USAID GLOBAL HEALTH SUPPLY CHAIN PROGRAM

PROCUREMENT AND SUPPLY MANAGEMENT

GS1 STANDARDS IMPLEMENTATION

Summary of Key Findings and Additional Recommendations

February 10, 2017

USAID FROM THE AMERICAN PEOPLE

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CONTENTS

ACRONYMS

ARTMIS	Automated Requisition Tracking Management Information System
ASN	advance ship notice
CMS	Central Medical Store
FIFO	First in, first out
GDSN	Global Data Synchronization Network
GHSC-PSM	Global Health Supply Chain – Procurement and Supply Management
GLN	Global Location Number
GTIN	Global Trade Item Number
K+N	Kuehne + Nagel
LMIS	logistics management information system
MDM	master data management
MSD	Medical Stores Department
RDC	regional distribution center
RFP	request for proposal
SCM	supply chain management
SME	subject matter expertise
SSCC	serial shipping container code

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 1) ensuring that the Automated Requisition Tracking Management Information System (ARTMIS) is designed properly to capture product information according to GS1 Standards, 2) developing a strategy for implementing GS1 Standards with the USAID supplier base, and 3) informing country-level logistics management information system (LMIS) tools on GS1 implementation in USAID's Global Health Supply Chain – Procurement and Supply Management (GHSC-PSM) project 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 5, *Summary of Key Findings and Additional Recommendations*. Based on research findings about the GHSC-PSM supply chain and the larger global health supply chain (as described in the annexes), this report seeks to help crystalize the challenges and the ripple effect of GS1 Standards implementation goals from GHSC-PSM, to countries and to other donor organizations. It covers key findings and recommendations for:

- GHSC-PSM and ARTMIS: connecting key concepts of the GS1 Standards-based supply chain to GHSC-PSM as part of the larger supply chain
- Recipient countries: connecting key concepts of GS1 Standards-based supply chains to help guide them in identifying process and system changes needed to leverage GS1 Standards
- Other partners (other donor organizations and business intelligence and analysis considerations): connecting supply chain information needs with GS1 Standards to highlight long-term goals and standards implementation efforts

STANDARDS IMPLEMENTATION: EXPECTATIONS AND EXPERIENCE

Many organizations struggle to understand what it means to "implement GS1 Standards," and how to approach standards implementation. In reality, it is a phased, iterative process with a learning curve that builds each capability piece by piece. Much progress has been achieved by GHSC-PSM in laying the groundwork, and the work will continue, as it always does. It's important to remember that it's a process, not a finish line. Key steps include the following:

- Set expectations and planning around implementing and using foundational elements across systems piece by piece for certain capabilities, e.g., master data = Global Trade Item Number (GTIN) and Global Data Syncronization Network (GDSN); order process = purchase order.
- Plan to conduct pilot testing with one or two key partners before wide-scale implementation if/where possible.
- Incorporate time to integrate learnings from implementation and use each piece to drive momentum and promote success.
- Identify benefits expected for each use and metrics for measuring them. Measure and monitor metrics throughout each phase to highlight benefits achieved as well as any potential adjustments that may need to be made.
- Plan rollout to leverage eduction and experience through each phase, understanding that standards education and experience are key performance indicators for success throughout the process.

GHSC-PSM AND ARTMIS

IMPLEMENTATION ROADMAP

Key Considerations

Annex 1: The GHSC-PSM Supply Chain details key considerations and research findings on which this roadmap and recommended GHSC-PSM rollout strategy were based.

Note About Serialization and Track and Trace

USAID and GHSC-PSM have a significant interest in learning about serialization and item-level applications through the GS1 Standards Implementation Project. However, these types of standards implementations are highly advanced. Although it is good to see the bigger picture and have a vision for the future, USAID/GHSC-PSM is just beginning the process of implementing GS1 Standards, and those types of goals lie much farther out in the future.

Recommended Rollout Strategy for GHSC-PSM

- The first step in any standards implementation is to lay the foundation: implementing GTIN and GDSNs in systems.
- Research revealed that logistics activities throughout the channel are heavily dependent on batch/lot and expiration date for inventory management — suggesting a significant need for, and potential benefits from, case-level identification and barcoding.
- At this time, we recommend that GHSC-PSM focus on:
    - GTINs and GDSN
    - Purchase orders
    - Case-level identification and barcoding
    - Pallet-level identification and advance ship notice (ASN)
- Notes and key activities for each focus are provided in the table below.

Implementation focus	Activities/notes *(before wide-scale rollout)*
GTINs* and the GDSN * lowest saleable unit and homogeneous case	• Plan and implement changes to ARTMIS to accommodate GTINs • Work with the data pool to prepare for the GDSN • When ready, identify one or two suppliers to run a GTIN/GDSN pilot to test the GDSN synchronization with the Product Master and flow-through of GTIN attributes to ARTMIS
Purchase order	• Plan and implement changes to ARTMIS to accommodate GTINs • Work with the data pool to prepare for the GDSN • When ready, identify one or two suppliers to run a GTIN/GDSN pilot to test GDSN synchronization to the Product Master and flow-through of GTIN attributes to ARTMIS
Case-level marking	• Homogeneous cases: GTIN, batch/lot, expiration date • Heterogeneous or partial cases: serial shipping container code (SSCC)
Pallet-level identification and ASN	• Plan and implement changes to ARTMIS ASN to accommodate SSCC and aggregation data • Identify one or two suppliers to run a pilot to test the new ASN

IMPACT OF CASE-LEVEL GTINS ON PROCUREMENT

Currently, there is a heavy item-level focus on USAID/GHSC-PSM operations (i.e., 30,000 items; 500,000 items; etc.). Although this is necessary to simplify certain activities (e.g., demand planning and quantifying requisition amounts), **case-level** GTINs should be leveraged wherever possible in **procurement** strategies. This lays the foundation for cases to be marked with GTIN, batch/lot, and expiration to support downstream operations and to enable more efficient and less costly procurement when possible. Key steps include the following:

- Define a procurement strategy for rounding up or down based on GTIN case quantity for selected product.
- Because specific products to be used for fulfillment are not selected until later in the process and case quantities vary across suppliers, requisition orders from countries and demand planning can still be based on unit estimates. However, those amounts will be adjusted during procurement based on case quantity for the product selected.
- Ensure ARTMIS can convert item-level requisition amounts to case-level purchase orders. (This should leverage the quantity fields associated with case GTINs in the Product Master.)
- Educate and train GHSC-PSM procurement teams on the case-level purchasing strategy and implementation. They are currently purchasing at the item level, and without training they will not know to implement case-level procurement.
    - *Note:* Supplier requirements for case-level GTINs, batch/lot, and expiration date marking will never be implemented (nor the benefits realized down the chain) unless GHSC-PSM procurement teams actually order by the case. GHSC-PSM must order at the case level for suppliers to implement case-level marking requirements.
- Work with suppliers to develop strategies to max out full cases and full pallets wherever possible, and minimize or eliminate partials.
- Do not limit the discussion and strategy to one product. Enable the evaluation of strategies for orders encompassing multiple products.
- Define the GHSC-PSM preferred strategy for "less than full" case quantities if/when they occur (e.g., would you prefer a full mixed case or a partial homogeneous case?).
- Define the GHSC-PSM preferred strategy for "less than full pallet" quantities if/when they occur (e.g., would you prefer a full mixed pallet or a partial homogeneous pallet?).
- Consider the costs, benefits, and operational impact of both options.

DATA QUALITY COMPLIANCE MONITORING METRICS

As discussed in the GDSN and data quality presentation, data quality is less about technology and more about data governance, organizational discipline. and formalized processes. Also, periodic auditing of certain key attributes to validate that they are correct against the physical product is part of a data quality program. However, GHSC-PSM can be strategic in how it approaches auditing and identification of data quality issues:

- Focus initial data quality efforts on weights and dimensions attributes, which are common areas for data quality issues and can cause significant waste in transport and logistics operations.
- Address errors in weights and dimensions that cause issues for transport and logistics operations (e.g., issues cubing out or weighing out trucks, fines for being overweight, problems with warehouse storage management due to pallets not fitting as expected). Therefore, leverage transport, warehouse, and in-country logistics operations teams to help identify products that need to be checked.
- Communicate the following list of questions to these teams to help them identify the types of issues they should be looking for **and reporting to GHSC-PSM** to help identify data quality issues in weights and dimension attributes:[1]
    - Do your distribution and transportation teams routinely struggle with certain items (e.g., pulling pallets off trucks because products would not fit or are too heavy; pallets too tall to double-stack; pallets too tall for racking)?
    - Does your customer service team routinely get complaints about certain items (e.g., order multiples, adjustments, damages)?
    - Are there certain regional distribution centers (RDCs) and warehouses where it is more challenging to build truckloads than others?
    - Are there cases with excessive head space, causing crushing?
    - Are there pallets with excessive overhang or underhang?
    - Do your distribution and transportation teams report problems with specific cases that have excessive or repetitive instances of damage?
- Formalize a process for transport, warehouse, in-country logistics, and even GHSC-PSM customer service teams to report issues to GHSC-PSM. Specify the GHSC-PSM data quality contact person, periodic reporting of issues, e.g., weekly, monthly, and the information that needs to be reported, e.g., GTINs, problem description, date, shipment, or ASN number.
- Formalize a process for the GHSC-PSM data quality contact person to report issues to suppliers. Require a data quality contact person at the supplier (name, phone number, email); a process for submitting issues, e.g., initial phone call, email, acknowledgement by supplier; and a timeline for the supplier to research and resolve the issue (by updating the data in the GDSN). These requirements may also be added to contracts.

[1] GS1 US Data Quality ROI Calculator for Brand Owners: Transportation Costs & Case Dimensions. GS1 US. 2016.

INSTITUTIONALIZING GS1 STANDARDS

Knowledge about and experience with the standards are key performance indicators. In fact, formalized, ongoing education and training is one of the pillars of a data quality program. The importance of institutionalizing GS1 Standards experience and expertise within GHSC-PSM cannot be overstated.

Formalized Education and Training

GS1 Standards are designed to support supply chain information needs, which are complex and layered. Numerous levels of design are embodied in each standard to support various needs and functionalities, e.g., GTIN structure, segments, length, check digit, and packaging levels.

- Formalized education and training throughout GHSC-PSM will enable teams to cultivate a deeper understanding of the standards to support successful and strategic implementation and use.
- The educational program should support progression from high-level understanding of standards, to technical considerations, to understanding the standards in action.
- Incorporating use-level education, e.g., functional implementations, case studies, best practices, and lessons learned, is important for gaining insight into strategic approaches to implementation based on business processes and use.
- Different teams may focus on different standards education, e.g., the GDSN, GTIN allocation, use of barcodes in receiving operations, enabling the teams to cross-pollinate knowledge and collaborate to bring it all together.

Training for Standards Integration into Business Processes

Implementation of GS1 Standards is not simply a technical/systems effort. In fact, if the standards are not implemented in **business processes** as well as systems, the benefits of the standards will be severely inhibited. For example GHSC-PSM procurement teams need to be trained to order at the case level because if they continue to order at the each level as they do now, GHSC-PSM supplier requirements for case-level GTINs, batch/lot, and expiration date marking will never be implemented and thus the benefits never realized down the chain. Operational teams need to be trained in the use and impact/import of GS1 Standards in their functions.

Documentation of Lessons Learned

GHSC-PSM teams implementing GS1 Standards in systems and operations should be required to submit periodic reports of lessons learned. GHSC-PSM should formally review these reports together on a standing basis, e.g., monthly or quarterly, to promote institutional knowledge sharing and collaborative learning.

GHSC-PSM Supply Chain Management SME Support

Consider incorporating supply chain management (SCM) professional(s) with experience managing supply chain operations using GS1 Standards into the GHSC-PSM team to help institutionalize subject matter expertise (SME).

- This SME can help identify opportunities to evolve business processes and operations across procurement, delivery and return, and warehouse operations to optimize the benefits of using GS1 Standards.
- Also, this SME can provide advice and support for in-country operations as standards implementation progresses.
- Pharmaceutical or medical device **distributors** are recommended, as their experience will more easily align with GHSC-PSM's business model.

GS1-based Regional Distribution Center/Warehouse Management SME

The GHSC-PSM warehouse management request for proposal (RFP) and contract included language about the ability to support and use GS1 Standards. To enforce that provision and ensure that the contractor can fulfill that obligation, it is recommended that GHSC-PSM have the contractor verify that it have someone in management who has significant experience managing RDCs/warehouses with GS1 Standards (identifying them and providing their CV). This SME is necessary to identify any needed process changes and to ensure that the contractor's operations actually leverage the standards to improve operations.

GS1-based Transport Operations SME

If the GHSC-PSM transport RFP and resulting contract with Kuehne + Nagel (K+N) includes language about the ability to support and use GS1 Standards, it is likewise recommended that GHSC-PSM use that provision to require K+N to have onsite management personnel with significant experience in managing storage and transport operations using GS1 Standards. This SME is necessary to identify any needed process changes and to ensure that the contractor's operations actually leverage the standards to improve operations.

FOLLOW-UP TECHNICAL NOTES FOR ARTMIS

Naming GHSC-PSM-specific Attributes and ARTMIS Fields

Care needs to be taken in naming GHSC-PSM-specific attributes and ARTMIS fields so they are clear about precise definitions, especially when they are close to an existing GTIN attribute and/or a regulatory attribute (e.g., pediatric/adult designation).

Global Data Dictionary versus GDSN Attribute Definitions

The GS1 Global Data Dictionary evolved from the use of data in transactions and the preexisting GDSN. Although there is strong overlap across the definitions, GHSC-PSM should leverage the GDSN (through GS1 US Attribute Explorer) for attribute definitions to ensure best understanding of the attributes in the context of master data management and data synchronization.

The Importance of GTIN Metadata Requirements

GTINs must be stored in systems in a fixed length, 14-digit, alpha-numeric field with leading zeros. These metadata requirements were noted in Report 1, but it is important to reinforce **why** they is needed because ARTMIS uses a default field length for most fields:

- GS1 Standards enable manufacturers to assign GTINs in different lengths (8, 12, 13, and 14 digits) depending on needs and applications.

- The GTIN metadata standards enable systems to parse and interpret GTINs no matter how they are assigned.

Sharing GDSN Data With Recipient Countries

In the GHSC-PSM business model, GHSC-PSM operates much like a distributor — with suppliers/manufacturers as their upstream partners and recipient countries as their downstream partners. In this model, downstream partners can receive product information either directly from the manufacturer, or from the distributor.

Although GHSC-PSM will receive GTIN attributes from suppliers/manufacturers through the GDSN, it will need to determine how to best share GTIN attributes with recipient countries for the products USAID/GHSC-PSM provides.

RECIPIENT COUNTRIES

One of USAID's goals is for recipient countries to be able to leverage the GS1 Standards that GHSC-PSM implements to support global health reporting and analytics, as well as their own operations. The following recommendations can help support that goal.

ESTABLISH A RECIPIENT COUNTRY ENGAGEMENT PROGRAM

As GSCS-PSM progresses through implementation and use of various standards, create a formal information exchange program with recipient countries to:

- Inform recipient countries about what GS1 Standards they will be experiencing/seeing with USAID-provided commodities in advance of those requirements sunrising.
- Look to provide practical insights and guidance for how to leverage the standards they will be seeing in their systems and operations.
- Leverage and share the lessons learned documentation developed by GHSC-PSM systems and operational teams (discussed above) to communicate and share this vital information with recipient-country counterparts.

  For example, the program may sponsor an annual or semiannual conference for recipient countries where GHSC-PSM and supply chain experts share insights based on their implementation experience that the countries can use for their own implementations and provide guidance on how to use the standards in their operations and business processes.

ADDRESS REGULATORY NEEDS

Some recipient countries are examining whether they should also adopt GS1 Standards and integrate them into regulatory requirements. These efforts would extend implementation of GS1 Standards across all commodities in the country, not just those provided by USAID.

Nonetheless, recipient countries today have certain regulatory needs. Although not standards-based, they will undermine the benefit and use of standards for such activities as traceability and authentication.

For example, in our report entitled *Ethiopia Anticounterfeit Pilots: Recommendations and Insights,* we discussed the importance of regulatory requirements for pharmaceutical packaging disposal. Disposed pharmaceutical packaging is a cheap, easy packaging option for counterfeiters. They simply collect the trash from facilities, and in return, get free, authentic packaging in which they can distribute their counterfeit goods. Many countries around the world have strict packaging disposal regulations for just this reason; however, Ethiopia does not. The pilot was looking to test an app that enables users to scan a GS1 barcode + serial number from a product label to authenticate the product and enhance patient safety. **However, counterfeit products in stolen/recycled packaging will be read as authentic** — completely undermining the valuable use of GTIN + serial number.

Therefore, beyond supporting regulatory requirements for GS1 Standards, it is also important to support regulations to resolve issues that inhibit a country from taking advantage of all that the standards have to offer, for example:

- Pharmaceutical packaging disposal regulations
- Customs procedures (to tie legal entry documents to supply chain information through SSCC, ASN, etc.)

DONOR COMMUNITY AND LONG-TERM STRATEGIES

GLOBAL LOCATION NUMBER STRATEGY

Location and party identification and data quality are significant issues within the USAID/GHSC-PSM supply chain in particular and across the global health supply chain in general. Evaluation of GS1 Global Location Numbers (GLNs) will be a longer-term strategy due to issues of compatibility with ARTMIS, as well as questions on how to implement by various actors, including recipient countries. Key considertions include the following:

- Each party assigns GLNs to its own location, defines the related party/location data associated with the GLN, and shares the GLN and data with its trading partners.
- Manufacturers will likely need only a few GLNs to support GHSC-PSM operational needs, e.g., manufactured-by, shipped-from.
- GHSC-PSM will likely need only a few GLNs, e.g., ordered-by, bill-to, warehouse locations, RDC locations.
    - *Note:* Since the original writing of this report, it has been discovered that GHSC-PSM is subcontracting warehouses and distribution centers. Therefore, GHSC-PSM would not assign those GLNs. Instead, the subcontractor would actually assign the GLNs to those locations.
- The real challenge involves the recipient countries, which have large, in-country distribution channels, often with hundreds of locations that would need GLNs.
- Although the supply chain ends for GHSC-PSM at the Central Medical Store (CMS)/Medical Stores Department (MSD) locations, there is a need for party/location information throughout the rest of the in-country distribution channel to support collaborative efforts, as well as global health reporting and analytics.
- Questions remain about who is best positioned to assign and manage GLNs, such as the country or a consortium of donor organizations.
- It is recommended that the donor community and recipient countries work together to assess and evaluate.

GLOBAL HEALTH COMMODITY CODES

- There is a need for commodity categories/classifications to be standardized across the global health supply chain so that all of the donor organizations and recipient countries can use the same commodity codes/values to support ordering, reporting, analytics, etc.
- GHSC-PSM evaluated various options when designing ARTMIS, including developinga new classification system for global health commodities.
- Ultimately, GHSC-PSM decided to use the United Nations Standard Products and Services Code for pharmaceuticals and GS1 Global Product Classification for medical devices and other commodities.

- If implementation and use of these classifications prove sufficient for global health commodity classification needs, USAID/GHSC-PSM should share this approach with the donor community and recipient countries to consider.

ANNEX 1. THE GHSC-PSM SUPPLY CHAIN

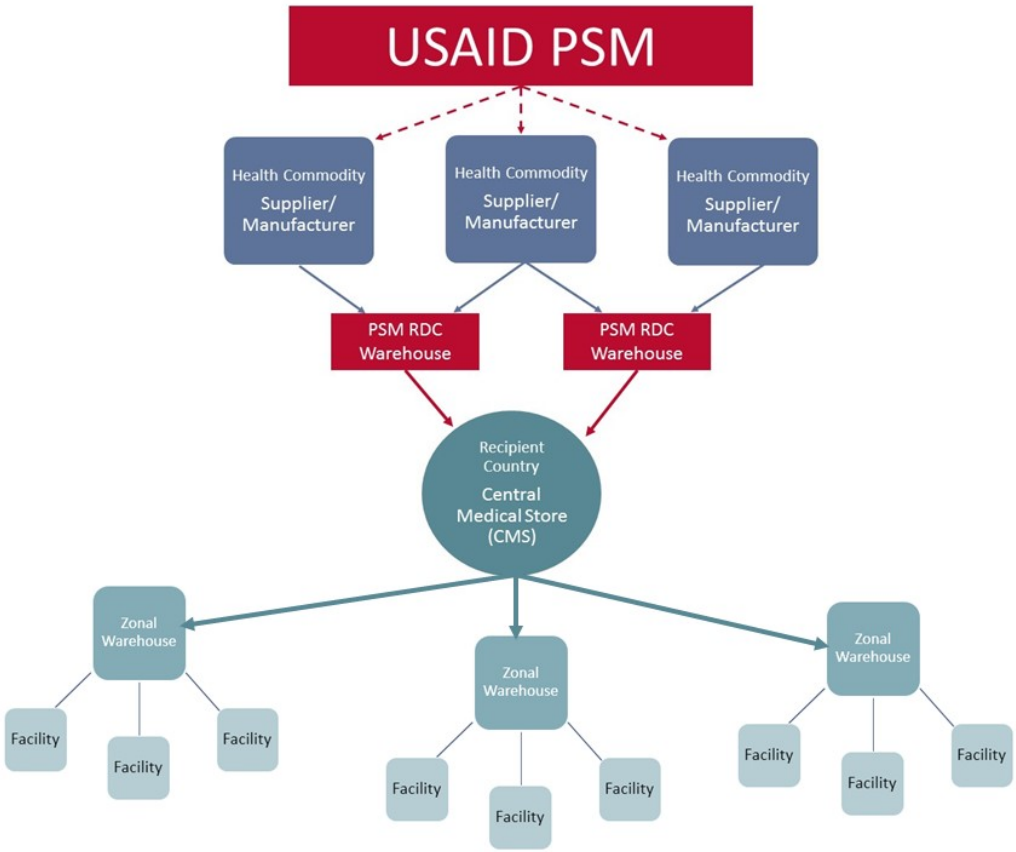
For this discussion, key members of the GHSC-PSM supply chain include GHSC-PSM Sourcing/Procurement, suppliers/manufacturers, GHSC-PSM warehouses RDCs, and the recipient country's Central Medical Store. GHSC-PSM operational and logistics activities end at the CMS.

Note: Although GHSC-PSM operational activities end at the CMS, USAID support and efforts in-country continue beyond the CMS, and it is a long-term goal for countries to be able to leverage the GS1 Standards that GHSC-PSM implements to support global health reporting and analytics, as well as their own operations. Therefore, they have been included in this discussion as well.

SNAPSHOT OF PARTICIPANTS AND PRODUCT FLOW

For simplicity, the diagram shows suppliers/manufacturers shipping only to GHSC-PSM RDCs and warehouses. However, they also ship directly to the country in certain circumstances.

Figure 1. Overview of the GHSC-PSM supply chain



CORE BUSINESS PROCESSES

As GHSC-PSM develops its implementation plan, it is essential to focus on the business processes being performed by the various participants. Research and analysis revealed the following core business processes for each participant.

Note: Where identified, the level at which each business process is conducted is noted in the table. It is important to differentiate between pallet-level, case-level, and item-level operations to understand standards needs and establish implementation priorities.

Supply chain participant	Core processes
USAID GHSC-PSM – Sourcing and Procurement	Product master data management (MDM) and data quality Demand planning and requisition management (commodity level) Order-to-cash transactions (product level)
USAID GHSC-PSM – warehouses and RDCs	Efficient receiving (pallet level) Disaggregation management First in, first out (FIFO) management Aggregation management Shipping
Recipient-country CMS/MSD	Product MDM Efficient receiving (pallet and/or case level) Disaggregation management (pallet to case) FIFO management (case level) Order management (case level) Aggregation management (level varies) Shipping
Recipient-country hubs and warehouses	Efficient receiving (level varies) Disaggregation management (package to case) FIFO management (case level) Order management (case level) Aggregation management Shipping
Recipient-country facilities	Efficient receiving (case level) Disaggregation management (case to item) FIFO management (item level) Inventory management (commodity level)

- GHSC-PSM supply chain activities are conducted at different levels: pallet, case, item commodity. Be acutely aware of each level when assessing standards needs and designing implementation/use strategies.
- Key standards implementation activities to support Sourcing/Procurement are product identification (GTINs), master data management (GDSN), and order-to-cash transactions.
- Key standards implementation activities to support all other participants include barcoding, logistics labelling, and logistics transactions (like ASN).

OPERATIONAL CONSIDERATIONS

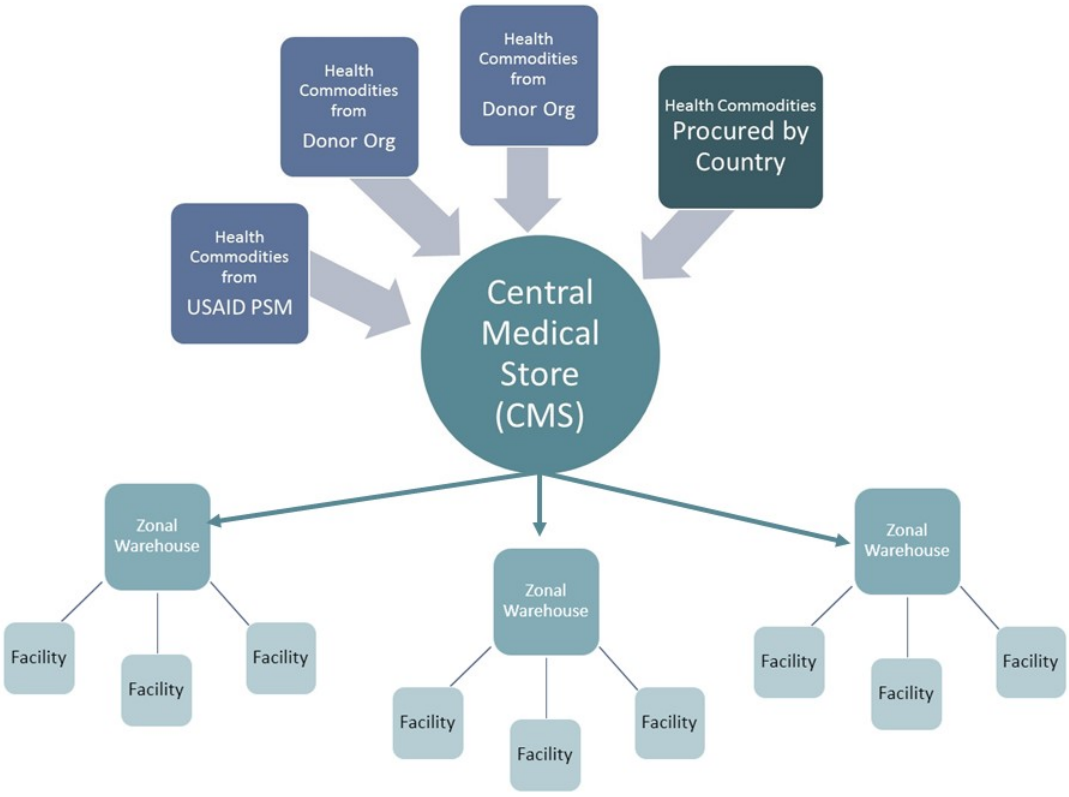
Research throughout the GS1 Standards project revealed the following operational considerations that should help guide prioritization of standards implementation activities across GHSC-PSM:

- USAID demand planning and country requisition activities are conducted at the commodity level with quantities expressed in terms of "eaches," e.g., 30,000 units; 500,000 units.
- Orderable unit for GHSC-PSM procurement was also described as the each level.
- Batch/lot number and expiration date are essential information for SCM activities throughout the channel.
- Visibility of batch/lot number and expiration date at the case level is key, as cases are not broken down to items until they reach the facility.
- There is an unknown level of breaking down inbound pallets and repalletizing cases for outbound shipment at GHSC-PSM warehouses and RDCs.
- In-country, CMS breaks down pallets to cases, stores cases, and configures cases for shipment to hubs.
- Hubs break down inbound deliveries into cases and configure cases for shipment to facilities.
- Facilities break down cases and manage inventory at the each level.
- Disaggregation and aggregation activities across the channel are not currently supported by standardized pallet-level identification.

ANNEX 2. THE GLOBAL HEALTH SUPPLY CHAIN

The global health supply chain is extremely complex: numerous donor organizations runnumerous health initiatives to provide numerous health commodities from numerous suppliers to numerous recipient countries. Regardless of source, all health commodities are received in country at a Central Medical Store or Medical Store Department. From there, recipient countries manage the in-country distribution channel to distribute health commodities throughout their country (from the CMS/MSD, to zonal warehouses or hubs, to sub-hubs, and ultimately to facilities).

Figure 2. Receipt and distribution of health commodities in recipient countries



Today, there is no widespread use of supply chain standards by the donor community or recipient countries, creating operational and informational challenges for all participants. USAID's adoption of GS1 Standards, along with its partnerships and collaboration with other donor organizations and recipient countries, provides an opportunity for positive transformation across the global health supply chain. This is the long-term, larger vision. USAID GHSC-PSM's implementation of GS1 Standards is the first step. Still, it is essential to bear that larger vision in mind to support strategy development throughout GHSC-PSM's implementation of GS1 Standards.

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