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.

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.



BELGIUM

by 2025.

Current system to change to EU model

IRAN

On all imported drugs.

GREECE

by 2025.

Current system to

change to EU model





DEC 2017

Tamper Evident

Aggregation

RUSSIA

Unit Serialisation

Unit Serialisation

Initial implementation



CHINA

Potential amends to drug

tracing system requirements is

SOUTH KOREA

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

Deadline Date

Probable Date



No deadlines agreed







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









AUSTRALIA

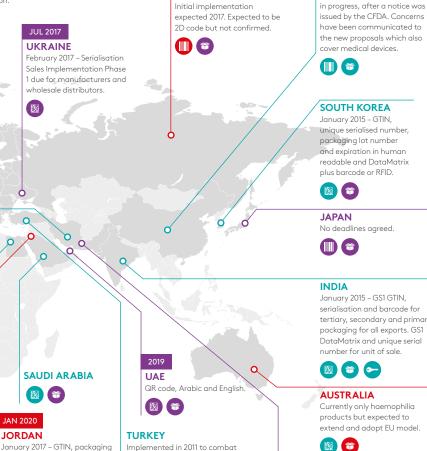
Currently only haemophilia products but expected to extend and adopt EU model. CFMAP/E/04-17 Last updated 07/17





DEC 2017







CANADA

USA model.

DEC 2017

NOV 2018

USA

Draft law covering National Health

Products (NHP) expected to adopt

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







USA model.

ARGENTINA

GS1 GTIN, unique

serialised number.

and expiration in

Expected to follow

CHILE

for general law of health.



DataMatrix.



packaging lot number



ANVISA to define products that will need to comply. 2D code, 13 digit licence number (ANVISA), 13 digit serial

DEC 2021

BRAZIL

number, expiry date, batch number must all be human readable and DataMatrix.









EGYPT











lot number, expiration date and

pack size in human readable









reimbursement fraud. GTIN, unique





PAKISTAN

Human and veterinary allopathis drugs only.

