

**Asia-Pacific · Medicines, tobacco, alcohol**

South Korea

Serial numbers were phased in from 2015, starting with products that make up 30% of each company's sales, and supply reporting to the national pharmaceutical information service KPIS became mandatory from 2016. Companies choose between 2D DataMatrix and RFID.

THE REGIME

SYSTEM	MFDS medicines serialization, reported to KPIS
CODE ON THE PRODUCT	2D DataMatrix or RFID with GTIN, serial, batch, expiry on the folding box
AGGREGATION	Not required.

STEPS FOR A SUPPLIER

- ☐ Register your products and GTINs in the national system: MFDS medicines serialization.
- ☐ Print a unique serialised code on every saleable pack.
- ☐ Verify every code on the line; aggregate into cases and pallets where required.
- ☐ Report production and shipments to the national system.

ON THE LINE, BEFORE THE FIRST SHIPMENT

- ☐ The data in the code is agreed: GTIN, serial number, batch, expiry date or crypto tail, as the rules for your product group require.
- ☐ A verifier has graded printed samples (ISO/IEC 15415 for 2D codes) before the first shipment.
- ☐ A camera after the printer reads every code at line speed, and packs with an unreadable code are rejected.
- ☐ Records show which code went on which pack, case and pallet, ready for the report to the system.

DATES AHEAD

No announced dates.

SOURCES

1. GS1 / KPIS: serialisation and traceability in South Korea:
https://mocdn.gs1.org/sites/default/files/docs/addisababa/PresentationDay2/20180501_Addis_Day%202_%20Plenary_Pharmaceutical%20serialisation%20and%20traceability%20system%20in%20South%20Korea_Kim%20Kyoung.pdf
2. Medigate News: serial number rule 2015: <https://medigatenews.com/news/1871832991>

Current version and all sources:
2dtracker.com/country/korea.html

Typical steps. This is not legal advice: check the regulation itself.