ANTARES VISION GROUP

HEALTHCARE WORLDWIDE

TRACK & TRACE REGULATIONS Updates

Antares Vision Group

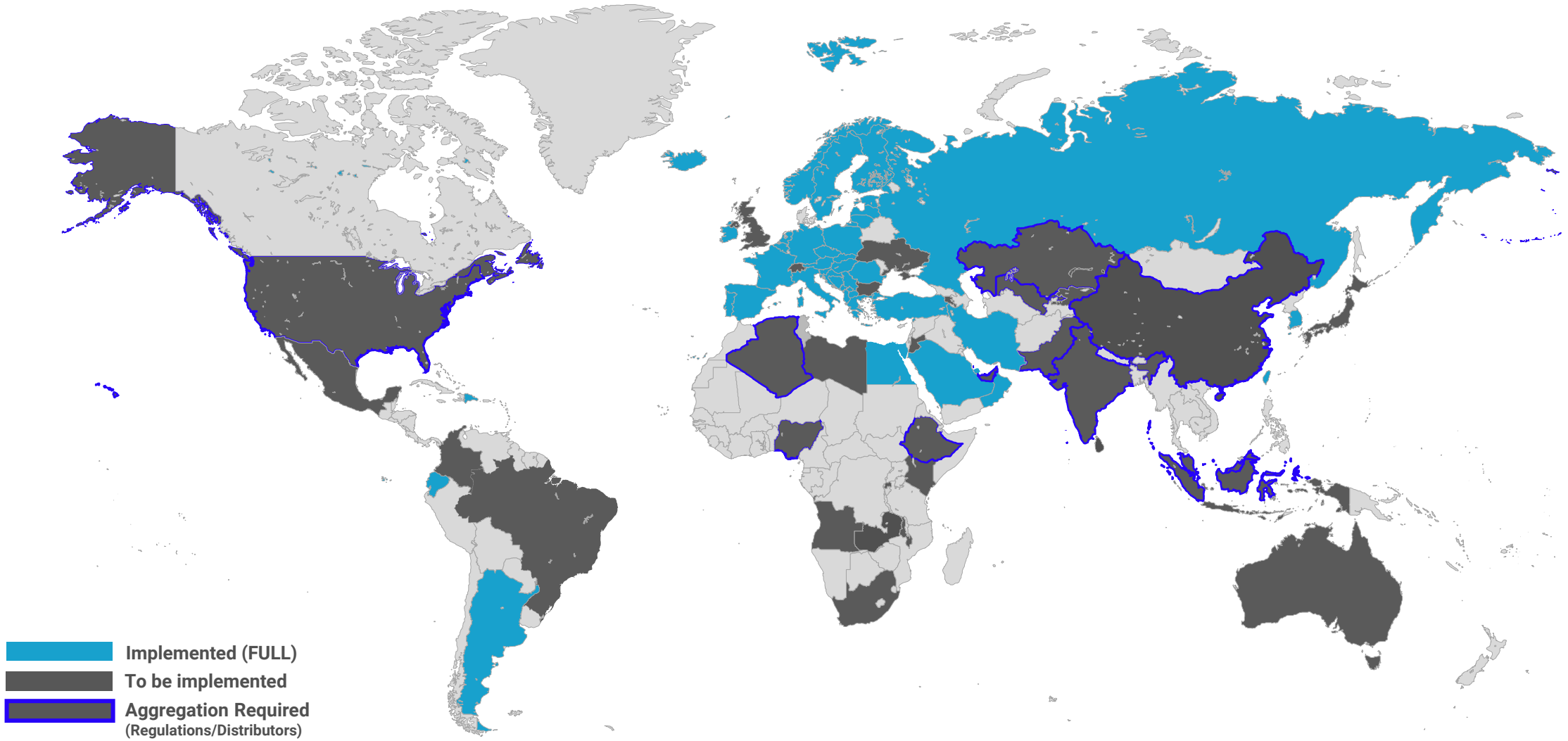
September 27th, 2022

ANTARES VISION GROUP

ROADMAP 2019-2025

PHARMA & MEDICAL DEVICES

TRACEABILITY – PHARMA (2010-2025)



PHARMA REGULATIONS – WORLDWIDE ROADMAP- **2019-2022**

ANTARES VISION GROUP

IDENTIFICATION SERIALIZATION

2019

- **Europe 2019 – 2025** (+Tamper Evident)
- **Taiwan** (China Taipei – API in 2021 +7 more drugs reporting)
- **Saudi Arabia** (Reporting)
- **Oman**
- **Egypt**
- **Bahrain** (till 31 Dec. 2021)

2020

- **Russia** (all drugs)
- **Egypt** (last pilot)
- **Malaysia** (poison products)
- **Australia** (Ident. & Marketing)
- **Lebanon** (Ident. with 2D DM, all imported drugs)
- **China** (Some key products)
- **Bahrain** (till 31 Dec. 2021)

2021

- **Ukraine** (draft & piloting ongoing for serialization)
- **Ethiopia** (till 2024-2027 ALL with SN)
- **Japan -2023** (Labeling, ser. of blood products)
- **United Arab Emirates** (13 Dec.2021)
- **Qatar** (asap, Ser. if applicable)
- **Canada** (31 Dec.2021 optional- 2025)
- **Bahrain** (till 31 Dec. 2021)

2022

- **China** (ecode, GS1 DM)
- **Japan** (Iden. with GS1 Databars, only Ser. of blood products)
- **Bulgaria**
- **Lebanon** (GS1 DM for imports)
- **Kazakstan** (Ser & Rep. up to 20%)
- **Uzbekistan** (1st & 2nd Groups)
- **Canada** (31 Dec.2021 optional- 2025)
- **Jordan** (30 Dec.)

AGGREGATION

2019

- **Egypt**

2020

- **Russia** (all drugs)
- **Egypt**
- **Saudi Arabia**
- **China** (key products, 31 Dec.)

2021

- **Qatar** (tender SSCC; Electronic dispatch advice (HMC)
- **Canada** (31 Dec.2021 optional- 2025)

2022

- **China** (ecode, GS1 DM)
- **Bahrain** (May 2022)
- **UAE** (Dec.2022)
- **Canada** (31 Dec.2021 optional- 2025)

P.S 1: 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 specifications and timeframe).

P.S 2: BRAZIL Full Track & Trace is no more mandatory by law, but ANVISA is working on its regulation for how to implement medicine traceability for companies being motivated by regulatory compliance and sanitary procedures. ANVISA wants to recognize the companies that had already invested several lines ready to run in Brazil.

PHARMA REGULATIONS – WORLDWIDE ROADMAP- 2023-2027

ANTARES VISION GROUP

IDENTIFICATION SERIALIZATION

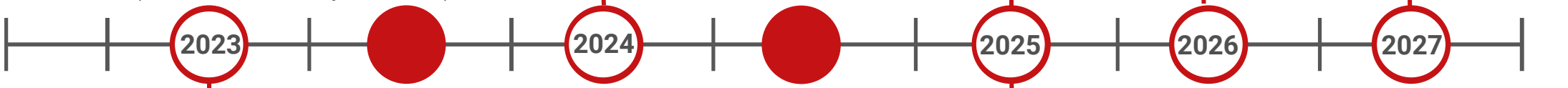
- **Indonesia** (ident. all drugs & bottles >=5ml)
- **Kazakstan** (100%)
- **Uzbekistan** (3rd Group)
- **Malaysia** (intention full T&T)
- **Qatar** (Primary Package Identification)-2025
- **Australia** (optional & must follow TGO106)
- **USA** (full traceability)
- **Algeria** (identification)
- **Hong Kong HA** (tender)
- **Japan**
- **Canada** (31 Dec.2021 optional- 2025)
- **India** (Imported/Domestic API Iden.: 1st Jan., Export drugs : 31 March, local 300 drugs by 1st May)
- **Lebanon** (GS1 DM for local by 1/1/2023)

- **Qatar** (Primary Package Identification)-2025
- **Ethiopia:** 19 February 2024: Serialization for listed pharmaceuticals

- **Indonesia -2027** (Serialization all drugs & bottles >=5ml)
- **Pakistan** (ident. & Serialization)
- **Algeria** (SER., local with GCP from GS1 Algeria)
- **Qatar** (Primary Package Identification)-2025
- **Canada** (31 Dec.2021 optional- 2025)
- **Italy** (MAX. 2025)
- **Greece** (MAX. 2025)
- **Nigeria** (by 2025 Full T&T)
- **Uzbekistan** (4th Group)

- **Rwanda:** 29 Aug.2026: SER. Mandatory
- **Indonesia:** Full T&T

- **Indonesia -2027** (FULL T&T all drugs & bottles >=5ml)
- **Ethiopia:** 19 February 2027: Full Track & Trace



AGGREGATION

- **USA** (1st Nov. 2023 full item-traceability, aggregation required by distributors & recommended by HDA)
- **Malaysia**
- **Australia** (optional starts 1st January 2023)
- **India** (& Reporting for drugs to export by 31 March)
- **Canada** (31 Dec.2021 optional- 2025)

- **Indonesia** (all drugs & bottles > =5ml)
- **Canada** (31 Dec.2021 optional- 2025)
- **Nigeria** (starting 2025 Full T&T)

- **Indonesia -** FULL T&T
- **Rwanda:** 29 Aug.2027: AGG. Mandatory
- **Ethiopia:** 19 February 2027: Full Track & Trace

Under Development: **Angola, Cambodia, Kenya, Sri lanka, Ghana, Zambia (draft consultation ends), Colombia, Libya, Vietnam(draft QR code), Malawi, South Africa (draft phased implementation to 2022 TBC), Afghanistan, Botswana(guidance for 2022-2023 regulation), Mexico, Ukraine (piloting only, following EU FMD)**

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** (26 May for class III MDR 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)
- **Taiwan** (class III not implantable)
- **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)
- **European Union** (26 May for IVDR Reg.)

2023

- **Qatar 2023-2025** (Implementing GS1 standards (HMC)
- **South Korea** (2023)
- **Saudi Arabia** (Saudi-D Implementation by Classes B,C (medium) and D(high risk) by 1st Sept.2023)
- **Taiwan** (class II)
- **Algeria** (Identification)
- **Uzbekistan**
- **European Union** (26 May for class II a or b MDR and class III DM reusable devices)

2024 +

- **Saudi Arabia** (Saudi-D Implementation class A (low risk) by 1° Sept. 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)
- **European Union** (26 May 2025 for class I and EUDAMED mandatory devices reg. in Q2 2026)

P.S 1: 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 specifications and timeframe)

Under Development: Colombia(draft), Australia (draft, TGA webinars, piloting till end of 2022, expected volontary compliance by Jan. 2023 and full compliance by July 2027), 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)

EU MEDICAL DEVICES REGULATIONS MDR/IVDR TIMEFRAMES

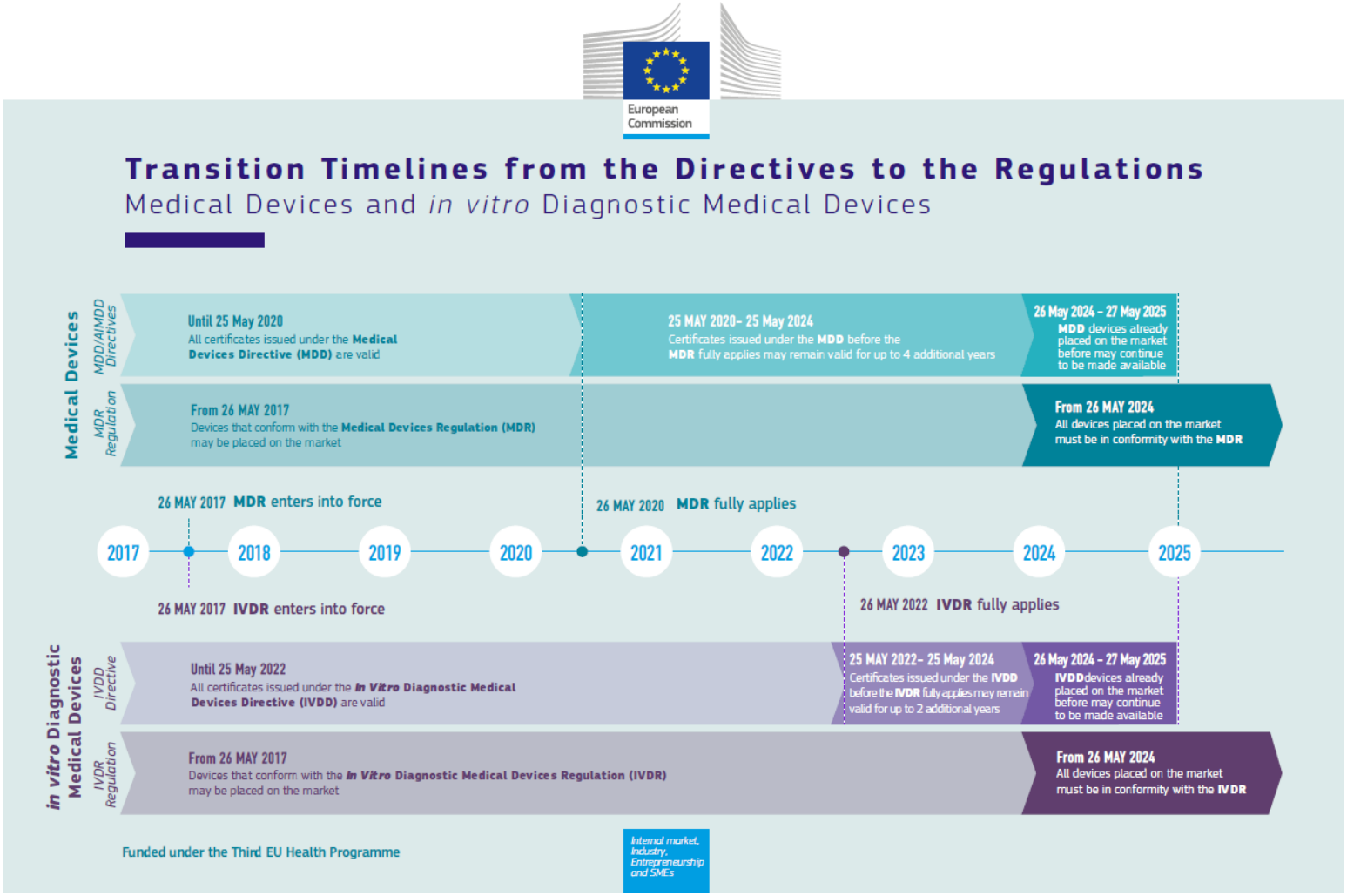
- The **MDR is fully applicable since 26 May 2021** and **the IVDR since 26 May 2022**, following the **transition periods of FOUR YEARS for MDR and FIVE YEARS for IVDR**.
- **Implementation for Label and Packaging**
  1. 26th May 2021: deadline for medical devices Class III and implantable
  2. 26th May 2023: deadline for Class IIa and IIb devices
  3. 26th May 2025: deadline for Class I
- **Implementation for Direct Marking and Reusable Devices**
  1. 26th May 2023: for Class III and implantable
  2. 26th May 2025: for Class IIa and IIb
  3. 26th May 2027: for Class I
- **Ref:** https://health.ec.europa.eu/medical-devices-new-regulations/getting-ready-new-regulations_en

MEDICAL DEVICES LEGISLATIVES

- The Regulations on Medical Devices (Regulation (EU) 2017/745) and on In-Vitro Diagnostic Devices (Regulation (EU) 2017/746) changed the European legal framework for medical devices, introducing new responsibilities for EMA and national competent authorities in the assessment of certain categories of medical device.
- The Medical Devices Regulation applies since 26 May 2021, following a four-year transition period. Manufacturers must comply with the Regulation when placing new medical devices on the market. It repeals Directive 93/42/EEC on medical devices and the Directive 90/385/EEC on active implantable medical devices.
- The In-Vitro Diagnostic Devices Regulation will apply from 26 May 2022, following a five-year transition period. In the meantime, manufacturers can opt to place in-vitro diagnostic devices on the market under Directive 98/79/EC or under the new Regulation if they fully comply with it.
- **Ref:** https://www.ema.europa.eu/en/human-regulatory/overview/medical-devices

TRANSITION TIMELINES- INFOGRAPHICS

- MDR is postponed one year due to Covid-19 so **by 26 May 2021 fully applies** with **a transition period of 4 years**



- **Ref:** https://health.ec.europa.eu/system/files/2020-07/md_infographic-timeline_en_0.pdf

EUDAMED NEW TIMELINE – LAST UPDATE JUNE 2022

EUDAMED - European Database on Medical Devices

EUDAMED Time line

The European Commission planning – June 2022

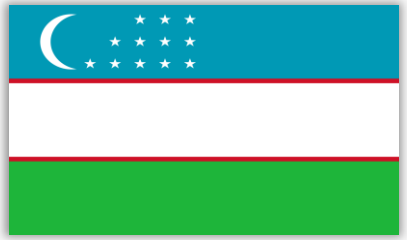
Q4 2023	Q1-Q2 2024	Q2 2024	Q2 2024	Q4 2024	Q2 2026
End of the EUDAMED MVP[1] development for all six modules	Independent **Audit**	Audit results presented to the Medical Devices Coordination Group (MDCG)	EUDAMED has achieved full functionality following the outcome of the Audit. **Publication of a Commission notice** in the *Official Journal of the European Union* **(OJEU)** The full EUDAMED system (all 6 modules) is released.	End of 6 months transitional period after publication of the notice in the OJEU The use of **EUDAMED** becomes **mandatory** as regards obligations and requirements related to **Actors, Vigilance, Clinical Investigation & Performance Studies and Market Surveillance modules**	End of 24 months transitional period after publication of the notice in the OJEU The use of **EUDAMED** becomes **mandatory** as regards obligations and requirements related to **UDI/Device and NB & Certificate modules**

[1] EUDAMED Minimum Viable Product (MVP) means that the system developed implements at least the minimum Medical Devices Regulations requirements and allows competent authorities and all stakeholders to comply with their legal obligations.

- **Ref:** https://health.ec.europa.eu/system/files/2022-07/md_eudamed_timeline_en.pdf

BY COUNTRY PHARMA UPDATES

UZBEKISTAN



UZBEKISTAN

Eurasia

PRODUCT SCOPE

Pharmaceuticals, medical devices, Bottled water & soft drinks, beer, tobacco, alcohol, and appliances.

REQUIREMENTS

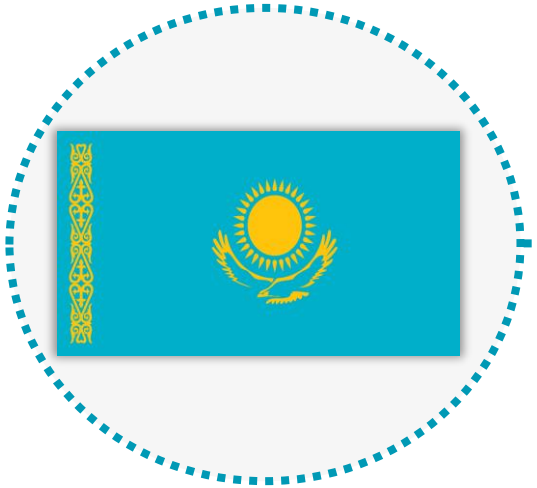
- **Traceability system**: Asl belgisi (developed by *CRPT Turon*)
- **GS1 DataMatrix Digital Marking codes** (identification code (GTIN, SN) **+ local crypto tail of 48 Characters** (Crypto code, Crypto key) generated by the Operator of T&T system in Uzbekistan
- Customs **aggregation code** for imported products and aggregation code for locally manufactured products
- Foreign manufacturers get access to the digital marking system after receiving a local individual taxpayer number (TIN) and an electronic digital signature (EDS).

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.)).
- Using stickers for serialization is allowed
- **Tertiary**: GS1 128 with SSCC / Aggregation possible
- Data Portal submission for **Reporting**: (tbc)

TIMEFRAME (not yet confirmed)

- **1 July 2022** – Introduction of labelling for approved 93 of medicines (1% from all drugs) -> **1st August 2022?**
- **1 October 2022 + 1 month?**- 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

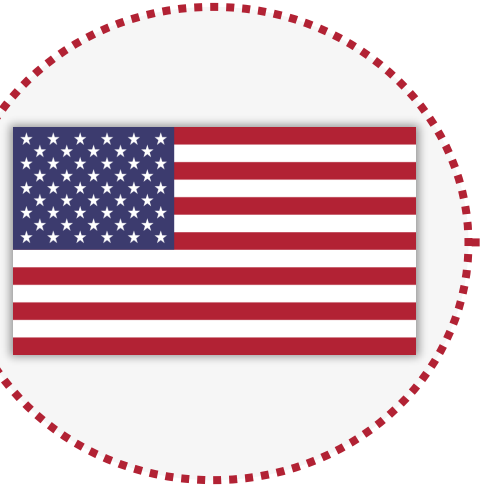
23. The proposed solutions set out in the above paragraphs would be implemented through:

- 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

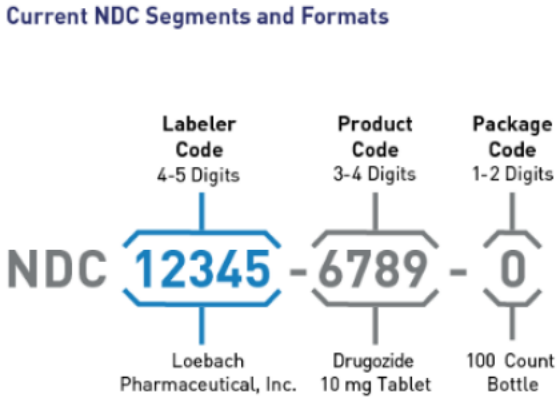
- The Drug Supply Chain Security Act (DSCSA) recommends to build an electronic, interoperable system by 2023 that can identify and trace products as they are distributed in US.
- Secondary Packaging with GS1 2D Datamatrix
- Data elements: GTIN, Batch/Lot Number, Expiration date, Serial Number
- Aggregation is not required by the FDA/DSCSA but by distributors and recommended by HDA
- Events communication via EPCIS among all stakeholders in a distributed way.

TIMEFRAME

- **1st January 2015:** Lot number (DSCSA Product tracing requirements)
- **1st November 2017:** Serialized product identifiers
- **1st November 2023:** Pkg (item-level) traceability

FDA Issues New Proposed Rule

- Revising the National Drug Code Format and Drug Label Barcode Requirements
- Published Monday, July 25th
- The comment period is July 25th to November 22nd (120 days)
- **Change Proposed:**
  - NDC to be a 12-digit code with a 6-4-2 structure (labeler code-product code-package code)
  - Allowance for barcodes that are linear or non-linear as long as they follow the prescribed standards (21CFR 201.25)



Revising the National Drug Code Format and Drug Label Barcode Requirements

- **Reason:**
  - 5-digit code labeler code inventory will be exhausted in 10-15 years
  - Benefits to standardization – all codes of the same length and structure
    - In the long run, costs are viewed as similar as to the alternatives with the benefit of standardization and elimination of changeover costs later
    - Eliminate the need to convert NDCs which can lead to errors, confusion, and patient safety concerns in addition to reducing the complexity of systems
  - The 12-digit NDC format was chosen based on the above reasons and stakeholder feedback from 2018

Revising the National Drug Code Format and Drug Label Barcode Requirements

- **Process of Change/Implementation:**
- A 5-year postponement of the effective date is proposed to enable trading partners to transition to the new structure
- On the effective date of the final rule
  - FDA will assign any new NDC with the 12-digit, 6-4-2 format
  - Existing 10-digit NDCs are required to convert over the next 3 years
    - This timeframe was determined based on the extended time to deplete current inventory that may have the 10-digit NDC and eliminate relabeling
  - All systems need to be able to handle the new structure as TPs can have a mix of 10 and 12-digit NDC codes
- Conversion of existing 10-digit NDCs by adding leading zeros to meet the new 12-digit model
  - 5-4-1 to 6 (with leading 0)-4-2 (with leading 0) [12345-1234-1 to 012345-1234-01]
  - 5-3-2 to 6 (with leading 0)-4 (with leading 0)-2 [12345-123-12 to 012345-0123-12]
  - 4-4-2 to 6 (with leading 0)-4 (with leading 0)-2 [1234-1234-12 to 001234-1234-12]
- Conversion to the 11-digit HIPAA standard by adding leading zero to meet the new 12-digit model
  - 5-4-2 to 6 (with leading 0)-4-2 [12345-1234-12 to 012345-1234-12]

__Does cite that the hope is that this standard will be updated to match the 12-digit model to eliminate conversion and duplication errors due to the non-standard use of hyphens__

Historical Background

- New NDC Format Workgroup (2018)
  - Through this workgroup, GS1 US worked directly with industry members to assess the impact of the transition to a new NDC format, analyze issues and options, and develop recommendations for the path forward.
- Submitted a comment letter on December 18, 2018, to Docket No. FDA-2018-N-2610
  - Future Format of the National Drug Code
- In 2021, a new AI (715) for a 12-digit NDC was created in preparation

Table of Contents

What they accepted in the proposed rule

- Option D
  - Harmonize NDC assignment at FDA with other stakeholders by moving toward a uniform NDC in a 6-4-2 sequenced format at a future date.
  - Once FDA starts assigning 6-digit Labeler Codes, all NDCs (new and existing) would be required to be presented in a 6-4-2 sequenced format.
  - Existing NDCs would be converted from their existing format by adding leading zeros to the short segments.
  - This would create one standard configuration for all NDCs and provide the industry with more product or package codes.
- Timing
  - 5-year postponement of the effective date and 3-year transition period once effective
- Revisiting the FDA linear barcode rule in advance of and as preparation for Option D implementation.

What they rejected in the proposed rule

- FDA adoption of a standards-based format for NDC
  - GTIN as the unique identifier – not addressed directly
- Outsource NDC assignment to standards body (addressed directly)

Not addressed in the proposed rule

- The SNI Guidance will need modification in advance of and as preparation for Option D implementation. The SNI guidance defined SNI as NDC + serial number. However, as described above, this does not support unique identification at every level of the packaging hierarchy, and therefore is not sufficient to support traceability. GS1 members had been able to overcome this challenge by embedding the NDC in a GTIN. However, with Option D, members will no longer have this technical mechanism.
- Once NDC is independent of the GTIN and in its own AI, DSCSA verification, tracing, notification, etc. cannot be based on SNI alone anymore without risk of collision between package and case SNIs. Therefore, additional guidance may be needed for DSCSA stakeholders.
- FDA should consider providing guidance that the hyphens should only be used for printing the human-readable NDC on packages and should not be included systems and databases.
- FDA should consider providing guidance that NDCs should be stored in IT systems and databases in an alpha-numeric field (not text) to avoid stripping away any leading zeros.
- FDA should conduct a mathematical and/or algorithmic analysis of the Option D format in the context of (i) existing NDC formats, (ii) the new 6-digit labeler code, and (iii) the practice of removing hyphens. Such an evaluation should be able to identify any potential collision or translation issues with the new NDC format.

Announcing a New Workgroup

- The **GS1 Healthcare US New NDC Format Workgroup** deliverables will include:
  - Comment letter to U.S.FDA under *Docket No. FDA-2021-N-1351*.
  - Create resource(s) to support the implementation of the changes based on the final rule by the U.S. FDA based on industry needs.
- **Workgroup facilitator and industry chairs**
  - Facilitator – Tracy Nasarenko, GS1 US (tnasarenko@gs1us.org)
  - Industry Chairs –Scott Mooney, McKesson, and Elizabeth Waldorf, TraceLink
- **Call Schedule:**

This workgroup will meet for one hour from **3:00 pm – 4:15 pm (EST) every Tuesday beginning on September 19, 2022.**

- If you are interested in participating in the GS1 Healthcare US New NDC Format Workgroup, please complete the Opt-in by September 15, 2022.
- Phase 1 of the Workgroup is expected to conclude with the first deliverable, the U.S.FDA comment letter which must be submitted by November 22, 2022.
- The workgroup will then reconvene for Phase 2 and be in service for a year to create resources for the impact of the final rule. The timing of this will be dependent on the publication date of the final rule and will be included in the corresponding GS1 Healthcare US business plans.

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, Cosmetics 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.
  - NMPA: 12 standards had been published to regulate the PH T&T and the NMPA Harmonization platform

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.**

CHINA UPDATES FOR 2 NEW STANDARDS

- **NMPAB/T 1011-2022 (by 23 June 2023 in one year): Identification specification for Drug Traceability Code .**
  For example: with GS1 DM: HRI must include GTIN, SN, Batch, exp. Date the Drug Traceability Code in Chinese and the sentence and instruction to scan the code for consumer information on carton and cases as below
  - Requirement on the placement and on the printing quality - The barcode should be easy to read -clearly printed – easy to spot
  - 2 additional elements should be printed near the barcode (only on the HRI): To be included only on the unit of sell level and not on the shipper unit/pallet.
    - The text “drug traceability code” (in Chinese) should be printed near the barcode;
    - Instruction on how to get the traceability data by scanning the (such as use XXX to scan).
  - Aggregation is still required for all the units of sell.
- **NMPAB/T 1012-2022 (by 23 June 2022 immediately from the date of release):** Display specification for consumer query results of drug traceability – This standard is focusing on what information the consumer will get when scanning the barcode.

CHINA- ANNEX 1

Appendix A
(Informative) Schematic Diagram of
Drug Traceability Code Identification

A.1Schematic diagram of drug traceability code identification using 1D barcode

Figure 1

A.2 Schematic diagram of drug traceability code identification using 2D code

Figure 2

Note: Figures 1 and 2 are schematic diagrams of drug traceability code identification, which provide a reference for drug traceability code identification.

NMPAB/T 1011—2022

附录 A
（资料性）
药品追溯码标识示意图

A.1 采用一维条码的药品追溯码标识示意图

图 1

A.2 采用二维码的药品追溯码标识示意图

图 2

注：图1、图2均为药品追溯码标识示意图，为药品追溯码标识提供参考。

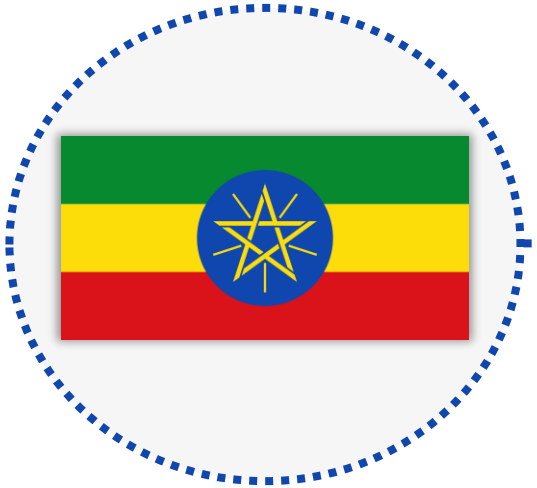
CHINA ANNEX 2

Appendix A
(Informative)
Schematic Diagram of consumer query results of drug traceability

Drug Traceability Information	
The provision of the traceability information by this traceability system is authorized by XXX	
Drug Traceability Code	XXXXXXXXXXXXXXXXXXXX
Drug Generic Name	XXXXXXXX
Drug Production Date	XXXXXXXX
Drug Expiry Date	XXXXXXXX
Drug Shelf Life	XX
Drug Batch No.	XXXXXX
Dosage Form	XXXX
Packaging Strength	XXXX
Drug Approval Document No.	XXXXXXXXXXXX
Drug Approval Document No. Valid Until	XXXXXXXX
Name of Domestic Drug Marketing Authorization Holder	XXXXXXXX
Unified Social Credit Code (Domestic Drug Marketing Authorization Holder)	XXXXXXXXXXXXXXXXXX
Name of Domestic Drug Manufacturer	XXXXXXXX
Unified Social Credit Code (Domestic Drug Manufacturer)	XXXXXXXXXXXXXXXXXX
•••••	•••••

Note: The Figure shows the schematic diagram of consumer query results of drug traceability, and provides a reference for consumer query results of drug traceability.

ETHIOPIA



ETHIOPIA

Africa

PRODUCT SCOPE

Pharmaceuticals.

REQUIREMENTS

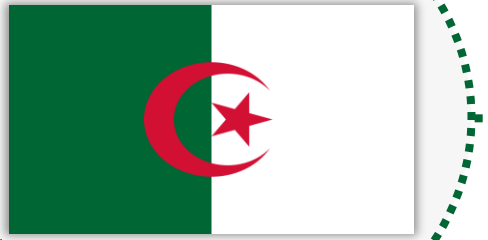
- Packaging level: secondary packaging
- Data elements: GTIN, Batch number, Expiry date, Serial number in a second phase
- Tertiary packages: GS1 DataMatrix or GS1 128
- Aggregation required, 128 with GTIN, batch number, expiry date. Logistics units identified with SSCC

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

A new Decree will be published by the government. The new requirement should be implemented as identification 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, ANVISA number – AI (713), Serial Number, Expiration Date, Batch/Lot Number.
- Data Reporting/Events communication to the ANVISA/SNCM portal (full T&T system with centralized data).
- Eleaflet Bill **3846** had been approved by the senate and the president.

PENDING TIMEFRAME

- Full Track & Trace is no more mandatory by the law, but ANVISA is working on its regulation/RDC for how to implement medicine traceability for companies who would like to leverage that differentiated business value beyond compliance towards their brand protection and patients' safety against counterfeiting and diversion while being harmonized globally with approx. 75 countries worldwide.
- ANVISA wants to recognize the companies that had already invested several lines ready to run in Brazil.

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

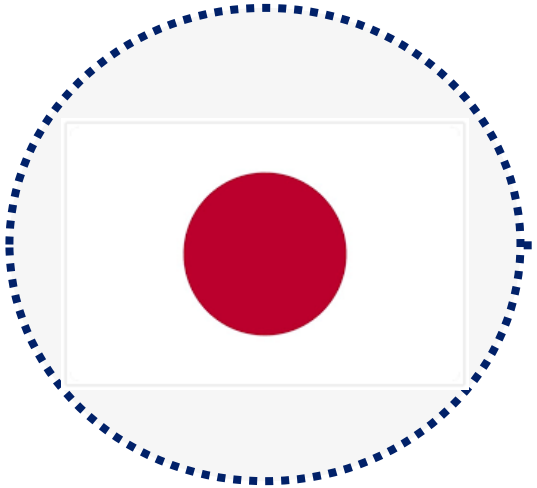
- **Primary packaging serialization is not required in the initial phases** but will be required after full track and trace is implemented
- **Data Submission Portal**: Centralized model will be used
- **Data sharing or registration methods**: EPCIS will be used for reporting to the central database.

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 Export drugs:**
  - **Packaging level**: Case / Shipper, secondary packaging, primary packaging
  - **Data elements**: GTIN, Batch/Lot Number AI (10), Expiration Date AI (17), Serial Number AI (21)
- **For API** (domestic and imported) traceability with QR code mandatory.
- **For Domestic/Local drugs:** for top 300 local brands with barcode/QR coding, a draft (GSR 448)was issued on 14 June 2022 and is open for public consultation for ONE month to review.

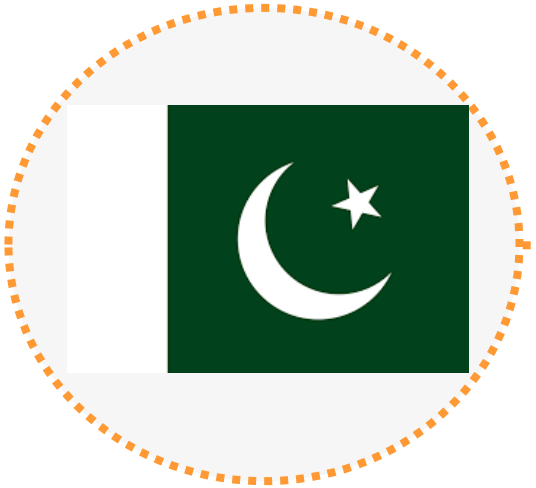
TIMEFRAME

API traceability by **1st January 2023.**

Full Track & Trace for export drugs and reporting to IVEDA portal **by 31 March 2023.**

Local Drugs traceability: Rule will be mandatory from **1st May 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**)

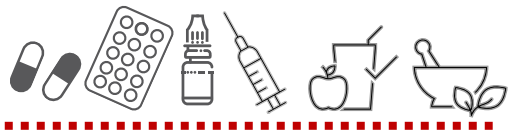
UNITED ARAB EMIRATES (UAE)

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.



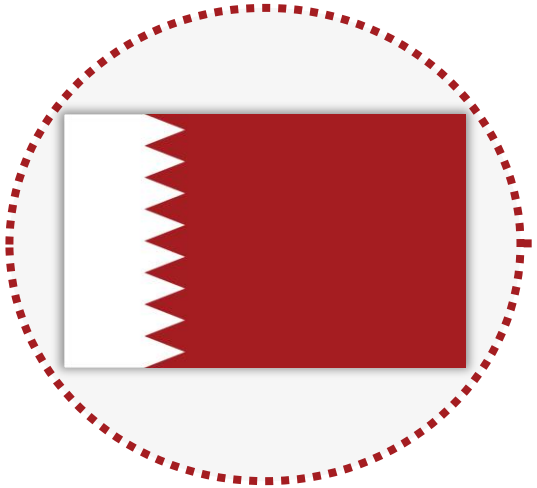
REQUIREMENTS

- **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

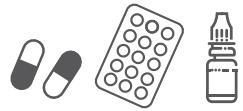


BAHRAIN

Middle East

PRODUCT SCOPE

Pharmaceuticals.



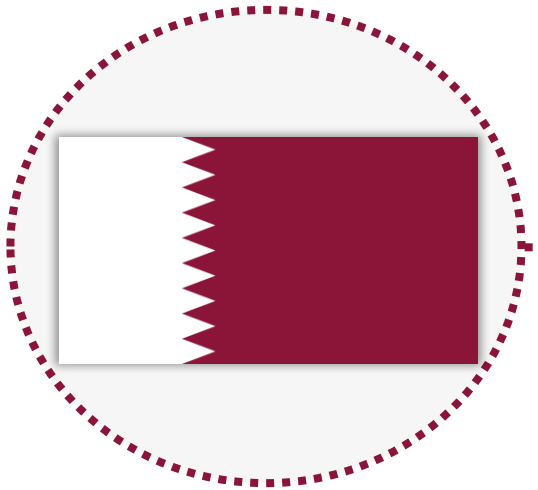
REQUIREMENTS

- **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

For Imports: Starting **1st January 2020**

For Local drugs: Starting **1st January 2023**

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, Nigeria too

EUROPE

EUROPE

PRODUCT SCOPE

Registered Pharmaceuticals.

REQUIREMENTS

- **Regulation Authority: European Commission Directorate General Health & Consumers (DG SANCO),**

TIMEFRAME

- The deadlines for implementation will be 3 years after publication of the Delegated Acts (ie. **9 Feb 2019)** and 6 years in addition to the 3 years (ie. **2025**) for Belgium (will be in 2019), Greece (in 2021 - tbc) and Italy.