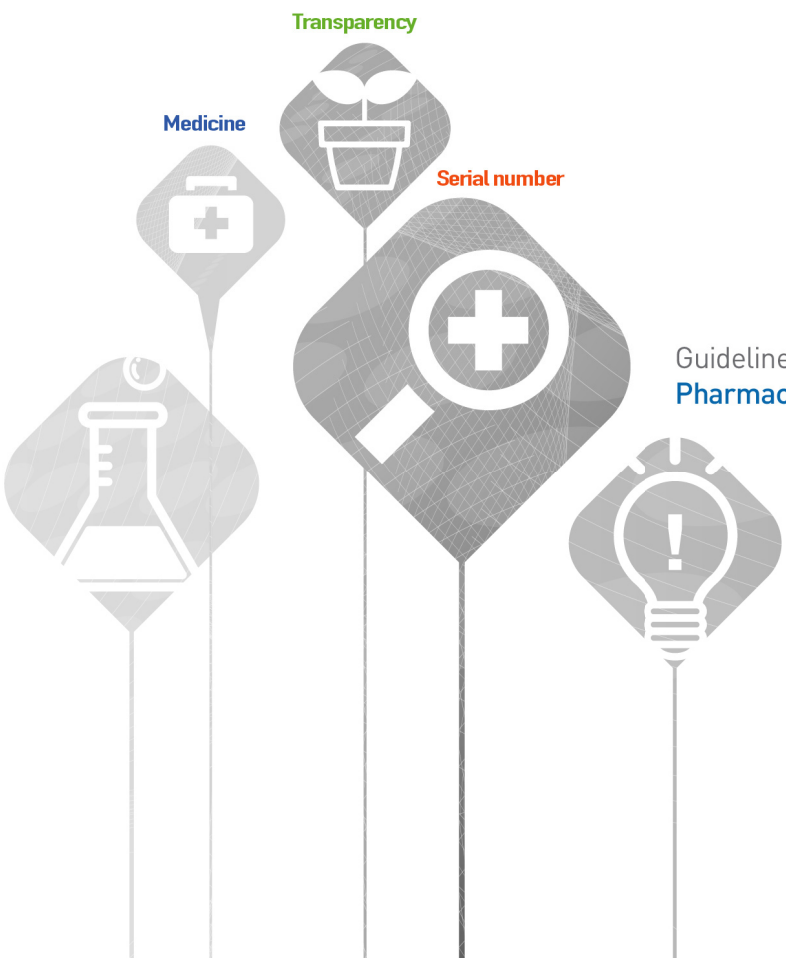
5-1. Pharmaceutical Serialization System Enforcement and transaction record reporting

5-2. Serial number labeling method

5-3. Aggregation

5-4. Data linkage for transaction record report (Agent, etc.)

5-5. Administrative measures



Guideline for
Pharmaceutical Serialization System

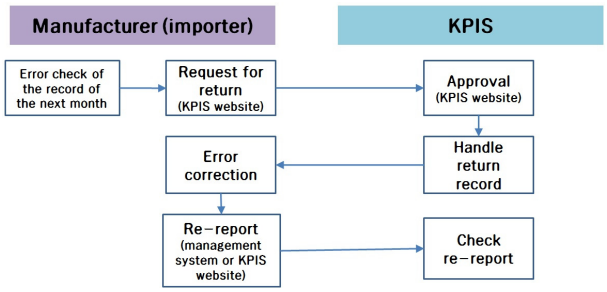
5-1. Pharmaceutical Serialization System Enforcement and transaction record reporting

No.	Q	A
1	Who reports the data (including serial number)?	● All drug suppliers (manufacturer/importer, wholesalers) ● Transactions within the same companies are excluded (no tax invoice issued for the transaction)
2	What are the newly introduced changes in transaction record reporting from 2016?	● Drug manufacturer/importer and wholesaler shall report data (including serial number) of all finished drug transaction "at the point of shipping" according to Form 24 of Annex-2 of Enforcement rule of the Pharmaceutical Affairs Act ● Transaction records of prescription drugs without serial number (Annex 24-2 of Enforcement rule of the Pharmaceutical Affairs Act) and OTC (Annex 24 of Enforcement rule of the Pharmaceutical Affairs Act) are allowed to be reported "by the end of next month" of the supply. ● Grace periods are allowed-by June 2016 for pharmaceutical companies, and by June 2017 for wholesalers, where they are allowed to "report by the end of the next month" of the supply of prescription drugs.
3	What does 'at the time of shipping' mean?	● From the shipping process of the supplier (manufacturer/importer, wholesaler), before the drugs are delivered and stocked at the wholesaler/provider. ● “Shipping” means that the manufacturer ships products out. "Report at the time of shipping" means that the manufacturer should report the data "before the products are delivered to the receiver", and it is allowed to report by next day of shipping.
4	When there is a disposal of returned drugs, what is the proper way of reporting?	● The supplier that received returned drugs shall report on the "return" and "disposal" by the end of next month.

No.	Q	A
5	Among the reporting forms, what are "Master template" and "Sub template"?	"Master template" is a form based on KD code and reports on supply amount (KRW), supply quantity, lot number, and expiration date. "Sub template" reports on the serial number and aggregation The two templates are separated for efficient management of data and minimization of data overlap. * It is determined by "① Sequence number"
6	How does the RFID tag data reporting change from 2016?	(Pharmaceutical company) From July 1 2016, when "report at the time of shipping" becomes mandatory, Form 24-2 of Annex reporting can replace the current RFID reporting system. ➡ But the separate RFID tag data reporting shall continue as it is until June 30 2016.
7	What should we do with prescription drugs like fluids and artificial perfusates that do not require serialization?	According to Table 1-2 of Annex of the 「Guideline on the Use and Management of Barcodes and RFID Tags for Drug (MOHW Notification)」, following drugs (GS1-128 code) are recognized as exceptions. (May 14 2015 Partial amendment) ➡ ① Fluids, ② Artificial perfusates, ③ Cleaning and disinfecting solvents of medical devices ④ Contrast medium * Search available on KPIS website-barcode-code mapping
8	Is X ray contrast medium (class number 721) a subject of serialization?	According to Table 1-2 of Annex of the 「Guideline on the Use and Management of Barcodes and RFID Tags for Drug」, among X ray contrast medium (721), only X ray and MRI contrast medium can be recognized as exception of serialization system. ➡ Among X ray contrast medium (721), "contrast medium adjurvants, purgative, colonic irrigation fluid" are subject to serialization.
9	Is the serialization and transaction reporting mandatory for drugs for military use and national	According to 「Guideline on the Use and Management of Barcodes and RFID Tags for Drug (MOHW Notification)」 and 「Enforcement rule of the Pharmaceutical Affairs Act」 Article 45, they are

No.	Q	A
	emergency stockpile?	subject to the serialization and transaction reporting. ➡ When there is an need for urgent supply, "reporting by the end of next month" is allowed with completing only "Master template" adding the reason in "Note". ※ Note example: ZA/Emergency drug supply
10	Is the serialization and transaction reporting mandatory for drugs for donation and sample offers? * Supply type: 2(Donation), 7(Sample)	Drug transaction data of donation or sample offering are allowed to be reported by the end of next month of supply in Form 24-2 of Annex. ➡ The receiver data (name, business registration number, provider code) is optional, serial number data is not necessary for drugs without serialization. ※ In the transaction record report file, enter "0" for business registration number. ▸ yymmdd_S01_1234567890_0000000000_Mnnn.csv
11	Is the serialization and realtime transaction reporting mandatory for exporting drugs?	KD code assignment is mandatory, but there is no obligation of barcodes, RFID tag, or supply data reporting. ※ Relevant rules – Article 45 of the 「Enforcement rule of the Pharmaceutical Affairs Act」 – Article 2 of the 「Standards on Labeling Subject of Barcodes and RFID Tags for Drug」
12	What about drugs for QC-test?	QC-test are not for sales therefore not included in the subject of barcode system.
13	How can we report about drugs supplied in December 2015?	By the end of January 2016 in Form 24 of Annex.
14	Will pharmaceutical companies be able to use track and trace service?	The transaction data will be provided only to the supplier and receiver, and other track and trace data will not be released. ※ The track and trace data of drugs are classified as confidential information according to 「Official Information Disclosure Act」 Article 9 Paragraph 1 Subparagraph 7

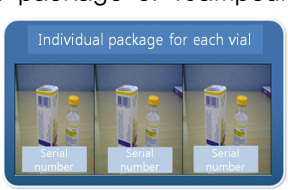
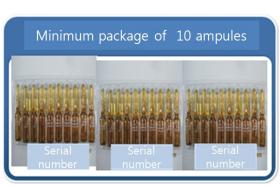
No.	Q	A
15	What is the retention period for transaction record data, serial numbers, and aggregation?	◓ Recommended retention period is 1 year after the expiration date.
16	Can a serial number be reused? If it can be, when does it become reusable?	◓ A serial number can be reused after 1 year from the expiration date (after expiration date + 1 year)
17	What should be done if the reporting at the time of shipping failed for inevitable reasons such as system failure?	◓ When the reporting was delayed for inevitable reasons, the reason of delay should be noted in "Note", and the data shall be reported immediately after the failure recovery. ※ Note example: ZB/System failure
18	In transaction data reporting form "Supply class", what do these terms mean? – 1. Shipping, 2. Return, 3. Disposal, 4. Error modification, 5.Cancelation	① Shipping: When manufacturers, importers, or wholesalers supply drugs to wholesalers or providers. ② Return: When supplied drugs were returned * Period for return report: By the end of next month ③ Disposal: When drugs are discarded * Period for disposal report: By the end of next month ④ Error modification: When modification is made in the data (KD code, unit price, total amount, etc.) ⑤ Cancelation: When supply data was reported without actual transaction, or when the transaction was cancelled before the tax invoice was issued. * The submitted transaction data can be modified/canceled until the tax invoice is issued. Once the tax invoice is issued, the supply should be returned and reported as such. – Before tax invoice: Modification/cancelation available – After tax invoice: Return and report as such * Error modification/cancelation period: Modification/cancelation is available until the last confirmation at the end of next month (monthly closing). After the monthly closing, return request should be sent, and re–reporting is available after obtaining manager's approval.

No.	Q	A
		
19	What is the reporting process for returns of individual units?	◓ Individual unit returns shall be reported on the basis of representative code * Representative code: Individual unit of each products (tablets, pills, etc.) or the minimum unit of NHI reimbursement
20	Should the serial numbers in the purchase data be retained?	◓ There is no regulation on the retention of purchase data. It shall be kept under the policy of each firm.
21	Shall the report submitted by each transaction, delivery, order, and product?	KPIS ESB Agent ◓ Every transaction shall create a file for each trading partner in accordance with the form. ➡ (Example) • Master template : yyyymmdd_S01_Supplier Business Registration Number_Receiver Business Registration Number_Mnnn.csv • Sub template : yyyymmdd_S01_Supplier Business Registration Number_Receiver Business Registration Number_Snnn.csv, {yyymmdd: Supply date, S01: Template number, M/S: Master/Sub, nnn: Sequence number (the same for Master/Sub)} Portal ◓ There is no limit in file name. (File creation standard: Supply date, supply class)
22	What if the date of issue of "specification on transaction" differs from	◓ When the date of supply (on specification on transaction) and actual delivery date do not match

<table>
<tr><th>No.</th><th>Q</th><th>A</th></tr>
<tr><td></td><td>actual date of supply?</td><td>Example) Date on specification on transaction (Oct. 1, 2015), Actual delivery date (Nov. 1, 2015, Dec. 1, 2015) divided delivery
- 1st reporting: Supply date (20151001), Note (ZC/20151101)
- 2nd reporting: Supply date(20151001), Note (ZC/20151201)</td></tr>
<tr><td>23</td><td>What is the supply reporting process when the report at the time of shipping is not available?</td><td>In such cases, note the code and reason in the "Note" from the table below with the delimiter /.
Example
<table>
<tr><th>Code</th><th>Meaning</th><th>Example</th></tr>
<tr><td>ZA</td><td>Emergency delivery</td><td>ZA/Emergency drugs</td></tr>
<tr><td>ZB</td><td>System failure</td><td>ZB/System failure</td></tr>
<tr><td>ZC</td><td>Supply date≠ Delivery date</td><td>ZC/20151201</td></tr>
<tr><td>ZD</td><td>Drug price reduction</td><td>ZD</td></tr>
<tr><td>ZE</td><td></td><td></td></tr>
</table>
* "Note" in reporting form holds up to 200 characters. For ZC, enter the actual delivery date</td></tr>
</table>

5-2. Serial number labeling method

<table>
<tr><th>No.</th><th>Q</th><th>A</th></tr>
<tr><td>24</td><td>What is GTIN (Global Trade Item Number)?</td><td>GTIN is globally unique product identification number. GTIN (read as [g–tin]) consists of 13 digits which identify company and individual product. Mainly encoded in 1D barcodes.</td></tr>
<tr><td>25</td><td>What are the differences between GTIN–13 and GTIN–14?</td><td>GTIN–13 is KD code assigned by KPIS. GTIN–14 is the logistics code assigned by companies to each logistics unit.
<table>
<tr><th>Digits</th><th>1</th><th>3</th><th>4</th><th>5</th><th>1</th></tr>
<tr><td>Content</td><td>Indicator digit</td><td>GS1 prefix</td><td>company#</td><td>Item reference</td><td>Check digit</td></tr>
<tr><td>KD code</td><td>0</td><td>880</td><td>6411</td><td>12345</td><td>9</td></tr>
<tr><td>Logistics code</td><td>1</td><td>880</td><td>6411</td><td>12345</td><td>6</td></tr>
</table>
With a logistics code, the number of product in a box is checkable. The logistics code should be assigned by pharmaceutical companies.</td></tr>
<tr><td>26</td><td>What is the encoding rule of lot number, expiration date, and serial number on the immediate container and outer package of drugs?</td><td>Article 5 Paragraph 2, Article 6 Paragraph 1 of 「Guideline on the Use and Management of Barcodes and RFID Tags for Drug」, if outer container/package has the serial number based on GS1–128 coding scheme on it, it is allowed to label only GTIN–13 on the immediate container/package.
If the drug has RFID tag, GTIN–13 encoded barcode is allowed to be printed on the container or package.
For drugs with RFID tag, the expiry date and lot number should be reported to KPIS right before shipping the drugs out.
➡ It is considered a violation of label regulation if a supplier fails to report about RFID tag data, and administrative measures will be imposed.</td></tr>
<tr><td>27</td><td>Is it possible for injections to open the imported package and affix barcords and RFID tags</td><td>It is not allowed to open a product package and reaffix barcords or RFID tags. but the importer may attach barcords on the outer container/package before shipping.</td></tr>
</table>

No.	Q	A
	on individual vials?	* (MFDS, Aug. 2014) Some drugs are imported from countries where barcord (GS1–128) label is not mandatory. In that case, the importer may attach barcode (GS1–128) on the container/ package before shipping.
28	Is it necessary to attach barcodes or RFID tags on the attached documents?	◓ No, it is not necessary. The barcord/RFID tag labeling is for drug container or package.
29	Is it possible to attach both barcode and RFID tag on the same drug?	◓ Yes, it is possible. In that case, the barcode and RFID tag must contain the same data (GTIN & Serial #), and should follow Article 5 and Article 6 of 「Guideline on the Use and Management of Barcodes and RFID Tags for Drug」 .
30	What types of characters can be used in the serialization?	◓ For serial number, we recommend the use of Arabic numerals, English capital letters, and English small letters. Also, among 82 characters defined by ISO/IEC 646, symbol characters are allowed to be used in serial numbers. ➡ Serial numbers have variable length, no longer than 20 digits. (e.g. "1", "001", "1234567890", "ABCDEFG") ◓ All elements of serial numbers are considered characters. Therefore, "01" and "001", and "A" and "a" are all different.
31	What is the serialization method for a package of many vials or ampules?	◓ A serial number should be given to a product that has a KD code. As such, a serial number should be assigned to the individual vial or ampule if the individual vial or ampule has a KD code. ◓ If the KD code is given to the minimum package unit of more than one vials or ampules, the serial number should also be given to the package unit. In case of individual package by 1vial each / In case of package of 10ampoule each  

No.	Q	A
32	What is the data order of GS1-128, GS1 Datamatrix?	● GTIN (13 digit KD code) should come first. Pharmaceutical companies may choose the order for the rest, but the recommended order is expiration date, lot number and serial number.
33	Where is the location for FNC 1(ASCII value 232) as a group separator?	● FNC1 are encoded at the end of the variable data (Lot number & serial #) when followed by another data. So that it can decode the pieces of data correctly. ● Only FNC1 can be used for For the starting character. **Variable length data** ➡ Number of digits for the data is not fixed. Rather, it is variable as long as the length is no longer than 20 digits such as "lot number/serial number". Function of FNC1: Starting character and field separator 1) KD code 8806411123459 2) Expiration data 2012.12.31. 3) Lot number GS1-128 4) Serial number Q12345 GS1 DataMatrix Scanned results AI AI AI AI FNC1 01 08806411123459 17 121231 10 GS1-128 FNC1 21 Q12345 Starting character / KD code / Expiration / Lot no / Field separator / Serial number
34	Can a barcode be verified?	● GS1 Korea of the Korea Chamber of Commerce and Industry provides barcode verification service, free of charge.
35	What are the standards for HRI?	● The HRI is not mandatory and there is no standard for HRI and its size. Yet, according to Article 56 Paragraph 1 Subparagraph 3 of the Pharmaceutical Affairs Act, lot number and expiration data should be labeled in accordance with the Regulation on Labels of Pharmaceuticals, etc.
36	When GS1-128 is used, is it allowed to use other Application Identifiers aside from the essential	● Other Application Identifiers (AI) may be used at the end of the essential data. In other words, at the end of KD code/expiration data/lot number/serial number. ● If an AI is put in before all essential data are placed,

No.	Q	A
	items such as KD code, expiration date, lot number, and serial number?	the software might recognize it as a barcode error.
37	When serializing prescription drugs with the same KD code, is it allowed to assign the same serial number if the expiration date/lot number are different?	◓ In the drug barcode system, serial number shall not be duplicated for one KD code. Therefore, it is not allowed to assign the same serial number even if the drug has a different lot number and/or expiration date if it has the same KD code. ◓ Reusing a serial number is allowed when 1 year has passed from the expiration date so the product is no longer in circulation.
38	For the drugs of ownership transfer, when should the replacement of new barcode and RFID tag take place?	◓ From the point when the transfer of ownership and reporting to the MFDS on the drug permission (report) change is completed, the product shall have the newly affixed barcode and RFID tag.

5-3. Aggregation

No.	Q	A
39	Is aggregation mandatory?	Aggregation is not mandatory. ➡ Yet it is recommended recommended since aggregation is necessary for convenience during receipt and release.
40	How should we handle the information about aggregation?	KPIS plan to provide additional API for aggregation so the information will be maintained.
41	What is aggregation coding rule?	According to Article 5 Paragraph 7 of the 「Guideline on the Use and Management of Barcodes and RFID Tags for Drug」, (GTIN-14)+Serial Number or SSCC can be used as an aggregation code. ※ SSCC (Serial Shipping Container Code)
42	When assigning SSCC to drugs produced by a contract manufacturer, whose GS1 company prefix should be used?	For SSCC (of aggregation), the GS1 company prefix of either the client or the manufacturer may be used. But the one who assigned aggregation should guarantee the exclusiveness.
43	What is the aggression labeling method for a box containing 2 packages of 60 sales units of products?	Label the KD code on the minimum package unit (of 60 sales unit) – Placing 2 packages of 60 units together in a box could be considered a container, and it is possible to add an aggregation code. (But not mandatory)
44	Can SSCC and GTIN-14+Serial number be used for a box of mixed products?	SSCC can be used both for boxes of homogeneous or heterogeneous products. But GTIN-14+Serial number can be used only for homogeneous boxes.
45	When SSCC is applied to the barcode on the drug package, would scanning the barcode provide information about the drug inside?	Only when the supplier provided product information to the receiver at the same time of supply. ➡ Therefore, in the utilization of aggregation, it is essential that the supplier provides drug information to the receiver at the time of supply when SSCC was applied on the package.

No.	Q	A
46	When labeling aggregation on the package, should a box have 2 sheets of aggregation?	◓ According to Table 4 of the 「Guideline on the Use and Management of Barcodes and RFID Tags for Drug」, aggregation (SSCC, logistics code (GTIN-14)+ Serial Number) can be attached only one side. It is recommended that logistics barcodes (ITF-14, etc.) be attached on at least two sides (adjacent surfaces) of the box..
47	In the transaction record report template, what is the order for aggregation?	◓ On the "Sub" template, aggregations can be added up to five by classifying them with "/" for each KD code and serial number.

5-4. Data linkage for transaction record report (Agent, etc.)

No.	Q	A
48	What is KPIS ESB Agent?	KPIS ESB Agent is a software that automatically transmits the data to KPIS when a transaction record report file is created in accordance with the standard.
49	How is the KPIS ESB Agent operated?	The operation method presumes that the proper template files are created in the proper folder through verification logic or ERG, ASP support technology. The system checks the folder on a regular basis and transfers files in the folder to serialization system through the linkage server. File creation logic function needs to be added by suppliers/ASP vendors in accordance with their own development environment/task logic of ERP or ASP.
50	What are the methods of data linkage?	One is to use KPIS ESB agent, and the other is to use web portal. Suppliers that are equipped with independent system or using ASP vendor can use KPIS ESB Agent, and the rest can use the web portal for file upload and download.
51	What should suppliers prepare for data linkage?	Suppliers can build a system that can electronically manage shipping and receiving in the Form 24–2 of Annex, and develop file creation and data storage program for data linkage in accordance with further notifications in the future.
52	In the data linkage template, hat does MODE mean?	"a" represents a character, "n" represents numbers. "an" means both character and number can be used. "n" means only numbers can be used. Numbers in the marks of parenthesis () means the maximum digits allowed. For example, "Business Registration Number" n(10) means that

No.	Q	A
		it can be a combination of numbers, no longer than 10 digits. "Person in Charge" an(20) means that it can be a combination of characters and numbers, no longer than 20 digits.
53	What is the file creation unit for data linkage?	Data linkage through KPIS ESB Agent will create a file for each specification on transaction. (Issued once a day for each trading partner) File upload through portal allows gathering of records of different trading partners in the same way with the previous monthly report.
54	What are the proposed solutions for various hardwares? ex) UNIX Server, DellServer, AS400	The hardware vendor is irrelevant (Dell, etc.), but it should have JDK1.6 or higher development environment. (Needs to be checked at member companies with old type servers like AS400) Various KPIS ESB Agents are planned to be provided for different OS (UNIX, Linux, Windows) (Default is Windows ESB agent)
55	What is the format of upload file? Is it possible to use EPCIS format of XML file in accordance with GS1 standard?	CSV file will be used. (Delimiter: " | ") EPCIS format of XML file is not allowed.
56	How can we receive purchase record from KPIS?	Through KPIS ESB Agent, the data is provided in the form of R01. The same data is available through the web portal.
57	How often the uploaded file (through KPIS ESB Agent) are sent to KPIS?	Real-time.
58	Does that mean "file to file transfer"?	We support "file to file". (Currently not considering DB to DB)
59	How can the supplier check the reports before submission?	In-advance checkup program and the master files of KD code and hazardous drugs will be provided through KPIS ESB Agent. For master files,

No.	Q	A
		complete files will be provided in the beginning, followed by updates. In case suppliers need to develop an independent checkup program, the checkup logic and checkup source will be made public. Independently developed programs can be verified by a test using sample data from HIRA.
60	Is there a way for data linkage through KPIS ESB Agent without a fixed IP?	Fixed IP is necessary for KPIS ESB Agent data linkage because the destination and confidence of the destination can be confirmed only through fixed IP.
61	Some importers have their servers located overseas and the system does not allow KPIS ESB agent installation. What can they do?	They can adopt a separate server for transmission in Korea, and install KPIS ESB agent on the server for data linkage Or, upload the files through web portal.
62	What types of API are provided?	Open API type for RFID data and KD code data, drug data by serial number, and aggregation code.
63	Among data linkage methods, what are the standards for choosing automated reporting and manual verification KPIS ESB Agent?	A supplier can choose manual verification KPIS ESB Agent when it is equipped with independent ERP system or ASP service and finds it difficult to develop self checkup logic, or wants to perform the check up through PC.
64	What is the reporting method of the government for serialization data? (File Upload, Web Portal, Web Services, FTP, AS2, etc.)	Adopted KPIS ESB (Enterprise Service Bus) data linkage technology and report file to file unit through KPIS ESB Agent.

5-5. Administrative measures

No.	Q	A
65	Who is responsible for assigning the serial number labeling?	◓ The manufacturer/importer that obtained permission for manufacture/import is responsible for assigning serial number labeling and data report. ◓ The pharmaceutical company that obtained permission for the item is responsible for the serialization management even for products for sale on a commission,
66	Is it a violation of regulation if the barcode is smaller or in different color than what is stated in the Notification, and the case may be subject to administrative measures?	◓ According to Article 71 Paragraph 2 of the 「Enforcement Regulation on the Safety of Pharmaceuticals, etc.」, barcode and electronic tag shall be readable by scanners and shall be properly labeled so they can be accurately read without confusion. The case may be subject to administrative measures if scanners fail to recognize the barcode or electronic tag. ◓ Therefore, the size, color, and location of the barcode should comply with Table 3 the 「Guideline on the Use and Management of Barcodes and RFID Tags for Drug」. ◓ For colors, GS1 Korea of the Korea Chamber of Commerce and Industry has more readable colors on their website (GS1 introduction – Utilization of GS1 barcode).
67	Is it impossible to pass customs clearance if the import drug is without a serial number?	◓ Serialization does not affect customs clearance. ➡ **Serialization is about supply chain security in Korean market. If a prescription drug, a subject of serialization from Jan. 1 of 2016, was circulated in Korean market without a serial number, it is a violation of the 「Guideline on the Use and Management of Barcodes and RFID Tags for Drug」.**

No.	Q	A
68	Regarding the adoption of pharmaceutical serialization system, when does the real-time reporting start? And what is the standard for administrative measures?	◓ Considering it is beginning phase of enforcing the system, the grace period (reporting by the end of next month of supply is allowed) is given to manufacturers/importers by Jun. 30 of 2016 and to wholesalers by Jun. 30 of 2017. * Amended Article 45 of the Enforcement rule of the Pharmaceutical Affairs Act (Nov. 11, 2015
69	Please explain the grace period for administrative measures regarding serialization system enforcement.	◓ Administrative measures will be suspended by Dec. 31, 2016 for manufacturers/importers, and by Dec. 31, 2017 for wholesalers regarding the enforcement of serial number reporting at the time of shipping. ➡ Administrative measures regarding existing transaction record reporting system continue to be in place. * There will be a further notice on the standards for administrative measures in case of serialization violation. ◓ For drugs with RFID tag, the tag data should be reported by Jun. 30, 2016. (After this point, realtime reporting can replace the RFID tag data reporting.)
70	Will the pharmaceutical company be subject to administrative measures if it fails to report transaction records on time or report falsely?	◓ Failing to report on time may result in KRW 1 million fine and following administrative measures. ◓ Inaccurate or fraudulent transaction record reporting may expose the firm to following administrative measures. 〈Enforcement Regulation on the Safety of Pharmaceuticals, etc. [Table 8 of Annex]〉 • Matter of Violation: 36. When failed to report in accordance with the Article 47-2 Paragraph 2 of the Act, or made a fraudulent report

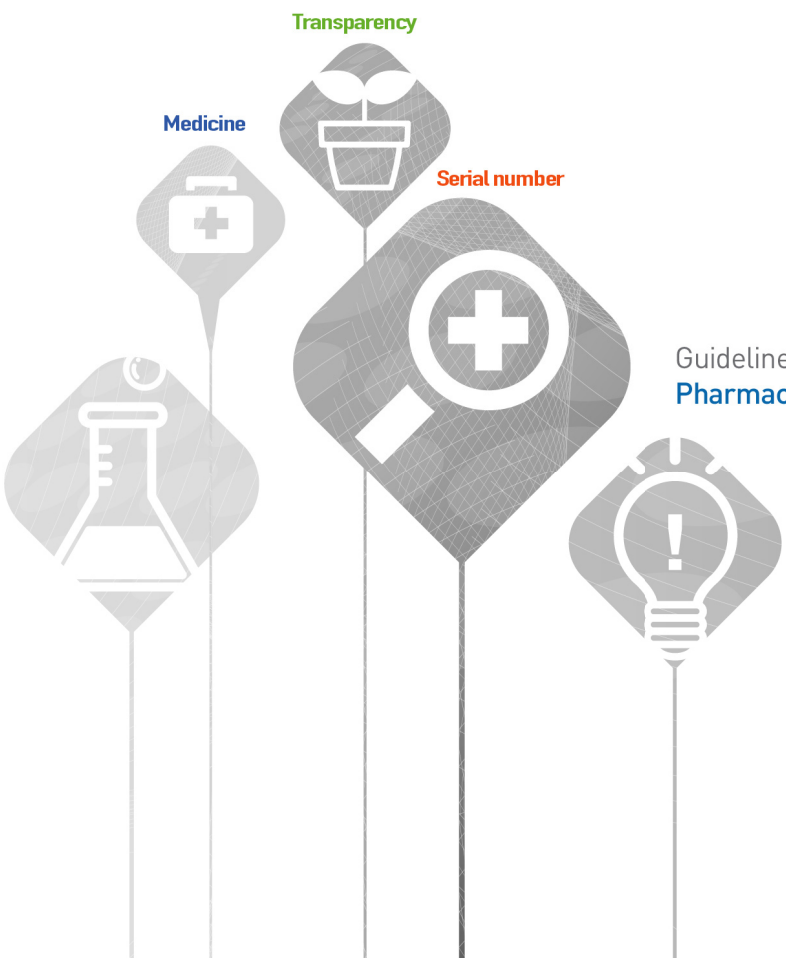
<table>
<tr><th>No.</th><th>Q</th><th>A</th></tr>
<tr><td></td><td></td><td>
<table>
<tr><td rowspan="2">Legal basis</td><td colspan="4">Administrative measures</td></tr>
<tr><td>1st</td><td>2nd</td><td>3rd</td><td>4th</td></tr>
<tr><td>Article 47–2</td><td>1 month of sales suspension of the product</td><td>3 month of sales suspension of the product</td><td>4 month of sales suspension of the product</td><td>revocation of permission of the product</td></tr>
</table>
</td></tr>
<tr><td>71</td><td>Will the seller (wholesaler) be subject to administrative measures if it fails to report transaction records on time or report falsely?</td><td>
• Failing to report on time may result in KRW 1 million fine and following administrative measures.
• Inaccurate or fraudulent transaction record reporting may expose the firm to following administrative measures.
〈Enforcement rule of the Pharmaceutical Affairs Act [Table 3 of Annex]〉
Standards for administrative measures (Regarding Article 50)
• Matter of Violation : 41. When a pharmaceutical wholesaler failed to report in accordance with the Article 45 of the Act, or made a fraudulent report
<table>
<tr><td rowspan="2">Legal basis</td><td colspan="4">Administrative measures</td></tr>
<tr><td>1st</td><td>2nd</td><td>3rd</td><td>4th</td></tr>
<tr><td>Article 76</td><td>15 days of suspension of operation</td><td>1 month of suspension of operation</td><td>3 month of suspension of operation</td><td>6 month of suspension of operation</td></tr>
</table>
</td></tr>
</table>

VI References

6-1. Forms

① Enforcement rule of the Pharmaceutical Affairs Act [form of Annex 24]

② Enforcement rule of the Pharmaceutical Affairs Act [form of Annex 24-2]



Guideline for
Pharmaceutical Serialization System

6-1. Forms

① Enforcement rule of the Pharmaceutical Affairs Act [Form 24 of Annex]

■ Enforcement rule of the Pharmaceutical Affairs Act [Form 24 of Annex]

Drug transaction records

(Front)

Receipt no.	Receipt date	Issue date

① Sequence no.	② Supplier type	③ Contract type	④ Supply class	⑤ Supply type	Receiver			⑨ KD code name (Product name)	⑩ KD code (Product code)	⑪ Package total unit (Standard)	⑫ Supply Qty.	⑬ Supply date	⑭ Supplied amount (KRW inc. VAT)	⑮ Unit price (inc. VAT)	⑯ Note
					⑥ Name	⑦ Business Registration No.	⑧ Provider code								

I hereby report on the drug transaction records in accordance with Article 45 of the 「Enforcement rule of the Pharmaceutical Affairs Act」.

Date:

⑰ Supplier name:

⑱ Business registration no.:

⑲ Representative (Person in charge): (Signature or Seal)

297㎜×210㎜[Common paper 60g/㎡(Recycled)]

(Back)

Guideline

② Provider type refers to the type of provider, such as the provider that obtained permission for the product, importer, and wholesaler.
1: Manufacture, 2: Import, 3: Wholesale, 4: Manufacture+Import, 5: Manufacture+Wholesale, 6: Import+Wholesale, 7: Manufacture+Import+Wholesale

③ Contract type refers to the type of contract between the supplier and receiver.
1: Private contract, 2: Competitive bidding

④ Supply class refers to the service – when the supplier shipped the products out (shipping), when the provider received returned products (return), when the provider discarded the products (disposal)
1: Shipping, 2: Return, 3: Disposal

⑤ Supply type refers to the type of drug supply.
1: For export, 2: For charity, 3: For military use, 4: For private use,
5: Provider (Medical institution, pharmacy, health center, etc.), 6: Drug supplier(Production · Import · Wholesaler, etc.), 7: Sample
8: Convenient store ,9: Special medical facility · Academic institute, etc. (School health room, nursing home for the elderly, prison, institute, academic society, public group, etc.)

⑥~⑧ In case the receiver is a healthcare provider, fill in Name, Business Registration No., and Provider code. In case the receiver is not a healthcare provider but a wholesaler or a convenient store, fill in Name and Business Registration No.

⑨~⑩ For KD code name and KD code, follow "List of Drug KD code announced by the President of KPIS under the 「Guideline on the Use and Management of Barcodes and RFID Tags for Drug」.

⑪ Package total unit (standard) refers to the "total quantity (total number of items in the package)" of the "List of Drug KD code".

⑫ Supply quantity refers to the total number of product (package).

⑬ Supply date, ⑭ Supply amount (KRW, including VAT), and ⑮ Unit price (including VAT) should be based on the specification on transaction.

⑰~⑲ Supplier name, Business registration no. and representative should match those of "Business license".

② Enforcement rule of the Pharmaceutical Affairs Act [Form 24-2 of Annex]

■ Enforcement rule of the Pharmaceutical Affairs Act [Form 24-2 of Annex]

Drug transaction records

(Front)

Receipt no.	Receipt date	Issued date

① Sequence no.	② Supplier type	③ Contract type	④ Supply class	⑤ Supply type	Receiver			⑨ KD code name (Product Name)	⑩ KD code (Product code)	⑪ Package total unit (Standard)	⑫ Supply Qty.	⑬ Supply date	⑭ Supplied amount (KRW inc. VAT)	⑮ Unit price (inc. VAT)	⑯ Receipt No. (Subject of re-report)	⑰ Return code (Subject of re-report)	⑱ Lot no.	⑲ Expiration date	⑳ Serial no.	㉑ Aggregation code	㉒ RFID tag code	㉓ Note
					⑥ Name	⑦ Business registratioin no.	⑧ Provider code															

I hereby report on the drug transaction records in accordance with Article 45 of the 「Enforcement rule of the Pharmaceutical Affairs Act」.

Date:

㉔ Supplier name:

㉕ Business registration no.:

㉖ Representative (Person in charge): (Signature or Seal)

297㎜×210㎜[Common paper 60g/㎡(Recycled)]

(Back)

Guideline

② Provider type refers to the type of provider, such as the provider that obtained permission for the product, importer, and wholesaler.
1: Manufacture, 2: Import, 3: Wholesale, 4: Manufacture+Import, 5: Manufacture+Wholesale, 6: Import+Wholesale, 7: Manufacture+Import+Wholesale

③ Contract type refers to the type of contract between the supplier and receiver.
1: Private contract, 2: Competitive bidding

④ Supply class refers to the service – when the supplier shipped the products out (shipping), when the provider received returned products (return), when the provider discarded the products (disposal)
1: Shipping, 2: Return, 3: Disposal

⑤ Supply type refers to the type of drug supply.
1: For export, 2: For charity, 3: For military use, 4: For private use,
5: Provider (Medical institution, pharmacy, health center, etc.), 6: Drug supplier(Production · Import · Wholesaler, etc.), 7: Sample
8: Convenient store ,9: Special medical facility · Academic institute, etc. (School health room, nursing home for the elderly, prison, institute, academic society, public group, etc.)

⑥~⑧ In case the receiver is a healthcare provider, fill in Name, Business Registration No., and Provider code. In case the receiver is not a healthcare provider but a wholesaler or a convenient store, fill in Name and Business Registration No.

⑨~⑩ For KD code name and KD code, follow "List of Drug KD code announced by the President of KPIS under the 「Guideline on the Use and Management of Barcodes and RFID Tags for Drug」 .

⑪ Package total unit (standard) refers to the "total quantity (total number of items in the package)" of the "List of Drug KD code".

⑫ Supply quantity refers to the total number of product (package).

⑬ Supply date, ⑭ Supply amount (KRW, including VAT), and ⑮ Unit price (including VAT) should be based on the specification on transaction.

㉔~㉖ Supplier name, Business registration no. and representative should match those of "Business license".

〈Regarding re-report of serial number return cases〉

⑯ Receipt no. (Subject of re-report) refers to the "returned receipt no." in case ④ supply class is "4. Error correction" or "5. Cancelation", or the case was returned due to electronic checkup.

⑰ Return code (Subject of re-report) for re-report refers to the applicable return code.

[※ Drug transaction record reporting (①~⑮ are the same with previous monthly report template), pharmaceutical serial number reporting (⑱~㉒ are for the report at shipping, ⑯~⑰ are for the re-report of returned cases)]

〈Regarding drug serial number reporting〉

⑱ Lot number is included in order to be able to check everything for a certain production unit.

⑲ Enter the expiration date.

⑳ Serial number is to distinguish and identify each product, therefore should not be repeated in the same KD code.

㉑ Aggregation code should be put in as many times as aggregation (e.g.: Primary aggregation code/ Secondary aggregation code / Tertiary aggregation code)

㉒ Enter RFID tag code (13 digits). (Country code (3)+Supplier code (4)+Logistics code (1)+Product code (5))