SERIALISATION & TRACK AND TRACE DEADLINES: PRINTABLE WORLDMAP

FMD Delegate Act live imposing Feb 2019 deadline.

Pharmaceutical Serialisation & Traceability 2016 SPEAKERS:

Dhermita Desai, Operations Projects Team Manager, Concordia UK Michael Kinsella, Industrial Operations Deputy Director, Servier France Stefano Zanobini, Serialization Global Project Manager, UCB Italy Daniela Guttmann, Packaging &

Serialisation Product & Service Manager, Vetter - Germany

USA

CANADA

November 2017 - USA Drug Supply Chain Security Act (DSCSA) 4 years post enactment, drugs must be serialised by manufacturers at the saleable unit and case level.

Technical barcode committee

December 2017 - phase 4.

- bar coding project

Pharmaceutical Serialisation & Traceability 2016 SPEAKER:

Ravi Kalyanaraman, Associate Director, Bristol Myers Squibb - USA

BRAZIL

At the time of writing - serialisation law RDC54 still stands. A new draft law, which would invalidate the existing legislation, has received Senate approval and is pending public consultation from ANVISA - publish date is scheduled for September.

Proposed timelines: Pilot for 3 batches in 1 year, 1 year's consideration and establishment of final requirements, followed by 3 years to enforcement. (1)

Pharmaceutical Serialisation &

Traceability 2016

MEXICO

Jan 2018 - Operational database enactment for Draft Mexico Regulation Amendment for general law of health. (4)

REASONS TO ATTEND:

Post conference site visit day-visiting local pharma organisations in Geneva

The IT stream on day one will cover topics such as IT itergration, interopability and data security and management

As the serialisation industry prepares for various approaching deadlines all over the globe, Pharma IQ has created a printable map to assist with your worldwide track and trace compliance strategies.

UKRAINE

Feb 2017 - Serialisation Sales Implementation Phase 1 due for Manufacturers and wholesale distributors.

Track and trace postponed

Aggregations requirements likely (4)

RUSSIA

Draft of regulation has been under consultation and is due to be laid down by June 2016 Nov 2016 - Pilot programs should begin

Jan 2017 – 1st drug class serialisted - The seven high-spending disease classes such as treatment of haemophilia or multiple sclerosis and patients after organ transplantation. Jan 2018 – 2nd drug class serialisted Vital and essential medicines. Subject to upper

price limit set by the authorities.

Jan 2019 – 3rd Drug class serialised all other medicines (5)

6

CHINA

ETHIOPIA

Understood to be discussing serialisation and conducting summer workshops. (1)

Serialisation implementation plan signed by the MoH is rumoured to be launched soon. (1)

JORDAN

EGYP1

1st July 2018 - AI 2d with GTIN, Lot number and Expiry date required.

1st July 2020 - Serial number added. (1)

Maturity zoned roundtable sessions: Take your pick of discussions depending on which stage of implementation you are in

Jan 2017 -Expected deadline for unit level serialisation

Draft regulations pendina.

LIBYA

SAUD

ARABIA

Clarification

on deadlines

pending.

NIGERIA

Global standards in regards to serialization are being shaped, no date of release known. (1)



Draft serialisation legislation reached the end of public review in June.

According to Be4ward Non-biologics serialisation deadline proposed for 2021. (1)

KOREA

Jan 2016 - All pharmaceutical products need to be serialised. (3)

PAKISTAN

The release of new requirements is expected soon, date is unknown.

PHILIPPINES

Serialisation regulations in draft, timelines are expected to be short.

INDIA

Looking to formulate an industry / ministry working group to combat complications encountered (1)

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. (1)

TAIWAN

Jan 2018 - stated deadline - All prescription drugs medication barcode requirements and implementation timelines (4)

\$ +44 (0)207 036 1300 Swww.pharmaserialisation.com/ enquire@iqpc.co.uk

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