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USAID GLOBAL HEALTH SUPPLY CHAIN PROGRAM
Procurement and Supply Management

Global Standards & Traceability Regulatory Compliance Monitoring & Enforcement Framework

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Photo: GHSC-PSM

Acronyms

GBT	Global Benchmarking Tool
GLN	Global Location Number
GTIN	Global Trade Item Number
MA	market authorization
MAH	Market Authorization Holder
ML	maturity level
MOH	Ministries of Health
NPC	National Product Catalog
NRA	National Regulatory Authority
PMS	post-market surveillance
PVIMS	Pharmacovigilance Information Management System
QA	quality assurance
RIMS	Regulatory Information Management System
SF	substandard or falsified
SSCC	Serial Shipping Container Code
SOP	standard operating procedure
WHO	World Health Organization

Welcome to the Traceability Compliance Monitoring Framework

National Regulatory Authorities (NRAs) around the world have issued regulations to advance pharmaceutical traceability leveraging GS1 global standards.

This document provides a framework for assessing and developing compliance monitoring and enforcement mechanisms within an NRA, based on issued regulations and guidelines. Compliance monitoring and enforcement is critical to driving industry adoption and implementation, as well as strengthening the position of the NRA in implementation and control of the regulations published.

Leveraging the Regulatory Compliance Monitoring & Enforcement Framework will help NRAs to identify and close gaps between existing processes within the core regulatory functions and those needed to enable the national pharmaceutical traceability mandate.

This resource is for YOU

If you have a background in GS1 standards and/or pharmaceutical traceability and are working with NRAs, MOHs, or development partners that are driving traceability policy, this document can support establishing an implementation framework. It explores the applicability of regulations and guidelines across various regulatory functions and suggests various components of those functions that should be reviewed and modified as necessary to support implementation.

Regulatory Scope of the Framework

IDENTIFY

Products & Locations

- GTIN for trade items
- GLNs for brand owner, manufacturing location, and MAH

CAPTURE

Trade Items

GS1 DataMatrix encoded with GTIN, Batch/Lot, Expiration Date and Serial Number

(01) 10857674002017
(17) 251231
(10) NYFUL01
(21) 192A837H7

Logistic Units

GS1 128-Linear Barcode encoded with SSCC

(00)006141411234567890

SHARE

Master Data

Product master data across 12 attribute groupings

The scope of this document is limited to compliance monitoring and enforcement for regulations pertaining to product identification and labelling and master data exchange. The structure can be leveraged to enable compliance monitoring and enforcement of traceability data sharing requirements, but the examples in this document do not extend to that scope.

Post-Compliance Regulatory Use Cases for GS1 Standards

The scope of this document is limited to **compliance monitoring and enforcement for regulations** pertaining to product identification and labelling and master data exchange. Once compliance is achieved, use cases can be identified within each regulatory function on how the capabilities gained through application of GS1 standards can enhance regulatory functions and performance. Some examples of those use cases are included below but are not in scope for implementation as part of compliance monitoring and enforcement.

Market Authorization	Inspection	Importation	Post-Market Surveillance
• Improve **analytics** for insight • **Link** market authorization to the NPC for data quality • Use standardized identifiers for clear **publication** of market authorization • Labeling guidelines leverage existing **barcoding standards** & best practices • Identify and separate **variants** using global industry norms	• Clear **communication** between internal and external inspection and licensing stakeholders • Can leverage barcoding and existing location master data to **accelerate** inspection processes	• Standards as a mechanism for **communication** between importation authority, product owners, and logistics • **Verify** importation license quickly through scanning	• Standards facilitate **communication** between inspectors, regulatory authority, manufacturers, and other stakeholders • Scanning and GTINs used to **access records** and **record information** quickly • Scanning, GTINs and Serial numbers leveraged to **automate reporting** adverse events or suspicious product

The Framework

Regulatory Functions That Have a Role in Compliance Monitoring and Enforcement

Market Authorization (MA)

Market authorization is the process by which products are reviewed and licensed to be offered on the market. Regulatory compliance with global standards requirements is monitored at the time of product registration, including initial submission of GTINs, GLNs, and product labels.

Inspection

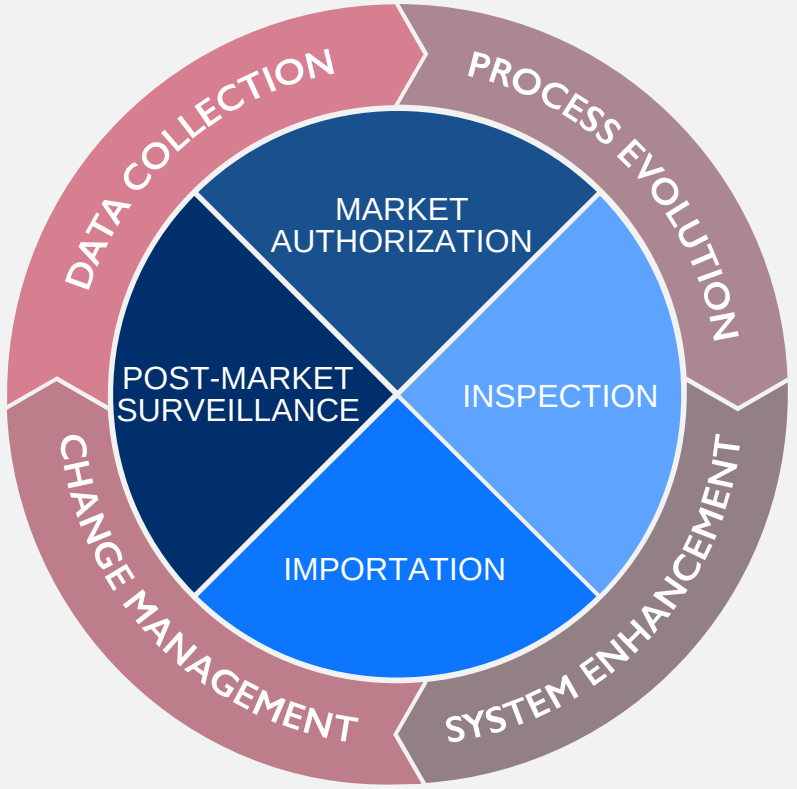
Inspection is the mechanism through which public and private manufacturers, distributors, wholesalers, and/or retailers are inspected to establish or maintain MA. Regulatory compliance is enforced at the time of inspection through direct inspection of identification and labeling.

Importation

Importation is the process by which shipments of medicine are brought into the country for further distribution and use. Regulatory compliance is enforced at the time of importation through scanning for data capture and the use of identifiers to liaise with established databases of authorized product.

Post-Market Surveillance (PMS)

Post-market surveillance is the mechanism through which medicines are sampled, inspected, and monitored on an ongoing basis for quality and authenticity in-country. Regulatory compliance is enforced at the time of PMS through assessment of physical sampled product for registered labeling and identification practices.



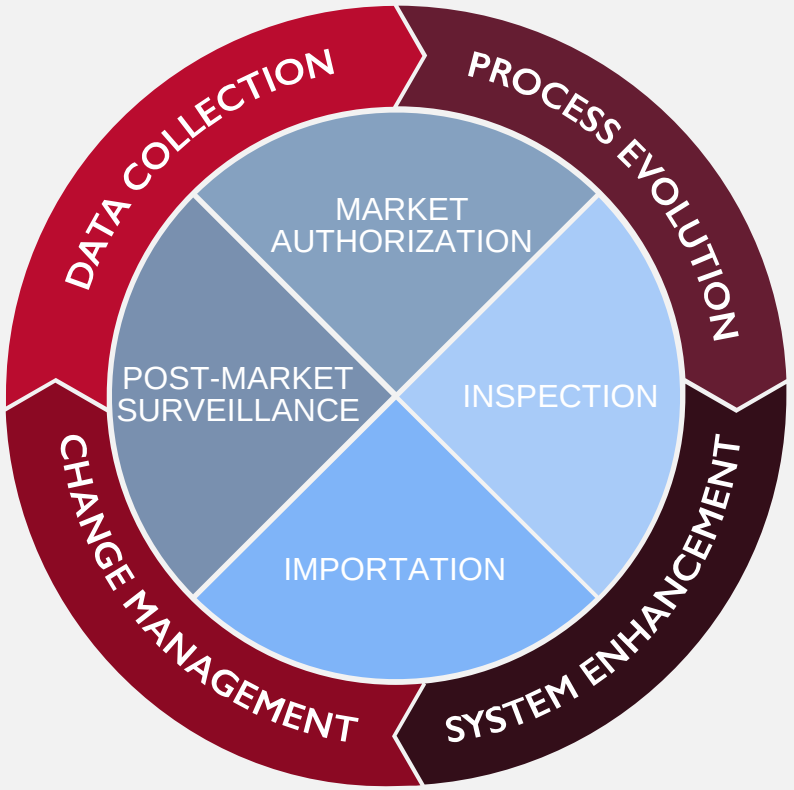
Implementation in Regulatory Functions

Data Collection
Includes first-time and ongoing data collection initiatives required to assess and validate compliance with identification, labelling, and data sharing requirements for new products, as well as those currently authorized for distribution on the market.

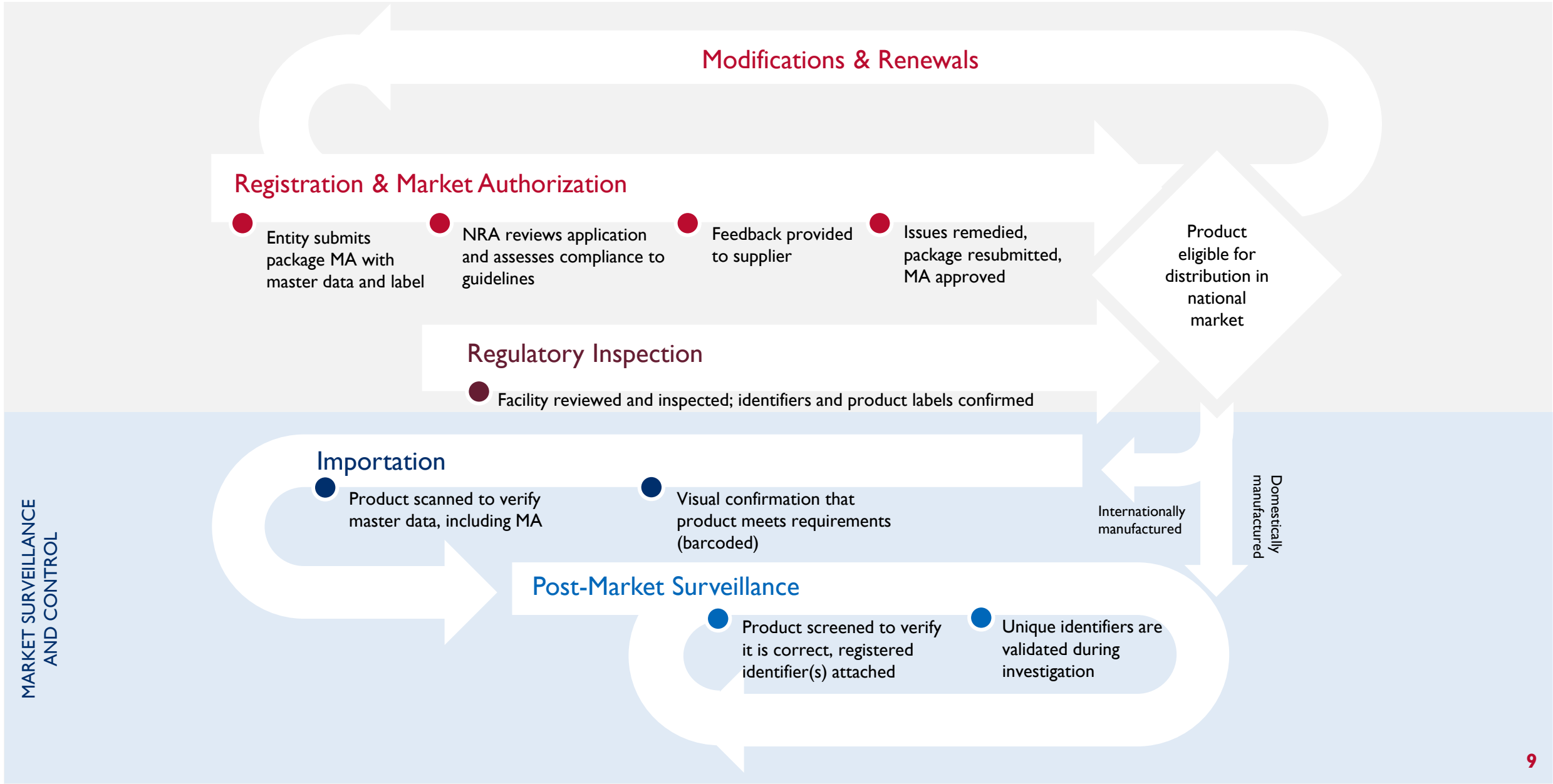
Process Evolution
Evaluates the modifications to existing regulatory processes or new/additional processes required to implement data collection and validate compliance to regulations and guidelines. Processes should also consider instances of noncompliance, enforcement mechanisms, and feedback loops to impacted stakeholders.

System Enhancement
Considers enhancements that may be required for existing information systems and/or new system capabilities required to capture and use standards-based data and effectively monitor compliance and enforcement.

Change Management
The controlled transition to new tools and processes leveraging global standards.



Product Identification & Labelling Compliance Monitoring Lifecycle



A Human-Centered Approach

Scenario 1: **Market Authorization**

Gloria

Dossier Evaluator

Responsible for reviewing and processing applications for market authorization

Key Components

Product Master Data Collection: GTIN provided for each variant as part of descriptive data at time of authorization or variant commercialization

Location Master Collection: GLN provided for each facility or sub-facility unit as part of location registry

Label Compliance Verification: Trade items are barcoded and labeled in accordance with the guideline

Feedback Loop: Communicate with trading partners in the instance of noncompliance

Potential Enforcement Mechanisms

- Withhold market authorization
- Require correction / resubmission prior to granting market authorization or renewal

MA: Example Implementation Components

Data Collection

- Core master data referenced in guideline (GTIN/GLN and attributes)
- Evidence of compliance to labelling requirements

System & Tools Enhancements

- Dossier modifications
- Master data sharing to NPC

Process Evolution

- Collection and validation of GTINs and GLNs added to SOPs
- Barcode verification added to SOP

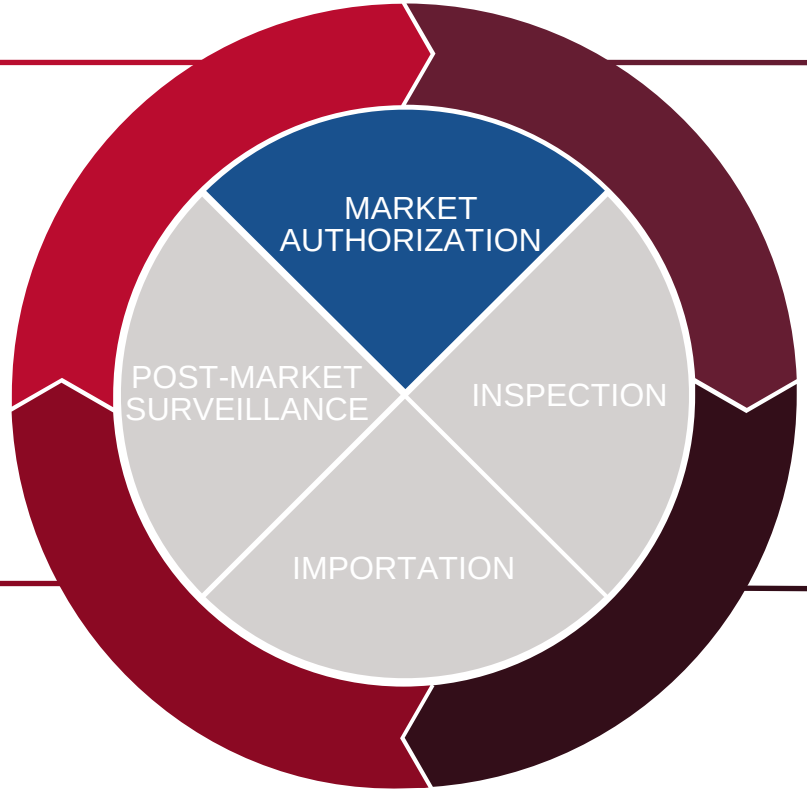
Change Management

- Education provided on collecting, understanding, and using GTINs/GLNs

MA: Example Country Framework

DATA COLLECTION

- GTIN and GLN
- Product Master Data Attribute Spreadsheet
- Product Labeling Artwork
- Sample Product



PROCESS EVOLUTION

Modification of the following SOPs:

- Screening and assessment of applications
- Assessment of post-approval changes
- Assessment of renewal of market authorizations
- Feedback to the applicant

CHANGE MANAGEMENT

- MAH requires training or sensitization on dossier updates
- Dossier evaluators require training in standards and tools
- Updated, validated, and endorsed SOPs

SYSTEM & TOOLS ENHANCEMENTS

- Dossier to include new data fields
- RIMS upload of Product Master Data Attribute Spreadsheet
- Updates to Dossier Assessment Report and Public Report templates
- Access to scanners and/or mobile app for quality verification upon dossier review

Scenario 2: **Inspection**

Nia

Site Inspector

Responsible for inspection of manufacturing facilities

Key Components

Location Master Recordkeeping: GLNs used to manage location data for inspection records

Label Compliance Verification: Ensure that trade items are labeled in keeping with artwork indicated during market authorization

Feedback Loop: Communicate with trading partners in the instance of noncompliance

Potential Enforcement Mechanisms

- Include standards-related issues as part of inspection findings report
- Require remediation of any standards-related issues identified
- Include standards as part of grading/scoring for inspection results

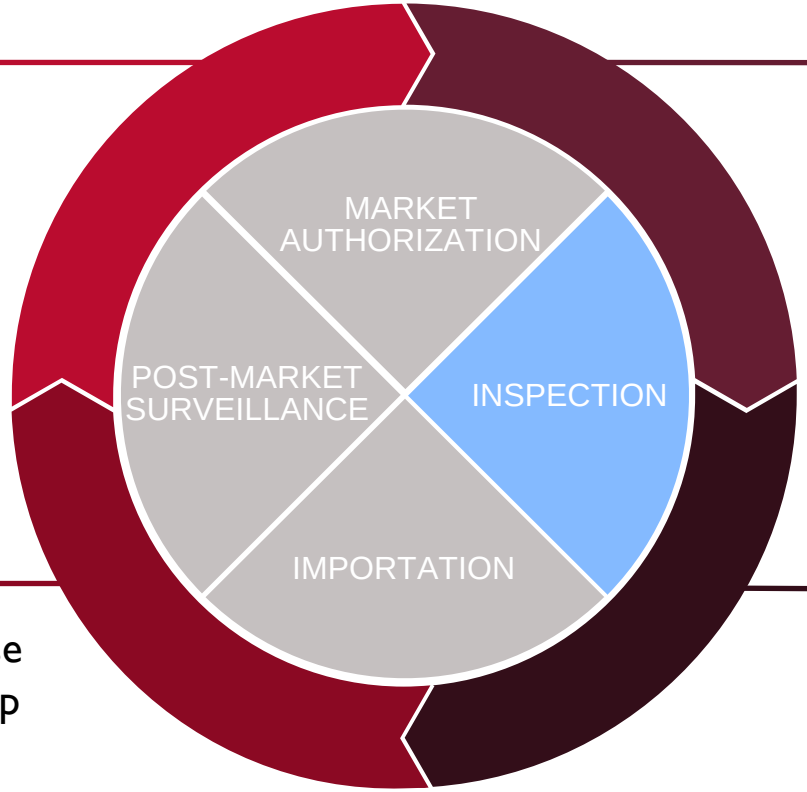
Inspection: Example Implementation Components

Data Collection	System & Tools Enhancements	Process Evolution	Change Management
			
Core identifiers referenced in SOPs, including GLN and supporting attributes GLNs used to collect and manage inspection information Evidence of compliance to identification and labeling requirements	Core identifiers (GLNs) incorporated into inspection records	Barcode verification incorporated into inspection process	Education provided on locating and interpreting logistic unit and trade item labels

Inspection: Example Country Framework

DATA COLLECTION

- GTIN and Product Master Data
- Site Master File with GTIN and GLN
- Product Labeling Artwork
- Sample Product



PROCESS EVOLUTION

Modification of the following SOPs to include verification of GTIN against NPC and visual inspection of trade item and logistic unit label:

- Inspection of product at port of entry
- Inspection of consignment released under seal at client premises

CHANGE MANAGEMENT

- Inspector training on updated SOPs and use of tools such as scanners and/or mobile app
- Implement as part of Inspector Training Programs

SYSTEM & TOOLS ENHANCEMENTS

- GTIN and GLN added to Site Master File
- Update to Inspection Assessment Report Templates
- Update to Inspection checklist
- Access to scanners and/or mobile app for verification during inspection
- Reporting tools and/or dashboard updates to display compliance results

Scenario 3: **Importation**

Abraham
Importation Inspector

Responsible for reviewing and approving product for import

Key Components

Visual inspection: Ensure that product is correctly barcoded

Scan-based Data Collection: Rapidly and accurately collect and store data including identifiers, batch/lot, expiration, and serial number(s) during import/sampling

Feedback Loop: Communicate with the trading partner authorized to import product in the instance of noncompliance

Potential Enforcement Mechanisms

- Hold or reject product that does not meet standards or registered product information
- Fees or penalties for clearance delays and holding of noncompliant product
- If product requires relabeling, level fees on importer to cover cost of addressing non-compliance

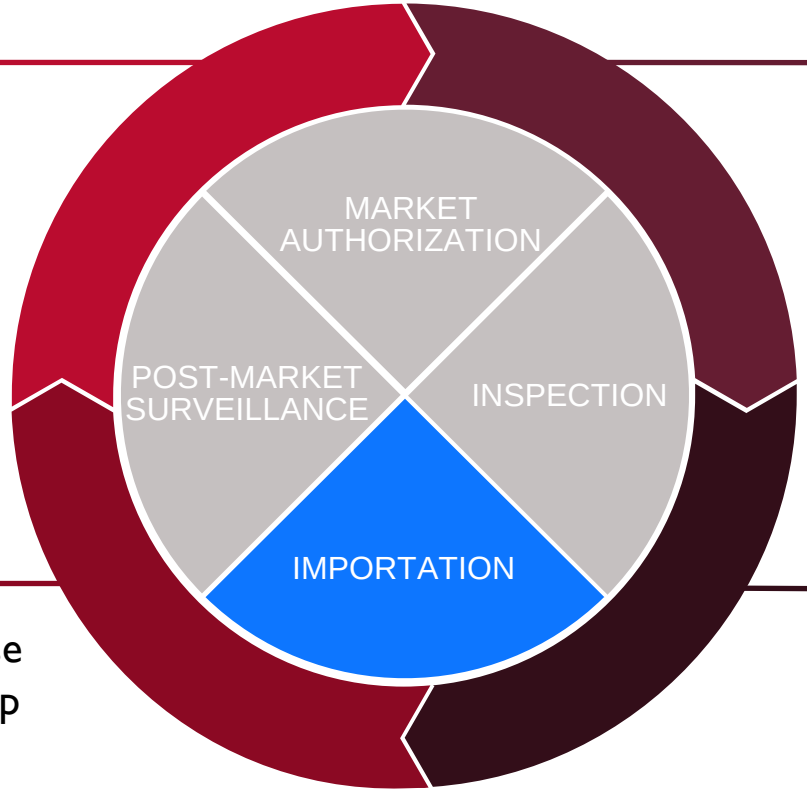
Importation: Example Implementation Components

Data Collection	System & Tools Enhancements	Process Evolution	Change Management
			
Identifiers collected and compared to known information in NPC and packing documents during importation processes	Scanning and alignment with existing data (e.g. NPC) supported by information systems used for importation	Collection and validation of GTINs & GLNs, leveraging scanning, and added to importation SOPs	Education provided on scanning practices and how to manage deviations from expected data SOPs established for deviations from expected data at time of import

Importation: Example Country Framework

DATA COLLECTION

- GTIN, Batch/Lot, Expiration Date, Serial Number, SSCC
- Import license applications
- Labels on trade item and logistic unit packaging



PROCESS EVOLUTION

Modification of the following SOPs:

- Screening of application
- Planning of inspection
- Conducting of inspection
- Report of inspection findings
- Feedback to the applicant

CHANGE MANAGEMENT

- Inspector training on updated SOPs and use of tools such as scanners and/or mobile app

SYSTEM & TOOLS ENHANCEMENTS

- Import License application updated to include GTIN, Batch/Lot, Expiration Date, Serial Number and SSCC
- Access to scanners and/or mobile app for NPC verification during importation

Scenario 4: **Post-Market Surveillance**

Eva

PMS Inspector

Responsible for sampling and assessing product on market

Key Components

GTIN Verification: Collect GTIN and compare to existing master data for sampled product

Scan-Based Data Verification: Rapidly verify label and data during sampling activities and PMS investigations

Feedback Loop: Communicate with trading partners in the instance of aberrations from expected data or noncompliance and/or channel feedback through the MA function

Enforcement Mechanisms

- Place alerts and trigger additional inspection of any product not found to meet standards during post-market surveillance
- Repercussions on market authorization status and import approvals until identified issues are resolved

PMS: Example Implementation Components

Data Collection	System & Tools Enhancements	Process Evolution	Change Management
			
Leverage data captured during market authorization and/or import to ensure that product on market aligns with expected information	Integration between NPC and QA system(s) used for post-market surveillance to access master data via trade item identifiers	Scanning-based data collection incorporated into SOPs for post-market surveillance	Training provided on assessing and addressing scanning errors

PMS: Example Country Framework

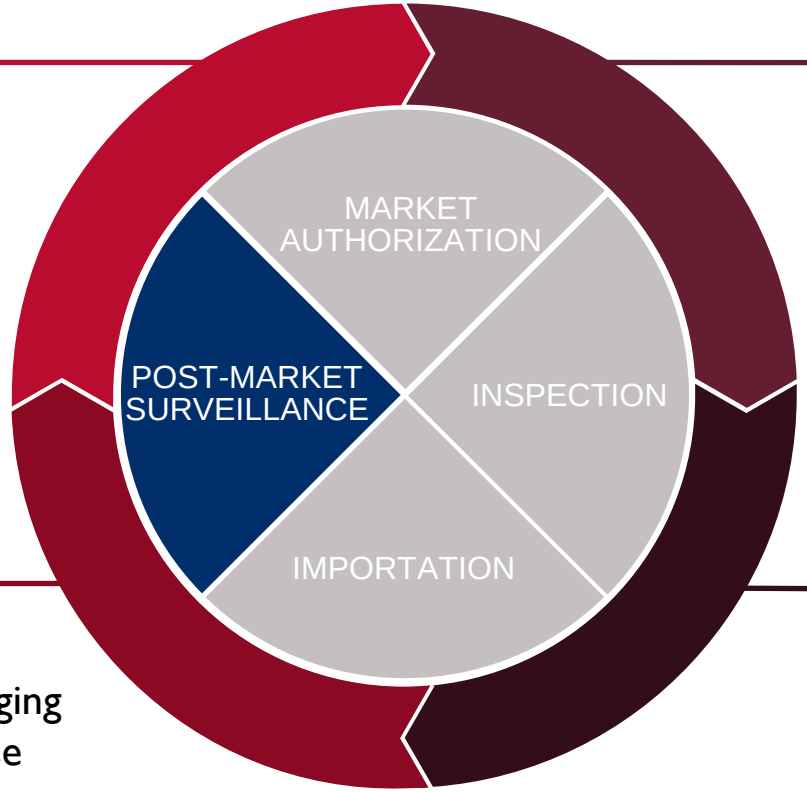
DATA COLLECTION

- GTIN
- Sample Product

PROCESS EVOLUTION

Modification of the following SOPS:

- Reporting suspicious product
- Reporting adverse events
- PMS assessment
- Investigation of complaints



CHANGE MANAGEMENT

- Public and health worker awareness on characteristics expected on product packaging
- Inspector training on updated SOPs and use of tools such as scanners and/or mobile app

SYSTEM & TOOLS ENHANCEMENTS

- PVIMS and manual reporting forms updated to include fields for data on product label
- Update to PMS inspection report templates
- Access to scanners and/or mobile app for NPC verification during importation

Alignment with the WHO Global Benchmarking Tool (GBT)

GS1, Traceability & the WHO GBT

- Standards-based identification, capture, and data sharing can support progress against the WHO GBT
- Implementation of standards can also help achieve progress indirectly by allowing the NRA to more easily implement other capabilities required
- Standards help achieve objectives in the following categories:
  - ✓ Information on marketed medical products, facilities, and companies is communicated between agencies, agencies internationally, and/or made publicly available
  - ✓ Definition, documentation, and assessment of variations
  - ✓ Guidelines on marketing authorization applications and labeling are established and collected information is used in future activities
  - ✓ Rapid alerts, recall, and communication for substandard and falsified (SF) medical products

WHO GBT Objectives supported by global standards

1 GS1 global standards can support the communication of information on marketed products, facilities, and companies between agencies, international bodies, and/or the public, supporting these WHO GBT indicators:

- RS09.04 Information on marketed medical products, authorized companies and licensed facilities is publicly available (ML3)
- MA05.02 Updated list of all medical products granted MA is regularly published and publicly available (ML3)
- MC02.02 Documented procedures or mechanisms are implemented to ensure the involvement and communication among all stakeholders relevant to market surveillance and control activities (ML3)
- RI06.02 The updated list of database of all inspected facilities along their regulatory decisions, actions and enforcement activities, is regularly published and publicly available (ML4)
- MC04.06 Documented and implemented procedures exist in the NRA to review any complaints or market reports received (ML3)
- MC06.01 Market surveillance and control activities are appropriately communicated within the NRA (ML3)
- MC06.03 Findings and regulatory decisions of market surveillance and control activities of common interest are appropriately communicated and shared with other countries and regional and international organizations (ML3)
- RI02.02 Documented procedures and mechanisms are implemented to ensure the involvement and communication among all stakeholders relevant to regulatory inspection activities (ML3)
- LI02.02 Documented procedures and mechanisms are implemented to ensure the involvement and communication between all stakeholders relevant to establishment licensing activities (ML3)

WHO GBT Objectives supported by global standards

2 Use of GS1 global standards for identification and labeling enables the definition, documentation, and assessment of variations, supporting these WHO GBT indicators:

- MA01.05 There are regulations or guidelines for the definitions, types and the scope of variations along with the required documentation for these variations (ML3)
- MA01.11 There are guidelines for MA holders that define the types and scope of variations, the format and content to be used for documenting the variations, and the identification of these variations that require prior approval or notification (ML3)

WHO GBT Objectives supported by global standards

3 The establishment of labeling guidelines for market authorization that include standardized unique identification and labeling requirements, supporting these WHO GBT indicators:

- MA01.10 There are guidelines on the format and content for submission of MA applications that are consistent with the WHO or other internationally accepted standards (ML3)
- MA01.13 There are guidelines on the content of product information leaflets, SPC-like information, and product packaging and labelling (ML3)
- MA04.08 SPC-like, labelling and packaging information are approved by the NRA as part of the MA procedure (ML3)
- LT06.02 There are documented procedures for performing tests in accordance with MA documentation (ML3)

WHO GBT Objectives supported by global standards

4 Use of GS1 global standards for identification and labeling can enable rapid alerts, recall, and communication for SF medical products, supporting these WHO GBT indicators:

- RS04.02 A rapid alert system to for managing the threads by SF medical products and for recalling these products from the market (ML2)
- RS04.04 Recall system based on documented confirmation that appropriate, batch-traceable action and/or destruction has been undertaken when necessary (ML3)
- MA06.01 There is a database of all product applications received, approved, rejected, suspended or withdrawn along with their supporting documentation (ML3)
- MC04.07 Documented and implemented procedures and mechanisms exist to prevent, detect, and respond to SF medical products (ML3)
- VL05.01 Vigilance information is used in timely manner to amend existing regulatory decisions or to issue new regulatory decisions or actions (ML3)

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. For more information, visit ghsupplychain.org.