



USAID GLOBAL HEALTH SUPPLY CHAIN PROGRAM  
Procurement and Supply Management

# Global Standards in Low- and Lower-Middle Income Settings: Policy Design Considerations to Address Domestic Manufacturer Needs

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# GLOBAL STANDARDS IN LOW- AND LOWER-MIDDLE INCOME SETTINGS: POLICY DESIGN CONSIDERATIONS TO ADDRESS DOMESTIC MANUFACTURER NEEDS

**December 2018**

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# ACRONYMS

<b>AIDC</b> .....	automatic identification and data capture
<b>DSCSA</b> .....	Drug Supply Chain Security Act
<b>EFMHACA</b> .....	Ethiopia Food, Medicine, and Health Care Administration and Control Authority
<b>GLN</b> .....	Global Location Number
<b>GTIN</b> .....	Global Trade Item Number
<b>MO</b> .....	Member Organization
<b>SF</b> .....	substandard and/or falsified
<b>VAT</b> .....	value-added tax
<b>WHO</b> .....	World Health Organization

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# BACKGROUND

Global standards provide the foundation for business communications, facilitating the provision of services, movement of products, and information about them across trading partners and borders. In recent years, drug regulatory authorities and the health care industry have been aligning on adoption of global standards for identification, including serialization; product labeling; and data exchange to enable pharmaceutical traceability. This is largely due to the recognized benefits that global standards provide, including:

- Detection of counterfeit or stolen product throughout the supply chain
- Increased accuracy and efficiency of the procurement operations, inventory management and distribution
- Improved visibility of product status (e.g. expiry, recalls) and where the product is in the supply chain
- Strengthened pharmacovigilance and post-market surveillance systems
- More efficient reverse logistics to address product recalls and unused product within the supply chain

A number of countries—such as Turkey<sup>1</sup>, Argentina<sup>2</sup>, the United States<sup>3</sup> and those within the European Union and European Economic Area<sup>4</sup>—have already passed regulations requiring use of global standards for pharmaceutical identification and labeling and are in the process of implementation. To comply with these regulations, multinational manufacturers are making significant investments in their information systems and production lines to ensure compliance so they can continue supplying major markets. While the implementation of global standards within the health sector is more limited in low- and lower-middle income countries<sup>5</sup> (LLMICs), several countries—including Ethiopia, Ghana, Nigeria, Pakistan, and Rwanda—have initiatives underway to enable their adoption and use.

With increasing support from governments and international health organizations, the domestic manufacturing industry for pharmaceutical products is rapidly growing in LLMICs.<sup>6</sup> These manufacturers often produce critical essential medicines for domestic and regional markets, including those vital to maternal, newborn, and child health programs such as oxytocin, amoxicillin, and misoprostol. Domestic manufacturing can in turn benefit local economies, through increasing exports to regional markets and, most importantly, providing sustainable and affordable access to these life-saving essential medicines.

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<sup>1</sup> "The Role of GS1 in International Trade and Border Regulatory Procedures." GS1. Accessed December 04, 2018.

[https://www.gs1.org/docs/tl/border-management-elearn/Role\\_of\\_GS1.pdf](https://www.gs1.org/docs/tl/border-management-elearn/Role_of_GS1.pdf).

<sup>2</sup> Derecho, Maximiliano. "Evolution of Drugs Traceability in Argentina." GS1. October 25, 2016. Accessed December 04, 2018.

[https://www.gs1.org/sites/default/files/docs/events/2016/beijing/MaximilianoDerecho\\_Beijing2016.pdf](https://www.gs1.org/sites/default/files/docs/events/2016/beijing/MaximilianoDerecho_Beijing2016.pdf).

<sup>3</sup> Center for Drug Evaluation and Research. "Drug Supply Chain Security Act - FDA Issues Draft Guidance: Product Identifier Requirements Under the Drug Supply Chain Security Act – Compliance Policy." U.S. Food and Drug Administration. June 30, 2017. Accessed December 04, 2018. <https://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/ucm565358.htm>.

<sup>4</sup> Rose, Mike. "European Union (EU) Falsified Medicines Directive." GS1. October 18, 2017. Accessed December 4, 2018.

[https://www.gs1.org/docs/healthcare/events/17-10-17/6\\_-\\_eufalsified\\_medicines\\_directive\\_-\\_rose.pdf](https://www.gs1.org/docs/healthcare/events/17-10-17/6_-_eufalsified_medicines_directive_-_rose.pdf).

<sup>5</sup> World Bank Country and Lending Groups. Accessed December 04, 2018. <https://datahelpdesk.worldbank.org/knowledgebase/articles/906519-world-bank-country-and-lending-groups>

<sup>6</sup> "Promoting and Supporting Local Manufacturing of Quality Medical Products in Developing Countries." Accessed December 5, 2018.

[https://www.who.int/phi/publications/1651\\_phi\\_brochure\\_130515.pdf](https://www.who.int/phi/publications/1651_phi_brochure_130515.pdf).

Despite this growth, domestic manufacturers in LLMICs often operate in capital-constrained environments and may have a limited ability to invest in technological infrastructure to support increasing innovation. These constraints may result in additional challenges in meeting the increasing number and stringency of regulatory requirements, including stricter quality standards and quality control measures and, moving forward, implementation of global standards for identification, labeling, and data exchange.

This document provides guidance and strategic considerations for national level policy makers in LLMICs who are developing policies for pharmaceutical traceability to address the particular needs of domestic pharmaceutical manufacturers. This document is intended to be used as one reference in a suite of resources developed by GHSC-PSM regarding the implementation of pharmaceutical traceability and global standards. Additional resources and information pertaining to these topics can be found at the GHSC-PSM website at [www.ghsupplychain.org/globalstandards](http://www.ghsupplychain.org/globalstandards) as well as the GS1 website at [www.gs1.org](http://www.gs1.org).

# AN OVERVIEW OF GS1 GLOBAL STANDARDS

## THE GS1 SYSTEM

From an information management perspective, well-functioning supply chain systems require all parties to systematically synchronize the physical flow of products with the flow of data about them. This can be achieved by using a common business language within the framework of a comprehensive standards system. The GS1 system of standards is such a system, providing a comprehensive platform for companies to identify products and business entities, capture supply chain data, and share data with trading partners.

GS1 standards encompass identification standards, data standards, and automatic identification data capture (AIDC) standards such as barcodes. The table below summarizes some of the GS1 standards that support supply chain management and data visibility:

GS1 Standards for Health Care Supply Chain Management			
Identification Standards	Trade Items	Global Trade Item Number (GTIN)	
	Locations & Parties	Global Location Number (GLN)	
	Logistics Units	Serial Shipping Container Code	
AIDC Standards	GS1 Barcodes	GS1-128 GS1 DataMatrix	
Data Standards	<b>Master Data:</b> GS1 Global Data Synchronization Network	<b>Transactional Data:</b> Electronic data interchange including: GS1 EANCOM GS1 XML	<b>Event Data:</b> Electronic Product Code Information Services Core Business Vocabulary

## TRACEABILITY MODELS

Fundamental to any traceability model is availability of product data in conjunction with product flow. A traceability system maintains the flow of data about the product, including the master, transaction, and event information related to an item in the supply chain. However, the design and scope of any given traceability system implementation depends on the specific context and what that implementer – in health care, most often a regulatory authority – seeks to achieve. Traceability systems generally take on one of three models: verification, track and trace, or a hybrid approach.

In a verification model, the identification data (i.e., GTIN and serial number) encoded into the barcode is checked at a single point in the supply chain to confirm that it is assigned by the manufacturer of the product. Countries that implement this model must clearly identify whether verification occurs at the point of dispense (e.g., check at hospital, retail, or pharmacy) or end consumer/point of use (e.g., checked by the patient).

In a track and trace model, data are captured from trading partners as the product moves through the



supply chain, from the manufacturer to the end user. Countries that implement this model must clearly identify whether the scope of track and trace is chain-of-ownership (e.g., reporting by entities that currently have or have had legal title to the product), or chain-of-custody (e.g., reporting by entities that currently have or have had physical possession of the product). Integral to track and trace is the availability of master, transaction, and event data associated with the product at each point of the supply chain in scope.

While many countries implement a single traceability system, some implement both using a phased approach. Because verification has fewer requirements from an infrastructure and process perspective, some countries consider implementing this approach in the initial phase and building out additional track and trace capabilities at various points in the supply chain over a longer period of time.

## **SUPPLY CHAIN TRANSFORMATION**

Without standards, trading partners and systems (e.g., purchasing, inventory management, logistics, reporting, etc.) each use their own identifiers and data formats. This approach severs the connection between those systems, creating a high-maintenance, error-prone environment that adds complexity, inaccuracy, and cost. Using standards maintains their connection, enabling systems to be used collectively to enhance the quality and amount of data available to support operational processes. These capabilities and the associated benefits are why standards are such an integral part of data-driven industries like grocery, retail, etc., and why adopting and implementing standards in the global health supply chain presents such a tremendous opportunity.

A lack of globally recognized standards for product identification and data exchange in health care poses a number of risks and challenges to the global health supply chain. Without a global standard for identification, proprietary identification numbers currently in use are often reassigned or possibly duplicated at various points in the supply chain. Consequently, product identification is inconsistent across procurement agencies and supply chain stakeholders through to the end user. This results in limited visibility into product movement and availability, which poses a risk to supply chain security. Additionally, inconsistent use of barcodes or data carriers that capture the identification numbers in a scannable symbol on package labels prevents standardization in supply chain processes and operations, limiting efficiencies and cost savings.

For manufacturers, diverging country requirements also cause a manufacturing headache that results in higher costs and, for those operating in low- and middle-income areas, lost market opportunities. For those receiving health commodities, lack of a global standard for product identification can cause confusion (e.g., which barcode to scan when there are multiple) and limit the end user from verifying the authenticity of the product.

# BENEFITS AND RISKS

Aligning around a single set of global standards can support processes and capabilities that create value for all participants in a supply chain, from business partners down to the patient. While the benefits of adopting global standards are numerous, the process of aligning around a single standard can also present inherent risks and challenges. This section discusses some of the major benefits and risks that regulators should consider when committing to the implementation of a global standard such as GS1 for identification of pharmaceutical products.

## BENEFITS

### Supply chain data visibility

Alignment of a product identification standard across the supply chain, in combination with automated data sharing via global networks, enhances the visibility of the product and its associated data from planning to delivery to the end user. Increasing data visibility can strengthen the supply chain in several ways:

- Improve visibility of product "status" (e.g., expired or about to expire product, previously recalled product)
- Improve product quality management (e.g., expired and/or recalled products are promptly identified)
- Provide visibility of where the product is within the supply chain
- Reduce data management costs
- Support systems interoperability, allowing access to linked data through identification keys across logistics, clinical services, insurance, and patient applications

### Increased patient safety

The goals of the supply chain are to provide the right medication, at the right dose, by the right route, to the right patient, at the right time. Patient safety issues can be addressed through the use of standardized information to:

- Enable medication authentication to remove falsified or stolen product from reaching patients
- Improve recall management effectiveness, reducing the risk of patient harm
- Reduce drug shortages
- Improve pharmacovigilance and pharmacoepidemiology
- Reduce medication errors, such as inaccurate administration, through bedside scanning

### Ensured supply chain security and control

Global supply chains, including for health commodities, face high security risks due to their complexity and global reach. Reporting movement of products through the supply chain, whether at the batch or unique item level, is important for security management and can allow protection against various threats, including:

- Falsified products
- Theft or diversion of products
- Reimbursement fraud

### **Increased supply chain efficiencies**

A supply chain that uses globally standardized product identifiers, labels, and transactions across a supply chain, from manufacturer to patient, can be much more efficient. Standardized labeling supports the automation of data capture (i.e., barcode scanning) at each point in the supply chain, reducing human error. The increased data quality from automatic and standardized data capture allows for the following benefits across the supply chain:

- Reduced manual processes in data capture for receiving, inventory management, picking, packing, and dispatching
- Improved ability to capture consumption data, resulting in better informed demand forecasting and inventory planning and reduced inventory management costs
- Improved efficiency and cost of "reverse" logistics processes (e.g., those used for returns, recalls)
- Improved efficiency of payment and payment monitoring processes
- Harmonized trade/customs clearance procedures

### **Improved trade and business across borders**

Countries' use of their own proprietary identifiers and national/domestic labeling requirements results in higher costs for manufacturers and limits their flexibility to produce larger batch runs to serve orders from multiple markets. Standardized identification and labeling can eliminate this trade barrier by enabling products to be identifiable globally.<sup>7</sup> For domestic manufacturers, use of global standards also increases their ability to compete in other markets; without a global standard, manufacturers may be required to invest in multiple packaging lines or to produce smaller runs to meet varying requirements, which ultimately increases costs. Standards therefore help domestic manufacturers to prepare their products for domestic and global markets while also making it easier for potential buyers to purchase and use those products.

## **RISKS**

### **Isolation of manufacturers in low resource settings**

Failing to consider the needs of domestic manufacturers during the development of a global standards implementation timeline can put them at risk of non-compliance and reduce their ability to compete in the marketplace. In many cases, domestic manufacturers may operate with less capital and more manual processes than their global counterparts. As such, they may not be able to respond to new regulations and requirements with the same speed as multinational manufacturers. Domestic manufacturers may then fail to become compliant, which places their business at risk. They may need additional support and extended phased timelines to assess the impact of new policies in order to plan, budget, and implement new systems and processes.

### **Implementation without investment can inhibit benefits**

Implementation of a global standards policy without investing in the associated technology and process re-engineering required throughout the supply chain can inhibit a country's ability to see the benefits of aligning with global standards. Global standards are a foundational step of the process toward traceability and the subsequent benefits discussed above. However, standards are an enabler and not the complete solution; though they are the means for enabling traceability, additional interventions are

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<sup>7</sup> "The Role of GS1 in International Trade and Border Regulatory Procedures." GS1. Accessed December 04, 2018. [https://www.gs1.org/docs/tl/border-management-elearn/Role\\_of\\_GS1.pdf](https://www.gs1.org/docs/tl/border-management-elearn/Role_of_GS1.pdf).

required to meet that end. In addition to adopting a global standards policy or requirement, manufacturers need to invest in the technology and business processes, such as barcode scanners, traceability systems, and network infrastructure, which are required to access and utilize the data that global standards provide. Without these technologies and business processes in place, the ability to capture the benefits of global standards will be limited and jeopardize policy goals.

### **Non-standard use of GS1 standards**

GS1 has worked with the health care community to develop and define a system of standards for use in the health care supply chain. Globally, there is consensus regarding which standards are needed to secure the supply chain—namely, the inclusion of a product's GTIN, batch/lot, expiry, and serial number. However, there is a risk that countries, in their implementation, will fail to harmonize fully with this global consensus. For example, countries may seek to build in additional requirements beyond globally used standards. This deviation from the global use of GS1 standards effectively creates a parallel or proprietary requirement for a specific market, increasing both costs and lead times. When those additional requirements are country-specific, they can also hinder the manufacturer's ability to supply that product across borders. To mitigate this risk, GS1 can advise on the recommended set of standards to use to accomplish traceability policy goals while minimizing cost and implementation challenges for the health care industry.

# CONSIDERATIONS FOR LEGISLATIVE DESIGN

Globally, a number of countries have already begun or completed implementation of traceability initiatives, with some leveraging global standards and others developing proprietary requirements. A review of these policies reveals a series of good practices and potential pitfalls. Based on the experiences of these countries, regulators and other stakeholders in the implementation journey should consider the following good practices and potential pitfalls when developing policy, legislation, and regulations.

## GOOD PRACTICES

### Engage key stakeholders from the start

It is important to identify and engage all key stakeholders (e.g., regulatory bodies, GS1, donors, procurement agencies, suppliers, domestic manufacturers, wholesalers, dispensers) from the beginning of the traceability planning process. Engagement should include education and awareness-building among these key stakeholder groups on the benefits of traceability and the existing global standards used in the health care industry to enable traceability across the supply chain. Prioritizing stakeholder engagement prior to launching an initiative facilitates consensus, achievability, and alignment prior to moving forward.

In many instances, this stakeholder group can form the basis of a governance body (e.g., steering committee, technical working group) to plan, organize, and drive the initiative. This can help prevent any misinterpretations and, for domestic manufacturers, can ensure their needs are heard and that developing policies are inclusive of their business. Stakeholder engagement can include convening stakeholder meetings, soliciting their input prior to drafting policy, and circulating draft policy for feedback prior to submitting it for ratification. Over the course of implementation in Argentina, 72 rounds of legislation were drafted before moving forward. Traceability implementation is an iterative process and providing stakeholders opportunities to engage and issue feedback results in a stronger end solution.

### Where in the world?

#### *Ethiopia*

In Ethiopia, the implementation of global standards is being driven by the Ethiopia Food, Medicine, and Health Care Administration and Control Authority (EFMHACA). From the conception of their traceability initiative, EFMHACA prioritized engaging domestic manufacturers, academia, GS1, and other key stakeholders in their planning and roadmap development, listing "Establish national alliance to support implementation of traceability" as a strategic objective in their latest draft implementation plan published on June 20, 2018. To this end, they have established a Traceability Office, a National Traceability Steering Committee, and technical working groups to support the continued involvement of all key stakeholders.<sup>8</sup>

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<sup>8</sup> "Pharmaceutical Traceability Strategic Plan." Accessed December 04, 2019. [http://www.fmhaca.gov.et/documents/Strategic plan For Traceability Implementation.pdf](http://www.fmhaca.gov.et/documents/Strategic%20plan%20For%20Traceability%20Implementation.pdf).

## Define your vision and develop a strategy for implementing traceability

The motivation for implementing traceability can vary by country and understanding and defining these motivations is important in directing the vision and strategy for implementation. Whether it is to address SF medicines in the supply chain or to control reimbursement fraud, a country should understand their reasons for implementing traceability and what they seek to achieve through the use of global standards. This understanding is crucial to defining the scope of the implementation as well as selecting what traceability model best fits the country's needs. Stakeholder engagement (discussed above) is foundational to developing a vision and strategy because it will capture and consider the perspective and capabilities of those who are required to participate in a country-specific traceability implementation.

### Where in the world?

#### *Rwanda*

In June 2018, the Rwandan Ministry of Health, with the support of the USAID's Global Health Supply Chain Program-Procurement and Supply Management (GHSC-PSM) project, hosted a workshop for public- and private-sector stakeholders to launch the pharmaceutical traceability initiative. The group worked to establish the vision for pharmaceutical traceability in Rwanda and defined a roadmap for implementation, leveraging GS1 global standards and assessing the current state and identifying gaps. One workshop output was a national strategy document, "Rwanda National Vision & Strategy for Pharmaceutical Traceability Leveraging GS1 Global Standards."

## Conduct pilots before scaling up traceability implementation

Pilot testing can validate whether proposed requirements will support achievement of the stated vision and confirm that the capabilities and technologies needed to ensure a scalable solution are in place and functioning as planned. Pilot testing allows countries to adjust their approach as needed based on practical implementation experience prior to scaling implementation across trading partners and product categories. Participation in pilots is particularly useful for domestic manufacturers, who have less flexibility to adjust to requirement changes once they have entered their production environment.

### Where in the world?

#### *Brazil*

Brazil rolled out a one-year pilot in August 2017 that affects three product categories. This was followed by an eight-month evaluation period, started in August 2018, to review pilot results and adjust the approach as necessary prior to full roll-out. Needed steps and modifications prior to full roll-out that the evaluation identified included definition of their full-scale implementation plan, revision of regulations, and analysis, correction, and validation of their system.<sup>9</sup>

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<sup>9</sup> "Brazil." Verification for Pharmaceutical Manufacturers | TraceLink. Accessed December 04, 2018. <https://www.tracelink.com/solutions/global-compliance/brazil>.

## Phase in implementation of capabilities

Due to the complexity of people, process, and technology change required by all trading partners to implement traceability, countries should consider developing a roadmap detailing iterative steps toward achieving the long-term vision. To date, many implementations that were successful used a phased approach, progressively developing capabilities over time based on the objectives defined by the country. This approach helps assure all trading partners have the time needed to plan, test, and scale each phase, adjust as necessary, and build momentum and promote long-term success.

Global standards can enable capabilities from batch-level traceability, to product authentication, to full-scale track-and-trace of serialized products through each step in the supply chain. These capabilities each require increasingly complex and sophisticated systems, technologies, processes, and coordination across the supply chain, and interdependencies within the system mean that all levels of the supply chain must adhere to the new system for it to work. For example, products must be labeled with barcodes prior to logistics partners being able to scan and report on the events surrounding those barcodes to a national system.

Implementing countries should understand these various capabilities and assess which requirements are needed to address the immediate needs of their country (i.e., which capabilities do we need now versus what can we phase in over time?). This assessment can help to inform the development of a roadmap for implementation that addresses both immediate needs and long-term goals.

### Where in the world?

#### *Turkey*

With a long-term vision in mind, Turkey began the first phase of their implementation in 2010 with the application of a serialized 2D/GS1 DataMatrix barcode. Each year since, they have phased in additional requirements and capabilities, from point-of-dispense verification in 2011, to introducing a smartphone application for point-of-use patient verification in 2014.<sup>10</sup>

#### *United States*

Through their 2013 Drug Supply Chain Security Act (DSCSA), the United States established a timeline for phasing in traceability capabilities over approximately 10 years. With the ultimate goal of serialized item-level traceability by 2023, the DSCSA introduced lot-level management in 2015 and began a two-year effort to phase in item serialization in 2017.<sup>11</sup>

#### *Argentina*

In addition to phasing in capabilities over the course of an implementation, countries may use a phased approach to scale regulations across product categories and manufacturers. Argentina implemented standards regulations for the highest risk commodities (e.g., high-cost, low-incidence medicines; oncology drugs; antiretrovirals) first in 2011. They then expanded these requirements by risk category to additional product groups each year after the initial implementation. As most domestic manufacturers focus on the production of essential medicines and not the highest risk commodities, this approach provides them with longer timelines needed for compliance.<sup>12</sup>

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<sup>10</sup> Geris, Yeliz. "GS1 Turkey, iTS -Turkish Pharmaceutical Track and Trace System." 2013. Accessed December 04, 2018. [https://www.gs1.org/docs/healthcare/Wed\\_9h25\\_YelizGeris\\_Turkey.pdf](https://www.gs1.org/docs/healthcare/Wed_9h25_YelizGeris_Turkey.pdf).

<sup>11</sup> "Meeting the Needs of DSCSA Requirements." GS1 US. 2018. Accessed December 04, 2018. <https://www.gs1us.org/industries/healthcare/standards-in-use/dscsa>.

<sup>12</sup> Maximiliano Derecho, "Evolution of Traceability in Argentina," GS1, accessed December 04, 2018, [https://www.gs1.org/docs/healthcare/10h30\\_Evolution\\_of\\_traceability\\_Derecho\\_eng.pdf](https://www.gs1.org/docs/healthcare/10h30_Evolution_of_traceability_Derecho_eng.pdf).

## POTENTIAL PITFALLS

### **Developing proprietary solutions in lieu of adopting global standards**

Countries that require proprietary solutions as part of their traceability implementations may increase the cost of manufacturing and reduce flexibility in the ability of manufacturers to supply their markets. This can also pose a risk to commodity security, in particular for countries with relatively small markets, which run an increased risk of manufacturers withdrawing from commerce. Domestic manufacturers are disproportionately affected by proprietary solutions, which can pose significant technical challenges and hinder their capacity to supply to global markets. Proprietary solutions, such as requiring a national tax stamp on packaging, commercial serialization solutions, or use of a national identification number rather than a global identification number, force manufacturers to manage varied requirements for products for export versus domestic sale. Limiting implementation to one standard that can be used domestically, regionally, and globally reduces equipment and processing costs. Some countries that have implemented proprietary solutions in the past have moved toward a single global standard after realizing the significance of this burden on their domestic manufacturing community and the departure of global manufacturers due to their unwillingness to implement single-country solutions.

### **Implementing prior to long-term strategic alignment**

Prior to moving forward with an implementation, all key stakeholders must be aligned on a clear, well-informed vision and strategy. Moving forward in the short-term without understanding the big picture and long-term goals can result in unforeseen challenges in the future. To prevent this, all critical stakeholders need to share a common understanding of the traceability initiative and global standards requirements. These stakeholders should develop a comprehensive, long-term (e.g., minimum 5-10 year) implementation roadmap, and all parties involved should understand both the immediate and long-term expectations, dependencies, and risks. This will help to ensure that any investments required by manufacturers and other trading partners are considered with the long-term requirements and capabilities in mind.

### **Misalignment with global use of a standard**

Collaboration with the global community (i.e., GS1, manufacturers, distributors, supply chain partners, donors, etc.) is essential when developing an implementation plan to ensure a clear vision of global standards and their application. Countries that have diverged from the largely harmonized requirements for health care have unintentionally created non-standard, customized requirements despite their intention to align with global standards. As such, domestic manufacturers are challenged with implementing dual processes and equipment configurations for domestic and export products.

The GS1 Global Office and/or local GS1 Member Organizations (MOs) can serve as an important resource during the development of an implementation plan. GS1 MOs have expert knowledge of the global standards and how they are applied globally and can provide education and training in this context. In an instance where a country does not have an MO, they can work with an MO of a nearby country, region, or the global office.<sup>13</sup> Engagement with local MOs, as well as other members of the health community (e.g., donors, WHO, World Bank, procurement agents), should take place throughout a traceability implementation journey to ensure initial and continued alignment with the global use of standards.

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<sup>13</sup> For a complete list of GS1 Member Organizations, please visit: <https://www.gs1.org/contact/overview>



**Accelerated implementation timelines**

Requiring manufacturers to comply under accelerated timelines can dramatically increase risk of non-compliance for domestic manufacturers and other members of the supply chain. For example, some countries have required full compliance with new requirements in as little as six months. Short timelines such as these do not allow the involved parties to identify appropriate resources, budget, fully execute required testing, or build on lessons learned from different stages of the implementation. Traceability implementation should be an iterative process, using observations and lessons learned from each stage to refine process, drive momentum, and promote success moving forward. Incorporating time into implementation roadmaps for this to occur is key to a successful implementation.

# IMPACT ON DOMESTIC MANUFACTURERS

## PEOPLE

Implementation of global standards and traceability is an ongoing process, not a one-time event. The processes, systems, and technology for traceability can be complex, especially around governance and management of master, transaction, serialization, and event data. Manufacturers will develop new capabilities within their existing workforce and in some cases, hire additional experts for assistance during their transition. This education and capabilities development is imperative and will be ongoing over the duration of implementation. Support through this process can be provided by those leading the traceability initiative, GS1 MOs, or solution providers who can partner with manufacturers to implement these requirements.

## SYSTEMS & TECHNOLOGY

Manufacturers will require additional investment in systems and technology to meet emerging mandates for product identification, labeling, and data exchange. Systems will need to have the capability to generate, manage, and share key data elements, and interfaces will need to be developed to share that data with national traceability systems. The investment required will depend on the scope and requirements of the implementation. For example, the capabilities required to print and manage serialization data are much more sophisticated than those required for GTIN, batch/lot, and expiry date. Similarly, the capabilities required for printing directly on the pack are more advanced than those required to print and place a sticker label. Additional investments (e.g., barcode printers and scanners) will be necessary to print and test barcoded product labels.

## BUSINESS PROCESSES

Identifying and labeling products leveraging GS1 standards will have limited benefit for the manufacturer if their business processes are not also updated to take advantage of these new capabilities. The evolution from implementing the standards in information technology systems to implementing them in business processes marks an important transition for any standards adoption effort. The effort involves reviewing and altering business processes in light of the new technical capabilities (e.g., AIDC, electronic transactions, etc.) to identify opportunities to fuel operational efficiencies both internally and with external trading partners. It is a vital turning point where an organization methodically charts a course for improving operations and seeing real world results.

## COSTS

This section is intended to provide a high-level understanding of the areas of investment required for manufacturers to implement global standards. The type and cost of the equipment and technologies listed below can vary greatly based on the market for solution providers, existing manufacturer capabilities, and the sophistication of a country's implementation. For more detailed information and cost estimates, please reach out to a certified solution provider.<sup>14</sup>

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<sup>14</sup> For a list of certified solution providers, please visit: <https://www.gs1us.org/tools/solution-provider-finder/solution-provider-finder>

**Capital investments** include the costs associated with acquiring the equipment and technologies for implementation. These represent a one-time investment that can be amortized over time, with expectation of recovery through earnings and costs savings over several years. These costs vary depending on the desired capabilities (more complex requirements often require more sophisticated technologies) and the scale of the solution (e.g., manufacturers with more production lines will require more scanners than those with fewer production lines). For a rough estimate of the equipment and software costs involved in a traceability implementation, please refer to Table 1 below.

Hardware ..... Manufacturers will need to invest in additional hardware, such as printers and scanners. The required level of investment in hardware will depend greatly on the manufacturer's existing technical infrastructure. In some instances, some of their existing hardware can be retrofitted to meet the manufacturer's needs while in others, a total replacement may be required.

Software ..... To operationalize their new or upgraded hardware, manufacturers will need to invest in software that can capture the GTINs, GLNs, and other related product data attributes in enterprise resource planning applications or other internal software applications. A manufacturer's investment for software will depend on their desired capabilities. For example, serialization will require a more sophisticated software application, and within that, aggregation for track and trace will be more sophisticated than serialization for verification alone.

**Table 1.** From GS1's "Regulatory Roadmap: Traceability of Medicinal Products", an example of capital investment costs for a traceability implementation<sup>15</sup>

Typical Track and Trace Solution in Emerging Markets				
Type	Capital	Item	Qty	Cost (\$)
Hardware	Serialization print & verify	Serialization print & verify equipment	1	\$13,000 - \$17,000
	Tamper evidence	Tamper evidence module	1	\$28,000 - \$50,000
	Warehouse station	Rework station	1	\$7,000 - \$17,000
	Quality assessment station	Rework station	1	\$7,000 - \$17,000
Software	Plant software	License	1	\$15,000 - \$50,000
	Line software	Included in equipment prices	1	\$0
	Integration to internal communication systems	If necessary	1	\$6,000 - \$25,000

**Operational startup costs** include the upfront operational costs associated with preparing a manufacturing environment for global standards implementation.

<sup>15</sup> "Regulatory Roadmap: Traceability of Medicinal Products." 2018. Accessed December 7, 2018. [https://www.gs1.org/docs/healthcare/Public-Policy/GS1\\_Healthcare-ROAD-MAP\\_FINAL.pdf](https://www.gs1.org/docs/healthcare/Public-Policy/GS1_Healthcare-ROAD-MAP_FINAL.pdf).

- GS1 Registration ..... Registration with a GS1 MO is required to receive a GS1 company prefix to support assignment of GTINs and GLNs. As enrollment is managed by GS1 MOs, this fee may vary by country.<sup>16</sup>
- Engineering Costs ..... Engineering personnel will be required to install the hardware, set up and integrate the new software applications, and test the validity of applications and labels.
- Training and Education ..... With new technologies, software, and business processes being introduced, training and education are vital components of the implementation process. To enhance understanding and support adoption of the GS1 system of standards, a manufacturer's workforce needs training to properly utilize the new technologies and operate under any revised business processes. The cost of this effort will vary by manufacturer and depend on factors such as workforce size, scope of process changes, and selected training resources.
- Downtime ..... Downtime should be expected as manufacturers work to retrofit or replace their production lines. Downtime will have a different financial impact on each manufacturer, depending on factors such as the time needed for upgrades, overhead costs, and the value of their production time.

**Ongoing costs** include the recurring costs that are expected for the remainder of a manufacturer's operations after an initial implementation. These recurring costs are to be included in an annual budget.

- GS1 licensing ..... Following the initial registration fee, a licensing fee is charged annually, commonly based on the number of GTINs or GLNs being managed by the manufacturer. This fee is managed by GS1 MOs and may vary by country.<sup>17</sup>
- Maintenance ..... To ensure continued operation of technological infrastructure, including any new hardware or software applications, routine maintenance will be required. This includes equipment maintenance, software maintenance licenses, and upgrades as necessary.

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<sup>16</sup> GS1 registration and licensing fees vary by country and can be found publicly on the GS1 MO websites. For a complete list of GS1 MOs, please visit <https://www.gs1.org/contact/overview>.

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# SUPPORTIVE FINANCING MODELS FOR NATIONAL GOVERNMENTS

Domestic manufacturers in low-and-middle income settings may not yet have the people, processes, or technology to meet global traceability mandates and subsequent global standards identification, labeling, and data exchange requirements. As such, significant investment may be required to develop the technological infrastructure and business processes needed for global standards compliance. While adoption of global standards will eventually translate to cost reductions and financial benefits for domestic manufacturers, they may struggle to finance the initial investments required to meet compliance mandates. National governments may want to consider enacting supporting mechanisms such as financial incentives to support domestic manufacturers' implementations.

## DIRECT SUPPORT

### **Value-added tax (VAT) waivers for capital investments**

To encourage domestic manufacturers to invest in the technologies needed for global standards adoption, governments may institute VAT waivers for fixed investments within the scope of the national mandate. Many countries have VAT systems in place with rates typically ranging from 10 to 20 percent. Exempting capital investments, such as barcode printers and scanners, from this VAT will significantly reduce the cost of implementation and be an incentive to invest. For those areas where local laws do not permit a complete waiver of VAT, long-term payment plans against accumulated VAT could be considered.

### **Grants, subsidies, soft loans**

Governments can use grants, subsidies, or soft loans to support domestic manufacturers in their implementation journey. As these domestic manufacturers often operate in a capital-constrained environment, these financial incentives can provide the liquid capital to invest in the technologies and process developments needed for successful adoption of global standards.

## INDIRECT SUPPORT

### **Tax incentives for solution providers to establish local presence**

To foster a growing and supportive local environment for global standards and traceability, governments can offer tax incentives for solution providers seeking to establish local businesses or service offerings. Such tax incentives would lower the barrier of entry into the domestic market for these providers and encourage them to operate locally. Solution providers, in providing manufacturers technical support and expertise for a successful implementation, can increase manufacturers' speed to compliance and decrease their costs.

### **Investment in government-owned central packaging facilities**

A government could invest in a government-owned central packaging facility to minimize the challenge of securing capital investments off of each domestic manufacturer individually. A government-owned central packaging facility can support manufacturers through various models, including printing and labeling as a service, or full print, label and packing services according to the requirements decided upon by the country.

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