



# Pharmaceutical Serialization and Traceability system in South Korea

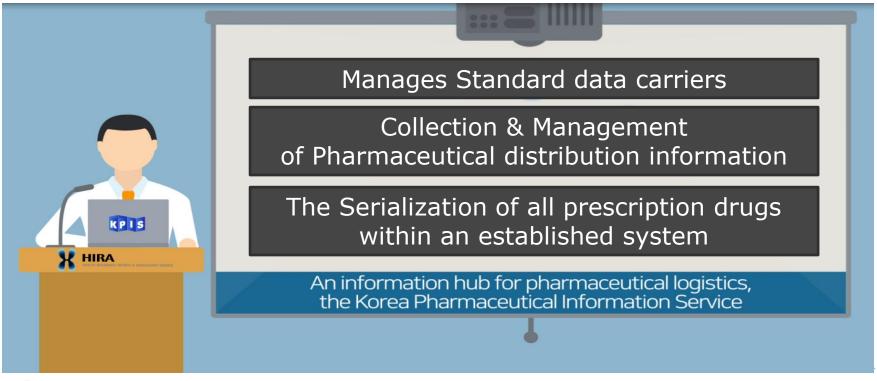
Progress and Status of national pharmaceutical serialization system

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### About KPIS(Korea Pharmaceutical information service)









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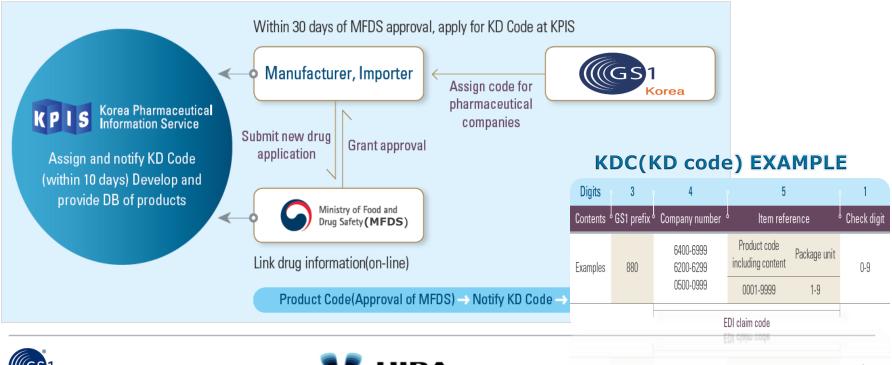




# KD code (GTIN)



National trade item numbering system







### Data Carrier Requirements



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

	Barcode	RFID tag		
Principle	(01)08806411057310	RFID Reader Electromagnetic wave (Energy)  Antenna  Electromagnetic wave (Energy)  Chip wave (data)		
Coding Structure	GTIN/ GS1 Application Identifiers	SGTIN-96 / SGTIN-198		
Company Usage Rate	96.5%	3.5% (*used by 16 companies)		





# Classification by Drugs category



Category	OTC drugs	ETC drugs (Prescription drugs)		
Data	KDC(GTIN)	KDC (GTIN) +Expiration date/Batch number /Serial number*		
Symbology	GS1-DataMatrix (01)08806411123459  or  EAN-13	(01)08806411123459(17)171231 or  (01)08806411123459(17)171231 GS1-128		





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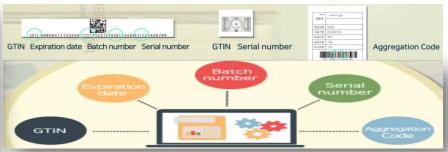
# Introduce of national PSS (Pharmaceutical Serialization System)



I. Serialization per smallest packing unit



**II.** Manage of data digitally including aggregation



**III.** Register data to KPIS upon shipment



IV. Real-time data linkage and Monitoring







# **Progress**



•	2015	<b>&gt;</b>	201	.6		2017	2018
Pharmaceuticals	Serialization		I	II	Re	port at the	time of shipping
Wholesalers				I		II	Report at the time of shipping

phase	I	П	Ш
Reporting system	Report at the time of shipping Allowed to report by the end of next month	Report at the time of shipping	Report at the time of shipping (** Apply administrative measures when violated)
Pharmaceuticals	Jan. 2016 - Jun. 2016	From Jul. 2016	From Jan. 2017
Wholesaler	Jan. 2016 – Jun. 2017	From Jul. 2017	From Jan. 2018

Base date for report is 'the date of supply'

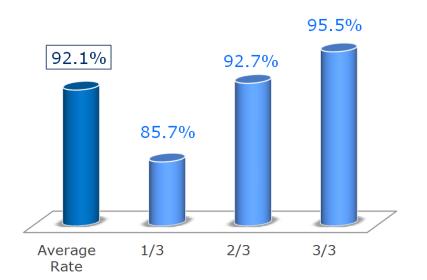




#### **Status**

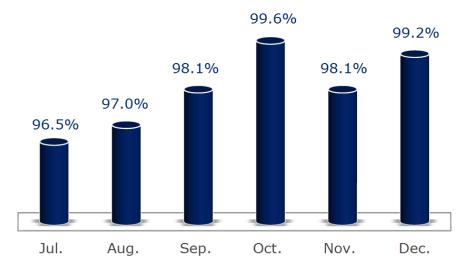


# Serialization on ETC drugs in 2016



# Registration of supply records with serial number

■ Participation Rate(%) of pharmaceutical companies in 2016

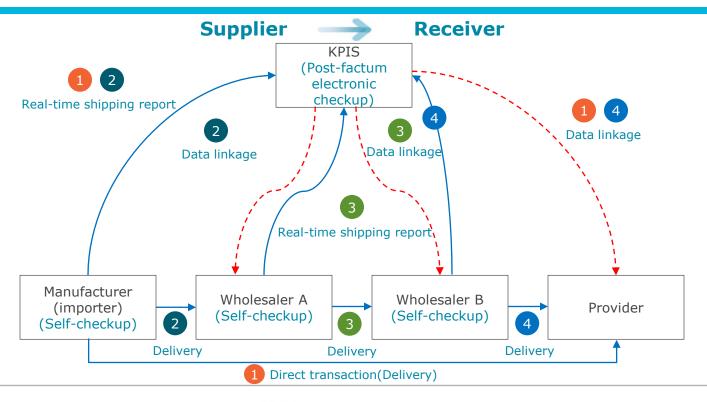






# Data linkage









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- Pharmaceutical Serialization system
- Traceability system
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  - Benefits of the pharmaceutical industry
  - AG data linkage service
  - Safety check service (Under plan)





#### Information Utilization







## Benefits of Pharmaceutical industry



# Manufacturer/Importer (approx. 460 companies)

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

#### **Hospital/Pharmacy**







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

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

- Build trust with patients
- Eliminates counterfeit and illegal medicines
- Easy expiry data management
- Accurate inventory control

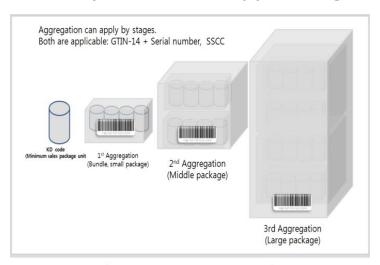




# AG Data linkage service (On-going)



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





Pharmaceutical aggregation units >





# Safety check service (Under plan)



Drug information lookup through Mobile application software









#### **Contact Information**



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