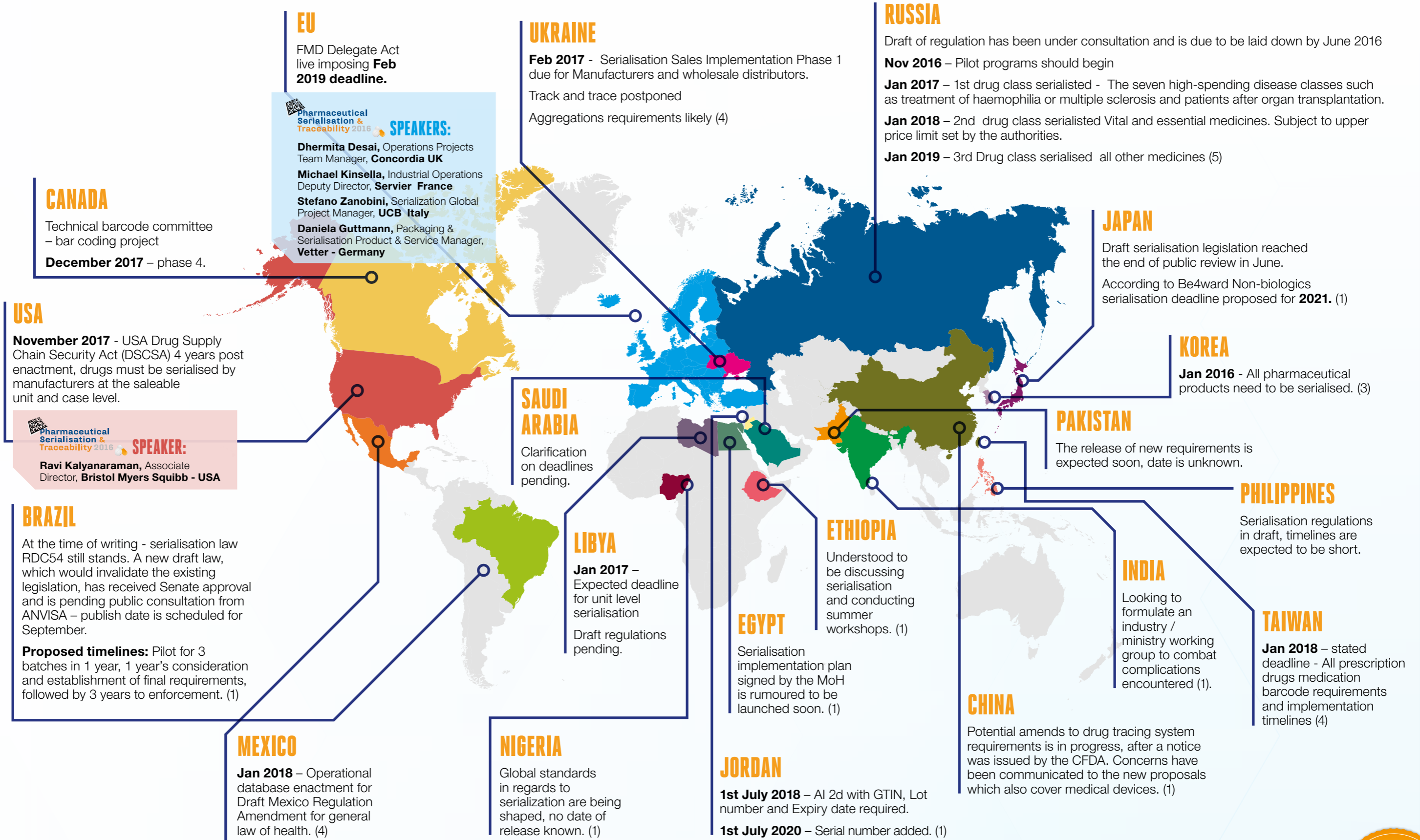# SERIALISATION & TRACK AND TRACE DEADLINES: PRINTABLE WORLDMAP

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.

EU

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**

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)

CANADA

Technical barcode committee – bar coding project

December 2017 – phase 4.

JAPAN

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

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

USA

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.

Pharmaceutical Serialisation & Traceability 2016
SPEAKER:

Ravi Kalyanaraman, Associate Director, **Bristol Myers Squibb - USA**

KOREA

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

SAUDI ARABIA

Clarification on deadlines pending.

PAKISTAN

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

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)

LIBYA

Jan 2017 – Expected deadline for unit level serialisation

Draft regulations pending.

ETHIOPIA

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

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).

EGYPT

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

TAIWAN

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

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. (1)

MEXICO

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

NIGERIA

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

JORDAN

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

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