USAID GLOBAL HEALTH SUPPLY CHAIN PROGRAM

PROCUREMENT AND SUPPLY MANAGEMENT

GS1 STANDARDS IMPLEMENTATION

Assessment of the USAID Supplier Base and the Ability of ARTMIS to Support GSI-compliant and Noncompliant Suppliers

February 9, 2017

USAID FROM THE AMERICAN PEOPLE

PEPFAR U.S. President's Emergency Plan for AIDS Relief

USAID FROM THE AMERICAN PEOPLE CDC U.S. President's Malaria Initiative

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ACRONYMS

ARTMIS	Automated Requisition Tracking Management Information System
EDI	electronic data interchange
GDSN	Global Data Synchronization Network
GHSC-PSM	Global Health Supply Chain-Procurement and Supply Management
GLN	Global Location Number
GTIN	Global Trade Item Number
IT	information technology
LMIS	logistics management information system
RDT	rapid diagnostic kit
RH	reproductive health
SKU	stock-keeping unit
SOW	Statement of Work

INTRODUCTION

The GS1 Standards Implementation Project developed strategic recommendations for implementing and supporting GS1 Standards across USAID's global health supply chain. The primary objectives included ensuring that ARTMIS is designed properly to capture product information according to GS1 Standards, developing a strategy for implementing GS1 Standards with the USAID supplier base, and informing country-level logistics management information system (LMIS) tools on USAID/GHSC-PSM GS1 implementation to help ensure data can continue down the chain to truly create end-to-end visibility.

Five reports were produced for this project:

- Report 1, Technical Review of the Ability of ARTMIS to Support GS1 Standards
- Report 2, Assessment of the USAID Supplier Base and the Ability of ARTMIS to Support GS1-compliant and Noncompliant Suppliers
- Report 3, Implementation Strategies for Engaging Suppliers and Capturing GS1 Data in ARTMIS
- Report 4, Guidance for USAID's In-country LMIS Projects
- Report 5, Summary of Key Findings and Additional Recommendations

This document is Report 2, Assessment of the USAID Supplier Base and the Ability of ARTMIS to Support GS1-compliant and Noncompliant Suppliers. It includes:

- An analysis of USAID's supplier base and its compliance with GS1 standards
- A compliance roadmap depicting steps that noncompliant suppliers need to take to become GS1 compliant within a reasonable timeframe
- Identification of associated risks with governance, data quality, reporting, and other identified areas of concern
- Risk mitigation strategies to address noncompliance
- A strategy to enable ARTMIS to capture and report on noncompliant and compliant suppliers.

THE USAID SUPPLIER BASE AND GS1 STANDARDS

USAID can gain insight about GS1 Standards readiness across its supplier base from:

- Anecdotal research of industry trends across the relevant industries
- Supplier scorecards in which each individual supplier responds to a set of questions about its use of specific GS1 Standards

The first vehicle is used to set expectations, and the second is used to gain a specific and measurable baseline for the USAID supplier community. This report provides the anecdotal research to help set expectations. We will be recommending and addressing supplier scorecards for the supplier engagement strategy in Report 3, *Implementation Strategies for Engaging Suppliers and Capturing GS1 Data in ARTMIS*.

USAID COMMODITY CATEGORIES

There are 10 USAID commodity categories and 719 USAID suppliers.

Exhibit 1. Overview of USAID commodity categories

Commodity category	No. of suppliers	Total spend (past four years)
HIV/AIDS pharma	17	$ 1,220,089,603
Lab equipment and diagnostics	312	$ 644,506,443
Voluntary male medical circumcision	8	$ 181,885,467
Malaria pharma	17	$ 293,163,466
Bed nets and malaria rapid diagnostic tests (RDTs)	13	$ 914,519,483
Reproductive health (RH) pharma	7	$ 376,229,776
Condoms, lubricants, and RH devices	12	$ 175,200,395
Essential medicines	150	$ 235,376,562
Global health commodities	130	$ 1,683,901,689
IT equipment, office supplies, and Infrastructure	53	$ 2,212,976,253
TOTAL	**719**	**$7,937,849,137.00**

CORE INDUSTRIES

The 10 USAID commodity categories can be grouped into three core industries:

- Pharmaceuticals
- Medical devices
- "Other, i.e., information technology (IT) equipment, office supplies, and infrastructure

To understand the relative importance of each of those industries to USAID, the tables below regroup the 10 USAID commodity categories into those three core industries.

Exhibit 2. USAID commodity categories from the pharmaceutical industry

Commodity category -- **PHARMA**	No. of suppliers	Total spend past four years
HIV/AIDS pharma	17	$ 1,220,089,603
Malaria pharma	17	$ 293,163,466
RH pharma	7	$ 376,229,776
Essential medicines	150	$ 235,376,562
Total	***191***	***$ 2,124,859,407***

Exhibit 3. USAID commodity categories from the medical device industry

Commodity category – **MED DEVICE**	No. of suppliers	Total spend past four years*
Lab equipment and diagnostics	312	64,450,6443
Voluntary male medical circumcision	8	181,885,467
Bed nets and malaria RDTs	13	914,519,483
Condoms lubricants and RH devices	12	175.200,395
Global health commodities	130	1.683,901,689
Total	***475***	***$ 3,600,013,477***

Exhibit 4. USAID commodity categories from the pharmaceutical industry

Commodity category – **OTHER**	No. of suppliers	Total spend past four years
IT equipment, office supplies, and infrastructure	53	$ 2,212,976,253
Total	***53***	***$ 2,212,976,253***

Exhibit 5 brings the figures together to show the relative importance of each of those industries to the USAID supplier community and USAID total spend for the past four years.

Exhibit 5. Suppliers and total USAID spend

Total number of suppliers	Total spend
719	$7,937,849,137.00

GS1 core industry group	Percent of USAID supplier community	Percent of USAID total spend
Pharmaceuticals	**27%**	**27%**
Medical devices	**66%**	**45%**
Other	**7%**	**28%**
TOTAL	**100%**	**100%**

As the exhibit shows, medical device suppliers are by far the largest contingent in the USAID supplier community, outnumbering pharmaceutical suppliers by almost 3 to 1, and "other" suppliers by over 9 to 1. Similarly, medical devices comprise nearly half of USAID total spend, with pharmaceuticals and "other" evenly splitting the other half.

There are a few key observations about USAID goals for GS1-standards compliance:

- Representing 66 percent of the USAID supplier community, medical device suppliers clearly have the greatest operational impact on USAID, and therefore implementation of GS1-standards for medical device commodities will have the greatest operational impact on USAID.

- Although pharmaceutical and "other" commodities represent about the same share of total spend, pharmaceutical suppliers outnumber "other" suppliers nearly 4 to 1. Because there are so many more pharmaceutical suppliers, pharmaceutical commodities have a much larger operational impact on USAID than "other" products. Therefore, progress in GS1 standards use across pharmaceutical suppliers will have a much larger operational impact on USAID than "other" products.

Based on these insights, the most important focus for USAID GS1 Standards implementation analysis and goals is medical devices and pharmaceuticals. The next section will discuss trends in both industries.

GS1 STANDARDS IN HEALTH CARE

GS1 Standards are widely used **today** across global health-care supply chains. Although this is not a new trend, the global regulatory environment has cemented the use of GS1 Standards in the two primary health-care product groups: pharmaceuticals and medical devices. Regulations to promote the safety of pharmaceutical and medical device supply chains generally encompass requirements for product identification, marking (e.g., barcodes and labels), serialization, and data sharing. Most regulations have either integrated GS1 Standards into the regulation itself (e.g., the United Kingdom) or have recognized GS1 Standards as an acceptable method of implementing the regulatory requirements (e.g., the United States). This information is important for understanding the current state of the USAID supplier base and its compliance with GS1 Standards.

Even though regulations are local (i.e., within the jurisdiction of the specific country), there is an important nuance to understand about how local regulations impact USAID pharmaceutical and medical device suppliers globally in their GS1 Standards capabilities. Specifically, if a manufacturer ships pharmaceutical and medical device products to a regulated country that mandates or accepts GS1 Standards for regulatory compliance, those companies **already** have GS1 Standards capabilities. For example:

- 100 percent of pharmaceutical suppliers shipping to the U.S. are using GS1 Standards
- 100 percent of pharmaceutical suppliers shipping to the UK are using GS1 Standards
- 100 percent of medical device suppliers shipping to the UK are using GS1 Standards
- 80 percent of medical device suppliers shipping to the U.S. are using GS1 Standards
- 100 percent of medical device suppliers shipping to China are using GS1 Standards

This means that any USAID pharmaceutical or medical device supplier that ships product (*any product*) to the US, UK, or China already has GS1 Standards implemented at some level.

Global Data Synchronization Network (GDSN) in Healthcare Statistics (from November 1, 2016) underscores this point and demonstrates the depth and breadth of GS1 Standards use across pharmaceutical and medical device products:

GDSN metric	Total
Health-care data source Global Location Numbers (GLNs)	**3,334**
Medical device Global Trade Item Numbers (GTINs)	**1,280,146**
Pharmaceutical drugs GTINs	**60,168**
All other health-care GTINs	**396,797**

The translation for USAID in terms of GS1 Standards use across pharmaceuticals and medical devices:

IN THE GDSN ALONE, THERE ARE:	
3,334	health-care manufacturers/brand owners who have technical capabilities to support GLN and who are using GDSN
1,280,146	medical device items identified with GTINs *(meaning their manufacturer has the technical capability to support GTIN)*
60,168	pharmaceutical items identified with GTINs *(meaning their manufacturer has the technical capability to support GTIN)*
396,797	all other health-care items identified with GTINs *(meaning their manufacturer has the technical capability to support GTIN)*

Although this is significant, these numbers reflect only GDSN users. There are also pharmaceutical and medical device suppliers who use GTIN and GLN, but not GDSN (and therefore are not included in the numbers above).

ASSESSMENT OPINION

As the discussion about global regulations and GS1 Standards use in health care illustrates, nearly all USAID pharmaceutical and medical device suppliers are likely using GS1 Standards *somewhere in the world*. Therefore, it really isn't a capability or technical issue for them.The real issue is getting them to use GS1 Standards in their business with USAID.

USAID will be defining its specific GS1 Standards requirements in the coming weeks. These requirements should be detailed as to which standards and for what, e.g., GTINs assigned to items and cases, marked on products, and used in transactions; GLNs assigned to shipped-from, corporate, and remit-to locations, registered in DataHub Location, and used in transactions. Once those requirements are fully defined and a supplier scorecard is distributed, USAID will gain insight into the breadth and depth of each individual supplier's capabilities.

But for now, the anecdotal assessment is that the USAID supplier base has a certain level of GS1 Standards capabilities and use in place today to leverage for USAID GS1 Standards implementation goals.

COMPLIANCE ROADMAP FOR NONCOMPLIANT SUPPLIERS

This section presents a high-level roadmap of steps that noncompliant suppliers need to take to become GS1 compliant within a reasonable timeframe.

An important thing to keep in mind is that the term "GS1 compliant" is not defined by GS1. The GS1 system encompasses many standards. "GS1 compliance" is actually a term used to refer to use of GS1 Standards *as required/specified by a trading partner, regulatory body, etc.*

For example, a trading partner may require use of GLNs for ship-to, bill-to, and remit-to locations in all transactions and electronic communication, and GTINs for all items and cases encoded in the GS1 DataMatrix barcodes and used in all transactions and electronic communication. As this example illustrates, trading partners define requirements for which GS1 Standards and how/where they are to be used, and the term "GS1 compliance" relates to trading partner compliance with those specific requirements.

We note this because USAID is still defining its specific requirements for GS1 Standards. Although it is clear USAID will require GTINs, it is still evaluating GLNs, serial shipping container codes, and other standards. For this section, we will define the high-level roadmap for GTIN and GLN based on requirements that are common among demand-side trading partners.

GTIN

The goal of USAID GTIN adoption is use of GS1 Standards-based product identifiers (GTINs) in lieu of custom product/item numbers. GTIN implementation requirements are usually electronic, i.e., EDI and database management, **and** physical, i.e., barcodes and scanning. The following list provides a roadmap of the process for supplier to implement GTINs.

- Assign GTINs to all products.
- Mark GTINs with barcodes on appropriate packaging levels.
- Use GTINs in business transactions.
- Use GTINs in product returns and recalls.
- Select a GS1 GDSN-certified data pool and load GTINs.

Note that this list for the GTIN roadmap is not numbered because it is not a chronological list. Rather, this is expected to be an iterative process in which suppliers can build on existing capabilities. Nonetheless, the first target area for manufacturers is assigning GTINs to products, and then possibly adding them to the GDSN for data synchronization.

GLN

The goal of USAID GLN adoption is use of GS1 Standards-based location identifiers (GLNs) in lieu of custom account/location numbers. The following list provides a roadmap of the process for suppliers to implement GLNs.

1. Assign GLNs to locations and parties.
2. Work with GHSC-PSM as needed to align existing account numbers and GHSC-PSM proprietary IDs to GLNs.
3. Begin to use GLNs to identify USAID/GHSC-PSM and suppliers in internal systems.
4. Use GLNs in electronic and EDI transactions to identify USAID/GHSC-PSM and supplier locations and parties, replacing the use of proprietary account numbers.
5. Use GLNs in paper transactions to identify USAID/GHSC-PSM and supplier locations and parties, replacing the use of proprietary account numbers (depending on technical capability).

SUPPORT

Statement of Work (SOW) 3 will outline a plan for managing USAID suppliers through a process that leads to compliance with USAID's GS1 Standards goals. In similar efforts, we have had success by first gathering key suppliers and painting a picture of what compliance looks like from a day-to-day operations perspective, followed by a detailed rollout plan around which suppliers can start to budget and prioritize. Our expectations are that USAID's major suppliers already have complied with similar requirements from customers and/or regulators, and have the capability of complying somewhere within their organization. Overall goals and requirements are covered in a first meeting, followed by regular calls to answer questions, work though issues, and provide feedback on supplier progress toward the goal.

Once the major suppliers are on their way toward compliance, plans should be enacted to bring along the smaller or less capable suppliers. This second group of suppliers will need more information and help than the first group. GHSC-PSM may need more hands-on learning aids for the second phase companies who may not have the resources that the first group had. Also, this next phase concerns education and engagement with a far greater number of companies than the first phase. We have found that preprepared education modules and materials such as frequently asked questions and learnings obtained from the Phase I supplier engagements are very helpful with the second round of suppliers.

NONCOMPLIANCE CHALLENGES AND MITIGATION STRATEGIES

Nothing is ever 100 percent — even standards implementation. It is expected that during the and after the transition there will be nonstandard data in ARTMIS. Understanding the challenges this poses and defining an "exceptions handling" approach for managing nonstandard data is key.

IDENTIFIERS

Dashboard

Various types of product and location identifiers can be used by noncompliant suppliers. One challenge is how to manage both compliant and noncompliant suppliers in the same dashboard. For this, we refer to our approach defined in SOW 1. Specifically, we recommended that the Product Master and the party/location tables use a name/value pair to accept multiple identifiers:

- For GTIN, the recommended approach is to create an *Alternate Item Key* table. This table should contain a name/value pair, in which one field is for *identifier type*, e.g., GTIN and HIN, and the other field is for the *identifier value*. i.e., the actual number. There should be a 0-to-many relationship between the Item table and the *Alternate Item Key* table to accept multiple values. It should include type option *Other* to be able to accommodate any unexpected value. This table should be used for the GTIN, the SKU, and any other product identifiers.

- For GLN, the recommended approach is to create an *Alternate Party Key* table to be associated with each ARTMIS party/location table. This table should contain a name/value pair, in which one field is for *identifier type*, e.g., GLN, DUNS, Federal Tax ID, and the other field is for the *identifier value*, i.e., the actual number. There should be a 0-to-many relationship between this ARTMIS party/location table and the new *Alternate Party Key* table to accept multiple values. It should include type option *Other* to be able to accommodate any unexpected value. Then, the *Alternate Party Key* table should be used for GLN, DUNS, Federal Tax ID, and any other party/location identifiers, and any party/location identifier fields in the current table design, e.g., GLN, DUNS, Federal Tax ID, can be omitted.

The benefit of this approach is that it standardizes queries and accommodates compliant suppliers (with GLN and GTIN) as well as any noncompliant suppliers (with other product identification types/values and party/location identification types/values) — enabling both to reside in the same dashboard.

Lack of Governance/Change Management Rules

A key feature of GS1 Standards is allocation rules, which specify when a new identifier must be assigned based on changes to the product to which the identifier corresponds. These top level governance rules for how identifiers are managed by individual users promote reliability and predictability. However, a common problem with proprietary identifiers that that there are no rules, and therefore they can change the product or the identifiers as they want, causing problems for their trading partners. For example, befpre the global effort to implement unique device identification, this was a significant problem with medical devices. The supplier may have changed something about the product, and then when the doctor scanned the barcode, the information in the system did not match the product. This is a troublesome challenge with no

technical solution. The primary mitigating strategy is more manual validation of noncompliant items to verify the product against the information. This can be time-consuming and labor-intensive.

Collision

Collision is a risk related to nonstandard identifiers. Without standards, suppliers generate their own proprietary identifiers based on their own schemes. However, suppliers can inadvertently use the same scheme causing collision, i.e., an identifier assigned to a product by one supplier is the same as an identifier assigned by another supplier to a diferent product.

Regardless of the risk of collision, noncompliant suppliers will obviously want to include their own proprietary identifier(s) in transactions and electronic communications. However, if these proprietary identifiers were the **only** identifiers used, the risk of collision with proprietary identifiers used by another noncompliant supplier is introduced. To minimize the risk of collision, it will be important not to leverage any proprietary identifier **on its own** in electronic communications and transactions, but to instead pair it with a corresponding USAID proprietary identifier. For example, the ARTMIS Product Master also includes a stock-keeping unit (SKU) field, and the party/location tables include various key fields, e.g., order header key, enterprise key, organization key, contact key, customer key, supplier key. as well as other types of party identifiers, e.g., DUNS, Federal Tax ID. Therefore, GHSC-PSM should require noncompliant suppliers to **also** include a corresponding GHSC-PSM proprietary identifier, e.g., SKU for products, party keys from the party/location tables, in all electronic communications and transactions.

PRODUCT ATTRIBUTES

Risks

Without standards, there is a high risk of data quality issues in definition, format, and value in product attributes and party/location data.

Mitigation Strategies

GHSC-PSM identifies the product attributes it requires from its suppliers. Whether or not they use GTIN and GDSN, suppliers need to provide that data set to GHSC-PSM. In Report 1, *Technical Review of the Ability of ARTMIS to Support GS1 Standards,* we recommended that GDSN data attributes be used wherever possible. This not only maximizes the benefits to be ultimately achieved from GS1 Standards and the GDSN with compliant suppliers but also provides a foundation for mitigating product attribute risks with noncompliant suppliers.

The recommendation is that ARTMIS use the GS1 standards-based definitions and metadata in the vehicle(s) it uses to receive data from noncompliant suppliers, e.g., spreadsheet, portal. This will enable GHSC-PSM to "push the standards out" to noncompliant suppliers to maintain alignment across product information in the master wherever possible. (*Note:* Any corresponding code lists should also be included.)

PARTY/LOCATION INFORMATION

Risks

Without standards, there is a high risk of data quality issues in definition, format, and value in party/location data.

Mitigation Strategies

In Report 1, we recommended that ARTMIS leverage the standardized GLN data set, e.g., name, address, location type (e.g., ship to, bill to, deliver to) in the ARTMIS party/location tables, e.g., suppliers, carriers, including the standardized definitions and metadata rules. This data set and accompanying standards can be obtained from GS1 US DataHub.

As with the product attributes discussed above, the recommendation is that ARTMIS use the standardized GLN data set, definitions, and metadata in the vehicle(s) it uses to receive party/location data from noncompliant suppliers, e.g., spreadsheet, portal. This will enable GHSC-PSM to "push the standards out" to noncompliant suppliers to maintain alignment across party/location information wherever possible. (*Note:* Any corresponding code lists should also be included.)

REPORTING STRATEGY

In Report 1, we recommended that ARTMIS use the name/value pair instead of the *GTIN* attribute. This approach will simplify the logic needed for creating a suite of reports that GHSC-PSM can use to assess supplier compliance and determine the amount and value of product yet to be migrated to GS1 Standards. These changes will also enable GHSC-PSM to provide suppliers with feedback on their own progress over time. (Report 3 will address how GHSC-PSM can use this information to create supplier scorecards, assess progress, and inform decisions on how best to motivate the noncompliant suppliers.)

At this point, GHSC-PSM should be able to generate reports to calculate compliance metrics. A set of query and report designs will need to be created to verify actual use of GS1 Standards. Those reports can include summary information on how the supplier community in general is doing, and how each individual supplier is doing in labeled product received and information passed. GHSC-PSM should also be able to see how the community is doing in its ability to transition from homegrown or other methods of determining the measure of items in quantity and/or value. And a series of reports should be specified to verify that a supplier has indeed switched to GS1 Standards in its transactions and other communications. Along with reports, GHSC-PSM should arrange for Kuehne + Nagel and its recipient countries to be able to provide feedback on label compliance, barcode grading, and performance.

We anticipate that a central tool for SOW 3 will be the creation of supplier scorecards. They will serve three purposes:

- To be a motivating factor (due to the competitive nature of suppliers)
- To determine when suppliers will be ready to migrate certain business processes to GS1 Standards (contracting, purchasing, logistics, etc.)
- To capture GHSC-PSM experience or proof that business is being transacted with a particular supplier through GS1 Standards

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