

THE WORLD OF COUNTERFEITING

HOW ARE DIFFERENT COUNTRIES RESPONDING TO ADDRESS THE THREAT OF COUNTERFEITERS?

The World Health Organisation estimates that up to 15% of all pharmaceutical drugs globally are counterfeited. While this translates to around 1% of drugs in Europe and the USA, this issue is particularly severe in the developing world. As the supply chains for pharmaceuticals are now global and increasingly complex, the opportunity for illegal activity will continue to grow. This must be countered with a focus on monitoring and maintaining the integrity of the supply chain by paying more attention to detail and having proper protocols in place.

UNITED STATES

November 2017 – USA Drug Supply Chain Security Act (DSCSA) GTIN, unique Standardised Numeric Identifier (SNI), packaging lot number and expiration in human readable and DataMatrix.

MEXICO

January 2018 – Operational database enactment expected for Draft Mexico Regulation Amendment for general law of health.

ARGENTINA

GS1 GTIN, unique serialised number, packaging lot number and expiration in human readable and DataMatrix.

BRAZIL

Expected to begin in 2020. ANVISA to define products that will need to comply. 2D code, 13 digit licence number (ANVISA), 13 digit serial number, expiry date, batch number must all be human readable and DataMatrix.

THE EU

FMD Delegated Act published, imposing a February 2019 deadline for implementation.



UKRAINE

February 2017 – Serialisation Sales Implementation Phase 1 due for Manufacturers and wholesale distributors.

CHINA

Potential amends to drug tracing system requirements is in progress, after a notice was issued by the CFDA. Concerns have been communicated to the new proposals which also cover medical devices.



RUSSIA

Initial implementation expected beginning 2017. Expected to be 2D code but not confirmed.

SOUTH KOREA

January 2015 – GTIN, unique serialised number, packaging lot number and expiration in human readable and DataMatrix plus barcode or RFID.

INDIA

January 2015 – GS1 GTIN, serialisation and barcode for tertiary, secondary and primary packaging for all exports. GS1 DataMatrix and unique serial number for unit of sale.

SAUDI ARABIA

March 107 – GTIN, unique serialised number, packaging lot number, expiration and pack size in human readable and DataMatrix.

JORDAN

January 2017 – GTIN, packaging lot number, expiration date and pack size in human readable and DataMatrix.

TURKEY

Implemented in 2011 to combat reimbursement fraud. GTIN, unique serialised number, packaging lot number and expiration in human readable and DataMatrix.