USAID GLOBAL HEALTH SUPPLY CHAIN PROGRAM
Procurement and Supply Management

MODEL DIRECTIVE FOR TRACEABILITY REGULATION DEVELOPMENT

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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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USING THE MODEL DIRECTIVE FOR TRACEABILITY REGULATION DEVELOPMENT

Model Directive For Traceability Regulation Development comprises of two sections: guidance and template. The first section provides guidance for regulation development and provides key considerations and assumptions that an national drug regulatory authorities (NDRAs) should consider at key decision points and aids in the application of the template to country context included as the section of this document.

The template component of the document is not intended to be prescriptive, but rather to serve as a guide for standardized labelling and packaging requirements for pharmaceutical products through regulation. This section includes numerous provisions that must be tailored specifically to country context. These provisions are noted in [blue brackets.]

Many tools are necessary to secure a country's drug supply. Complementary tools not addressed in this Model Directive For Traceability Regulation Development may be valuable in securing a country supply chain. For example, a requirement that all supply chain entities be authorized (e.g., licensed, registered) can significantly improve the security of the legitimate supply chain.

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GUIDANCE MODEL DIRECTIVE FOR TRACEABILITY REGULATION DEVELOPMENT

INTRODUCTION

This document is intended for use by NDRAs in the implementation of pharmaceutical labelling and packaging requirements to advance supply chain security. Implementation of serialization, verification and traceability to enhance security of the pharmaceutical supply chain is a significant endeavor. In doing so, every regulator must assess and account for local market dynamics, including local legal requirements (e.g., whether serialization will be implemented by statute, regulation, or other guidance), technological sophistication (e.g., internet connectivity in various geographic regions), trade practices (e.g., whether unit-of-use, unit-dose, or bulk packaging is used; the variety of distribution channels used), and other similar dynamics. The regulation template should be adapted to account for such market dynamics.

ASSUMPTIONS

GHSC-PSM employed the following key assumptions as foundational to the drafting of the Model Directive for Traceability Regulation Template.

1. **Manufacturer Capabilities—** The Model Directive for Traceability Regulation Template assumes manufacturers in the relevant market have the technical capability to implement labelling and packaging requirements within the recommended timelines for consideration based on the global and regional momentum for standardization.
2. **Pharmacy and Other Users—** The Model Directive for Traceability Regulation Template assumes that pharmacies or other authorized dispensers in the market can establish the necessary verification technology (e.g., internet, Scanners or smartphone connectivity).
3. **Pharmaceutical Products —**The scope of the Draft Model Directive is limited to pharmaceutical products for human use (i.e., those drugs that will be verified by a pharmacist or health professional) and does not apply to other products, such as animal drugs, or food products.
4. **Phased Approach to Pharmaceutical Traceability -** As written, GHSC-PSM assumes the countries will support a phased approach to achieving pharmaceutical traceability:
    - Phase 1: Identification & Labelling
    - Phase 2: Product & Location Master Data Reporting
    - Phase 3: Serialization & Point-of-Dispense Verification
    - Phase 4: Aggregation & Traceability

    If a phase approach is employed for pharmaceutical traceability, Phases 3 and 4 requires a significant jump in the maturity of supply chain people, processes and technology, countries should revisit these regulations after completion of phases 1 and 2.

KEY CONSIDERATIONS

To support the application of the template to 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.

Regulation Focus Area	Consideration	Regulation Reference Section
Scope	a. NDRAs should determine what pharmaceutical products will be subject to these regulations and those that are considered out of scope. b. Regulation should be informed by assessments that define functional and business requirements for a framework based on scope of products, events, and trading partner reporting mandates	section 1-11
1. Identification & Labelling	a. NDRAs should make a determination on whether serialization should be required in this phase of traceability implementation or not and guidance on the type of barcode on packaging types should be updated to align with the scope.	section 1(c) (iv); section 1 (e); section 1 (f)
2. Trade Item and Location Master Data Sharing	b. NDRAs should consider existing country technology requirements for master data identification, capture and reporting c. NDRA to decide on the responsible party for master data submission such as Manufacturer, Market Authorization Holder or Importer d. Recommend countries develop a Master Data Guideline that specifies specific data attributes to be reported and the mechanism for master data sharing	section 2(a) (iii) and section b.(b)
3. Obligations of the to Support Verification of Pharmaceutical Products	a. Verification should be considered in instances where NDRA wishes to determine the authenticity of products in the supply chain as the first step before full track and trace. b. NDRAs to determine whether verification is part of the country strategy to determine whether considerations should be included in regulation.	section 3; section 5; and, section 6
4. Traceability	a. The NDRA needs to determine whether traceability is part of the country strategy to determine whether considerations should be included in regulation. b. Level of maturity of technology (e.g. printing capability) and system capability to manage transaction data should be considered when implementing traceability.	section 4; and, section 7
5. Obligations of Persons Authorized or Entitled to Supply Pharmaceutical Products to the Public	a. The NDRA need to define which trading partners are in scope for the verification and/or traceability requirements including reporting mechanism and requirements b. Level of trading partner capability to collect and remit data should be considered when implementing verification and/or traceability.	section 5
6. Access to Verification Repository by National Authorities	a. Access to Verification Repository is dependent on whether verification will be in the scope of the in-country traceability regulatory requirement.	section 5; and, section 6

Regulation Focus Area	Consideration	Regulation Reference Section
7. Transition Measures	a. NDRAs should consider the following minimum transition timelines: i. 1-2 years for GTIN, batch/lot number and expiration date identification on secondary packages and higher; ii. 2-3 years for GTIN, batch/lot number, expiration date, and serial number provision identification on secondary packages and higher iii. 2-3 years for SSCC identification on logistics items	section 11 (a); section11 (b); and, section 11(c) (ii)

REGULATION TEMPLATE

GOVERNMENT OF [COUNTRY]

REGULATION No. …. of ……. /…. /2020 GOVERNING THE IMPLEMENTATION OF GLOBAL STANDARDS AND TRACEABILITY FOR PHARMACEUTICAL PRODUCTS

PURPOSE

The purpose of [Act] is to enhance the security of the pharmaceutical supply chain by establishing standardized labelling and packaging requirements for pharmaceutical products.

OBJECTIVE

The objective of this Directive is:

(a) to protect the public from falsified, substandard, unregistered, expired, recalled or otherwise harmful pharmaceuticals;
(b) to set out a system in which the identification and authentication of a pharmaceutical product is enabled from manufacturers to points of dispense (e.g. hospitals, retail outlets, healthcare providers)
(c) to improve data visibility and efficiency in the pharmaceutical supply chain;
(d) to inform supply chain actors about the mandatory requirements for the identification, authentication and traceability of pharmaceutical products.

SCOPE

This Directive applies to:

(a) [All pharmaceutical products] that are registered in [country] and are intended for human use. There exist categories of products that might be exempted to the regulation but its upto the specific country to come up with the recommended list of the same.
(b) All supply chain entities involved in the physical movement of pharmaceutical products, from manufacture to points of dispense (e.g. hospitals, clinicals, healthcare providers).

DEFINITIONS

For the purposes of this Directive, the following definitions shall apply;

(a) “Authority” means the country-designated body or organization.
(b) “Automatic identification and data capture (AIDC)" means ability to automatically capture data. AIDC technologies include barcodes, smart cards, biometrics, and radio frequency identification devices
(c) “Barcode” means a symbol that encodes data into a machine-readable pattern of adjacent, varying width, parallel, rectangular dark bars and pale spaces.
(d) “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.
(e) “Data Matrix” means a standalone, two-dimensional matrix symbology that is made up of square modules arranged within a perimeter finder pattern. ECC 200 is the only version that supports GS1 system identification numbers, including the Function 1 Symbol Character (FNC1). Data Matrix symbols are read by two-dimensional imaging scanners or vision systems.
(f) “economic operator” means a manufacturer, an importer, a distributer or authorized representative.
(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 locations (operational or legal) that needs to be identified in the supply chain. The key comprises a GS1 Company Prefix, location reference, and check digit.

(i) “GS1-128” means a subset of Code 128 that is utilized exclusively for GS1 system data structures.

(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 characters, such as letters and numbers, which can be read by persons and are encoded in GS1 AIDC data carriers confined to a GS1 standard structure and format. The human readable interpretation is a one-to-one illustration of the encoded data. However, start, stop, shift and function characters, as well as the symbol check character, are not shown in the human readable interpretation

(l) “Label” means any material which is printed or affixed to a packing material which provides the necessary information about a pharmaceutical.

(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. It is identified with an SSCC.

(n) “Master data” means attributes of a real-world entity that are static (unchanging through the life of the entity) or nearly so.

(o) “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;

(p) “Patient or client” means the end user of the pharmaceutical product.

(q) “Pharmaceutical” means any substance or mixture of substance:

   i. used in the diagnosis, treatment, mitigation or prevention of human disease, disorder, abnormal physical or mental state, or the symptoms thereof;
   ii. used in restoring, correcting or beneficial modification of organic or mental functions in humans;
   iii. which are articles other than food, intended to affect the structure or any function of the body of humans; and
   iv. which includes articles intended for use as a component of any articles specified in clause (a), (b) or (c).

(r) “Pharmaceutical supply chain” means the flow from the origin to the consumption of pharmaceuticals covering the manufacturing, import, distribution, transportation, storage and dispensing stages, as well as other types of flows.

(s) “Person” means a natural and juridical person.

(t) “Recall” means a process for removing a pharmaceutical product from the pharmaceutical supply chain because of a proven defect in quality, safety or efficacy, a falsified label or any other similar defect.

(u) “Serial number” means a numeric or alphanumeric sequence of maximum 20 characters, generated by a deterministic or a non-deterministic randomization algorithm.

(v) “Serial Shipping Container Code (SSCC)” means the GS1 identification key used to identify logistics units. The key comprises an extension digit, GS1 Company Prefix, serial reference, and check digit.

(w) “Supply chain entity” means any person in the supply chain to manufacture, import, distribute, transport, store or dispense pharmaceuticals or is involved in related activities.

(x) “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.

(y) "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.
(z) "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.
(aa) "Unregistered products" means pharmaceuticals that have not undergone evaluation and/or approval by the national regulatory authority for the market in which they are marketed/distributed or used, subject to permitted conditions under national legislation.
(bb) "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 repackage.
(cc) Any expression in the masculine gender includes the feminine.

IDENTIFICATION & LABELLING

(a) The manufacturer or repackager shall affix or imprint a unique identifier to each secondary and tertiary pack trade item and logistic unit pack prior to introducing such pack into commerce in [country] by sale to a supply chain entity.
(b) The manufacturer or repackager shall maintain records about each such unique identifier until the date that is 2 years after the expiry of the prescription drug to which the unique identifier is affixed or imprinted and provide those records to [NDRA] upon request.
(c) The unique identifier for the secondary pack shall be encoded in a 2D DataMatrix and be printed adjacent in human readable form in a manner that conforms to the GS1 General Specifications including:
    (i.) the Global Trade Item Number (GTIN);
    (ii.) the expiration date of the prescription drug;
    (iii.) the batch or lot number of the prescription drug, expressed as a variable alphanumeric code up to 20-digits in length; and
    (iv.) the serial number, expressed as up to 20 alphanumeric digits or characters unique for that GTIN
(d) The unique identifier for the tertiary pack shall be encoded in a 2D DataMatrix or GS1-128 Linear Barcode and be printed adjacent in human readable form in a manner that conforms to international standards developed by GS1 including:
    (i.) the GTIN;
    (ii.) the expiration date of the prescription drug;
    (iii.) the batch or lot number of the prescription drug, expressed as a variable alphanumeric code up to 20-digits in length; and
    (iv.) the serial number of the package.
(e) The unique identifier for the logistic unit shall be encoded in a GS1-128 Linear Barcode and be printed adjacent in human readable form in a manner that conforms to international standards developed by GS1 including:
    (i.) the Serial Shipping Container Code (SSCC) of the individual logistic unit.
(f) Where the logistic unit is an orderable trade item, the logistic unit shall be identified with:
    (i.) the GTIN;
    (ii.) the expiration date of the prescription drug;
    (iii.) the batch or lot number of the prescription drug; and
    (iv.) the SSCC of the individual logistic unit.

TRADE ITEM AND LOCATION MASTER DATA SHARING

(a) Global Location Numbers (GLNs) must be assigned and reported to identify the following legal entities or locations associated with a trade item:
  (i.) The legal entity that is the Brand Owner of the trade item
  (ii.) The location where the trade item is manufactured
  (iii.) The legal entity that holds the marketing authorization for the trade item in [country]

The [supply chain entity] shall share product and location master data, including relevant GLNs and GTINs, with [NDRA] for all trade items within the scope of this Directive.

OBLIGATIONS OF THE [SUPPLY CHAIN ENTITY] TO SUPPORT VERIFICATION OF PHARMACEUTICAL PRODUCTS

(a) The [supply chain entity] authorized to [manufacture, market, import] pharmaceutical products shall have systems in place to share data on the unique identifiers for the products being distributed on the [country] market.
(b) The specific guidelines and format for sharing this data will be detailed under a separate guideline.

TRACEABILITY

Not earlier than [X years] after the date of enactment of the [Act], [NDRA] will:
(a) identify remaining risks to the security of the pharmaceutical supply chain that have not been, and cannot be expected to be, minimized by the full implementation of systems for traceability described in [Section X] of this [Act], and
(b) whether additional systems for the traceability of pharmaceutical packages would be likely to minimize such remaining risks.

If the study described in subsection (a) identifies remaining risks to supply chain security that cannot be expected to be minimized by the full implementation of system for traceability and would likely be minimized through additional systems for tracing, [NDRA] may establish additional requirements necessary to implement systems for the traceability of pharmaceutical packages through the pharmaceutical supply chain.

OBLIGATIONS OF PERSONS AUTHORIZED OR ENTITLED TO SUPPLY PHARMACEUTICAL PRODUCTS TO THE PUBLIC

(a) Persons authorized or entitled to supply pharmaceutical products to the public shall:
  (i.) Verify that the unique identifier of pharmaceutical products does not

indicate that the product is expired, recalled, withdrawn, or indicated as stolen at the time of supplying it to the public.

(ii.) Decommission the unique identifier of pharmaceutical products at the time of supplying it to the public.

(iii.) They shall also verify the safety features and decommission the unique identifier of the following pharmaceutical products:

i. Pharmaceutical products in their physical possession that are not suitable for dispense (e.g. damaged, expired);

ii. medicinal products that, while in their physical possession, are requested as samples by competent authorities, in accordance with national legislation;

(b) Notwithstanding paragraph (a), persons authorized or entitled to supply medicinal products to the public operating within a healthcare institution may carry out the verification at any time the medicinal product is in the physical possession of the healthcare institution, provided that no sale of the medicinal product takes place between the delivery of the product to the healthcare institution and the supplying of it to the public.

(c) Notwithstanding, where technical problems prevent persons authorized or entitled to supply pharmaceutical products to the public from verifying the authenticity of and decommissioning a unique identifier at the time the medicinal product bearing that unique identifier is supplied to the public, those persons shall record the unique identifier and, as soon as the technical problems are solved, verify the authenticity of and decommission the unique identifier.

(d) Where persons authorized or entitled to supply pharmaceutical products to the public have reason to believe that a product is suspicious, those shall quarantine the product and shall immediately inform the relevant competent authorities.

(e) The specific guidelines and format for sharing this data will be detailed under a separate guideline.

ACCESS TO VERIFICATION REPOSITORY BY NATIONAL AUTHORITIES

A legal entity establishing and managing a repository used to verify the authenticity of or decommission the unique identifiers of pharmaceutical products placed on the market in the country shall grant access to that repository and to the information contained therein, to competent authorities of that for the following purposes:

(a) supervising the functioning of the repositories and investigating potential incidents of falsification;

(b) reimbursement;

(c) pharmacovigilance or pharmacoepidemiology.

NOTIFICATIONS TO THE 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.

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 Directive.

ADMINISTRATIVE MEASURE

In accordance with the [Act that allows for Administrative Measure], [NDRA] depending on the severity of the violation, shall take one or more administrative measures on non-complying persons.

TRANSITIONAL MEASURES

(a) The following transitional measures apply for unique identification:
  (i.) Within [X years] of the entry into force of this Directive, listed pharmaceutical products 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.
  (ii.) Within [X years] of the entry into force of this Directive, listed pharmaceutical products 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.
  (iii.) Within [X years] of the entry into force of this Directive, logistics items containing listed pharmaceutical products shall be identified with a SSCC encoded in the specified data carrier.
  (iv.) Any pharmaceutical product manufactured, imported, distributed and dispensed without the unique identifier before the effective dates and are not repackaged or relabeled thereafter, may be placed on the market until their expiry date.

(b) The following transitional measures apply for master data reporting:
  (i.) Within [X years] of the entry into force of this Directive, location and product master data for listed supply chain actors and listed pharmaceutical products and their packaging levels respectively shall be shared with [NDRA].

(c) The following transitional measures apply for unique identification data reporting:
  (i.) Within [X years] of the entry into force of this Directive, [supply chain entity from Section 4] shall have systems in place to enable sharing of unique identifiers for all pharmaceutical products being distributed on the [country] market.
  (ii.) Within [X years] of the entry into force of this Directive, persons authorized or entitled to supply pharmaceutical products to the public shall be required to verify and decommission pharmaceutical products upon dispense to the public.

ENTRY INTO FORCE

This Directive shall enter into force on [insert date].

ANNEX I: Pharmaceutical products judged to be at risk of falsification *(Optional)*

Entry No.	Active Substance (Common Name)	Pharmaceutical Form	Strength	Anatomical Therapeutical Chemonical (ATC) Code	Remarks

ANNEX II: List of pharmaceutical products that shall not bear safety features (Optional)

Entry No.	Active Substance (Common Name)	Pharmaceutical Form	Strength	Anatomical Therapeutical Chemonical (ATC) Code	Remarks