

Pharma Serialisation Deadlines

Pharma IQ has created this easy-to-assimilate summary of serialisation requirements around the world, whether they are already being followed or have impending deadlines (e.g. much of Europe due to the Falsified Medicines Act). You can keep it as a handy reference, share it around your colleagues or even stick it on your wall!

Questions asked

A DEADLINE DATE
(if applicable. If country already serialised, please simply state 'current')

B METHOD OF SERIALISATION
(e.g. 2D datamatrix, RFID, linear barcodes, e-pedigree, etc)

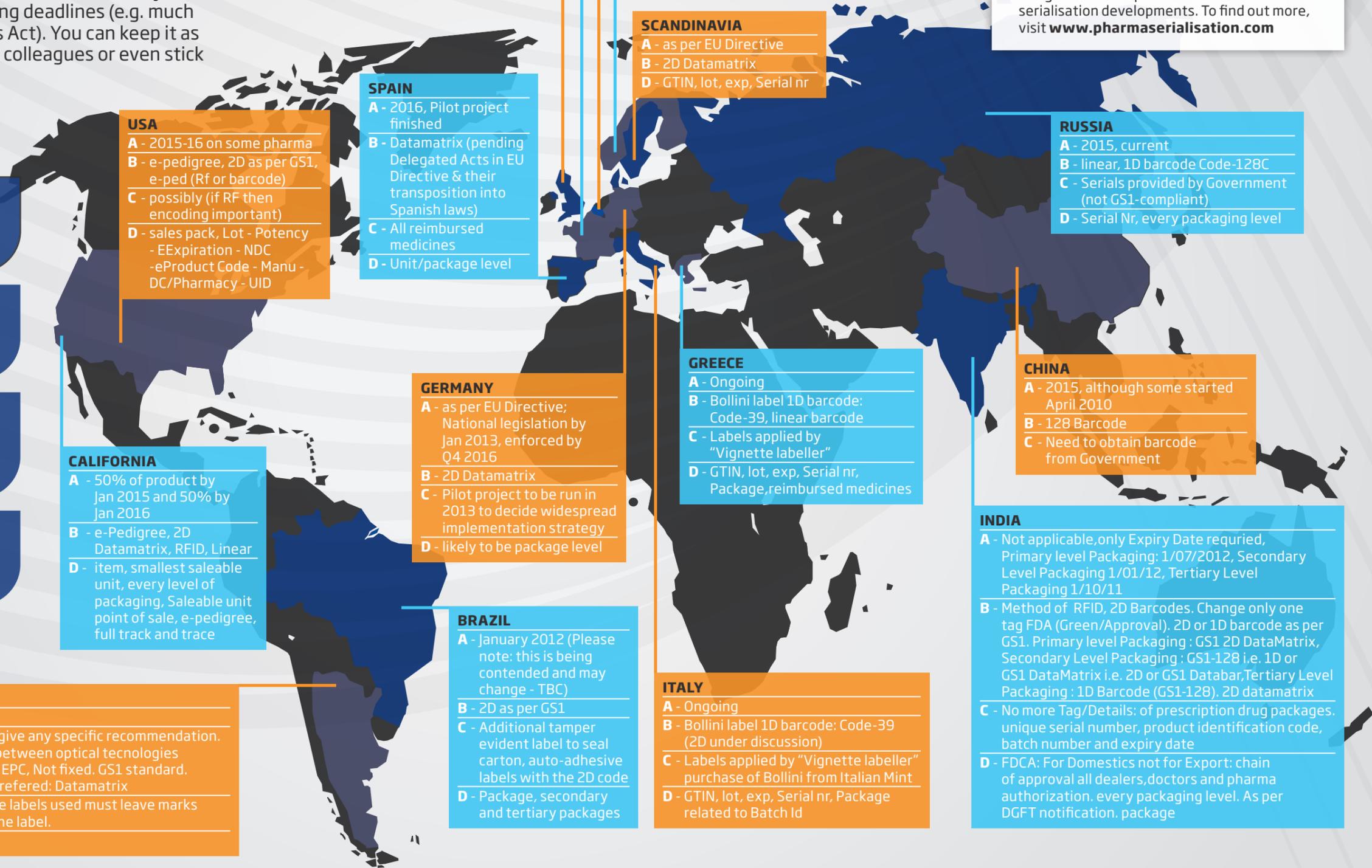
C ANY ADDITIONAL RESTRICTIONS OR REQUIREMENTS?
(e.g. special labels? Where from? etc)

D LEVEL OF SERIALISATION REQUIRED
(e.g. country, lot, package, etc)



Pharmaceutical Serialisation & Traceability 2011

This infographic was developed for the Pharmaceutical Serialisation & Traceability summit in Geneva on November 2-4th, 2011. The event features expert speakers from industry leaders, EFPIA and GS1 and will bring attendees up-to-date with the latest serialisation developments. To find out more, visit www.pharmaserialisation.com



FRANCE
A - as per EU Directive - possible extension to 2022 pending
B - 2D Datamatrix, 2D required for CIP code
D - GTIN, lot, exp, Serial nr

BELGIUM
A - Current
B - 2D - Sequential Barcode, 1D barcode Code-128C, linear barcode
C - Special Labels - IPEX, Labels applied by "Vignette labeller"
D - Package no lot info, GTIN, lot, exp, Serial nr, Package, reimbursed medicines

UK
A - as per EU Directive
B - 2D datamatrix
D - GTIN, lot, exp, Serial nr

NORDIC COUNTRIES
A - as per EU Directive
D - GTIN, lot, exp, Serial nr

SCANDINAVIA
A - as per EU Directive
B - 2D Datamatrix
D - GTIN, lot, exp, Serial nr

USA
A - 2015-16 on some pharma
B - e-pedigree, 2D as per GS1, e-ped (Rf or barcode)
C - possibly (if RF then encoding important)
D - sales pack, Lot - Potency - EExpiration - NDC - eProduct Code - Manu - DC/Pharmacy - UID

SPAIN
A - 2016, Pilot project finished
B - Datamatrix (pending Delegated Acts in EU Directive & their transposition into Spanish laws)
C - All reimbursed medicines
D - Unit/package level

RUSSIA
A - 2015, current
B - linear, 1D barcode Code-128C
C - Serials provided by Government (not GS1-compliant)
D - Serial Nr, every packaging level

CHINA
A - 2015, although some started April 2010
B - 128 Barcode
C - Need to obtain barcode from Government

GREECE
A - Ongoing
B - Bollini label 1D barcode: Code-39, linear barcode
C - Labels applied by "Vignette labeller"
D - GTIN, lot, exp, Serial nr, Package, reimbursed medicines

GERMANY
A - as per EU Directive; National legislation by Jan 2013, enforced by Q4 2016
B - 2D Datamatrix
C - Pilot project to be run in 2013 to decide widespread implementation strategy
D - likely to be package level

CALIFORNIA
A - 50% of product by Jan 2015 and 50% by Jan 2016
B - e-Pedigree, 2D Datamatrix, RFID, Linear
D - item, smallest saleable unit, every level of packaging, Saleable unit point of sale, e-pedigree, full track and trace

BRAZIL
A - January 2012 (Please note: this is being contended and may change - TBC)
B - 2D as per GS1
C - Additional tamper evident label to seal carton, auto-adhesive labels with the 2D code
D - Package, secondary and tertiary packages

ITALY
A - Ongoing
B - Bollini label 1D barcode: Code-39 (2D under discussion)
C - Labels applied by "Vignette labeller" purchase of Bollini from Italian Mint
D - GTIN, lot, exp, Serial nr, Package related to Batch Id

INDIA
A - Not applicable, only Expiry Date required, Primary level Packaging: 1/07/2012, Secondary Level Packaging 1/01/12, Tertiary Level Packaging 1/10/11
B - Method of RFID, 2D Barcodes. Change only one tag FDA (Green/Approval). 2D or 1D barcode as per GS1. Primary level Packaging : GS1 2D DataMatrix, Secondary Level Packaging : GS1-128 i.e. 1D or GS1 DataMatrix i.e. 2D or GS1 Databar, Tertiary Level Packaging : 1D Barcode (GS1-128). 2D datamatrix
C - No more Tag/Details: of prescription drug packages. unique serial number, product identification code, batch number and expiry date
D - FDCA: For Domestic not for Export: chain of approval all dealers, doctors and pharma authorization. every packaging level. As per DGFT notification. package

ARGENTINA
A - 15/12/2011
B - 2D, The Health Authority don't give any specific recommendation. The laboratories could choose between optical technologies (Datamatrix & GS1-128) or RFID EPC, Not fixed. GS1 standard. (Bar code, datamatrix or RFID) Preferred: Datamatrix
C - Security labels are required. The labels used must leave marks when removed. Visual code in the label.
D - GTIN + SERIAL

All data and information depicted was collected from an industry survey conducted by Pharma IQ in September 2011. This information is accurate to the best of the respondents knowledge at that time, and may subsequently have changed. Pharma IQ cannot take responsibility for the accuracy of this information.