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Emerging Market Regulatory Updates

This is a compilation of the recent regulatory updates from emerging markets. Every week, we post an update of what's new, which you can **view here**.

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Algeria

2022

- **March 27:** The government clarified that previous master data requirements for products of human consumption do not include the medicines category. Separate legislation for medicines barcoding and/or serialization is to be published on an as-yet unspecified date.

2021

- **May 30:** The government has published a regulation for barcoding of goods destined for human consumption, including medicines. In addition to the GTIN in barcoded form, other mandatory information will be required on product labels. A regulation on pharma serialization is reported to be in development.

Africa

2023

2022

- **May 1:** The Meeting Report for the first Global Steering Committee (GSC) Africa Traceability Group (GSCA) meeting, held March 29, was published on April 29. The committee's goal is to establish a regulator-focused body to coordinate pharmaceutical traceability initiatives and build more resilient supply chains. The meeting was chaired by NAFDAC, Nigeria's medicines regulator, and attended by representatives from 15 African countries.

2021

- **October 10:** The Zambia Medicines Regulatory Authority (ZAMRA) has launched a public consultation on proposed requirements for Master Data and barcoding and serialization of medicines.
- **July 11:** Nigeria's National Agency for Food and Drug Administration (NAFDA) published a report on a proof of concept conducted for traceability through scanning of COVID medicines. The report is intended to inform future traceability initiatives.
- **May 30:** With the support of GS1, Zambia, Ghana, and Mauritius have been holding sessions independently on standards awareness, track-and-trace benefits, and local piloting. There is no formally coordinated effort for a common traceability system or centralized regulation in Africa.
- **May 2:** At the GS1 Summit held April 20 – 22, The Nigerian National Agency for Food and Drug Administration and Control (NAFDAC) communicated that

they will be issuing master data guidelines soon. Currently no legal requirements in place for traceability, though there is a “5 Year Plan.”

- **January 10:** GS1 Africa summarized activity throughout the continent, which consisted primarily of awareness workshops on GS1 standards and traceability in 2020 and continuing into 2021. Countries noted were Kenya, Botswana, Namibia, Senegal, Benin, Burkina Faso, Togo, Ghana, Rwanda, and Ethiopia. The bulk of these efforts has been driven alongside USAID.

2019

- **November 24:** The South African Development Community (SADC) circulated draft guidelines for product labeling and barcoding with QR codes. The guidelines, which are early stage, are being reviewed by the 16 countries that participate in the SADC and may influence serialization and traceability requirements in those countries in the future.

Australia

2021

- **March 28:** Therapeutic Goods Order (TGO) 106 goes into effect on January 1, 2023 and lays out requirements for medicine packs that a manufacturer may choose to serialize (serialization will continue to be optional) or which include a GS1 Data Matrix code that contains a GTIN. The guideline differentiates the terms “primary pack” (saleable pack) and “primary packaging.

2020

- **July 26:** Australia’s new medicine coding and identification requirements are being circulated for public consultation. These requirements would formalize barcoding and serialization for all medicines. Today, barcoding is required on many medicines, and serialization for some blood-related products.

2019

- **July 21:** The Australian government's Therapeutic Goods Association (TGA) has published updates to their guidance documents on TGA 91/92 about the identity of medicines. One of the key updates provides clarification on product coding.

2018

- **July 6:** The Australian Digital Health Agency published its new Framework for Action, outlining a strategic work plan for implementing digital health over the next four years. The framework features the use of GS1 coding standards, supply chain solutions (master data/GDSN/GLN, and national recall solutions), patient identification, etc. The roadmap is supposed to help establish a foundation for future regulations and requirements.
- **June 17:** The government announced new barcoding and potential serialization requirements for products under "special pricing arrangements" and high cost medicines. Five different models are being reviewed, one of which would require secondary level serialization. The requirements will go into effect July 1, 2019 and internal consultations are starting June 20 to determine the model.
- **June 3:** A new circular was issued for supplying medicinal products to the Australia government for government programs. This circular mandates a July 1, 2019 deadline to include serialization.

Bahrain

2023

- **April 3:** The National Health Regulatory Authority (NHRA), along with the Gulf Health Council, has commenced work on the “e-PIL” (Electronic Patient Information Leaflet) project. The implementation will take place gradually throughout 2023.

2021

- **February 6:** The National Health Regulatory Authority (NHRA) reminded Invoicing Companies of 2022 subscription fees for the MVC Traceability Hub.
- **January 23:** The National Health Regulatory Authority (NHRA) distributed Circular (38) 2021 which reiterates deadlines for implementing traceability:
    - Phase 1 (MAHs) - December 31, 2021: Serialization and EPCIS reporting to MVC Hub required for Marketing Authorization Holders (MAHs)
    - Phase 2 (MAHs) - May 1, 2022: Aggregation to cases and pallets
    - Phase 3 (Customs, Agents/Distributors, Pharmacies, Dispensers) - June 1, 2022: Scanning for shipment and medicines authentication
- **November 7:** The National Health Regulatory Authority (NHRA) published a circular which gives a 90-day grace period to Invoicing Companies / MAHs in submitting reports to the MVC Hub. The grace period ends December 31, 2021.
- **October 10:** TraceLink is seeking clarification from the National Health Regulatory Authority (NHRA) on reporting requirements for in-country shipments from agents/distributors and whether an Invoicing Company can delegate its reporting responsibilities to another entity such as a distributor.
- **September 19:** TraceLink is seeking clarification from the National Health Regulatory Authority (NHRA) on whether reporting of in-country shipments from agents/distributors is required because that operation was not explicitly mentioned in the July circular.
- **September 5:** The industry continues to discuss the recent National Health Regulatory Authority (NHRA) Circular directed at wholesalers and agents, who must report shipment receipt from Invoicing Companies.
- **August 29:** The industry continues to discuss the recent National Health Regulatory Authority (NHRA) Circular directed at wholesalers and agents, who must report shipment receipt from Invoicing Companies.
- **August 15:** The National Health Regulatory Authority (NHRA) published a circular that lays out requirements for agents and distributors to report

shipment receipts to the NHRA-MVC Hub no later than December 1, 2021. The October 1, 2021 reporting deadline for Invoicing Companies remains firm for reporting shipments into Bahrain.

- **August 8:** The National Health Regulatory Authority (NHRA) has extended its sign-up form to agents and distributors (which may include importers), with 14 such entities currently listed.
- **August 8:** The NHRA cites responsibilities for disaggregation of pallets and for reporting shipments to hospitals/dispensers.
- **August 8:** The October 1, 2021 reporting deadline for Invoicing Companies remains firm.
- **June 20:** The recently-published Circular No. (12) 2021 and version 1.3 of the Medicines and Barcoding and Serialization Guidelines are minor updates that incorporate the current deadlines: October 1, 2021 for reporting and May 1, 2022 for aggregation.
- **May 30:** The National Health Regulatory Administration (NHRA) recently updated its Technical Onboarding Guideline, now in version 1.5. While there were no major changes in reporting requirements from version 1.4, this version clarified some technical information.
- **May 23:** The National Health Regulatory Authority (NHRA) issued Circular No. (12) 2021 to remind Invoicing Companies of the October 1, 2021 traceability reporting deadline and the May 1, 2022 aggregation deadline.
- **January 24:** The National Health Regulatory Authority (NHRA) held a meeting for manufacturers to understand deadlines and submission requirements for EPCIS files. Next week NHRA is holding a preparatory meeting for solution providers.

2020

- **December 13:** The National Health Regualatory Authority (NHRA) released v1.2 of its Technical Onboarding Guideline.
- **November 15:** The NHRA-MVC issued Circular No. (46) 2020 that moved the aggregation requirement to May 1, 2022. An update to the technical

guidelines, now v1.1, has also been issued.

- **November 8:** The National Health Regulatory Authority (NHRA) issued its initial draft of the Technical Onboarding guidelines v1.0 for connection to the Traceability Hub.
- **September 27:** Bahrain's government published a circular documenting the next steps for traceability reporting. The steps must be implemented by October 1, 2021.

2019

- **January 20:** Version 1.1 of the Medicines Barcoding and Serialization Guidelines document was published. The changes to this version included adjustments to the mandatory and optional fields.

2018

- **August 5:** The NHRA published a new medicines guideline and FAQ with deadlines for master data and barcoding/serialization set for Dec. 31, 2019.

Belarus

2023

- **July 24:** Details of the implementation timeline for the voluntary marking and traceability pilot for medicines have begun to emerge, with the timeframe estimated to be 2025.
- **May 8:** The Ministry of Health announced a voluntary marking and traceability pilot for medicines. Starting and ending dates for the pilot have not been communicated, but interested manufacturers should reach out to the Ministry of Health.

2021

- **November 14:** There are indications that traceability in this Eurasian

Economic Union (EAEU) country will be coming soon and is expected to be aligned with other EAEU countries on cryptography and labeling requirements.

Botswana

2021

- **October 31:** The Botswana Medicines Regulatory Authority (BOMRA) published its medicines traceability vision and strategy:
  - 2021–2022: Focus on strategic objectives and program benefits.
  - 2022–2023: Definition of coding standards and master data architecture.
  - 2024+: Deployment of initial software and requirements definition for traceability systems.

Bulgaria

2020

- **October 25:** A new draft law has been circulated. The main changes relate to the National Product Number and remove the obligation for it to be printed on the packs as part of the verification code. Instead, the National Product Number will be generated by the Bulgarian Drug Authority (BDA), used in the products registries, and digitally linked to the product numbers already printed on the packs.

Canada

2021

- **September 5:** GS1 Canada and the local Pharmacy Working Group are advocating barcoding and serialization, but this roadmap is voluntary and not

government-mandated. It is believed that some major pharma companies are considering barcoding and application of the GS1 2D Data Matrix at this stage.

Columbia

2018

- **August 5**: Manufacturers and wholesalers in the country are considering implementation of a track and trace regulation. GS1 is working on a draft position paper to support those local efforts.
- **April 1:** A new regulatory draft was circulated for Pharmaceuticals and Medical Devices submission of product data. Neither serialization nor reporting was mentioned in the draft.

Ecuador

2023

- **July 24:** A public consultation is underway on e-leaflets for patients.

2022

- **January 30:** Article 79 of Decree 337 published by the Ecuadorian government on February 1 describes very high-level requirements for medicines traceability when supplied to the RPIS (Public Health Network). No further details have been made available.
- **January 16:** Ecuador’s previous regulation on medicines and medical products traceability has been revoked by presidential decree. No plans for a new or revised regulation have been communicated.
- **January 2:** A recently published government decree may have revoked an earlier traceability mandate for medical products. Industry is seeking further

clarification.

2021

- **October 31:** There are unconfirmed reports from industry stakeholders that the 5-week pilot to test traceability readiness for medical devices has begun.
- **October 24:** No updates from the Agencia Nacional de Regulación, Control y Vigilancia Sanitaria (ARCSA) on the status of the launch of a 5-week pilot to test traceability readiness for medical devices.
- **October 10:** No updates from the Agencia Nacional de Regulación, Control y Vigilancia Sanitaria (ARCSA) on the status of the launch of a 5-week pilot to test traceability readiness for medical devices. The launch was scheduled for September 27.
- **October 3:** No updates from the Agencia Nacional de Regulación, Control y Vigilancia Sanitaria (ARCSA) on the status of the launch of a 5-week pilot to test traceability readiness for medical devices. The launch was scheduled for September 27.
- **September 26:** The Agencia Nacional de Regulación, Control y Vigilancia Sanitaria (ARCSA) is launching a 5-week pilot on September 27 to test traceability readiness for medical devices, which use GS1 identifiers.
- **September 19:** The Agencia Nacional de Regulación, Control y Vigilancia Sanitaria (ARCSA) is launching a 5-week pilot to test traceability readiness for medical devices, which use GS1 identifiers. It appears that medicines are excluded from this pilot, despite having earlier traceability deadlines than those for medical devices.
- **September 5:** The Phase 1 deadline is November 26, 2022. There are discussions of a potential pilot for traceability of medical devices, which is covered under the same regulation as traceability of medicines.
- **August 29:** The Phase 1 deadline is November 26, 2022. There are discussions of a potential pilot for traceability of medical devices, which is covered under the same regulation as traceability of medicines.
- **August 1:** TraceLink has confirmed that deadlines begin with Phase 1

medications on November 26, 2022. Traceability scope for this phase is 400 products in the public healthcare system (RPIS).

- **July 25:** Deadlines with Phase 1 medications appear to be set for November, 2022 based on the latest amendment. Traceability scope for this phase is 400 products in the public healthcare system (RPIS).
- **July 18:** Deadlines begin with Phase 1 medications in November 2022. Traceability scope for this phase is 400 products in the public healthcare system (RPIS).
- **July 4:** Industry is seeking clarification on further revisions to medicines/devices traceability requirements as the scope appears to be restricted to supply for the RPIS (public health network). Deadlines have also been pushed out.
- **June 27:** Further revisions have been published by the Agencia Nacional de Regulación, Control y Vigilancia Sanitaria (ARCSA) for medicines and devices traceability. Scope is now described as medicines/devices in the RPIS (public health network) and not in private pharmacies. Deadlines have also been moved out.
- **June 6:** The Agencia Nacional de Regulación, Control y Vigilancia Sanitaria (ARCSA) has published instructions for filling out its “Gradual Plan” template for implementing traceability of medicines, biological products, and medical devices. Phase 1 products, whose traceability deadline is November 26, 2021, will require a PDF-formatted plan to be submitted via email to ARCSA by July 26, 2021. ARCSA has stated that companies will be required to hold traceability event information until a national system is available.
- **May 30:** GS1 Public Policy is assembling questions to clarify deadlines and requirements in the May 19 resolution from the Agencia Nacional de Regulación, Control y Vigilancia Sanitaria (ARCSA). The resolution states that companies will be required to
    - Hold traceability event information in their own systems until the ARCSA national system is ready

    - Present a “Rolling Plan” for implementing traceability for a given phase’s products four months prior to that phase’s deadline.
- **May 23:** The Agencia Nacional de Regulación, Control y Vigilancia Sanitaria (ARCSA) issued a draft update on its traceability regime, which appears to suggest that a national system will not be implemented immediately, but that stakeholders will be responsible for maintaining their own traceability data and will need to serialize packs.
- **May 2:** The Agencia Nacional de Regulación, Control y Vigilancia Sanitaria (ARCSA) has stated that they will be communicating new dates for the traceability system and for the traceability deadlines. The previously stated deadline was March 26, 2021 for the system guidelines to be published and 26 May 26, 2021 for Phase 1 traceability for products in the public sector.
- **March 7:** The Agencia Nacional de Regulación, Control y Vigilancia Sanitaria (ARCSA) updated the list of drugs, biological products and medical devices subject to traceability in Phase 1. First-phase deadline for traceability of selected products in the public health system channel is May 26, 2021. Technical specifications are stated to be available by March 26, 2021. ARCSA has not published formal procedures for administrative/contractual onboarding, generally a precursor to standing up a traceability program.

2020

- **December 13:** The Agencia Nacional de Regulación, Control y Vigilancia Sanitaria (ARCSA) published the list of Phase 1 products for traceability in the public health sector by May 26, 2021. Traceability for these products will extend to private channels such as community pharmacies by November 26, 2021.
- **December 6:** The Agencia Nacional de Regulación, Control y Vigilancia Sanitaria (ARCSA) has published their traceability regulation in the country’s Official Gazette, establishing a first-phase deadline for May 26, 2021. Products in the various phases have not been announced. The central system and technical guidelines are scheduled to be published by March 26, 2021.

- **November 29:** The Agencia Nacional de Regulación, Control y Vigilancia Sanitaria (ARCSA) published an updated guideline that indicates the first-phase deadline as May 2021 for certain medicines as determined by the health authority. It also states that ARCSA will be acquiring a central reporting system by mid-March 2021 and that technical guidelines will be available then.
- **November 15:** The current draft regulations indicate a phase-in by product and dispensation channel beginning 6 months after the final regulation is published, with deadlines ranging from May 2021 to November 2022 if the final regulation is published at end of November 2020 as communicated. Traceability system guidelines are stated to be published within 60 days of the Resolution publication date, so are expected by January 2021.
- **November 8:** The Agencia Nacional de Regulación, Control y Vigilancia Sanitaria (ARCSA) issued an updated draft regulation document from the August 2020 version. Technical guidelines still have not been issued.
- **September 13:** Ecuador's government published new regulations mandating that serialization and traceability reporting be implemented in six months.

Ethiopia

2021

- **July 11:** The Ethiopia Food and Drug Administration (EFDA) reminded MAHs of the August 19, 2021 deadline to share their product master data via email/spreadsheet while it works on an online platform to collect this data.
- **May 2:** At the GS1 Summit held April 20 – 22, the Ethiopian Food and Drug Authority (EFDA) presented their launch of their master data guidelines and plans for lot-level traceability. New timelines will be released.
- **March 28:** A 15-minute Facebook streaming event was held to cover the Ethiopian National Traceability System for health commodities and featured the Director of the Ethiopian Food & Drug Administration (EFDA). Presenters

covered progress on the EFDA's digital transformation, which targeted processing of marketing authorization applications and import licenses. In the less than 5 minutes devoted specifically to medicines traceability in the supply chain, leaders stated they would be looking at integration of their systems with the Covax Trust Repository and subsequently make plans for downstream traceability; no timelines were provided.

2020

- **December 13:** The Ethiopian Food and Drug Administration (EFDA) published a list of Master Data Attributes based on GS1 standards. The deadline for submission is still under discussion.

Eurasian Economic Union (EAEU)

2019

- **August 4:** The Eurasian Economic Commission met to discuss the adoption of uniform serialization and cryptographic requirements across the five-member countries of the Eurasian Economic Union (EAEU) based on those being adopted by Russia. Future discussions are expected to address members' concerns about implementation timelines and complexity as the roadmap is finalized.

Indonesia

2022

- **October 5:** A new law regarding medicine traceability was put into effect, though the technical specifications have not been published.
- **July 11:** The Indonesian Food and Drug Authority (BPOM) is in the process of revising its traceability legislation. A definitive date for the publication of the

updated legislation has not been set. BPOM stated that new technical specifications will be issued at the end of 2022.

2021

- **November 7:** The National Agency of Drug and Food Control (BPOM) ends its call for comments on the latest revisions to Regulation 33/2018 on November 5. The latest draft would establish a first deadline in December, 2022, as opposed to the December 2020 deadline in the current regulation.
- **October 31:** The National Agency of Drug and Food Control (BPOM) continues to consult with industry stakeholders on the latest draft of its traceability regulation.
- **October 24:** The National Agency of Drug and Food Control (BPOM) continues to consult with industry stakeholders, including TraceLink, and plans to issue a revised draft regulation in the next several weeks. BPOM indicated that the new version may be published in Q1 2022, pursuant to ongoing industry consultation.
- **October 17:** National Agency of Drug and Food Control (BPOM) continues to consult with industry stakeholders, including TraceLink, and plans to issue a revised draft regulation in the next several weeks. BPOM indicated that the new version may be published in Q1 2022, pending legal approval.
- **October 10:** The National Agency of Drug and Food Control (BPOM) recently updated its portal with version 3.0.1 of its APIs and version 2.0 of its Track and Trace Anti-Counterfeit (TTAC) website manuals.
- **October 3:** The National Agency of Drug and Food Control (BPOM) recently updated its portal with version 3.0.1 of its APIs and version 2.0 of its Track and Trace Anti-Counterfeit (TTAC) website manuals.
- **September 26:** The National Agency of Drug and Food Control (BPOM) recently updated its portal with version 3.0.1 of its APIs and version 2.0 of its Track and Trace Anti-Counterfeit (TTAC) website manuals.
- **September 19:** The National Agency of Drug and Food Control (BPOM) recently updated its portal with version 3.0.1 of its APIs and version 2.0 of its

Track and Trace Anti-Counterfeit (TTAC) website manuals.

- **March 21:** Discussions continue between the industry and the National Agency of Drug and Food Control (BPOM) on revising the current regulation. BPOM does not appear to be prescriptive on the serialized shipping container code (SSCC) carrier for the aggregation requirement (which will be purportedly included in a revised regulation).

2020

- **December 13:** The Indonesian food and drug authority, Badan Pengawas Obat dan Makanan (BPOM) held an industry consultation on December 10 to discuss a new draft version of the regulation. This version extends the traceability deadline from 2 years to 3 years from electronic license renewal. Aggregation is required, and there are minor changes in product exemptions in primary packaging.

2019

- **January 20:** An updated background summary was circulated on the upcoming barcoding, serialization, and reporting requirements that will be phased in from 2020 to 2025.

2018

- **April 1:** Meetings continue with regulators to discuss the criteria for serialization in 2020. Both 2D DM and QR Codes are allowed today and the industry is advocating for continued allowance of 2D when the 2020 regulation goes into effect.
- **February 25:** It is expected that technical guidelines will be published in 2018 for the 2020/2025 serialization/track and trace requirements that are in draft form. BPOM has asked the industry for feedback on their potential timelines. Some pharmaceutical companies have been stating they will be ready for serialization using GS1 2D in early 2019.
- **February 11:** The use of QR codes (not 2D DataMatrix barcodes) has been

officially adopted, with an initial focus on Vaccines starting in 2018 for adoption through 2020.

Iraq

2023

- **July 24:** A new process is under development for Ministry of Health-issued stickers, including the introduction of a QR code. This code can be used for patients as well as for the identification of products by stakeholders, such as customs officials.

Japan

2023

- **January 13**: Barcoding for pharmaceuticals and medical products has officially become mandatory. Prior, this practice was already widely adopted.

2021

- **April 18:** While details have not been published, deadlines for obligatory barcoding of drugs and medical devices, based on the amendment of Japan's Pharmaceutical and Medical Devices Act (PMDA) have been set for December 2022. Serialization does not appear to be a legal requirement.

2019

- **January 20:** The Ministry of Health circulated an outline of discussions for a proposed new electronic Product Information Leaflet, which will include a QR code.

Jordan

2022

- **July 3:** The government announced a delay to serialization and barcoding,

shifting the date to the end of 2022.

2021

- **September 26:** Serialization, no reporting, required by December 31, 2021.
- **September 5:** Serialization, but not reporting, will be required by Dec 31, 2021.
- **August 8:** Serialization, but not reporting, will be required by Dec 31, 2021.
- **August 1:** The Jordan Food and Drug Administration (JFDA) has provided a grace period for its data matrix/serialization requirement until December 31, 2021.
- **January 31:** The Jordan Food and Drug Administration (JFDA) published a new circular on barcoding and serialization. The serialization deadline has been changed to June 30, 2021.

2018

- **September 9:** JFDA has postponed the implementation of barcoding and serialization until Dec. 31, 2019.

Kazakhstan

2023

- **August 14:** A new draft decree on medicines traceability is in circulation to revise - and possibly move up - the previous iteration's stated deadlines.
- **July 3:** The government of Kazakhstan has released a draft decree that proposes a phased approach to achieve 100% serialization by 2025. Key milestones include:
  - July 1, 2024: 100% of medicines must be labeled.
  - January 1, 2025: Prescription drugs must be traceable and labeled.
  - July 1, 2025: Over-the-counter drugs and medical devices must be traceable and labeled.

2022

- **June 5:** The Ministry of Health amended its traceability rules issued in 2021 with the new rules going into effect on August 1, 2022. These rules do not specify implementation deadlines or phases.

2021

- **April 3:** In a letter dated April 5, 2022, the Association of International Pharmaceutical Manufacturers (AIPM) in Kazakhstan requested that the Prime Minister revoke the current timeline for mandatory labeling and to review implementation milestones with Industry:
  - Phase 1 “working” deadline (93 products): July 2022
  - Phase 2 “working” deadline (20% of products): October 2022
- **November 14:** The government has issued version 4 of the draft instructions for mandatory serialization to pilot participants, who have been providing feedback.
- **October 24:** Latest unofficial timelines and scope:
  - July 1, 2022 - Marking only for 93 medications. The latest list indicates marketing authorization number and manufacturer.
  - October 1, 2022 - Marking only expanded to 20% of medications.
  - January 1, 2023 - Marking and traceability for 60% of medications.
  - April 1, 2023 - Marking and traceability expanded to 80% of medications.
  - July 1, 2023 - Marking and traceability expanded to 100% of medications.
- **October 3:** The Kazakh Ministry of Trade and Integration sent a letter to the Eurasian Economic Union (EAEU) declaring a July 1, 2022 deadline for the beginning phase of mandatory labeling. The latest timelines from the Kazakh Ministry of Health represent a slight shift from the previous update:
  - July 1, 2022 - labeling for 93 medications; list indicates marketing authorization number and manufacturer
  - October 1, 2022 - expansion of list to cover 20% of medications on market

    - January 1, 2023 - 60% of medications to be covered
    - April 1, 2023 - 80% of medications to be covered
    - July 1, 2023 - 100% coverage
- **October 3:** Discussions are ongoing with Kazakhtelecom to accept e-signatures from entities outside Kazakhstan.
- **September 26:** Kazakhtelecom updated their regulatory timeline on their website with a more general deadline of 2022 for compulsory labeling. Previously this was listed as January 2022 for Phase 1.
- **August 8:** 93 products are proposed for the initial serialization phase in May 2022. There are still differences between the published deadlines and those communicated by traceability pilot participants.
- **July 25:** Current information indicates phased implementation of traceability, with serialization for 93 products beginning in May, 2022 and reporting for that same product scope in January, 2023. The industry is seeking confirmation of this phased approach and consequent dates.
- **May 30:** Kazakhtelecom published an organizational action plan for medicines traceability. This timeline includes an analysis of the regulatory impact of a drug marking/traceability system that is due to be delivered to the Kazakh government in July 2021.
- **May 30:** Kazakhtelecom updated their high-level roadmap on their website with the text “Stage 1” alongside mandatory labelling for January 2022. There is no current listing of what products/activities might be in scope for Stage 1.
- **April 25:** Kazakhtelecom has published a traceability deadline of January 2022 on its website. However, the page does not reference the latest legislation, which does not contain a deadline. In addition, it is believed that the pilot kickoff itself has been delayed.
- **April 18:** Despite rumors about traceability deadlines, the Kazakh government has not yet published an official date.
- **March 14:** At a March 5 industry meeting, the Kazakh Ministry of Health reportedly stated they would be issuing a traceability roadmap in Q1 or Q2

2021 and will make a decision as to full deployment, possibly as early as January 1, 2022 for some product groups which will be specified. The “PMT” system appears to be largely modelled on the Russian MDLP and Russia Decree 1556.

- **February 21:** The Kazakh Ministry of Health published guidelines for its pilot on medicinal product marking and traceability, the system for which is operated by Kazakhtelecom. Serialization requirements, including crypto codes and their acquisition, appear nearly identical to those of the Russian Federation. A detailed description of traceability events has not been described, so it is unknown whether the regime will rise to the same level of complexity as those of Russia. GS1 has reported that the pilot will finish in March 2021.

2019

- **March 10:** The Kazakhstan Ministry of Health (MOH) continues work on their pilot program for pharmaceutical track and trace regulations. The MOH plans to focus on GS1 standards, but it has yet to be determined if they will align more closely with the European Union/Turkey approach or the Russia approach to GS1 standards.

2018

- **July 15:** Government is moving forward with their plans for serialization and traceability with a target of draft regulations by the end of the year. Potential timelines: Pilot (2018-2019); voluntary coding (2020-2021); and serialization of all products (2023).
- **April 8:** Formal general guidelines were circulated for a future track and trace system, with an initial pilot project being slated for 2018-19 and phase in of labeling/reporting in 2020-2024.
- **March 11:** Government is looking at serialization and traceability of all medicines. An internal letter has been circulated in government ministries but nothing formal has been stated.

Kuwait

2023

- **April 3:** The government published a corrective circular to amend its previous communication on serialization requirements for medicines in January 2024. The correction removed “pack size” from the required data elements.

Kyrgyz Republic

2023

- **April 17:** The government amended the contents of the medicine lists. However, the deadlines remain the same: Phase 1 for medicines is March 2023 to July 2023. Phase 2 for medicines is July 2023 to November 2023. Phase 3 for medicines is November 2023 to March 2024. Phase 4 for all medicines is March 2024 to June 2024..
- **April 3:** The government has established a number guidelines to phase in the traceability of medicines. Phase 1 for medicines is March 2023 to July 2023. Phase 2 for medicines is July 2023 to November 2023. Phase 3 for medicines is November 2023 to March 2024. Phase 4 for all medicines is March 2024 to June 2024.

2022

- **October 10:** The Department of Medicines under the Kyrgyz Ministry of Health announced that it is planning to implement a drug traceability system. The first step of this implementation will be a market analysis to inform a draft resolution.

- **March 27:** The State Tax Service and the Cabinet of Ministers launched a pilot project for labeling of beer, bottled water, soft drinks, tobacco, and nicotine products. Medicines are not currently in scope.

Lebanon

2022

- **July 11:** The Lebanon Ministry of Health issued a circular reminding manufacturers that they must apply the requisite DataMatrix by January 1, 2023.

2021

- **October 3:** Deadlines for full implementation are not yet published, but a traceability committee is being organized by the MoPH (Ministry of Public Health).
- **September 26:** The Lebanese Ministry of Public Health (MoPH) announced it would be working further on its Meditrack implementation for importers and manufacturers, whose deadline was August 18, 2021.
- **September 26:** Deadlines for full implementation are not yet published, but a traceability committee is being organized by the MoPH.
- **May 2:** The Ministry of Public Health is requiring importers and distributors to use the MediTrack information system as of April 5, 2021 for importation and sales.

2020

- **November 29:** The Lebanese Ministry of Health issued an update to its barcoding guideline and the use of the MediTrack system for uploading product information. No deadline has been communicated.

2018

- **October 28:** A new government decree extended the implementation date for 2D barcoding until December 31, 2019 for imported medicines and December 31, 2022 for domestically produced medicines. Based on this decision, serialization updates are still pending.
- **August 5:** Ministry of Health published a statement allowing for pharmaceutical companies unable to make the Jan. 2019 deadline to follow an alternative transitional strategy using stickers.

Libya

2023

- **July 24:** Plans are underway to require the GS1 2D DataMatrix on pharmaceutical products.

2021

- **May 2:** The Minister of Economy and Trade has founded a committee to establish a “National Project for a Pharmaceutical Verification System.”

Malaysia

2022

- **September 5:** The government announced that its track-and-trace pilot project will take place from January 2023 to June 2023.

2020

- **August 30:** Malaysia’s government issued an update on the country’s serialization and traceability plans, reinforcing its intention to move forward with a 2023 deadline for full implementation of regulations.

2018

- **October 7:** Malaysian Ministry of Health (MoH) published their formal regulatory requirements this past week, including a timeline for full implementation by 2023 with phased implementation to start in 2020. These requirements include serialization and full track and trace to a central government repository using EPCIS. The overall transaction event model is based on Turkey.
- **September 9:** Draft regulatory requirements were published by the Ministry of Health for serialization and track and trace reporting to a government system. These regulations will be phased in over the next two years, with firm deadlines still being worked out.
- **September 2:** The Malyasian National Regulatory Conference (NRC) 2018 in early October will discuss the upcoming serialization and reporting requirements on day 3 of the conference.
- **April 1:** Draft regulation is expected to be published 6/13 but no data has been released thus far on scale/scope.

Mexico

2021

- **November 7:** A traceability recommendation will be presented in December, 2021.
- **October 31:** The Ministry of Health has taken initial steps to outline the benefits of a potential medicines serialization and traceability program. A traceability recommendation will be presented in December, 2021.
- **October 24:** The Ministry of Health has taken initial steps to outline the benefits of a potential medicines serialization and traceability program. The outcome of the consultation is expected to be presented in December, 2021.
- **October 17:** The Ministry of Health has taken initial steps to outline the

benefits of a potential medicines serialization and traceability program. The outcome of the consultation is expected to be presented in December, 2021.

Middle East

2020

- **November 22:** The government of the UAE circulated a formal announcement for their forthcoming track-and-trace system which was mentioned in their 2019 future vision document. No specifics on requirements or deadlines were included.
- **September 13:** The Abu Dhabi emirate published a circular announcing new coding and serialization requirements for 2021 as well as information on submitting product master data to the United Arab Emirates portal.

2018

- **September 16:** The Gulf Health Council has published new barcoding requirements for Gulf Cooperation Council (GCC) countries. Deadlines for these requirements have not yet been set.

Mongolia

2018

- **December 16:** An article was published in CoinReport, which mentioned that the government will be launching their first blockchain track and trace pilot project designed to remove counterfeit drugs in the country.

Nigeria

2022

- **May 15:** The National Agency for Food and Drug Administration and Control (NAFDAC) has enacted a consultation period on master data guidelines, which are expected to be finalized in the next two months.
- **May 15:** Full track-and-trace is expected before the end of 2024.
- **May 8:** NAFDAC published a draft of their medicines master data guidelines for public comment; the guidelines serve as a foundation for medicines traceability in the coming years.

Oman

2018

- **December 16:** A new government circular clarified that their barcoding/serialization requirements only cover pharmaceutical products while herbal and other medical products and devices are not in scope for the regulation.
- **June 3:** A new government circular on serialization regulations with standards GS1 identifiers will be issued March 1, 2019, which will cover all registered Rx, health products, and registered medical devices.

Pakistan

2021

- **October 17:** The industry is seeking official confirmation that serialization will begin in 2025.

2019

- **March 31:** The government circulated a draft of Statutory Regulatory Order (SRO) 470 among internal ministries to finalize the adjusted serialization

timelines that were first stated in January.

2018

- **December 9:** An agreement between regulatory and the Supreme Court has laid out new timelines and requirements for coding, serialization, and track and trace implementation.
- **October 7:** PharmaBureau and DRAP met on September 26 to continue discussing the alignment of regulatory requirements and identification needs with the global framework for serialization and traceability.
- **September 23:** The Drug Regulatory Authority of Pakistan (DRAP) published a compilation of public comments for review prior to a meeting scheduled for September 28 with a broad group of industry stakeholders. This meeting will discuss the path forward for national serialization regulations and implementation requirements.
- **June 10:** Government reaffirmed that the AI240 may not be removed from the serialization requirements for the fifth data element, although individual companies may apply for exemptions.
- **April 29:** An update was published to coding regulations with enhancements to require the barcode not only on the outside box but also on the wrappers/containers of the medicine. This may be a push to introduce Primary level serialization on the medicines in Pakistan.
- **March 18:** Pakistan Court of Justice determined during a recent hearing that DRAP, Pharma Bureau, and industry will have three months to agree to an implementation timeline for barcoding and serialization, upon which the timeline will be formalized and published and the industry will be required to meet such a timeline.
- **February 11:** Punjab province regulators announced the removal of Application Identification (AI) coding in barcode to better align with GS1 standards, but the existing barcoding/serialization regulations for the country at large still include them.
- **January 14:** DRAP published minutes of a Dec. 14 2017 meeting discussing

the current state of barcoding of medicines. With only partial compliance by the industry thus far and a new recommended product coding identification scheme, DRAP recommended to the government to extend the deadline for barcoding.

Paraguay

2022

- **September 19:** The government published a proposed drug coding scheme, which hints at future traceability requirements.

Portugal

2018

- **April 29:** Government legislation was published that reaffirmed the alignment of scope under EU FMD and formalized the content of the product identifier.

Qatar

2023

- **July 24:** The Qatari Ministry of Health issued a circular on using QR codes to give patients access to product information. This initiative was spawned from the Gulf Central Committee group.

Romania

2018

- **August 5:** GS1 is working with local authorities to help clarify the use of

GTIN-13 with leading 0 vs. GTIN-14.

Rwanda

2022

- **October 10:** The Ministry of Health of Rwanda published guidelines for the identification and labeling of pharmaceutical products. The guidelines set deadlines for master data reporting in 2024, and further phased deadlines for barcoding, serialization, and aggregation to 2025 and beyond.

Singapore

2019

- An eHealth circular was published with initial thoughts on placing a QR code on pharmaceutical packages to enable identification and product information access. The industry is also considering the use of GS1 2D barcodes with DigitalLink capabilities.

2018

- **November 25:** The government published draft guidance to gain feedback on electronic labeling of therapeutic products. Deadlines have not yet been outlined for the labeling requirements.

Sri Lanka

2019

- **March 10:** The government is beginning to look into digital track and trace requirements and other global approaches as they create their pharmaceutical regulations.

South Africa

2018

- **September 2:** Regulators have noted that the final regulatory requirements are expected to be published by the end of September.
- **January 14:** Department of Health is reviewing comments submitted in 2017 on draft serialization requirements but no final timeline was stated for when the review will be completed.

Taiwan

2018

- **March 11:** Government added 30 more products to a list of products targeted for the upcoming track and trace regulations.

Turkey

2022

- **March 27:** The Ministry of Health has announced a major change in Turkey's Drug Tracking System (ITS), with existing SOAP services to be transformed into a REST API structure.

Ukraine

2022

- **April 24:** The government is considering a ban on medicines sourced from Russia and from Belarus.
- **December 5:** The public consultation text and associated information in the draft regulation has been archived, leading to uncertainty as to the Ministry of

Health’s proposed framework and October 2022 deadline.

- **October 24:** The Ministry of Health (MoH) published a draft resolution for labeling and traceability. The public comment period ended on October 22, 2021. The resolution aims to introduce its monitoring system, known as “e-Stock”, for medicines and medical devices by October 1, 2022.

2019

- **July 21:** The SAFEMed project to improve the safety of medicines in the supply chain through identity and traceability was published by the United States Agency for International Development (USAID). This project is distinct from the Ministry of Health’s similar project.
- **March 17:** The Ukraine Ministry of Health (MOH) published a draft regulatory circular outlining the implementation of a serialization and traceability system from 2019 to 2024. The first step is the launch of a pilot project in Q4 of 2019 that will last until the end of 2020, which includes the development and creation of the main components of the system—labeling, software, changes in legislation, and monitoring. Mandatory labeling on the list of drugs established by the MoH will be introduced in 2021, and that list will be expanded in 2024.

2018

- **August 5:** The Ministry of Health circulated a list of 15 questions for public feedback regarding data requirements and data management for serialization and traceability. The current draft law "On Medicines" only refers to lot-level traceability and the MoH is also working on potentially cross-tying traceability with medicine reimbursement.

UAE

2022

- **June 20:** Evoteq, the Tatmeen traceability system operator, held a 5-hour workshop for Tatmeen Onboarding. During this session, Evoteq provided system-specific support addresses for Serialization / BrandSync, Business Processes / Tatmeen, Tatmeen Mobile and APIs.
- **April 24:** Evoteq has further updated its guidelines, now at v2, for wholesale distributors and dispensers.
- **April 17:** Evoteq published an update to technical specifications for manufacturers and issued a first version of specifications for wholesale distributors and for dispensers.
- **March 6:** The Tatmeen MVP system is scheduled for release by the end of March 2022. A fully-functioning production system is expected by October.
- **January 2:** Tatmeen's technical provider, Evoteq, has published version 1.0 of its Technical Guide for Manufacturers. The Guide describes traceability prerequisites for MAHs, such as registering products in BrandSync and obtaining GLNs. The formal traceability deadline remains December 13, 2022. The initial version covers importation of foreign manufactured registered drugs; importation of unregistered drugs will be documented in future versions.

2021

- **November 7:** There was a meeting on November 8th with the Evoteq team, operators of the Tatmeen system, to understand technical specs and traceability events to be reported. Current deadlines are:
  - December 2021: Master Data reporting to BrandSync and barcoding.
  - December 2022: Aggregation, serial number reporting, and obtaining GLNs.
- **October 3:** The December 13, 2022 deadline for aggregation, serial number reporting, and obtaining GLNs has been confirmed by the Ministry of Health and Prevention (MoHAP) . December 2021 deadlines are in place for Master

Data reporting and barcoding, but no technical details on the Tatmeen system have been published

- **September 26:** The Ministry of Health and Prevention (MoHAP) has set deadlines for master data, barcoding, and traceability. These dates assume signature of the governmental decree on June 14, 2021, and not the later publication into the Official Gazette on July 1, 2021:
  - Master Data Reporting (BrandSync): December 13, 2021
  - Barcoding on Secondary Packs: December 13, 2021
  - Aggregation: December 13, 2022
  - Serial number reporting: December 13, 2022
  - Deadline to get GLNs for all stakeholders: December 13, 2022
- **September 5:** The Ministry of Health and Prevention (MoHAP) published a draft resolution for traceability of medicines using the Tatmeen system.
- **September 5:** Traceability will take effect 18 months after publication of the regulation into the Official Gazette. The date of publication is expected to be announced shortly.
- **April 18:** The UAE's Ministry of Health and Prevention (MoHAP) held a webinar to announce its "Tatmeen" traceability system which is GS1-standards based and runs across the supply chain from manufacturer to patient. A 24-month implementation plan was mentioned, but no start date, reference date, or deadline was provided.
- **January 24:** The Ministry of Health and Prevention (MoHAP) circulated a survey to some manufacturers and packaging sites on industry readiness to inform planning for their "Tatmeen" traceability system.

Uzbekistan

2022

- **April 17:** A meeting between TraceLink and CRPT Turon clarified the acquisition and reporting of crypto codes:

    - Uzbekistan crypto codes are prepaid only, unlike those of the Russian Federation, which have a “pay upon utilization” option.
    - The Utilization Report is automated by CRPT Turon and is triggered upon download of cryptos from the Uzbekistan Order Management Station.
- **April 3:** Decree 149 signed into law on April 2, 2022 defines mandatory labeling for four groups of medicines and medical products. The decree lays out a detailed, five-phase plan, including contractual and administrative tasks to be completed ahead of the labeling deadline for a given group. The labeling deadline for Group 1 is September 1, 2022.
- **March 27:** A draft decree for the mandatory phase of medicines traceability is reportedly in circulation amongst some MAHs. Onset of the mandatory medicines phase has not been communicated formally.
- **March 20:** The government published Decree 758, which imposes fines for non-compliance in all industry sectors with respect to mandatory digital marking rules.
- **March 20:** No announcements have been made on the legal framework or deadlines for mandatory marking of medicines.
- **February 6:** The State Tax Committee has responded to an Industry Association (ARFPCM) letter to the Cabinet of Ministers to reconsider deadlines and to clarify legal requirements and other procedures:
    - The timeline for phased introduction of labeling will be communicated in an upcoming decree.
    - Technical Regulations for medicines packaging and labeling will be updated.
    - The Committee will take account of the request for the Uzbek traceability system to recognize marking codes from other EAEU countries (specifically Russia at this time).
    - The Committee will clarify how foreign legal entities can obtain Electronic Digital Signatures from outside Uzbekistan.
- **January 30:** Industry Associations have asked the Uzbek government for a

delay in implementation deadlines. As the previously reported deadlines have not been enshrined by the Uzbek government, it remains uncertain whether the traceability deadline will be or has been postponed.

2021

- **November 14:** TraceLink met with CRPT Turon, who stated that a government decree will be issued shortly to establish the phased deadlines for traceability beginning in February 2022.
- **September 5:** Obtained additional information on the traceability pilot and on methods for foreign manufacturers to retrieve crypto codes from the Uzbek OMS.
- **September 5:** CRPT Turon is currently seeking legal advice on connecting foreign manufacturers.
- **May 30:** The Uzbek government issued Resolution No. 322, which describes traceability pilots and mandatory marking not only for medicines and medical products, but for a variety of other industries as well. The document references the original Resolution No. 737 from November 2020 and cites “Medicines and Medical Supplies” with Eurasian Economic Union Customs Codes 3003 and 3004 in scope for mandatory labelling for February 2022.
- **May 23:** The Center for Research in Perspective Technologies (CRPT) Turon has published a medicines traceability section on its website.
- **April 25:** Industry discussion continues on the traceability pilot guidelines since the scope appears to be “medical products'' as opposed to medicines only.
- **April 18:** Industry discussion continues on the traceability pilot guidelines since the scope appears to be “medical products" as opposed to medicines only. According to the Center for Research in Perspective Technologies (CRPT), beer/alcohol/tobacco labelling has been launched, while medicines are in pilot mode.
- **April 11:** Industry discussion continues on the traceability pilot guidelines since the scope appears to be “medical products” as opposed to medicines

only.

- **March 28:** The Uzbek Cabinet of Ministers (State Tax Committee, Ministry of Health, and others) issued a temporary regulation on the government's pilot for medicines traceability. No implementation timelines are given, but serialization and central technical operation are similar to those of Russia traceability, including the use of crypto codes in the marking and traceability system (ASL BELGISI) managed by CRPT Turon.
- **January 25:** Recent issuance of its Decree 737 indicates the government's desire to implement traceability in a number of sectors. However, there are no deadlines set for pharmaceutical companies. It is expected that an eventual system will be managed by CRPT, the same operator as the MDLP system in Russia.

Vietnam

2021

- **December 12:** Discussions and Industry consultations are ongoing regarding a new regulatory approval number and potential requirement to apply barcoding.

2018

- **September 23:** A draft government circular was published for drug registration, quality documentation, and barcoding using standard barcodes or QR codes. This circular included a few technical details, but did not include final deadlines.
- **September 9:** A government circular was published that lists the draft requirements to put a QR Code on the outer box of medicines.

Zambia

2023

- **September 11:** The Zambia Medicines Regulatory Authority published its final guideline on the traceability of medicines.

2022

- **September 19:** The government has entered a consultation phase on Master Data requirements.

2021

- **October 17:** The Zambia Medicines Regulatory Authority (ZAMRA) has launched a public consultation on proposed requirements for Master Data and barcoding and serialization of medicines.

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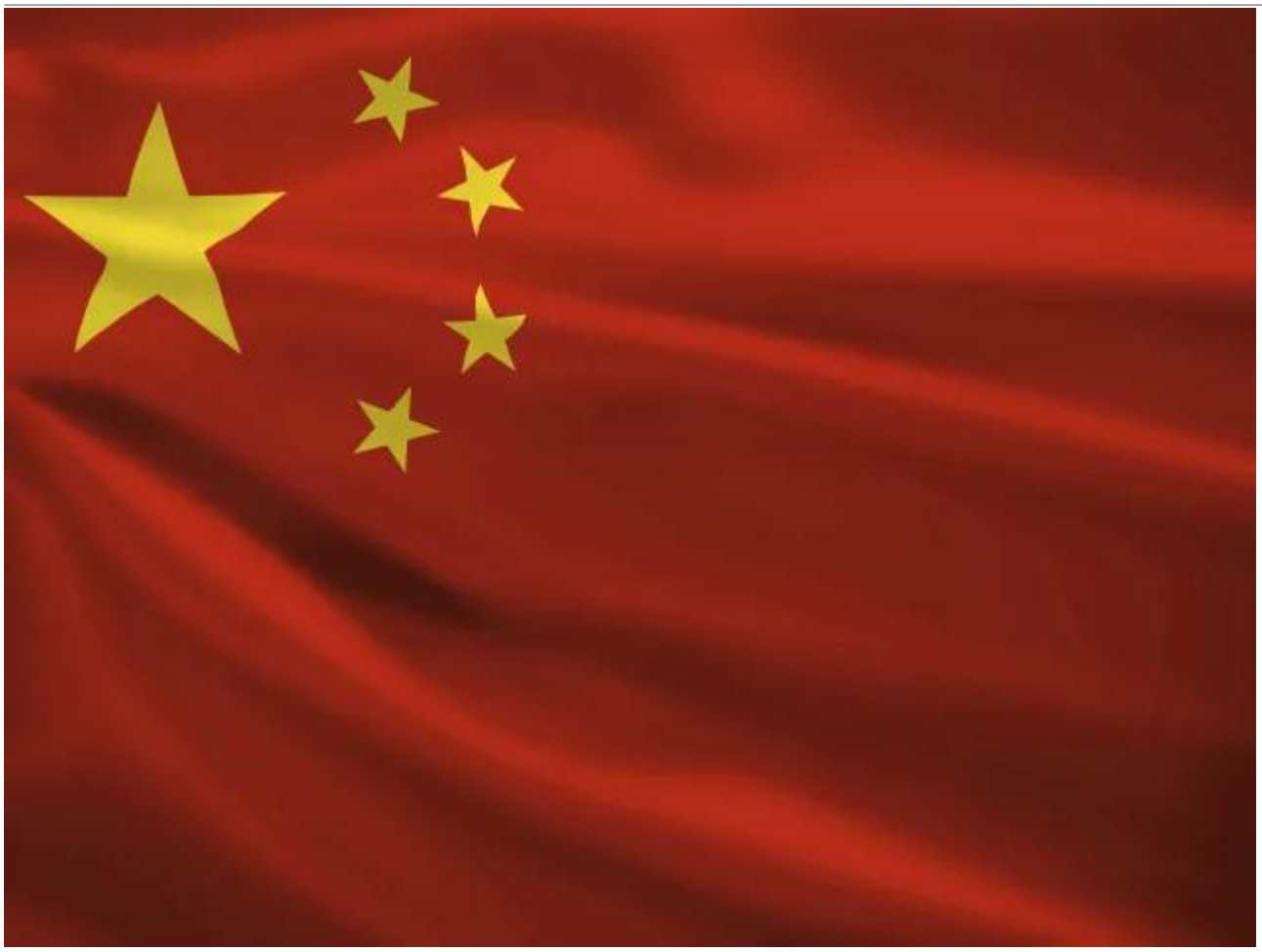

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