



# Drug Distribution Management Policy in Korea

## Regarding introduction of Drug Serial Number System (Serialization)



Ministry of Health and Welfare





# Drug Distribution Management Policy Overview

## ❖ Policy Objectives

- ✓ Establishing **efficient and transparent drug distribution system**
- ✓ The **safe use** of medicines

## ❖ Main Progress

- ✓ **Standardization of codes** containing medical information
- ✓ Making **drug supply history report mandatory**
- ✓ **Extending Drug Information Display**
- ✓ **Utilizing collected drug information**



## Related Legislation

### ❖ **Pharmaceutical Affairs Act**

- ✓ Article 45(Matters to be reported drug supply), Article 56(Matters to be Stated on Containers, etc), Article 57(Matters to be Stated on Outside Packages)

### ❖ **Regulation on Safety of Drugs, Etc.**

- ✓ Article 69 (Markings and notices on drugs)

*As regards to pills that are individually packaged within a packaging unit, the name of the product, the trade name of the holder of product registration or importer, the manufacturing number, and the use-by or expiration date should be printed on each packaging unit.*

- ✓ Article 71 (Cautions on written notices)

### ❖ **Notification on the Use and Management of Drug Bar Codes and RFID tags**

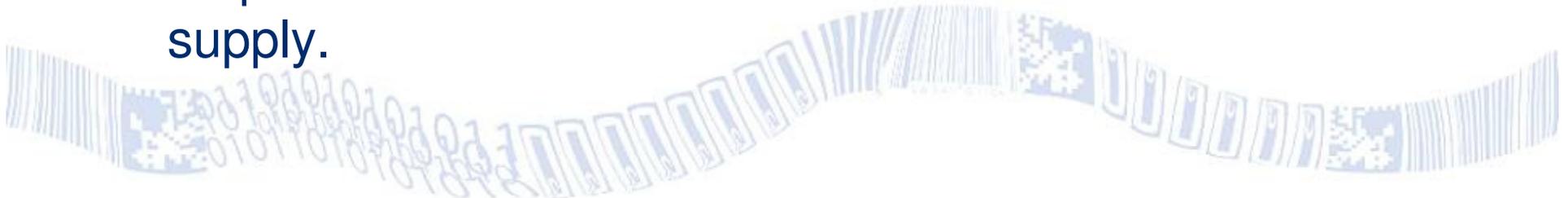
### ❖ **General Principles on Drug Bar Codes, Etc.**



# The Competent Authorities

## ❖ **Ministry of Health and Welfare,** Division of Pharmaceutical Policy

- ✓ General Health Care Policy Administration, especially responsible for Drug and Medical Device Distribution·Management Policy
- ✓ It established '**KPIS(Korea Pharmaceutical Information Service)**', and is mandated for managing Drug Bar Codes and distribution history, providing corporate and business with information about the supply.





# Progress





# Basic Directions

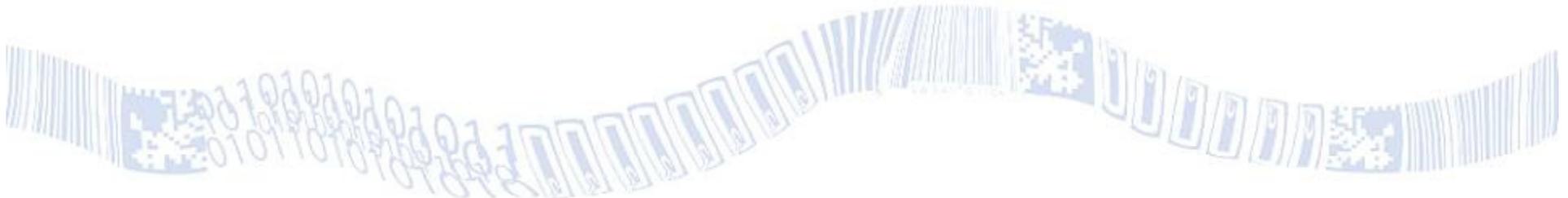
- ❖ **Composition of fair and transparent drug distribution environment ('11)**  
: Phased in **Bar code, RFID, Serial Number System**
- ❖ **We're planning to assign serial number to minimum distribution unit from 2015 and preparation is in progress**

		2012	2013	2015
units		10 million	2.5 billion	2.5 billion
indication	2D Bar Code	shelf life+lot number	shelf life+lot number	shelf life+lot number+serial number
	RFID		serial number	serial number
Distribution History	company	Supplier, distributor quantity report	Addition of Distribution date, manufacture's serial number	Addition of serial number
	Wholesaler	Importer, distributor quantity report	Addition of Distribution date, manufacture's serial number	Addition of serial number



## Major progress

- ① **Implementation of Drug Barcode Labeling system**  
(2000)
  
- ② **Unification of Item Codes to 13 digit Drug Standards Code, so-called 'KD Code'**( 2009)
  - ✓ **Korea Drug Code**, a unique number which consists of 13 digits comprising **country code**(3digits), **the code of the product registration holder/importer**(4digits), the **product code**(5digits) and the **check digit**(1digit)





# Major progress

## ③ Introduction of labeling system with extended Bar Codes (GS1-128) including Serial number, expiration date in addition to Standard Codes

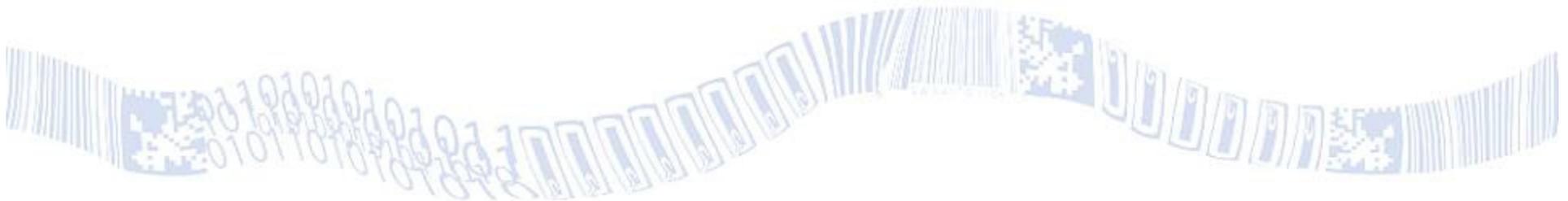
- ✓ the GS1-128 code from the international standard codes were implemented for prescription drugs(2013)

Application Identifier	01	17	10	21
Definition	GS1 product code	Maximum shelf life (use-by or expiration date)	Batch or Lot number	Serial Number
Data format	14 digit number	6 digit number	combination of numbers / capital letters not to exceed 20 characters	combination of numbers / capital letters not to exceed 20 characters



## Major progress

- ④ **Set up for regulations about selective use of RFID tag aside from Drug Bar Codes (2011)**
- ⑤ **Mandatory Serial Number Display system for prescription drugs (2015)**
  - ✓ the addition of serial numbers be implemented from Jan 1st 2015





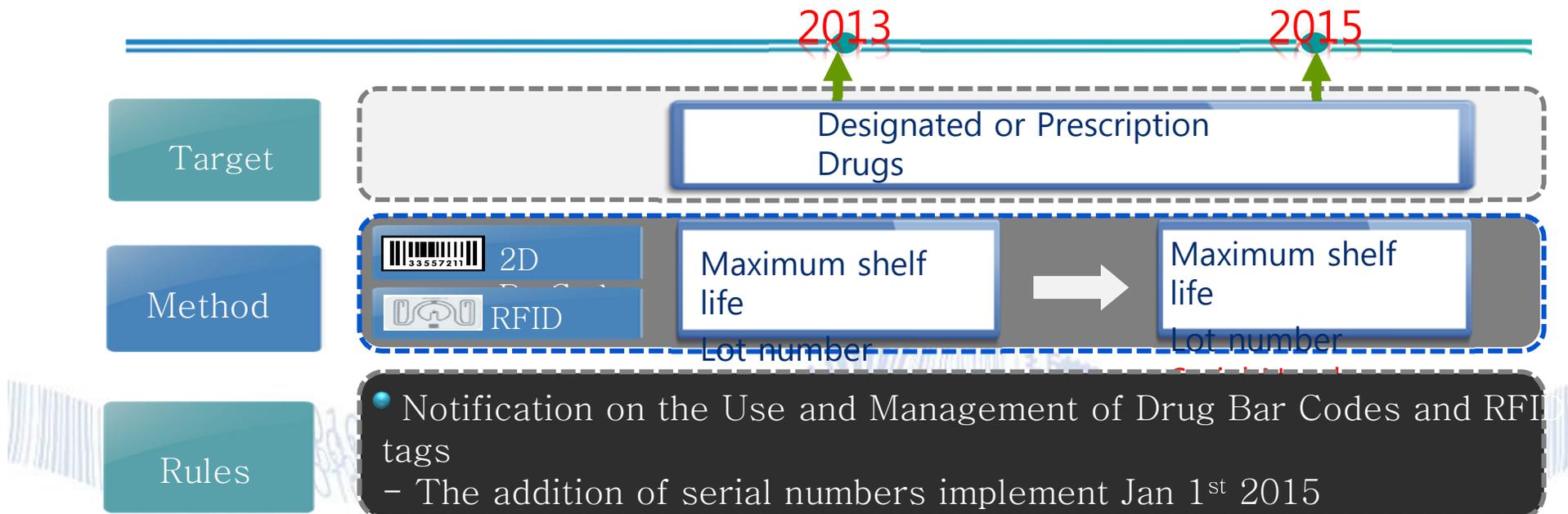
# Institutionalizing Serialization





# Serial Number System Overview

- ❖ Attaching RFID or 2D Bar Codes on prescription drugs, setting up **the track and trace system** and **Aggregation base**
- ✓ To make people to use medicines safely and to manage drug distribution efficiently by assigning serial number to minimum distribution unit.





## Significance of introducing Serialization

### ❖ Prescription drugs are being managed with assigned Unique Number

- ✓ Drug production, Supply, Sales, Distribution flow can be verified and validated electronically

### ① Efficient distribution management

- ✓ Inventory Management by computerizing distribution records
- ✓ Sales Management classified by each distributor's product, quantity, unit price, etc.
- ✓ Drug's return and recover status, time, unit price can be checked



# Significance of introducing Serialization

## ② National Health Promotion

- ✓ Blocking potential source of counterfeit medicines
- ✓ Blocking sales of medicines that have passed their expiry date
- ✓ Preventing drug abuse and misuse
- ✓ Managing medication records such as Dose per patient, medication administration

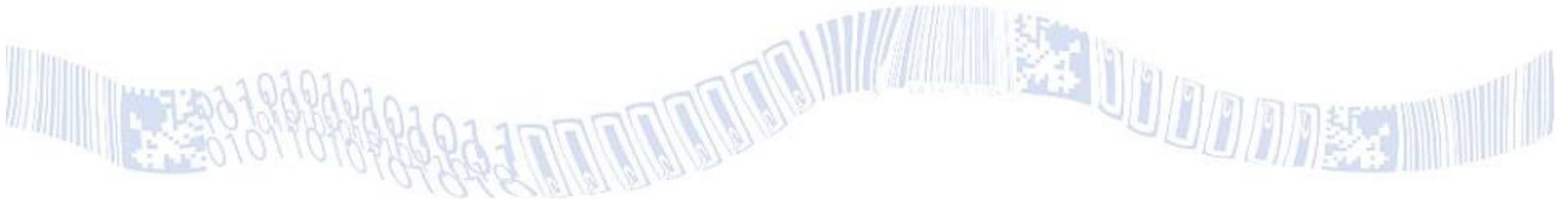
## ③ Others

- ✓ Establishing Stepping stone in development of Pharmaceutical Industry
- ✓ Strengthening supervision (effectively establishing government's drug-related policies)



## Future Plans

- ❖ Collecting opinions of people in related industry continuously
- ❖ Establishing, educating and informing guidelines for granting serial number
- ❖ Improving system in order to facilitate Real-time management (current drug supply management system has one month time lag)
- ❖ Expanding RFID utilization.





## Contact Details

Ministry of Health and Welfare,  
13, Doum 4-Ro, Sejong-si, Korea

T + 88 44 202 2487

W [www.mw.go.kr](http://www.mw.go.kr)

E [goun.lee@korea.kr](mailto:goun.lee@korea.kr)

