

SERIALISATION TRACK AND TRACE PRINTABLE MAP 2018

The global pharmaceutical industry is moving towards a serialised world. In over 40 countries, regulatory mandates to secure the supply chain are already in place or in development. We have created this printable map to provide an overview of various nations' progress in their serialisation journey.

USA

With the 2015 DSCSA traceability deadline behind them, pharmaceutical companies have turned their attention to full drug serialisation. DSCSA requires that manufacturers mark packages with a product identifier, serial number, lot number, and expiration date by November 2017. FDA compliance policy pushes enforcement to November 2018.

European Union

EU manufacturers have until February 2019 to comply with regulations outlined in the FMD.

Turkey

Turkey has one of the longest standing Track and Trace systems in place, they have serialisation and government reporting requirements which cover all pharmaceutical products. Turkey has a unit level with aggregation requirement in effect, and follows GS1 standards.

Russia

Full implementation of serialisation firming up for end of 2018, with recent discussions strongly hinting that the original interim phases for 7HCN products, etc. will be removed.

South Korea

As of 2016, serialisation requirements in South Korea cover 100% of pharmaceutical drug product manufacturers. As of July 1, 2017 reporting enforcement was introduced for wholesale distributors.

Brazil

December 10th 2016 - serialisation and tracking for all pharmaceuticals was introduced. From May 2017 ANVISA schedule includes:

- A 1-year pilot that includes at least 3 batches of serialised product.
- An 8-month period to review pilot results
- A 3-year deployment for all industry stakeholders

Ukraine

Phase 1 of serialisation introduced for manufacturers and wholesale distributors in 2017

Argentina

Manufacturers must serialise every salable unit in accordance with GS1 standards for both the serial number and bar code format.

Saudi Arabia

From March 12 2017, all domestically-produced and imported pharmaceutical products intended for human use are required to carry a GS1 2D datamatrix bar code. Presence of the code on the pack is sufficient as an interim stage towards the implementation of the national traceability system.

Jordan

From January 1, 2017, all prescription drug products must contain both human readable text, and a DataMatrix symbol encoded with GS1 GTIN to identify the item, the packaging lot number, expiration date and pack size.

China

China's original serialization requirement was suspended in 2016, shortly after it expanded to cover all drugs. Serialisation of drugs in China is now "encouraged", but not required. A new pharma serialization requirement is expected at some point in the future.

India

Since 2017, all drugs manufactured in India can be exported only if both tertiary and secondary packaging carry serialized barcoding and the data is uploaded on a government portal.

Pakistan

Serialisation of primary and secondary packaging of drugs is mandatory by June 2019. Serial number capture by members of the supply chain by June 2020. Data must be uploaded to DRAP via email, but once their online system is operational, switch to online transactions.