South Korea Drug Serialization System

Regulatory Update
February 2020

Regulatory Agency	Ministry of Health and Welfare (MoHW), Ministry of Food and Drug Safety (Korea MFDS)
Regulation Name or System Name	Korea Drug Serialization System, Korea Pharmaceutical Information Services (KPIS)
Compliance Dates	All drugs imported must be serialized by January 1, 2015, unless the importer submitted a plan prior to October 1, 2015 with a different date, prior to January 1, 2016.
	Government reporting started in 2016: Between January 1, 2016 and July 1, 2016, data may be reported, with no penalty for not reporting. Starting on July 1, 2016 reporting became mandatory.
Applies to	Prescription drug suppliers: manufacturers, importers and wholesalers

Unit-level Packaging ("units of sale")

Barcode Symbology	2-dimentional GS1 Datamatrix, linear GS1-128 or GS1 RFID tag
Barcode Contents	Korea Drug (KD) Code
	A GS1 serial number (up to 20 alphanumeric characters);
	The expiration date of the drug;
	The lot/batch number of the product, up to 20 alphanumeric characters.
RFID Tag (optional) Contents	KD Code and serial number
Serial Number Randomization	Yes
Serial Number Reuse	1 year after expiry
Human Readable Expiry Date Format	Not specified
Barcode Data Encoding	GS1 standard
Product Code notes	The KD Code is apparently a GTIN-13 assigned by GS1 South Korea specifically for drugs, or by the government, in cooperation with GS1 South Korea. The KD Code is converted to a GTIN-14 by prepending a zero.
Free Samples must be marked?	Yes, unless the product is exempt
Stickering after manufacturing allowed?	Not discussed

Homogeneous Cases

Barcode Symbology	GS1-128
Barcode Contents	KD Code (GTIN) and serial number

Logistics Units

Logistics Units Must be Serialized?	Yes
Barcode Symbology	GS1-128 or ITF-14
Barcode Contents	GS1 Serial Shipping Container Code (SSCC) or KD Code (GTIN) and serial number if homogeneous cases

Data Capture

Unit-to-Case Aggregation Capture?	Not required but "needed for convenience during warehousing, release"

Data Exchange

Send Unit Data to Government Repository?	Yes
Send Unit Data to Third-Party Repository?	No
Send Unit Data to Trading Partner?	Yes
Send Aggregation Data to Government Repository?	Yes
Send Aggregation Data to Third-Party Repository?	No
Send Aggregation Data to Trading Partner?	Yes

Authentication

Who Offers Data Repository for Authentication?	Government
Manufacturers Must Register Shipments in Repository?	Yes
Downstream Trading Partners Must Authenticate on Receipt?	No
Downstream Trading Partners Must Authenticate on Shipment?	No

Government Reporting

Manufacturer Activity Reported?	Yes
Downstream Trading Partner Activity Reported?	Yes

Challenges

Government reporting started out as a CSV file and has transitioned to an online data feed.

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Global brands across industries rely on us to keep their products authentic, safe and connected—from manufacturing to the consumer's hands. Together we are revolutionizing brand protection!