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Argentina National Drug Traceability System

Regulatory Update

August 2020

Regulatory Agency	Ministry of Health (MoH), National Administration of Drugs, Food and Medical Technology of Argentina (ANMAT)
Regulation Name or System Name	Resolution 435/11, Argentina National Drug Traceability System
Compliance Dates	March 1, 2015: All drugs containing APIs in a select list must be serialized and traced from manufacturer or importer through all steps of the distribution chain; April 30, 2015: All drugs containing another select list of APIs; June 30, 2015: All drugs containing another select list of APIs; August 30, 2015: All drugs containing another select list of APIs Note: In the fall of 2015 ANMAT reduced the number of APIs that require serialization of finished drug packages.
Applies to	Prescription drug "laboratories" (manufacturers and importers), "distributors", "logistics operators", "pharmaceutical companies" and dispensers, *including deliveries by pharmacies to patients but not outpatient dispensation by "public and private healthcare centers".*

Unit-level Packaging ("units of sale")

Barcode Symbology	A data carrier "according to GS1 standards recommendations
Barcode Contents	The "unambiguous code" consisting of: • A GTIN or similar code granted by ANMAT; • A serial number (up to 20 alphanumeric characters, but when using 20 characters, must not start with "779"); • When using DataMatrix or RFID, also include: – The expiration date of the drug; – Medicinal specialty lot.
Serial Number Randomization	Not specified
Serial Number Reuse	DD/MM/YY, or DD/MM/YYYY
Human Readable Expiry Date Format	GS1 standard

Barcode Data Encoding	• "Medicinal specialties packaged for hospitals, as registered in the ANMAT, shall only be codified in its secondary packaging." • "When their fractioned distribution is authorized by pharmaceutical companies, only those movements corresponding to the full unit and not the fractioned unit shall be reported." • Pharmaceutical companies, distributors, and logistics operators shall only identify medicinal specialties when they are not being serialized by holders, and they are acquired by laboratories, distributors or logistics operators, in those cases they shall proceed according to section 3 of ANMAT's Provision 3683/11 and section 13 of ANMAT's Provision 1831/12. The serial to be used shall have a maximum of seven (7) alphanumeric characters, case sensitive.
Product Code notes	Yes
Free Samples must be marked?	Yes, by implication

Homogeneous Cases

Barcode Symbology	Optional but same as unit-level if done;
Barcode Contents	Optional but same as unit-level if done

Logistics Units

Logistics Units Must be Serialized?	No. Logistics containers are not included in the serialization mandate, but to prevent distributors and logistics operators from needing to open cases and scanning barcodes, these containers should be serialized and aggregation data collected. This would not be necessary if RFID is used at the unit level.

Data Capture

Unit-to-Case Aggregation Capture?	Not mandated but when using barcodes it becomes a necessity

Data Exchange

Send Unit Data to Government Repository?	Yes
Send Unit Data to Third-Party Repository?	No
Send Unit Data to Trading Partner?	Not mandated but appears to be a necessity when using barcodes.
Send Aggregation Data to Government Repository?	No
Send Aggregation Data to Third-Party Repository?	No

Send Aggregation Data to Trading Partner?	Not mandated but appears to be a necessity when using barcodes.

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

- Serialization and aggregation of logistics containers are not mandated but they appear to be a necessity when using barcodes but not RFID.
- From a GS1 Healthcare presentation "The Health Authority accepted GS1 128 and RFID for a period of transition, but they prefer the companies adopt in the near future GS1 Datamatrix."

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About Systech

Systech provides digital product authentication and traceability solutions to combat counterfeiting, prevent diversion and meet regulatory compliance. Built on decades of experience as the leader in pharmaceutical serialization, our comprehensive brand protection suite delivers the real-time insight, actionable product data, digital connectivity and consumer engagement functionality needed to fight supply chain threats.

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!

Regulatory Questions?

Contact us at info@systechone.com or visit us online here.