ANTARES VISION GROUP

HEALTHCARE WORLDWIDE
REGULATIONS Update

Antares Vision Group

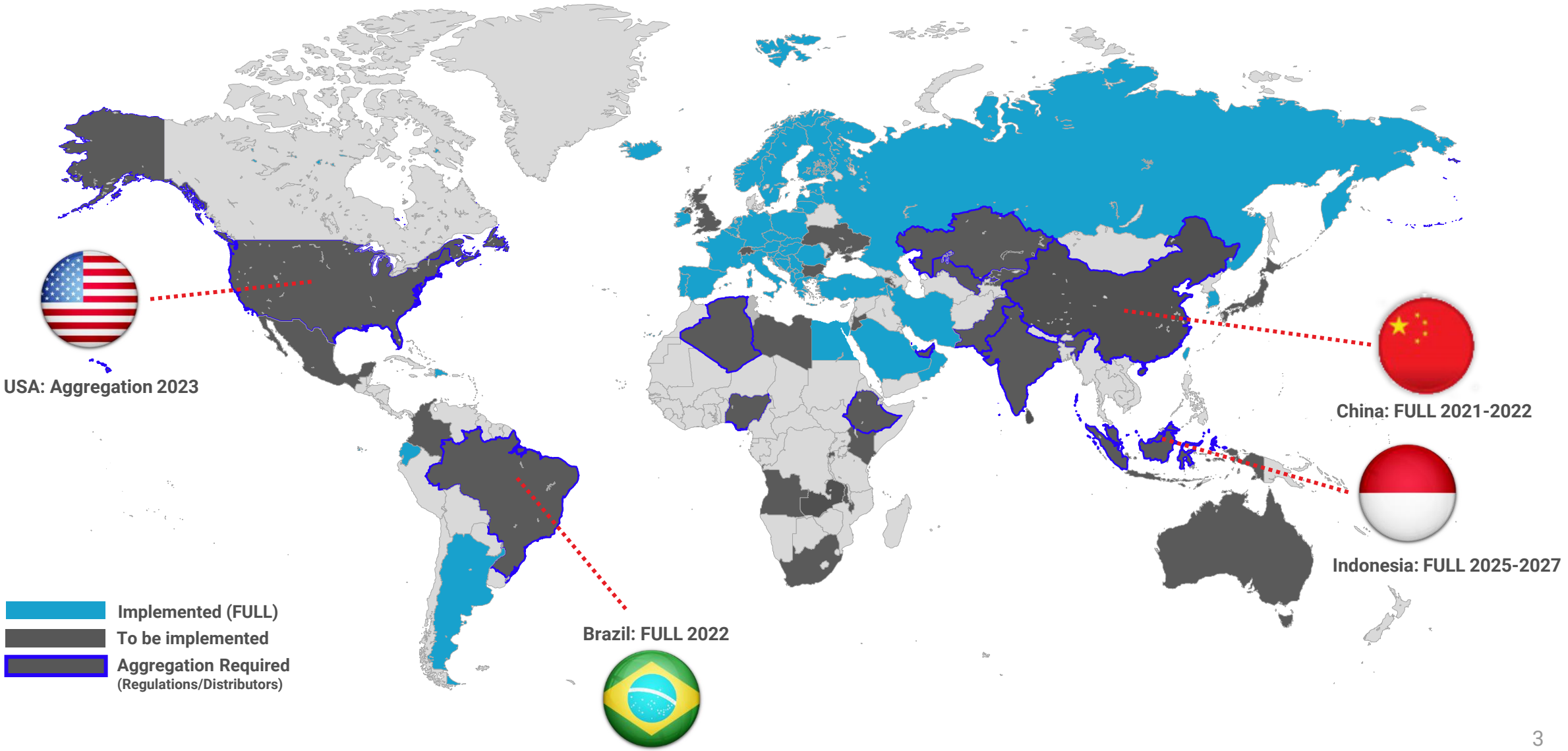
April 07th, 2022

ANTARES VISION GROUP

ROADMAP 2019-2025

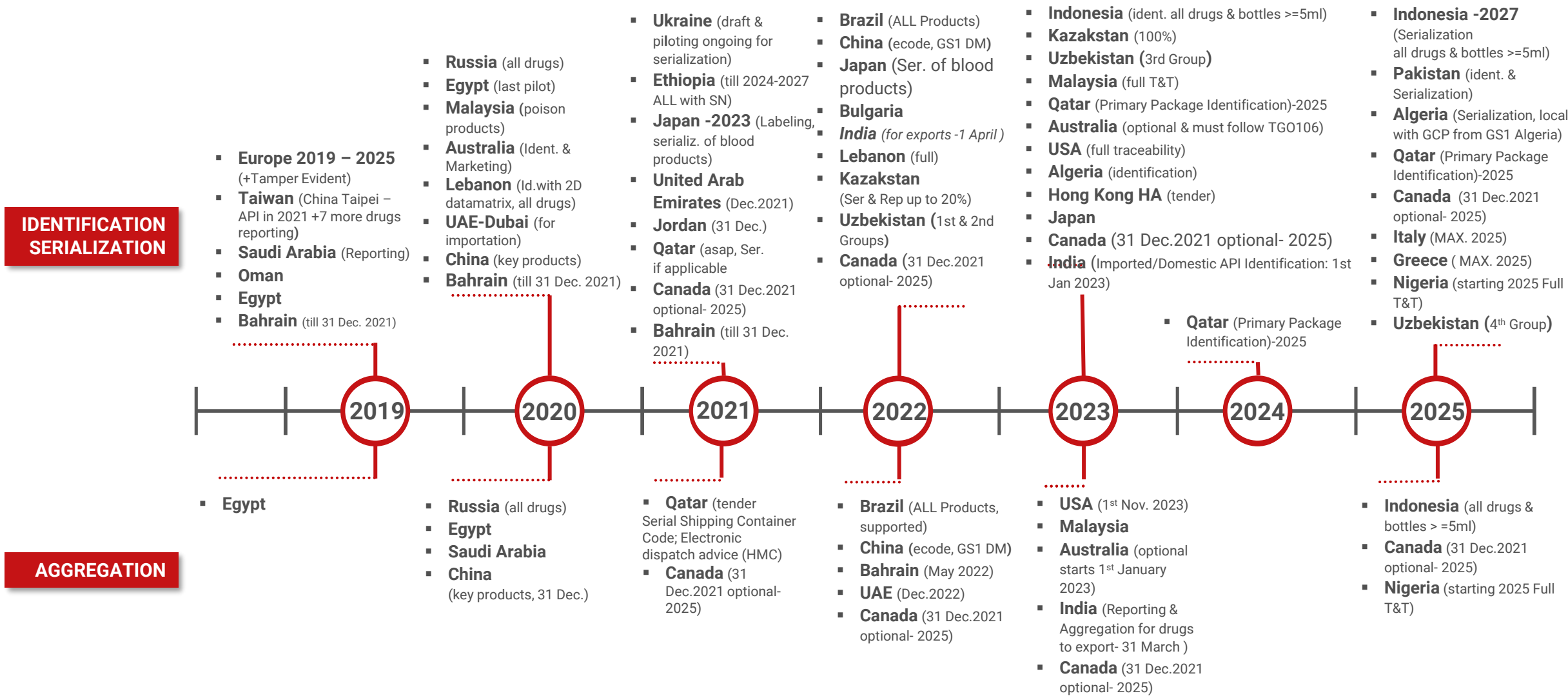
PHARMA & MEDICAL DEVICES

TRACEABILITY – PHARMA (2010-2025)



PHARMA REGULATIONS – WORLDWIDE ROADMAP

ANTARES VISION GROUP



P.S: ECUADOR Track & Trace Regulation for Pharma and Medical Devices is Cancelled as being officially mentioned on 4 January 2022. A new Decree is published on 1° February 2022 (We are still monitoring all its specificifations and timeframe)

Under Development: Angola, Cambodia, Kenya, Sri lanka, Zambia (draft consultation ends), Rwanda, Nigeria, India for domestic drugs, Colombia, Libya, Vietnam(draft QR code), Malawi, South Africa (draft phased implementation to 2022 TBC), Afghanistan, Botswana(guidance for 2022-2023 regulation), Mexico (consultancy till 31 Dec 2021), Nigeria most probable (full implementation end of 2024), Ukraine (piloting only)

MEDICAL DEVICES REGULATIONS – WORLDWIDE ROADMAP

IDENTIFICATION / SERIALIZATION / AGGREGATION

2019

- **South Korea** (UDI class4 devices)
- **Turkey** (deadline all classes of products) UTS (product tracking system)

2020

- **Ireland** (HSE Medical consumables for the National Distribution Centre)
- **Brazil** (Barcoding certain implants)
- **USA** (FDA UDI Implementation Class I, since 2014 GUDID Serialization class III)
- **Australia** (TBC Release of the UDI regulation)
- **South Korea** (UDI class 3 devices IMDS)

2021

- **South Korea** (UDI class2 and class 1 devices)
- **European Union** (UDI assignment class III and 3 modules for EUDAMED live)
- **China** (UDI high risk class III serialization)
- **Saudi Arabia** (Saudi-D Implementation by Classes D to A till 2023)
- **Taiwan** (2021 class III -2023)

2022

- **China** (UDI rest of class III)
- ***India*** *(Implementation UDI Labelling :postponed)*
- **Singapore** (SMDR database -2028 with high risk first)
- **Saudi Arabia** (Saudi-D Implementation by Classes B-C-D in Sept.2022 to A by Sept. 2023)
- **Taiwan** (class III not implantable)
- **European Union** (EUDAMED fully operational)
- **Korea** (UDI class2 and class 1 devices)
- **Japan** (1° Dec 2022)
- **USA** (unclassified and class I)
- **Egypt** (all medical devices)
- **Brazil** (published 10 Jan.2022, + 2.5 years for class IV - +6 years class I)

2023

- **Qatar 2023-2025** (Implementing GS1 standards (HMC)
- **South Korea** (2023)
- **Saudi Arabia** (Saudi-D Implementation by Classes D to A by 2023)
- **Taiwan** (class II)
- **Algeria** (Identification)
- **Uzbekistan**

2024 +

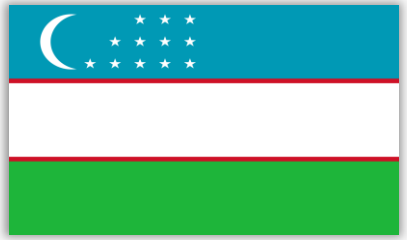
- **China 2024 -2026** (UDI class II and remaining)
- **Singapore(-2028):** 2024 (Class D), 2026 (Class C), 2028 (class b)
- **Brazil** (class IV(2024), (class III(2025)- class II (2026), class I (2028)

P.S: ECUADOR Track & Trace Regulation for Pharma and Medical Devices is Cancelled as being officially mentioned on 4 January 2022. A new Decree is published on 1° February 2022 (We are still monitoring all its specificifations and timeframe)

Under Development: Colombia(draft), Australia (draft, TGA webinars), Russia (draft 2022-2023), Kazakhstan,Canada (consultation ends), UK (Consultation ends, no later than July 2023), South Africa (Consultation ends), Singapore (Consultation ends), Ecuador (piloting 2021 finished), USA FDA (draft guidance on GUDID for consultation), China UDI (public opinion UDI and data carrier marking.ends)

BY COUNTRY PHARMA UPDATES

UZBEKISTAN



UZBEKISTAN

Eurasia

PRODUCT SCOPE

Tobacco, alcohol, pharmaceuticals, soft drinks and appliances.

REQUIREMENTS

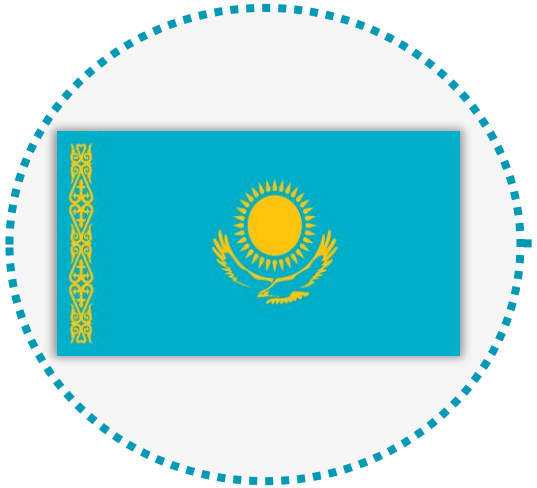
- **Traceability system**: Asl belgisi (developed by *CRPT Turon*)
- **Marking codes** (identification code (GTIN, SN) **+ local crypto tail of 48 Characters** (Crypto code, Crypto key) generated by the Operator of T&T system in Uzbekistan
- Customs **aggregation code** for imported products and aggregation code for locally manufactured products

TIMEFRAME

Starting date of the phased introduction of mandatory digital marking for medicines and medical devices (resolution N.149).

- **From September 1, 2022** – 1st group;
- **From November 1, 2022** - 2nd group;
- **From March 1, 2023** - 3rd group;
- **From February 1, 2025** - 4th group.

KAZAKSTAN



KAZAKSTAN

Eurasia

PRODUCT SCOPE

Pharmaceuticals.

REQUIREMENTS: FULL T&T

- **Secondary**: 2D barcode with GTIN + SN + local crypto code 48 characters length (AI 91(4 Char) and AI 92(44 Char.)).
- **Tertiary**: GS1 128 with SSCC / Aggregation possible
- Data Portal submission for **Reporting**: IS MPT

TIMEFRAME

- **1 July 2022 –** Introduction of labelling for approved 93 of medicines (1% from all drugs)
- **1 October 2022 -** expansion list of drugs at least for 20%
- **1 January 2023 -** expansion of the list of drugs at least for 60% and starting traceability of marked drugs
- **1 April 2023 -** expansion list of drugs at least for 80%
- **1 July 2023 -** Implementation 100% marking and traceability

UK (BREXIT)

UK (Brexit)

Europe

PRODUCT SCOPE

Pharmaceuticals.

REQUIREMENTS

Most of the manufacturers have already split the multimarket pack and assigned **a new GTIN to the Great Britain pack**.

TIMEFRAME

Starting 1st January 2021

Northern Ireland: 1 year more as grace period

EU COMMISSION NON-PAPER FOR UK-NI (BREXIT)

Ref 1:July 2021
https://ec.europa.eu/info/sites/default/files/eu_non-paper-proposed-solution_medicines_en.pdf

NON-PAPER

Medicines and the implementation of the Protocol on Ireland and Northern Ireland

Issue

1. Pursuant to the Protocol on Ireland / Northern Ireland ("the Protocol"), medicines placed on the market in Northern Ireland (NI) must be covered by a valid marketing authorisation issued by the Commission (EU-wide authorisations) or the UK for NI in applying the Union legislation for medicinal products listed in Section 20 of Annex 2 to the Protocol (UK national authorisations).

2. The implementation issues that have been identified in the various talks to date between the UK Government and the European Commission solely concern **medicines covered by national marketing authorisations**. There are two possible UK national authorisation routes: purely UK national authorisations ("NI-only authorisations"), which concern medicines that are made available in NI only, and UK national authorisations granted via the Mutual Recognition or Decentralised Procedures (MRP/DCP), which is mandatory[1].

3. The Commission Notice of 25 January 2021[2] provides for a grace period of one year (until end-December 2021) for maintaining batch testing and manufacturing / logistics in Great Britain (GB) to ensure undisrupted supply of medicines to NI and those EU Member States (Cyprus, Ireland and Malta) that have been historically dependent on medicines supply from or through GB.[3]

4. The grace period aimed to give all relevant stakeholders sufficient time to adapt to the UK's withdrawal and to establish new supply routes where necessary, while providing for undisrupted supply of medicines and a high level of public health protection.

5. However, adapting supply chains to the new situation is still particularly challenging (in particular for suppliers of generics and over the counter medicines). Specifically, in relation to the implementation of the Protocol, it is proving too costly for certain operators currently based in GB to move relevant regulatory compliance functions (namely, the marketing authorisation holder, quality control (batch) testing, the qualified persons responsible for batch testing and release and for pharmacovigilance) to NI or the EU in respect of UK nationally authorised products for NI, as required by the Protocol.

Ref 2: Oct.2021 (to replace previous one)
https://ec.europa.eu/info/system/files/attachment_i_medicines_non_paper.pdf

18. The UK competent authorities and the EU Coordination Group for Mutual Recognition and Decentralised Procedures should work together to ensure consistency in relevant guidance issued to stakeholders.

Investigational medicinal products

19. The proposed solution would provide a derogation from the manufacturing import authorisation requirement to allow clinical trial sites or sponsors in Northern Ireland to continue to use investigational medicinal products supplied from or through Great Britain provided the conditions set out in para. 11 above are complied with.

Requirements relating to the safety features for medicinal products for human use

20. In order to provide further flexibility with respect to compliance with the safety features (namely, an anti-tampering device and unique identifier) that are mandatory for prescription medicinal products for human use pursuant to applicable EU legislation, the proposed solution consists of a further three-year derogation from the obligation to decommission the unique identifier when medicines are exported from the EU to the UK in respect of both single- and multi-market packs.

21. In order to ensure that medicines made available to Northern Ireland (or Cyprus, Malta and Ireland, which may also benefit from the same flexibility[4]) are not placed on the market elsewhere in the EU, the EU repository system should be adapted so as to ensure that an alert is generated when the medicine is verified for sale outside these markets.

Veterinary medicines

22. The Commission stands ready to continue discussions with the UK and stakeholders to identify any outstanding implementation issue with a view to finding the most appropriate way forward for ensuring continuity of veterinary medicines supply to Northern Ireland.

Implementation of the proposed solutions

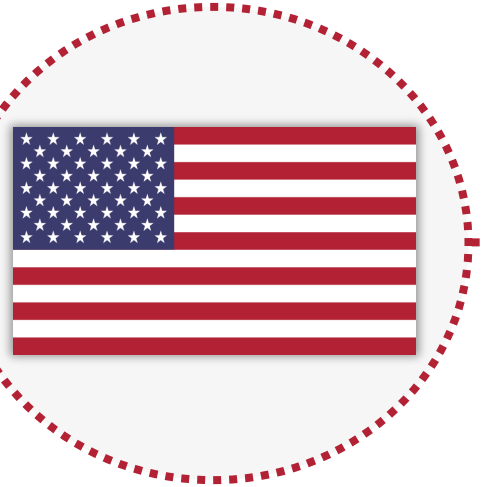
23. The proposed solutions set out in the above paragraphs would be implemented through:

- a targeted legislative amendment of the relevant legal acts in the EU pharmaceutical legislation, namely Directive 2001/83/EC (framework directive for medicinal products for

[4] Pending the development of longer-term policy or legislative initiatives, a temporary time-limited derogation on sourcing medicines for Cyprus, Malta and Ireland from the UK could be considered on the basis of justified public health reasons.

4

USA



USA

North America

PRODUCT SCOPE

Pharmaceuticals.

REQUIREMENTS

- The Drug Supply Chain Security Act (DSCSA) recommends to build an electronic, interoperable system by 2023 that can identify and trace products as they are distributed in the United States.
- Secondary Packaging with GS1 2D Datamatrix
- Data elements: GTIN, Batch/Lot Number, Expiration date, Serial Number

TIMEFRAME

1st November 2023

for the full item-level traceability

AUSTRALIA

AUSTRALIA

Oceania

PRODUCT SCOPE

All medicines, prescribed, OTC and complementaries, and surely biological products

REQUIREMENTS

The **GS1 DataMatrix** should include the 4 data elements GTIN, expiry date, batch/lot and/or serial number (not mandatory).

TIMEFRAME

Implementation will start on
1st January 2023

CHINA

CHINA

Asia

PRODUCT SCOPE

Pharmaceuticals, Vaccines and Medical Devices.

REQUIREMENTS

- Data carrier: linear/2D barcode, RFID, with Human Readable Interpretation
- Currently two coding systems are still issued in China:
  - GS1 standards using a GTIN as product code with the required set of AIs, all embedded in a DataMatrix
  - AliHealth eCode: a 20 digits code (7 digits product ID + 9 digits serial number + 4 digits check digits) given by AliHealth and embedded in a 128 barcode.

TIMEFRAME

- **All pharma drugs** will be serialized & aggregated **by 2022**
- **All vaccines –** full track and trace of the smallest saleable packing unit should be implemented by 31 March 2020 with national code **and with GS1 by July 2022.**

ETHIOPIA

ETHIOPIA

Africa

PRODUCT SCOPE

Pharmaceuticals.

REQUIREMENTS

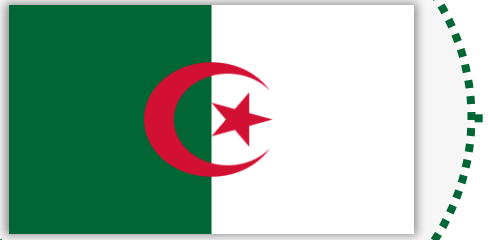
- Packaging level: secondary packaging
- Data elements: GTIN, Batch number, Expiry date, Serial number in a second phase
- Tertiary packages: GS1 DataMatrix or GS1 128
- Aggregation required, 128 with GTIN, batch number, expiry date. Logistics units identified with SSCC

TIMEFRAME

The deadline for master data to be submitted is 19 August 2021, and data (both product and location data) can be submitted in excel format. The portal is not yet ready:

- **19 August 2022**: for locally manufactured pharmaceuticals
- **19 August 2023**: manufacturer, wholesaler and healthcare provider shall comply with batch traceability for listed pharmaceutic
- **19 February 2024**: start serialization for listed pharmaceuticals
- **19 February 2027**: Full Track & Trace

ALGERIA



ALGERIA

Africa

PRODUCT SCOPE

Pharmaceuticals and Medical Devices.

REQUIREMENTS

- Local products must be identified with a GTIN including a GCP issued by GS1 Algeria; imported products follow GS1 rules without GCP.
- The products, locally manufactured and placed on the market with a GTIN already assigned have 2 years to change the GTIN including an Algerian GCP.
- The importer must register the product master data on the Mantooj.net platform and it is possible to do the submission manually or as batch.
- The Pharma regulation will be published and a new portal for reporting to government will be implemented.

TIMEFRAME

The new requirement should be implemented by **2023** and serialization is required for **2025**

BRAZIL

BRAZIL

South America

PRODUCT SCOPE

Pharmaceuticals.

REQUIREMENTS

- GS1 2D Datamatrix on secondary packaging
- Data elements must be in this order: GTIN (01), ANVISA number – AI (713), Serial Number - AI (21), Expiration Date - AI (17), Batch/Lot Number - AI (10).
- Data Reporting/Events communication to the ANVISA/SNCM portal (full T&T system with centralized data: Serialization & Aggregation req.).

TIMEFRAME

- Deadline for All products(full T&T and reporting): **28 April 2022.**
- Mandatory Reporting of events related to serialized drugs transacted **after 28 April 2022.**
- The serialization plan submission to SNCM becomes optional after the last approval of the Normative Instruction
- Approved **on 25 Nov. 2021** the updated Normative Instruction - NI 100/2021 and published .

CANADA

CANADA

North America

PRODUCT SCOPE

Pharmaceuticals and Vaccines.

REQUIREMENTS (recommendation not regulation)

- Products and packaging (primary and secondary) be labelled with GS1 DataMatrix
- GTIN at the unit dose level (where feasible)
- GS1 128 at the case level
- Barcode includes: GTIN, lot number, expiry date, SN is optional

TIMEFRAME

- **31st December 2021**
  (for Manufacturer, to be extended to **2023** if manufacture is not ready)
- **31st December 2023** (for Distributors)
- **31st December 2025** (for Pharmacies)

MALAYSIA

MALAYSIA

Asia

PRODUCT SCOPE

Pharmaceuticals.

REQUIREMENTS

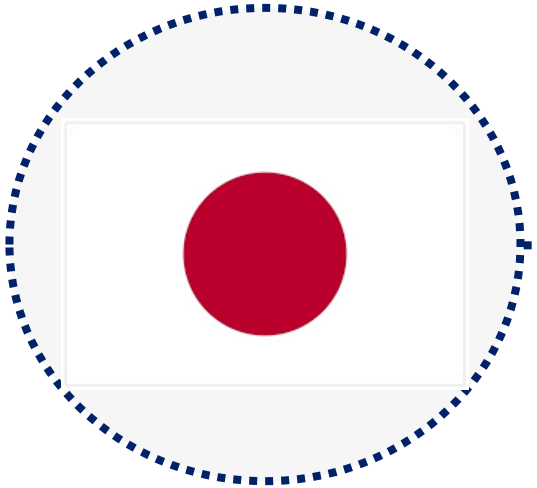
- **Primary packaging serialization is not required in the initial phases** but will be required after full track and trace is implemented
- **Data Submission Portal**: Centralized model will be used
- **Data sharing or registration methods**: EPCIS will be used for reporting to the central database.

TIMEFRAME

Starts in 2020 with scheduled poisons products

Intention as of 2023: full implementation of Track & Trace

JAPAN



JAPAN

Asia

PRODUCT SCOPE

Pharmaceuticals.

REQUIREMENTS

- Serialization not required but only for blood/biological products.
- Sales package (Secondary Packaging level): GTIN, expiration date, batch/lot, serial number (optional) with GS1 DataBar.
- Outer package (Tertiary Packaging level): GTIN, expiration date, lot, serial number(optional), and quantity with GS1-128

TIMEFRAME

- The new labeling by the end of **March 2021**
- Deadline of electronic leaflet: **1st August 2021**
- Deadline barcoding for drugs and medical devices: **1st December 2022**

INDONESIA

INDONESIA

Asia

PRODUCT SCOPE

Pharmaceuticals, Vaccines, Cosmetics, Processed Food.

REQUIREMENTS

- Requirements as per the regulation issued on Dec.2018 for authentication (not identification):
  - Data carrier: use of 2D barcode: QR Code or DataMatrix issued by POM T&T application or applying GS1 Datamatrix as per client's request)
  - Data elements: GTIN or AI(90)national NIE + SN + Exp. date + Lot number
- Primary level packaging should include SN when there is no anti-tampering evidence on the secondary packaging level above and not exempted from the list of products due to space limitation. Aggregation to secondary level packaging is considered mandatory if serializing at primary level.
- 22 October another draft shared: ampoule, pre-filled syringe, stick pack, suppository, and catch cover are removed from exemption (for primary coding)

TIMEFRAME

- **Deadline for identification:** all products from **2023**
- **Deadline for authentication/serialization:** all products from **2025 - 2027**

INDIA

INDIA

Asia

PRODUCT SCOPE

Pharmaceuticals and Cosmetics.

REQUIREMENTS

For drugs in export (to monitor for domestic drugs and QR coding):

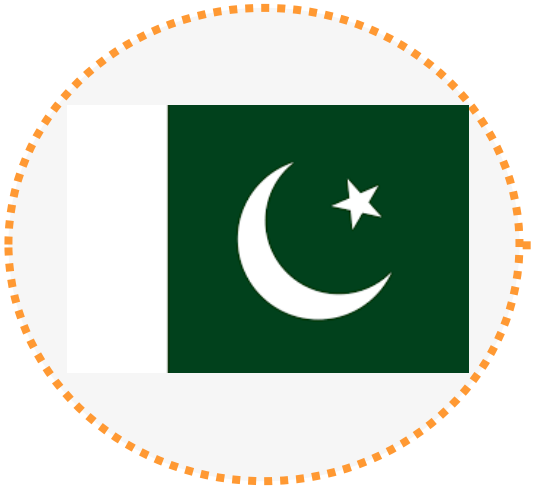
- **Packaging level**: Case / Shipper, secondary packaging, primary packaging
- **Data elements**: GTIN, Batch/Lot Number AI (10), Expiration Date AI (17), Serial Number AI (21)

TIMEFRAME

Full Track & Trace for export drugs and reporting to IVEDA portal **by 1st April 2022**

-> postponed to 31 March 2023

PAKISTAN



PAKISTAN

Asia

PRODUCT SCOPE

Pharmaceuticals.

REQUIREMENTS

- **Packaging level**: Case / Shipper, secondary packaging, primary packaging will be omitted
- **Data elements**: GTIN, Batch/Lot Number AI (10), Expiration Date AI (17), Serial Number AI (21). AI 240 data element in the 2D barcode will also be omitted.
- There is no requirement that the **GS1 Company Prefix (GCP)** must be licensed by GS1 Pakistan and GCP licensed by any GS1 MO are allowed.

TIMEFRAME

- Serialization and full track and trace will be required in 6 years.
- The date of release of the amendment DRAP requirements (August 2019) is used as a start of **the timeframe for implementation (6 years - leading to a deadline in 2025**)

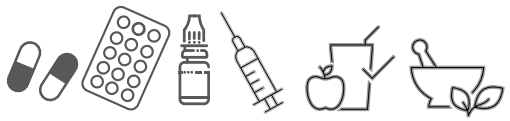
UNITED ARAB EMIRATES (UAE)

United Arab Emirates

Middle East

PRODUCT SCOPE

Supplied Rx Drugs (registered and non-registered), Supplied OTC Drugs (registered and non-registered), vaccines, narcotics, food supplements, herbal supplements.



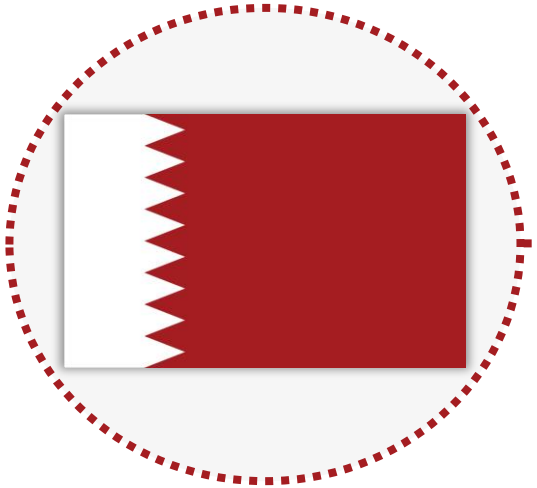
REQUIREMENTS

- **Secondary packaging level** requires a GS1 DataMatrix with:
  - **GTIN (01) encoded in a 14-digit format**
  - **Expiry date (17) in format YYMMDD**
  - **Batch Number (10) alphanumeric** and can contain 1 to 20 characters
  - **Serial number (21) alphanumeric** and up to 20 characters
- **Master Data to be uploaded in GS1 UAE's BrandSync Portal**
- **GLNs** required for pharma manufacturers, dispatching and warehouse sites, importers, wholesalers and distributors, pharmacies, hospital pharmacies

TIMEFRAME

- Master Data Management: **13 December 2021**
- Serialization on Secondary Packaging: **13 December 2021**
- Aggregation: **13 December 2022**
- Reporting to MOHAP through Tatmeen platform: **13 December 2022**
- Deadline for all stakeholders to get GLN: **13 December 2022**

BAHRAIN



BAHRAIN

Middle East

PRODUCT SCOPE

Pharmaceuticals.

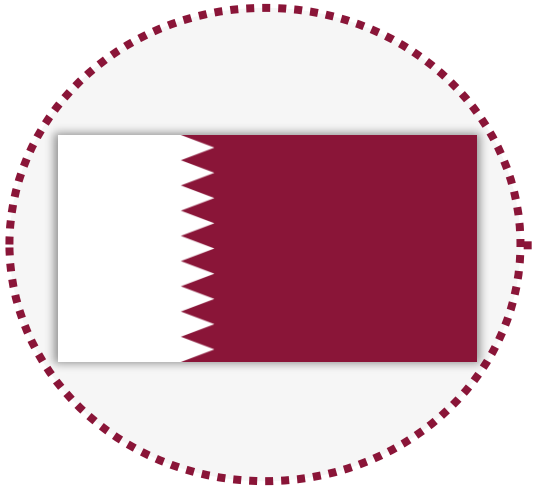
REQUIREMENTS

- **Secondary Package**: Data carrier: GS1 DataMatrix
- **Data elements**: GTIN – AI (01), Expiration Date - AI (17), Batch/Lot Number - AI (10), Serial Number of each package - AI (21)
- **Data Submission Portal**: GS1 UAE portal BrandSync

TIMEFRAME

- Dates are for the manufacturers that are exporting to the Kingdom of Bahrain:
  - all MAHs to be registered by **1st January 2021**
  - Begin sending EPCIS events by **31 December 2021**
  - **May 2022:** deadline to comply with the aggregation requirements

QATAR



QATAR

Middle East

PRODUCT SCOPE

Pharmaceuticals.

REQUIREMENTS

- **Packaging level**: primary, secondary and tertiary levels
- **Data elements**: GTIN, plus Expiry Date, Batch Number serial number if applicable on secondary
- **Data carrier**: GS1 DataMatrix (secondary), GS1 DataMatrix or GS1 128 (tertiary)
- **Human Readable Interpretation** of the barcode will be provided, portal to be defined (xml file by email now).

TIMEFRAME

- **Short term**: immediately, valid for on-going orders; Secondary and tertiary packaging identification; Minimal product information
- **Mid-term**: by **1st January 2021** (Serial Shipping Container Code; Electronic dispatch advice
- **Long term**: by **1st January 2023 / 1st January 2025** (Primary packaging identification)

LEBANON

LEBANON

Middle East

PRODUCT SCOPE

Pharmaceuticals, imported or locally manufactured. Exceptions: free medical samples and the IV fluids.

REQUIREMENTS

- **Packaging level**: secondary packaging
- **Data carrier**: GS1 DataMatrix
- **Data elements**: GTIN, Lot number, Expiry date, SN optional
- MediTrack system to record the movement of importation and sales should start to be used no later than **5 April 2021**(upload excel file or via API).

TIMEFRAME

Starting **1st January 2020**

AFRICA

AFRICA

PRODUCT SCOPE

Pharmaceuticals, Medical Devices and Retail.

REQUIREMENTS

Master Data Initiatives and National Product Catalog for each country

TIMEFRAME

Under Development

- Countries developing culture-awareness via workshops: Botswana, Namibia, Senegal, Benin, Burkina Faso and Togo, Ghana supported by USAID, Kenya, Ethiopia (starting) and Rwanda, Zambia
- SADC (Southern African Development Community) is working with GS1 to align and collaborate on traceability activities.
- Nigeria: NAFDAC conducted a pilot for the implementation of traceability for COVID-19 vaccines using GS1 standards.
- Ethiopia is the most advanced concerning Full Track & Trace