

USAID GLOBAL HEALTH SUPPLY CHAIN PROGRAM
Procurement and Supply Management



MODEL REGULATION FOR PHARMACEUTICAL TRACEABILITY

Template and Guidance

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The USAID Global Health Supply Chain Program-Procurement and Supply Management (GHSC-PSM) project is funded under USAID Contract No. AID-OAA-I-15-0004. GHSC-PSM connects technical solutions and proven commercial processes to promote efficient and cost-effective health supply chains worldwide. Our goal is to ensure uninterrupted supplies of health commodities to save lives and create a healthier future for all. The project purchases and delivers health commodities, offers comprehensive technical assistance to strengthen national supply chain systems, and provides global supply chain leadership.

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Introduction

The *Model Regulation for Pharmaceutical Traceability Template and Guidance* document is intended for use by Ministries of Health (MoHs) and/or national drug regulatory authorities (NDRAs) in implementing verification and/or traceability strategies. Foundational to achieving verification and/or track and trace implementation is the presence of an appropriate incentive structure and clear requirements for the entities involved. Regulation is commonly used to accomplish this framework.

This resource may be used to develop a statutory instrument that provides a legal framework to define roles and responsibilities for supply chain entities and healthcare providers as a basis for a verification and/or traceability systems. Typically, a regulation is supported by guidelines that provide additional detail enabling those entities subject to it to comply. This resource may be used alongside the *Guideline for Identification and Labelling of Pharmaceutical Products Template¹ and Guidance* and the *Guideline for Pharmaceutical Product and Location Master Data Template and Guidance²*.

How to Use this Document

This document includes two sections: guidance and template. The first section provides guidance on key considerations NDRA should account for when issuing regulations for traceability. It includes assumptions for each section of the template that NDRAs should consider when adapting the template. The second section provides a structure and illustrative text that can be adapted and adopted to develop traceability regulation based on GS1 global standards with a focus on pharmaceuticals. The illustrative traceability regulation text assumes that regulation will mandate unique identification of secondary, tertiary, and logistics units. It does not include illustrative text for inclusion for applications of requirements on the primary packaging level in accordance with current global trends in regulation³. However, the 'Key Considerations' section of this guidance provides direction on how the regulation text may be adapted to accommodate inclusion of requirements at the primary packaging level.

In using the template, you will need to change the structure and content to reflect context-specific requirements. If the language is adopted as is, you will need to update the fields denoted in blue to reflect context-specific information.

Key Considerations

To support application of the template to the country context, the following key considerations must be taken into account when drafting regulation to support pharmaceutical traceability. Key considerations are referenced against sections of the regulation template.

Focus Area	Consideration	Template Section
Adoption and Approval of the Regulation	NDRAs should reference and cite existing regulations and other statutory instruments that give authority to traceability. NDRAs may opt to publish new mandates or adapt existing regulations for traceability. Care has to be taken to assess whether existing regulations (if not sunset) are aligned with the traceability	

¹ Available: <https://www.ghsupplychain.org/ProdIdentificationLabellingGuidance>

² Available: <https://www.ghsupplychain.org/guideline-pharmaceutical-product-location-master-data-template-and-guidance>

³ GS1, "Discussion paper on medicines identification requirements on primary level packaging using GS1 standards." Retrieved from <https://www.gs1.org/docs/healthcare/position-papers/Discussion-paper-on-medicines-identification-requirements-on-primary-level-packaging-using-GS1-standards-final.pdf>

Focus Area	Consideration	Template Section
	regulation to ensure consistency in guidance and minimize cost to supply chain stakeholders.	
Purpose	Amend the purpose of the regulation to reflect context-specific objectives as outlined in the country’s traceability strategy.	Chapter I, Article I
Application	<p>NDRAs should determine which pharmaceutical products will be subject to this regulation and which are considered out of scope. Product scope and the timelines for when entities are expected to be in compliance should be informed by assessments or benchmarked against other markets that have issued similar regulations that define functional and business requirements and industry capabilities to comply.</p> <p>Similarly, it is recommended for NDRAs to specify supply chain parties that would be subject to these traceability reporting requirements.</p>	Chapter I, Article 2
Definitions	This section provides a set of definitions that are required to understand the content of the regulation. Revise them to reflect any new content that is added to the regulation or terms specific to your market	Chapter I, Article 3
Technical Specifications of the Unique Identifier	<p>This section provides guidance on the unique identification of pharmaceutical products. The guidance is aligned with the GSI General Specification and does not require further modification.</p> <p>NDRAs should determine whether or not serialization should be required in this phase of traceability implementation.</p> <p>Recommend that the primary level packaging identification be optional when the manufacturer can accommodate. This is good practice in global regulations today given the capabilities to label on the primary pack are still emerging. If regulation is extended to the primary packaging level, sub-articles 4(e), 5(b), 5(c), should be amended to extend to all packaging levels.</p>	Chapter 2, Articles 4–5
Technical Specifications of Data Carriers	This section provides guidance on the unique identification of pharmaceutical products. The guidance is aligned with the GSI General Specification . If regulation is extended to the primary packaging level, an additional sub-article should be added to indicate, “the unique identifier of the primary package shall be encoded in a GSI DataMatrix”	Chapter 3, Articles 6–9
Human Readable Interpretation (HRI)	This section provides guidance on how product labeling must also include HRI, or text next to the barcode that describes the encoded data. This guidance is aligned with the GSI General Specification and should not require further modification.	Chapter 4, Article 10
General Requirements for Master Data Sharing	<p>NDRAs should decide on the responsible party for master data submission such as manufacturer, market authorization holder (MAH), or importer.</p> <p>The directive may contain minimum details. It should be technology agnostic but can reference further guidance that will provide MAHs with the detailed information they will need to exchange data. Development of a Master Data Guideline is recommended to complement the directive that specifies specific</p>	Chapter 5, Article 11

Focus Area	Consideration	Template Section
	data attributes to be reported and the mechanism for master data sharing.	
General Requirements for Traceability Reporting	This section is intentionally high level to provide initial provisions that will enable requirements for traceability reporting in the future. NDRA can provide additional information on what reporting is required and in what timeline if a detailed exercise has been completed that document these future requirements. Development of a Traceability Data Sharing Guidelines is recommended to complement the directive that specifies specific information to be reported and the mechanism for traceability data sharing.	Chapter 6, Article 12
Miscellaneous Provisions	This section includes additional provisions, including notifications to the authority, duty to cooperate, administrative measures, and inapplicable laws. Review and make them more specific if appropriate in the country context. Specifically, where more detail is available, review and refine considerations for penalties for non-compliance.	Chapter 7, Articles 13–16
Transitional Measures	Use market research to inform the timelines by which compliance is required. NDRA should consider whether a longer lead time is needed for domestic and/or regional in-scope supply chain entities and/or providers. The following <u>minimum</u> transition timelines should be considered: <ul style="list-style-type: none"> • 1–2 years for Global Trade Item Number (GTIN), batch/lot number, and expiration date identification on secondary packages and higher • 2–3 years for GTIN, batch/lot number, expiration date, and serial number provision identification on secondary packages and higher • 2–3 years for Serial Shipping Container Code (SSCC) identification on logistics items • 1–2 years for master data sharing 	Chapter 7, Article 17

GOVERNMENT OF [COUNTRY]

[REGULATION No. of /.... /YYYY] GOVERNING THE
IMPLEMENTATION OF IDENTIFICATION, DATA CAPTURE, AND DATA
SHARING FOR TRACEABILITY OF PHARMACEUTICAL PRODUCTS

Arrangement of the Regulation

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Regulation Development History

Author	Date
Draft zero	
Adoption by [NDRA]	
Stakeholder consultation	
Adoption of stakeholder comments	
Effective date	

Template

Adoption and Approval of the Regulation

In EXERCISE of the powers conferred upon [NDRA] by [ACT] establishing [NDRA] and determining its mission, organization, and functioning, hereby ADOPTS and ISSUES this Regulation [No. of /.... /2020] Governing the Implementation of Identification, Data Capture, and Data Sharing for Traceability of Pharmaceutical Products, made this [XX] day of [Month], [Year].

Template

CHAPTER I: PRELIMINARY PROVISIONS

Article 1. Purpose

Purpose of this Regulation:

- a) *To protect the public from falsified, substandard, expired, recalled, or otherwise harmful pharmaceuticals.*
- b) *To improve efficiency in the supply chain to ensure that the right products are available at the right time in a cost-effective manner.*
- c) *To provide the measures for placing a unique identifier on the package of pharmaceutical products for human use allowing for identification and authentication of the product.*
- d) *To provide the measures for assurance of traceability to track and trace the product at every step of the supply chain.*

Article 2. Application

This Regulation shall apply to *all pharmaceuticals* intended for human use that are registered in [country] that are reimbursed or prescribed, with the exception of [insert list of products exempt from regulation, for example]:

- a) Products imported for personal use but not to be distributed in the official supply chain.
- b) Non-registered pharmaceuticals ordered by hospitals for specific patients and in limited quantities.
- c) Products submitted for quality analysis.
- d) Free samples of pharmaceutical products.
- e) Blood or blood components.
- f) Homeopathic pharmaceuticals.
- g) Traditional medicines.
- h) Extemporaneous preparations.

Article 3. Definitions

For the purposes of this Regulation, the following definitions shall apply:

- a) **“Authority”** means [the country-designated body or organization].
- b) **“Barcode”** means a symbol that encodes data into a machine-readable pattern of adjacent, varying width; parallel, rectangular or square dark bars; and pale spaces.
- c) **“Batch/Lot number”** means a designation in numbers and/or letters to identify and trace a set of identical products that shares certain characteristics of production, including production time, production date, or other similar characteristics.
- d) **“Brand owner”** is the organization that owns the specifications of a trade item, regardless of where and by whom it is manufactured. The brand owner is normally responsible for the management of the Global Trade Item Number (GTIN).
- e) **“Data matrix”** means a standalone, two-dimensional matrix symbology that is made up of square modules arranged within a perimeter finder pattern.
- f) **“EAN-13 barcode”** means barcode of the EAN/UPC symbology that encodes a 13-digit GTIN for retail purposes.
- g) **“Expiration date”** means the date up until which the manufacturer can guarantee that the medicine is fully potent and safe to take based on scientifically sound product testing.
- h) **“Global Location Number (GLN)”** means the GS1 identification key used to identify physical or digital locations (operational or legal) or parties. The key comprises a GS1 company prefix, location reference, and check digit.
- i) **“GS1-128”** means a subset of Code 128 which uses the function that allows the encoding of element strings

- j) **“Global Trade Item Number (GTIN)”** means the GS1 identification key used to identify trade items. The key comprises a GS1 Company Prefix, an item reference and check digit.
- k) **“Human Readable Interpretation (HRI)”** means a one-to-one illustration of the data encoded in a data carrier using characters such as letters and numbers that can be read by persons.
- l) **“Label”** means any tag, brand, mark, pictorial, or other descriptive matter, written, printed stenciled, marked, embossed, or impressed on or attached to a container of any medicinal product.
- m) **“Logistic unit”** means an item of any composition established for transport and/or storage of pharmaceuticals that needs to be managed through the supply chain.
- n) **“Manufacturer”** means a person or a firm that is engaged in the manufacture of medicinal products.
- o) **“Marketing authorization holder (MAH)”** means any legal entity that holds a marketing authorization issued by the [the country-designated body or organization] to distribute and sell its pharmaceutical products in [country].
- p) **“Master data”** means the identification number and descriptive attributes of an object that are static or nearly so, that provide more information or characteristics of the object identified.
- q) **“Package”** means any article that may be used for filling, inserting, or wrapping or packing regulated products and includes the immediate container and other wrapping materials.
- r) **“Patient or client”** means the actual or intended end user of the pharmaceutical product.
- s) **“Pharmaceutical”** means any substance, or mixture of substances, manufactured, sold, or presented as capable of preventing and treating human or animal diseases and any other substance intended for administration to a human being or an animal to diagnose diseases, restore, correct, or carry out modification of organic or mental functions. It does not include medical devices or their components, parts, or accessories.
- t) **“Pharmaceutical supply chain”** means the physical flow of pharmaceutical products from the origin to consumption, covering the manufacturing, import, distribution, transportation, storage, and dispensing stages.
- u) **“Primary packaging”** means the first level of packaging for the product marked with a data carrier either on the packaging or on a label affixed to the packaging. For non-sterile packaging, the first level of packaging can be in direct contact with the product. For sterile packaging, the first level of packaging can be any combination of the sterile packaging system and may consist of a single item or group of items for a single therapy such as a kit.
- v) **“Secondary packaging”** means the level of packaging marked with a data carrier that may contain one or more primary packages each of which may contain a single item or multiple items.
- w) **“Serial number”** means a code, numeric or alphanumeric, assigned to an individual instance of an item for its lifetime.
- x) **“Serial Shipping Container Code (SSCC)”** means the GS1 identification key used to identify logistic units. The key comprises an extension digit, GS1 Company Prefix, serial reference and check digit.
- y) **“Supply chain entity”** means any person in the supply chain who manufactures, imports, distributes, transports, stores, or dispenses pharmaceuticals or is involved in related activities.
- z) **“Tertiary packaging”** means higher levels of packaging that may include a pallet that contains (one or usually) several cases or a case that contains (one or usually) several items in its primary or secondary packaging. Tertiary packaging may refer to either a logistic unit or a trade item.
- aa) **“Traceability”** means the ability to track forward the movement through specified

- stage(s) of the extended supply chain and trace backward the history, application, or location of a pharmaceutical product.
- bb) **“Trade item”** means any pharmaceutical product upon which there is a need to retrieve pre-defined information and that may be priced, or ordered, or invoiced at any point in any supply chain.
 - cc) **“Unique identifier”** means a numeric or alphanumeric string captured in a machine-readable data carrier and human-readable form on the label of the pharmaceutical package that is associated with a single product or product group.
 - dd) **“Verification”** means determining whether the unique identifier affixed to, or imprinted upon, a pharmaceutical package corresponds to the unique identifier assigned to the product by the manufacturer or the repackager.

CHAPTER II. TECHNIAL SPECIFICATIONS OF THE UNIQUE IDENTIFIER

Article 4. General requirements for unique identification

- a) All pharmaceutical trade items and/or logistic units that are distributed in [\[country\]](#) shall be identified with a unique identifier.
- b) The manufacturer or repackager shall maintain records about each such unique identifier affixed or imprinted on the trade item until at least one year after the pack’s expiration date or five years after the pack has been released for sale or distribution, whichever is the longer period, and provide those records to [\[NDRA\]](#) upon request.
- c) The unique identifier for a trade item shall be assigned and labelled, at the latest, when the trade item is physically created by the manufacturer of the product.
- d) When a new trade item is created by co-packing of two or more physical items (e.g., creating a kit, overpacking), the re-packer shall assign a new unique identifier.
- e) The unique identification data carrier for all secondary and higher packaging levels in scope shall remain on or attached to the pharmaceutical throughout the life cycle.

Article 5. Composition of the unique identifier

- a) The unique identifier shall be constructed according to the globally accepted [GS1 General Specifications](#).
- b) The unique identifier shall be a sequence of numeric or alphanumeric characters that is unique to a given secondary packaged trade item, tertiary packaged trade item, or logistic unit.
- c) The unique identifier of the secondary and tertiary package shall consist of the following data elements:
 - i) GTIN
 - ii) Batch/lot number
 - iii) Expiration date
 - iv) Serial number
- d) Notwithstanding to sub-article 5(c), the manufacturer shall notify the Authority if it needs to add information other than the listed data elements in sub-article 5(c) in the unique identifier.
- e) Logistic units shall be identified with a SSCC.
- f) When the logistic unit is an orderable trade item, the logistic unit shall be identified with an SSCC and a GTIN.
- g) The relationship between the unique identifiers of different packaging levels shall be captured in the manufacturer’s electronic internal systems.

CHAPTER III: TECHNICAL SPECIFICATIONS OF DATA CARRIERS

Article 6. General requirements for data carriers

- a) The [GS1 General Specifications](#) shall be used to construct the unique identifier in the data carrier, which allows the identification and accurate decoding of each data element of which the unique identifier is composed.
- b) The unique identifier of the secondary package shall be encoded in a GS1 DataMatrix.
- c) The unique identifier of the tertiary package(s) shall be encoded in a GS1 DataMatrix, and/or GS1-128 linear barcode.
- d) The unique identifier of the logistics unit shall be encoded as stated in the [GS1 General Specifications](#).

Article 7. Data carrier specifications

- a) It is prohibited to use multiple two-dimensional data carriers on a single packaging of a pharmaceutical product to identify and verify the authenticity.
- a) An additional data carrier, besides a GS1 DataMatrix for identifying the secondary package in dispensing, is allowed (e.g., use of the EAN-13 for retail purposes), if done in accordance with the [GS1 General Specifications](#). The GTIN for identifying the product in both barcode symbols, however, shall be the same.
- b) For the data carrier specifications regarding placing, printing, and quality, the [GS1 General Specifications](#) shall be followed.

Article 8. Quality and readability

- a) The data carrier quality measurement processes and minimum quality levels detailed in the [GS1 General Specifications](#) shall be followed.
- b) The manufacturer shall have a procedure in place to control and document the print quality of the data carrier and shall be able to provide documentation to the Authority upon request at any time.
- c) The manufacturer shall ensure consistent printing quality across packages.
- d) The manufacturer shall verify through testing that the data carrier can stand moisture, abrasion, and other external factors possibly influencing the data carrier quality.

Article 9. Placing of the data carrier on the label

- a) The data carrier shall be printed on the label of the product in a good visible manner.
- b) The data carrier shall be printed on a flat surface.
- c) The data carrier shall not be covered by anything that prevents scanning of the data carrier.
- d) The data carrier shall be placed on the same side of each package.
- e) Placing the unique identifier on the secondary package by means of stickers is acceptable under the following conditions:
 - i) As per article 17 of this Regulation, during the grace period of the implementation of the unique identifier.
 - ii) When no legal and/or technically feasible alternative exists, as agreed between the supplier and the Authority.
- f) When placing the unique identifier on a sticker, the following conditions should be met:
 - i) The sticker shall be tamper-evident and not possible to remove without damaging the package, the sticker itself, or otherwise leaving visible signs.
 - ii) The sticker on which the unique identifier is printed should be placed by a manufacturer under Good Manufacturing Practice conditions.

CHAPTER IV: HUMAN READABLE INTERPRETATION (HRI)

Article 10. General requirements for HRI

The data elements of the unique identifier encoded within the data carrier shall be printed on the label or package as HRI following the rules and recommendations of the [GS1 General Specifications](#).

CHAPTER V: MASTER DATA SHARING

Article 11. General requirements for master data sharing

- a) The manufacturer shall share product master data with the Authority for all trade items within the scope of this Regulation:
 - i) At the time that an application for marketing authorization is submitted
 - ii) Upon request by the Authority at any other time
- b) The manufacturer shall ensure that product master data are maintained for all trade items and notify the Authority within 30 days of any effective change.
- c) A unique identification number in the form of a Global Location Number (GLN) must be assigned and shared with the Authority to identify the following legal entities or locations associated with a trade item:
 - i) the brand owner of the trade item
 - ii) the manufacturing location of the trade item
 - iii) the legal entity applying for or holding a marketing authorization of the trade item in [country]
- d) A guideline will be issued by the Authority to guide the submission of product and location master data.

CHAPTER VI: TRACEABILITY REPORTING

Article 12. General requirements for traceability reporting

- a) All in-scope supply chain entities and/or providers shall establish a system to electronically record and communicate data including location, date and time, and event occurring corresponding to traceability events.
- b) All in-scope supply chain entities shall record and communicate traceability data to a national traceability system.
- c) Proven impossibility of complying with the requirements of capturing and sharing traceability data shall be communicated to the Authority immediately.
- d) A guideline will be issued by the Authority with instructions on how to comply with the traceability requirements and connect to the national traceability system at a future date.

CHAPTER VII: MISCELLANEOUS PROVISIONS

Article 13. Notifications of authority

Any supply chain entity that encounters trade items or logistic units within the specific scope without required unique identification captured in the required data carrier or non-scannable data carrier shall inform [NDRA] immediately.

Article 14. Duty to cooperate

The concerned governmental bodies and pharmaceutical supply chain actors shall have the duty to cooperate with all appropriate organs to execute their responsibility given in this Regulation.

Article 15. Administrative measures

In accordance with the [ACT], [NDRA], depending on the severity of the violation, shall take one or more administrative measures on non-complying persons.

Article 16. Inapplicable laws

No regulations, practice, or circular letter shall, in so far as it is inconsistent with this Regulation, be applicable with respect to issues provided under this Regulation.

Article 17. Transitional measures

The following transitional measures apply:

- a) Any pharmaceutical product manufactured, imported, distributed, and dispensed without the unique identifier before the effective date of this Regulation, and that is not repackaged or re-labelled thereafter, may be placed on the market until its expiry date.
- b) Within [#] years of the effective date of this Regulation, master data for all listed pharmaceutical trade items, their packaging levels, and their associated locations and legal entities and pharmaceutical products shall be shared with the Authority.
- c) Within [#] years of the entry into force of this Regulation, listed pharmaceutical trade items in secondary packages and higher packaging levels shall be identified with a GTIN, batch/lot number, and expiration date encoded in the specified data carrier.
- d) Within [#] years of the effective date of this Regulation, listed pharmaceutical trade items in secondary packages and higher packaging levels shall be identified with a GTIN, batch/lot number, expiration date, and serial number encoded in the specified data carrier.
- e) Within [#] years of the effective date of this Regulation, logistic units containing listed pharmaceutical trade items shall be identified with a SSCC encoded in the specified data carrier.