

THE WORLD OF COUNTERFEITING

HOW ARE COUNTRIES RESPONDING TO ADDRESS THE THREAT OF COUNTERFEITERS?

The World Health Organization 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.

	Unit Serialisation Datamatrix		Tamper Evident		In Place
	Unit Serialisation Barcode		Aggregation		Deadline Date
					Probable Date

CANADA
Draft law covering National Health Products (NHP) expected to adopt USA model.



DEC 2017

NOV 2018

USA
November 2018 – USA Drug Supply Chain Security Act (DSCSA) GTIN, unique Standardised Numeric Identifier (SNI), packaging lot number and expiration in human readable and DataMatrix.



JAN 2018

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



CHILE
Expected to follow USA model.



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



DEC 2021

BRAZIL
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.



FEB 2019

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



ITALY
Current system to change to EU model by 2025.



JUL 2017

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



BELGIUM

Current system to change to EU model by 2025.



IRAN

On all imported drugs.



GREECE

Current system to change to EU model by 2025.



2019

SAUDI ARABIA
UAE
QR code, Arabic and English.



JAN 2020

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.



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.



SOUTH KOREA

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



JAPAN

No deadlines agreed.



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.



AUSTRALIA

Currently only haemophilia products but expected to extend and adopt EU model.



DEC 2017

PAKISTAN

Human and veterinary allopathis drugs only.



ESSENTRA