




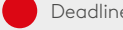



THE WORLD OF COUNTERFEITING

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.



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.



EGYPT
Would like to follow Turkish model.



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 for manufacturers and wholesale distributors.



MAR 2017
SAUDI ARABIA
Domestic and imported drugs for human consumption GS1 2D matrix.



JAN 2020
JORDAN
January 2017 – GTIN, packaging lot number, expiration date and pack size in human readable and DataMatrix.



DEC 2017
RUSSIA
Initial implementation expected to end 2018. Expected to be 2D code but not confirmed.



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
2016 – Unique serialised number, packaging lot number and expiration in human readable and DataMatrix plus barcode or RFID.



JAPAN
No deadlines agreed.



INDIA
November 2017, phase 2 DSCSA but ½ not ready and facing global acceptance issues.



2019
UAE
QR code, Arabic and English.



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



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



TBC
PAKISTAN
Human and veterinary allopathis drugs only. Little progress made.



ESSENTRA