USAID GLOBAL HEALTH SUPPLY CHAIN PROGRAM

Procurement and Supply Management









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Contents

Contents I	
Acronyms 2	
Context 4	
Problem Statement 4	
What is Product Master Data Management? 5	
Lessons Learned 6	
Lesson I: Start with a Minimum Dataset 6	
Lesson 2: Reduce Complexity of Data Architecture 7	
Capturing and Maintaining Trade Item (Packaging) Hierarchies 8	
Lesson 3: Maintain a Core Set of Product Classifications Linked to Trade Items 9	
Classification for Treatment Guidelines 10	
Classification for Procurement and Planning II	
Lesson 4: Manage Discrepancies in Unit of Measure (UOM) Conversion II	
Lesson 6: Design PMD for Supply Chain Automation and Optimization 13	
Lesson 7: Gauge whether a National or Localized PMD Architecture is Required 15	
Lesson 7: Gauge whether a National or Localized PMD Architecture is Required 15 Lesson 8: Empower Workforce for PMDM 17	
Lesson 8: Empower Workforce for PMDM 17	
Lesson 8: Empower Workforce for PMDM 17 Lesson 9: Establish a Process for Sourcing PMD 19	
Lesson 8: Empower Workforce for PMDM17Lesson 9: Establish a Process for Sourcing PMD19Annex A. Product Master Data Governance Roles and Responsibilities22	
Lesson 8: Empower Workforce for PMDM17Lesson 9: Establish a Process for Sourcing PMD19Annex A. Product Master Data Governance Roles and Responsibilities22Annex B. Catalog Manager Job Description23	
Lesson 8: Empower Workforce for PMDM 17 Lesson 9: Establish a Process for Sourcing PMD 19 Annex A. Product Master Data Governance Roles and Responsibilities 22 Annex B. Catalog Manager Job Description 23 Role Overview 23	
Lesson 8: Empower Workforce for PMDM 17 Lesson 9: Establish a Process for Sourcing PMD 19 Annex A. Product Master Data Governance Roles and Responsibilities 22 Annex B. Catalog Manager Job Description 23 Role Overview 23 Expected Deliverables 23	
Lesson 8: Empower Workforce for PMDM 17 Lesson 9: Establish a Process for Sourcing PMD 19 Annex A. Product Master Data Governance Roles and Responsibilities 22 Annex B. Catalog Manager Job Description 23 Role Overview 23 Expected Deliverables 23 Technical Competencies 23	
Lesson 8: Empower Workforce for PMDM 17 Lesson 9: Establish a Process for Sourcing PMD 19 Annex A. Product Master Data Governance Roles and Responsibilities 22 Annex B. Catalog Manager Job Description 23 Role Overview 23 Expected Deliverables 23 Technical Competencies 23 Managerial Competencies 23	
Lesson 8: Empower Workforce for PMDM 17 Lesson 9: Establish a Process for Sourcing PMD 19 Annex A. Product Master Data Governance Roles and Responsibilities 22 Annex B. Catalog Manager Job Description 23 Role Overview 23 Expected Deliverables 23 Technical Competencies 23 Managerial Competencies 23 Skills/Training 24	
Lesson 8: Empower Workforce for PMDM 17 Lesson 9: Establish a Process for Sourcing PMD 19 Annex A. Product Master Data Governance Roles and Responsibilities 22 Annex B. Catalog Manager Job Description 23 Role Overview 23 Expected Deliverables 23 Technical Competencies 23 Skills/Training 24 Required 24	

Acronyms

AIDC	Automated Identification and Data Capture
API	Application Programming Interface
ATC	Anatomical Therapeutic Chemical
CMS	Central Medical Store
DDD	Defined Daily Dose
DNS	Domain Name System
eLMIS	Electronic Logistics Management Information System
ERP	Enterprise Resource Planning
FDA	Food and Drug Administration
FTP	File Transfer Protocol
GDSN	Global Data Synchronization Network
GHSC-PSM	USAID Global Health Supply Chain-Procurement and Supply Management
GMDN	Global Medical Device Nomenclature
GPC	GS1 Global Product Classification
GTIN	Global Trade Item Number
HIE	Health Information Exchange
IP	Internet Protocol
MDM	Master Data Management
MoH	Ministry of Health
NPC	National Product Catalog
PCMT	Product Catalog Management Tool
PIM	Product Information Management
PMD	Product Master Data
PMDM	Product Master Data Management
SKU	Stock Keeping Unit
SMART	Standards-based, Machine-readable, Adaptive, Requirements-based, and Testable
SMTP	Simple Mail Transfer Protocol
SOP	Standard Operating Procedure
UMDNS	Universal Medical Device Nomenclature System
UNSPSC	United Nations Standard Product and Services Code
UOM	Unit Of Measure
USAID	United States Agency for International Development
WHO	World Health Organization
WMS	Warehouse Management System

Context

The U.S. Agency for International Development (USAID) has funded several activities to advance the use of global standards for improved supply chain data visibility and product traceability in USAID partner countries. These activities have included standardizing product identification protocols and implementing product master data (PMD) programs. In Ethiopia, Malawi, Rwanda, and Zambia, the National Product Catalog (NPC) programs have leveraged an open-source product information management (PIM) tool called Product Catalog Management Tool (PCMT), which allows organizations to publish and manage product catalogs. PCMT is an open-source software based on Akeneo. As more countries are looking to implement similar programs, there is a need to document lessons learned during these NPC reference implementations to inform national strategies for deploying national product master data management (PMDM) programs. It is recognized that PMD should be supplemented with transactional and event data such as batch/lot and/or serial for precise product identification and visibility. However, please note that transaction and event data types are out of the scope of this document.

HIGHLIGHTS OF PMDM LESSONS

- Flexible data models & hierarchies
- Applies product classifications
- Integrates easily with enterprise applications
- Delivers against use cases
- Empowered PMDM workforce
- Reliable data sources

Problem Statement

Ethiopia, Malawi, Rwanda, and Zambia are examples of countries that have deployed PMDM programs. As more countries are looking into similar programs, there is a need to reflect on the best approaches to actualize these programs in a way that meets the scale and the unique needs for their implementation. However, published resources on PMDM have focused on normative approaches, with few resources available that draw on experiences in the context of low- or middle-income countries. This document aims to address this gap by drawing on PMDM lessons, challenges encountered (Figure 1), and successes from these countries to guide future implementations of PMDM programs in other low- and middle-income settings.

FIGURE I

Documented Challenges of PMDM in Reference Implementations

Data Architecture

- Different identification protocols in the supply chain limit data harmonization
- Complexity in managing and maintaining data hierarchies in PIM solutions
- Maintaining attributes in PIM that do not support the intended use case

Integration

- Challenges with UOM conversion
- Change in file structure (additional configuration attributes add extra fields in the export profile)
- Out-of-the-box PIM API capability not always compatible with the country approach to PMDM
- GDSN integrations can be complex, for example, receiving published changes to data requires rigorous change processes

Workforce Capacity

Use Case

- Lack of formalized training for PMDM
- Role of pharmacist under-resourced
- Lack of dedicated PMDM resources
- Missing technical resources to sustainably support PIM development & operations

- Lack of a clearly defined business case leads to

expensive configuration costs, lack of data maintenance,



NPC Challenges

Data quality

- GTIN data collection and validations highly manual
- Missing and incomplete data fields
- Missing hierarchy (each, pack, case, pallet) information for most GTINs

Regulations & Digital Supply Chain Readiness

- Absence of HIE infrastructure to support data exchange between PIM and other systems
- Lack of regulation on standardized identification, capture, and exchange based on standards

Infrastructure and Scalability

and an unresponsive governance

- Lengthy approval process of setting up DNS and public IP & testing environment
- Intermittent internet interruptions, firewall changes (connectivity issues)
- Mail server connectivity (SMTP configuration), server low in disk space
- Lack of infrastructure for monitoring and alerting tools

Governance

- Data sharing agreements/requests with suppliers prone to delays in the absence of regulations
- Lack of collaboration between key stakeholders (MOH, FDA, CMS)
- Lack of direct communication with suppliers and manufacturers to request product data
- Lack of leadership in executing a transition plan to in-country resources

Acronyms: API, Application Programming Interface; CMS, Central Medical Store; DNS, Domain Name System; FDA, Food and Drug Administration; GDSN, Global Data Synchronization Network; GTIN, Global Trade Item Number; HIE, Health Information Exchange; IP, Internet Protocol; MOH, Ministry of Health; PCMT, Product Catalog Management Tool; PIM, Product Information Management; PMDM, Product Master Data Management; SMTP, Simple Mail Transfer Protocol; UOM, Unit Of Measure.

What is Product Master Data Management?

Master data refers to the core information about products¹, customers, suppliers, and locations an organization relies on to run its business.

PMDM is a set of processes, technologies, and tools organizations use to ensure the accuracy, consistency, and completeness of their PMD. PMDM helps organizations create a single, unified view of their master data across all their systems and applications.

PMDM is a powerful tool that can help organizations:

- Improve the quality of their data
- Enhance data governance and compliance
- Reduce data silos
- Improve decision making
- Increase operational efficiency



PHOTO CREDIT: USAID GHSC-PSM

1. In this document, the terms "product" and "trade item" are not interchangeable. The term "product" is used when referring to the generic form of a pharmaceutical good (i.e., not brand-, manufacturer-, or pack-specific) or to refer to the general concept of PMD, which may encompass product/trade item hierarchies. The term "trade item" is used when referring to a manufacturer- and pack-specific instance of the generic product that can be priced, ordered, invoiced, or marketed at any point in the supply chain.

Lessons Learned

PMDM can be implemented in various ways, either as a single instance for the entire country, usually deployed through an NPC approach, or modularly to meet a specific use case, such as at the national warehouse. Either approach creates a source of truth for PMD, allowing organizations to track changes to data more easily and to ensure that it complies with all applicable regulations. The approach taken by a country should be driven by the use case or problem(s) that the PMDM program seeks to address. A PMDM use case describes how users will interact with PMD and the pain points that will be addressed from such deployments. The deployment of PMD solutions without a clearly defined use case may fail to scale, incur unnecessary expenses, or become another investment that is not used. Functional and data requirements, including the number of attributes, data structures, system requirements, and governance, will vary depending on how users are intended to interact with PMD information. This document presents some of the key lessons from PMDM deployments from USAIDsupported implementations in several low- and middle-income countries.

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Lesson 1: Start with a Minimum Dataset

We recommend identifying a minimum number of attributes required to support core functions initially (Table I) and evaluating the need for additional "nice-to-have" data in the future as the PMDM program matures.

The number and complexity of the attributes captured and maintained in an NPC solution directly impact the level of effort required to source and maintain the associated data. As a result, we recommend identifying a minimum number of attributes required to support core functions initially (Table 1) and evaluating the need for additional "nice-to-have" data in the future as the PMDM program matures. Attributes are characteristics of a product or trade item that distinguish it from similar concepts or commodities. A key to successful implementation is to gain a clear understanding of the data landscape and develop simple and flexible data model solutions that align with the country's use case. Countries implementing PMDM/NPC should invest in a thorough assessment of their data architecture (few hierarchies, if possible, and a limited set of attributes in initial implementation). This approach eliminates compatibility challenges, minimizes the need for complex transformation logic in data integrations, and reduces the level of effort for managing and maintaining the data in PCMT.When deploying a PIM solution, internal stock keeping units (SKUs) for systems targeted for integration, such as a warehouse management system (WMS), must be represented as attributes at the product level in the PIM solution to establish linkages with NPC data.

	Attribute groups	Attribute
	Product information	Generic name, product short description, product description, strength
	Product code	UNIQUE_ID (PCMT SKU), MSL SKU
Product	Product classification	Level of prescribing,VEN, category of distribution, ATC code, UNSPSC code, GPC code
	Pharmacy	Product form, dosage form, pack count,pack measure, route of administration
	GSI general items information	GTIN,Trade item unique descriptor code, barcode type, brand name
	GSI product description information	Trade item description, description short, variant
	GSI unit indicators	IS A base unit, IS A consumer unit
	GSI dimensions	Gross weight, net weight, packaging weight, height, width, depth, volume, diameter; net content
GTIN trade item	GSI contact / role information	Market authorisation no, market authorisation holder; market authorisation holder address, information provider GLN, information provider name, information provider address, manufacturer GLN, manufacturer name, manufacturer address
	GSI classifications	GPC code, ATC code
	GSI pharmaceutical information	Dosage form type code reference, route of administration code value, route of administration code description
		Options (base unit or each, pack or inner pack, case, pallet, display shipper, mixed module, transport load)
	GSI hierarchy	Child next lower level GTIN item, quantity of next level trade item within inner pack, quantity of next lower-level trade item, total quantity of next lower level trade item
	General item information	Trade item unique descriptor, brand name, trade item description, strength
	Product code	UNIQUE ID, child trade item SKU
Non GTIN	Unit indicators	Is trade item A base unit
trade item	Dimensions	Gross weight, height measure, width measure, depth measure, volume measure, net content, net content UOM, packaging, pack count, pack measure, unit size, base unit multiplier
	Contact / Role information	Manufacturer name, manufacturer location, market authorisation holder, market authorisation no, market authorisation holder address



Lesson 2: Reduce Complexity of Data Architecture

Countries should limit the number of parent-child relationships to only what is critical for the business needs.

Part of the process involves aligning master data to manage trade items at different packaging levels as products move through the supply chain. For example, receiving items into a warehouse at the case level and packing them at an inner pack level. This involves organizing and categorizing PMD into a (tree-like) structured hierarchy based on shared attributes and characteristics and managing each trade item uniquely while establishing the parent-child relationships between those trade items and the generic "product level." It is recommended to begin with a two-tier data structure that includes a "product" layer as the parent and a "trade item" layer as a child.

• Product-Level Data: This represents the generic product level based on a limited set of defining characteristics such as active pharmaceutical ingredient, dosage, dosage form, and pack size. This level is the most common at which the WMS and the electronic logistics management information system (eLMIS) establish internal identifiers, such as Product Codes or SKUs. Supply chains procure, stock, and distribute at this level of product

FIGURE 2

Simplified Data Structure Product-Item-Trade Item Hierarchy



definition to promote visibility for planning, replenishment, and dispense. Supply chains require visibility of the overall supply and demand of the generic product for planning and response to supply imbalances.

• Trade Item-Level Data: This level of data is essential for uniquely identifying a specific manufacturer's product within the supply chain. This layer will associate Global Trade Item Numbers (GTINs), packaging hierarchies, and associated attributes with a generic product. WMS solutions can be configured to show the association between the generic product or SKU and supporting data to identify each product manufacturer, GTINs for each level of the item packaging hierarchy, and other attributes, including pack UOM and associated UOM conversions, and pack dimensions and weights. Supply chains leverage Net Content and packaging dimensions (volumetrics) to automate and optimize supply chain operations.

This hierarchy is also known as a parent-child relationship where multiple unique "child" items and trade items are associated with a "parent" product, as shown in Figure 2.

Note that the presented scenario is focused on trade item-level packaging. Additional capabilities, such as receiving a Serial-Shipping Container Code (SSCC) against an advanced shipping notice, are needed to enable parent-child relationship between logistic units and trade items. When establishing parentchild relationships, it is important to consider the PIM solution's capability to maintain those relationships in data. Ideally, PIMs should be configured to support simple select-type attributes, meaning the values should be already configured and prepopulated in the attribute value list for a catalog manager to add an item or trade item record. This would avoid the manual (user) generation of keys to establish the parent-child relationships, which can be error-prone and introduce duplications in creating the same record with different keys.

Capturing and Maintaining Trade Item (Packaging) Hierarchies

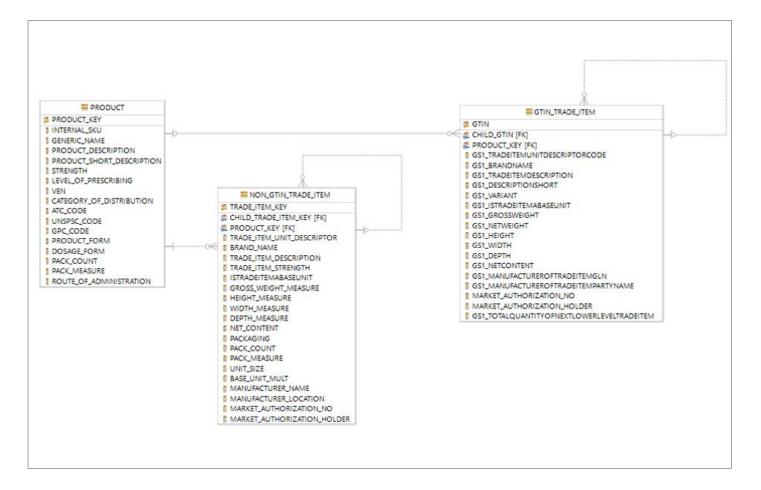
In addition to managing parent-child relationships between the products and trade items, PMD needs to establish relationships between different packaging hierarchies (pallet, case, pack, each). In instances where the GTIN is available, it should be assigned as a unique identifier (primary key), and the relationship between the packaging hierarchies should then be defined using GTIN and Child GTIN. The quantity of child trade items should be captured in the GS1_ TOTALQUANTITYOFNEXTLOWER-TRADEITEM attribute. The packaging type (pallet, case, pack, each) is captured in the GS1_ TRDEITEMDESCRIPTORCODE attribute.

In a scenario where a GTIN is not available, a TRADE_ITEM_KEY should be assigned, and the relationship between the packaging hierarchies should be defined using the CHILD_TRADE_ITEM_KEY attribute. The packaging UOM (pallet, case, pack, each) should be captured in the TRADE_ITEM_UNIT_DESCRIPTOR attribute.The BASE_UNIT_MULT attribute captures the number of eaches in each packaging hierarchy.

Figure 3 presents a recommended two-level data architecture (producttrade item) with built-in trade item-level hierarchies harmonizing both GTIN and non-GTIN trade items under one generic product.

FIGURE 3

Recommended Data Model: Product-Trade Item, GTIN, and Non-GTIN Data Architecture





Lesson 3: Maintain a Core Set of Product Classifications Linked to Trade Items

Multiple classification structures can be maintained within a master data structure to enable various business processes, e.g., spend analysis, financial analysis, procurement, strategic sourcing, tendering, enterprise resource planning (ERP), and asset management.

Product classification can be defined as a process for grouping products into categories based on similar properties and relationships between them. A classification system is used to group products into categories, such as medical devices or pharmaceutical drugs, at various levels of detail. Classifications are the foundation of commodity analytics and improve the ability to roll up or drill down into commodity-related information. Established classification systems commonly used in healthcare include:

- GS1 Global Product Classification (GPC)
- United Nations Standard Product and Services Code (UNSPSC)
- Anatomical Therapeutic Chemical/ Defined Daily Dose (ATC/DDD)
- Global Medical Device Nomenclature (GMDN)
- Universal Medical Device
 Nomenclature System (UMDNS)

A key challenge in managing classifications for PMDM is the availability of qualified pharmacists to represent classification information accurately in the PMD data structures. The extent to which these different classification structures must be incorporated and managed through the PMDM program should be determined by the use case; for example, a Procurement Specialist may receive training in UNSPSC, which enables reporting on spend and consumption at various levels of detail across many product categories, including pharmaceuticals, medical devices, and consumables.

Classification for Treatment Guidelines When treatment guidelines are the primary use case for PMDM deployment, it is recommended to maintain ATC as the primary classifier for PMD. This should be accompanied by a limited set of defining characteristics such as active pharmaceutical ingredient, dosage, and dosage form hosted in dispensing or

- ATC Code
- Product Description
- Dosage Form
- Strength
- UNSPSC Code
- Active Ingredient
- Route of Administration

Illustrative attributes to support treatment guidelines

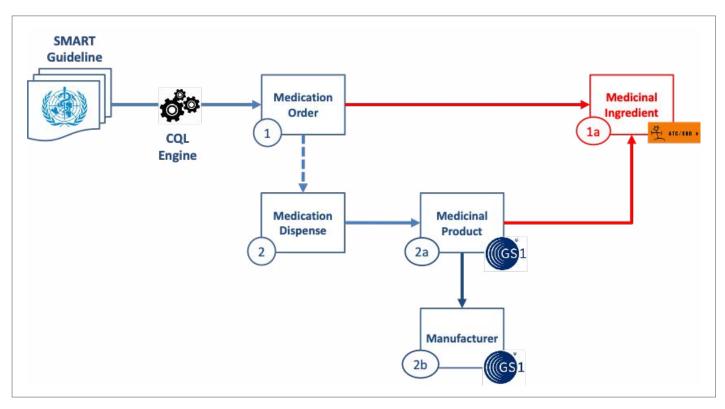
point-of-service systems such as the eLMIS or DHIS2 software.

ATC classifications play a critical role in the operationalization of treatment guidelines such as the World Health Organization (WHO) Standards-based, Machinereadable, Adaptive, Requirements-based, and Testable (SMART) guidelines, a set of clinical, public health policy, and data recommendations to advise countries on health interventions and evidence-based practices for improving the health of individuals and populations.

Similar workflows to guide treatment administration exist at the national level, such as the Level of Prescribing guidelines or the VEN system for classifying vital,

FIGURE 4

Example of Classification in Prescribe/Dispense Clinical Quality Language



essential, and non-essential medicines. These guidelines leverage medicinal ingredient codes, such as the WHO's ATC code, to dispense drugs. The goal is to ensure the classifications and attributes provide a common description of products with the same performance characteristics, which can be substituted for one another (e.g., two syringes with differing product descriptions from two different manufacturers but designed for the same purpose or use). This aligns with treatment guidelines allowing therapeutic substitution of an originally prescribed drug with an alternative molecule with an assumed equivalent therapeutic effect. As countries advance in their traceability implementation and adopt point-ofdispense scanning to increase efficiencies in service delivery care, such as minimizing medication errors, the PMD should be further developed. It should include additional attributes at the trade item level and the relationships established between the generic product (2a) and the trade item instance of that product at the GTIN level (2b). The GTINs can associate multiple manufacturers of a trade item to the generic ATC/GMDN product code, thus facilitating the capture of unique trade item data (e.g., shelf life) and the use of point-of-dispense scanning (Figure 4).

Classification for Procurement and Planning

Where procurement and planning are the primary use cases, UNSPSC classification codes are recommended as the primary classifier. UNSPSC helps perform tactical and strategic sourcing at different levels, integrate business needs, and prevent undisciplined procurement processes. For example, the USAID Global Health Supply Chain Program-Procurement and Supply Management (GHSC-PSM) program extends the hierarchical UNSPSC commodity classification system a level down to add more differentiation to the commodities already in the UNSPSC. This extension aids procurement by adding typical active drug strengths (e.g., 200 mg) and form factors (e.g., pill, capsule) in a consistent schema (Figure 5).

FIGURE 5

Example of GHSC-PSM UNSPSC Level 5 Data Schema

	Segment	51000000 Dru	gs and Pharma	aceutical Products
8	Family	51340000	Antiviral drugs	5
	Class	513438	00 Combinatio	on antivirals
	Commo	lity 51	343801 Abaca	vir/lamivudine
		51343801	100100AAA06Z	Abacavir/Lamivudine 60/30 mg Tablet, 30 Tablets
		51343801	100100AAA07G	Abacavir/Lamivudine 60/30 mg Tablet, 60 Tablets
		51343801	100101AAA06Z	Abacavir/Lamivudine 600/300 mg Tablet, 30 Tablets
		51343801	100101AAA0A1	Abacavir/Lamivudine 600/300 mg Tablet, 10 Blister Pack Tablets
		51343801	100100AAK07G	Abacavir/Lamivudine 60/30 mg Dispersible Tablet, 60 Tablets
		51343801	103181AAK06Z	Abacavir/Lamivudine 120/60 mg Scored Dispersible Tablet, 30 Tablets
		51343801	103181AAK07G	Abacavir/Lamivudine 120/60 mg Scored Dispersible Tablet, 60 Tablets



Lesson 4: Manage Discrepancies in Unit of Measure (UOM) Conversion

A key challenge in managing packaging hierarchies is that hierarchy information for each packaging (pallet, case, each) needs to be available for UOM conversion.

Missing a packaging record (e.g., case) in the master data will break the relationship and ability to calculate the total of eaches in a pallet. Therefore, it is crucial to ensure that data is available for all packaging levels (Figure 6).

UOM codes in the PIM must align with the coding structure of data sources. For example, PCMT is configured to capture the UOM description (MILLIMETRE, GRAM, etc.) in the GS1 configured attributes (example in Figure 7). However, the Global Data Synchronization Network (GDSN) data uses the standard codes (MMT, MTR) published by GS1.This creates complexity in the data integration/ automation. A transformation logic will be needed to convert the codes into descriptions while inserting them into the PCMT. Similarly, additional transformation is required while exporting the data from PCMT to downstream systems. It is recommended to fix the issue within a PIM solution to align with the standard codes.

FIGURE 6

Sample Data Extract from PCMT

PRODUCT_ GTIN_TRAD		GSJ TRADEITEMUNITOR		651 GR05	Gross	GS1 NET	GS1 NETWEI		G\$1 HEIGHT-	GS1 WIDT	GS1 WIDTH-	GS1 DEPT			GST INBOXCUREDIM			GS1_GTIN_CHILD_NE	
products	GTIN	SCRIPTORCODE	GS1_TRADEITEMDESCRIPTION	SWEIGHT	Uom	WEIGHT	GHT-unit	GS1_HEIGHT	unit	н	unit	H .	unit	ENSION	ENSION-unit	ONTENT	unit	EITEMINFORMATION	RADEITEM
P10010	05901175600052	BASE_UNIT_OR_EACH	Lopinavir/Ritonavir 200/50 mg Tablet- 120 Tablet	245 0000	GRAM	149.0000	GRAM	115 0000	MILLIMETRE	76 0000	MILLIMETRE	115,0000	MILLIMETRE	0 0006	CLIDIC MILLIMETRE	120 0000	COUNT		
P10010	58901175600057	CASE	Lopinavir/Ritonavir 200/50 mg Tablet- 120 Tablet	7.3500	KILOGRAM	4.4700	KILOGRAM	310.0000	MILLIMETRE	275.0000	MILLIMETRE	310.0000	MILLIMETRE	0.0006	CUBIC MILLIMETRE	30.0000	COUNT	08901175500052	30
P10010	78901175600051	PALLET	Lopinavir/Ritonavir 200/90 mg Tablet- 120 Tablet	188.4000	KILDGRAM	107.2800	KILOGRAM	108 0000	CENTIMETRE	0000.08	CENTIMETRE	1.0000	CENTIMETRE	0 0006	CUBIC MILLIMETRE	24.0000	COUNT	58901175500057	24

FIGURE 7

Sample UOM extract from PCMT

Column19 💌	Column20	Column21	Column22	Column25 💌	Column26	Column27 💌	Column28	Column29 💌	Column30 👻	Column31 💌	Column32
GS1_GROSSWEIGHT	Gross Weight Uom	GS1_NETWEIGHT	GS1_NETWEIGHT-unit	G\$1_HEIGHT	GS1_HEIGHT-unit	GS1_WIDTH	GS1_WIDTH-unit	GS1_DEPTH	GS1_DEPTH-unit	GS1_INBOXCUBEDIMENSION	GS1_INBOXCUBEDIMENSION-unit
245.0000	GRAM	149.0000	GRAM	115.0000	MILLIMETRE	76.0000	MILLIMETRE	115.0000	MILLIMETRE	0.0006	CUBIC MILLIMETRE
7.3500	KILOGRAM	4.4700	KILOGRAM	310.0000	MILLIMETRE	275.0000	MILLIMETRE	310.0000	MILLIMETRE	0.0006	CUBIC MILLIMETRE
188.4000	KILOGRAM	107.2800	KILOGRAM	108.0000	CENTIMETRE	80.0000	CENTIMETRE	1.0000	CENTIMETRE	0.0006	CUBIC MILLIMETRE
10.0800	KILOGRAM	7.9080	KILOGRAM	240.0000	MILLIMETRE	290.0000	MILLIMETRE	430.0000	MILLIMETRE	29928000.0000	CUBIC MILLIMETRE
195.2500	GRAM	150.0000	GRAM	103.8000	MILLIMETRE	67.7000	MILLIMETRE	67.7000	MILLIMETRE	292.6000	CUBIC MILLIMETRE

Another notable challenge countries faced is the inconsistencies in capturing packaging hierarchies in downstream systems. In most countries' current state of PMDM, each downstream system has a different way of capturing packaging hierarchies. A typical WMS (Figure 8) uses a supporting UOM table as a unique identifier, typically a manufacturer-specific trade item and its packaging. In the example, the relationship between GTIN and its next lower level GTIN (CHILD) is defined by the (Lower UOM) attribute. The system also captures the lowest UOM at each packaging hierarchy (for example, 720 "each" units in a pallet, 30 "each" units in a case, and one "each" unit at the base unit), making it easy for the UOM conversions. However, this attribute is a calculated field in WMS and heavily dependent on all the packaging hierarchies of a trade item being available in the PIM solution integrated with the WMS. In the case of PCMT, converting the PCMT data model to support transactions to WMS required significant transformation logic.

FIGURE 8

Sample Packaging Hierarchy in WMS

SKI	U Se	tup												
1	2 9		@ ` Q	四11	山 🗗 🕜									
3	-	-	Client	SKU	SKU Descriptio	on		Defau	It UOM	Notes				
•	0	1	COM	ARV0018	Lopinavir/Ritona	vir 200/50mg T	ablet(120)							
>	0	1	MOH	ARV0018	Lopinavir/Ritona	vir 200/50mg T	ablet(120)	Each						
>	0	21	MSL	ARV0018	Lopinavir/Ritor	avir 200/50m	g Tablet(120)	Each						
0	Gene	eral	Invento	ory SI	KU Definitions	Unit of N	Aeasure (UC	DM)	BOM	Sku Su	bstitution	Pick Locations	Labor Performance	
	۲	0	彩山	20	< << 1 / 2 (13 Records) Show All >> >								
ø		UOM	EAN/U	JPC	Gross Weight	Net Weight	Length	Width	Height	Volume	Lower UOM	Units per UOM	Units per Lowest UOM	SI
0	>1	EACH	3 189037	26221850	0	0	0	0	145	751680	Each	1	1	Yes
Q	> 1	EACH	2 089040	93823381	0	0	0	0	120	734400	Each	1	1	Yes
Q	> 1	EACH	1 089037	26221853	0	0	0	0	125	440706.5	Each	1	1	Yes
Q	> 1	Each	08901	175600052	245	149	115	76	115	0.0006		1	1	Yes
0	>1	EACH	4 080540	83013220	200	200	0	64	108	387072	Each	1	1	Yes
Q	> 1	EACH	5 089040	93826399	195.25	150	67.7	67.7	103.8	292.6	Each	1	1	Yes
Q	> 1	24CA	SE 289037	26221857	0	0	0	0	165	23128880	Each	24	24	Yes
0	> 1	30CA	SE 58901	175600057	7350	4470	310	275	310	0.0006	Each	30	30	Yes
Q	> 1	35CA	SE 380540	083018653	0	0	0	0	0	0	Each	35	35	Yes
0	> 0	30PAL	LET 7890	1175600051	188400	107280	10	800	1080	0.0006	30CASE	24	720	Yes

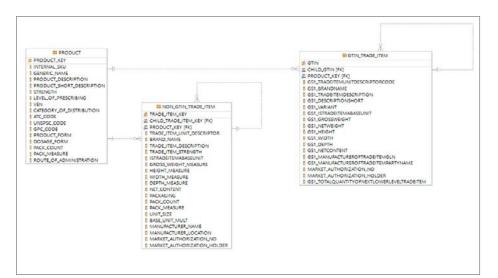


Lesson 5: Determine an Approach for Managing GTIN and Non-GTIN Items² in Trade Item Data

It is important to design the data architecture to accommodate internal product and trade item keys, as GTINs may not be widely used as a form of identification.

FIGURE 9 GTIN, Non-GTIN Trade Item Data Model

Although brand owners are increasingly deploying GTINs to identify trade items, it is important to design the data architecture to accommodate internal product and trade item keys, as GTINs may not be widely used as a form of identification. A GTIN is a unique number used to univocally identify an item globally. All GTIN numbers follow the same structure, which numerically identifies the manufacturer prefix and the trade item. A trade item hierarchy consists of multiple GTINs linked together to represent an item's packaging, such as an each, case, inner-pack, or pallet level hierarchy. Each hierarchy level is assigned a unique GTIN, representing that specific unit, pack, case, or pallet. While manufacturers can assign GTINs, not all trade items will have a GTIN. Thus, it is essential to consider different strategies for managing GTIN and non-GTIN trade items while implementing an NPC.We recommend using the GTIN as a secondary identifier for items, where available, to capture GTINs for all trade items over time. The internal trade item key can be mapped or "anchored" to GTINs and other identification keys already used in the supply chain (e.g., marketing authorization codes, health insurance



reimbursement codes, warehouse SKU codes) to enable linkages across the health sector ecosystem.

The internal identifier should be unique to the item packaging level (pallet, case, pack, each) and nonsignificant, as attributing a specific nomenclature will create unnecessary complexity. Associations should be created in the PIM tool to link a generic product to both GTIN and non-GTIN trade items. Figure 9 shows an example of such a reference data model. Separate trade item entities (families in PCMT) were created for GTIN-based and non-GTIN trade items to account for their structural differences and to manage the data in PCMT easily.

2. Non-GTIN items in this context refer to products unidentified by a GTIN. As a transition measure to full GTIN adoption, a non-significant internal SKU unique to each packaging hierarchy must be assigned.



Lesson 6: Design PMD for Supply Chain Automation and Optimization

Improving supply chain efficiency through standards-based automation relies on complete and accurate PMD availability.

Aligning existing PMD with GS1 standards is critical for successfully deploying automatic identification and data capture (AIDC) solutions. This document examines two ways to achieve efficiency in supply chain operations anchored on well-defined PMD. Both rely on clearly defined product and trade item packaging hierarchies and several key attributes.

Use Case A: Automation in Warehouses

Supply chains seek to automate data capture of system transactions associated with every aspect of item movement throughout the supply chain. AIDC solutions leverage GTINs and the availability of packaging barcode labeling for data capture. However, introducing automation in the warehouse requires the following capabilities in PMD:

a. Associating GTINs with Internal Product Identifier: Countries usually define the SKU at the generic product level for visibility across the supply chain regarding the number of treatments of a drug in supply. The generic product then must be associated with trade items from multiple manufacturers, their associated GTINs for each packaging level, and UOM conversions. This association may be provisioned in an AIDC solution or a separate PIM solution to be accessed by the AIDC solution. *The result is one product associated with multiple GTINs,* such that scanning a GS1 barcode at any level of the packaging hierarchy of a trade item will identify the SKU used by the WMS.

Furthermore, PMD must be able to accommodate known exceptions. For example, some supply chain organizations, such as third-party logistics providers, may identify SKUs by donor or client to physically segregate stocked items. In this case, the ERP/WMS must support *multiple products aligned with multiple GTINs*, where each GTIN in a packaging hierarchy will associate with multiple products. This creates an exception in the AIDC solution where the scan of the GS1 barcode will require operator intervention to determine the specific SKU being transacted.

b. Capture Packaging Hierarchy

for Non-GTIN Products: The key to deploying an AIDC solution for all items in a warehouse is applying labels with an internal SKU/customer part number captured in a standardized label known as GS1 Application Identifier (AI) (241) and encoded on a barcode for items that do not have GTINs encoded in the standardsbased data carrier. Here, it is critical to capture the same granular data about products and trade items, including the manufacturers and their specific packaging hierarchies and attributes, using an internal SKU/customer part number instead of a GTIN. After receiving the item, the operator should print a GS1 label using the AI (241), which is the SKU or internal product identifier instead of the GTIN. These labels may be printed for each trade item packaging hierarchy to support data capture in further downstream distribution. GS1AI (241) indicates the customer part number. This element string aims to enable identification data other than the GTIN to be represented in a GS1 system data carrier. The element string should only be used between trading partners currently using the customer part number for ordering and who have agreed on a timetable to convert to the GTIN for their business purposes. Therefore, the use of the GTIN and the AI (241) on trade items is for **transitional use** during the conversion process. The customer part number must not be used in place of the GTIN.

c. Design Automation to Support

WMS: An AIDC solution is usually deployed to automate the transaction processing currently supported in the WMS. These processes typically span from receiving through to shipping/distribution, and all of the inventory movements, adjustments, and inventory management functions that occur in between. Detailed role-based standard operating procedures (SOPs) are needed to align what is expected by the WMS transactions and what is being performed in the AIDC solution, such as receiving items by scanning the serial-shipping container code (SSCC) label available on logistics units to receive against an advanced shipping notice. These SOPs also guide operators through potential process exceptions, such as methods for tracking non-GTIN labeled products or what to do when PMD is insufficient to support a particular process. For example, if PMD is in the system but a Case Quantity definition is missing, the operator may have to manually count units for a transaction and/or be directed to correct the PMD to support the process. The SOPs should include rigorous PMDM practices to support the operations when needed.

Use Case B: Optimization

Supply chains have several opportunities to optimize product flow throughout their distribution networks, including: **Visible Supply and Demand:** Visibility to supply and demand is essential for planning systems and processes to adequately assess the current state of the supply chain, plan new supplies, and distribute the supplies across the healthcare network based on patient demand. Most countries have established their forecasting and supply planning processes using generic products to have visibility on total supply and total demand for the product at the treatment level. The



PHOTO CREDIT: 5Fifty Production | USAID GHSC-PSM

generic product and associated attributes captured mainly support the planning and procurement processes.

Inventory Optimization: Optimizing inventory levels to balance supply with demand requires visibility to inventories at the generic product level (which is often but not always the same as the SKU or internal identifier in a WMS) while also leveraging unique GTIN identifiers and barcoded labels to move items across the supply chain with visibility to specific packaging net content. While most countries establish blanket inventory stocking policies for different nodes in the distribution network, in-stock performance can be dramatically improved when stocking policies are specific to the demand and supply characteristics of each individual product. Capturing manufacturer-specific information about trade items, including packaging hierarchies, manufacturer lead times, and product forecasts, is needed to support more targeted inventory planning methods.

Improve Warehouse Capacity:

Optimizing warehouse capacity goes hand in hand with inventory optimization. Keeping adequate inventory levels may be constrained by the space needed to store the product. Optimizing storage and retrieval to balance warehouse capacity with demand requires visibility to packaging hierarchies for each product manufacturer to determine unique item dimensions and the net content in given storage locations. The WMS will provide capabilities such as the direct put-away of items after receipt using information about warehouse capacity at each storage location and item dimensions specific to each manufacturer's packaging hierarchy. Capturing PMD associated with each manufacturer's packaging hierarchy enables warehouse space optimization and can be used for load planning on outbound shipments.



Lesson 7: Gauge whether a National or Localized PMD Architecture is Required

Countries should consider starting with singular instances of PMD solutions that can be (or become) NPC as the processes for managing, governing, and sharing the data across the community of healthcare delivery systems mature and stabilize.

This can often be accomplished using existing systems that may need to be reconfigured for the intended use cases and, in most cases, support GTIN and packaging hierarchies.

Countries pursuing a standard PMD to drive supply chain initiatives have been steered towards an NPC initiative. If not appropriately chartered, though, this can result in simply an additional system in the healthcare delivery network that requires PMDM and may not result in a true NPC.

A true charter³ for NPC initiatives should ensure that:

- I.The NPC is the singular process for building PMD.
- 2. All PMD users subscribe to the singular process as the source of that data.
- 3.All (or most) PMD attributes are present in NPC to satisfy all users/use cases.

4. Governance is in place to monitor the PMDM processes and use cases.

Most critically, if PMD is maintained in multiple systems of record that do not source data from NPC, there is a high likelihood of disparities in data. To meet the objectives of an NPC, the PMD should be managed in a singular process and then shared with other healthcare delivery systems as a source of that PMD. Each of these systems relying on NPC for PMD should be represented in a governance process that assures the data is being built and maintained to support their use cases. This includes the nomenclature, attributes, and classifications needed in their respective operations.

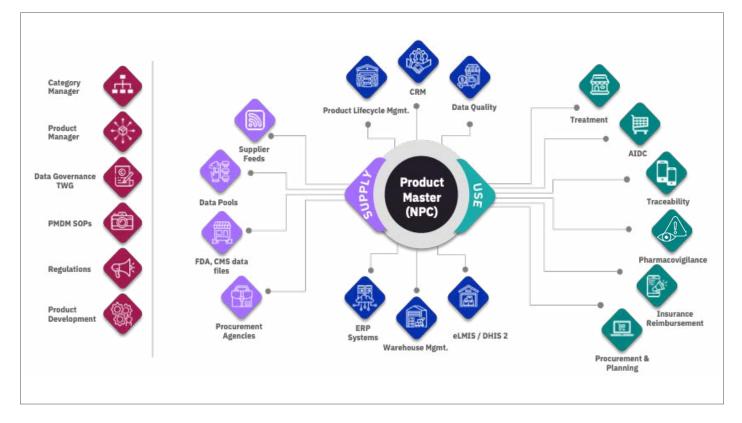
Where countries need to immediately support multiple traceability initiatives at once—such as deployment of AIDC solutions, supply chain optimization, product verification, and product traceability—a robust PMDM process should be implemented through an NPC to eliminate disparity across the swath of healthcare systems that use PMD and homogenize the data for in-country systems and use cases. If new technology solutions are needed to support the targeted initiatives, these may be planned as replacements or layered solutions to enable those initiatives. Countries. however, must understand that the NPC investment level can be substantial, such as investments in a health information exchange infrastructure. It is important to ensure that the NPC is gradually integrated across the country's PMDM ecosystem, including change and adaptive management, resource allocation, etc., as shown below (Figure 10).

Infrastructure readiness plays a crucial role in enabling the PMDM ecosystem, requiring specialized skills and expertise in data management, networking, onpremises or cloud computing, security, integrations, change management, continuous monitoring, and technology:

 Ensuring the availability of infrastructure resources (data storage, processing power, network connectivity) before

FIGURE 10

PMDM Ecosystem



implementation is critical. Delays in procuring servers, storage, Internet Protocol (IP) addresses, Domain Name System, and MDM/NPC software can add delays in the installation and configuration process, impacting the implementation timeline and resulting in an additional level of effort.

- Ensuring that the infrastructure can handle the data volume and processing demand is important. This may involve adding additional storage and processing power when needed. Lack of infrastructure scalability can lead to performance bottlenecks, limited data growth, data loss, system outages, and increased costs.
- Implementing robust security measures to protect master data is critical. This may include encrypting data at rest/ transit, providing the least access privileges, and complying with defined regulations to avoid data breaches, data manipulation, compliance violations, and loss of trust.
- Ensuring that a robust data integration framework exists to facilitate data flow from source systems to MDM/NPC and downstream systems. This includes data extraction, transformation, loading, and real-time synchronization capabilities. A

lack of data integration tools can lead to data silos, discrepancies in data across systems, inefficiencies in MDM processes, and delays.

- Developing a comprehensive plan to address potential issues, bugs, enhancements, and change requests identified throughout the software development lifecycle is essential. A lack of change management process may result in user dissatisfaction, introduce errors and inconsistencies in the system, and reduce system efficiency.
- Continuous monitoring of MDM/NPC infrastructure should be undertaken to identify and respond to bottlenecks, issues, and system outages and disruptions. Alerting the responsible personnel is critical. Failure to implement a monitoring tool (most private clouds provide basic monitoring capabilities for free) may impact business operations and productivity, leading to data loss and corruption.
- Data validations should be automated whenever possible. Defining and applying business rules to ensure data accuracy and compliance with standards are critical processes in PMDM implementation. Ensuring consistency in data formats across various sources,

including units of measurement, date formats, naming conventions, and identification of duplicates and missing values, are pivotal tasks. Lack of automation can lead to inefficient data management (manual data cleansing, validation, and standardization processes that are time-consuming and errorprone).

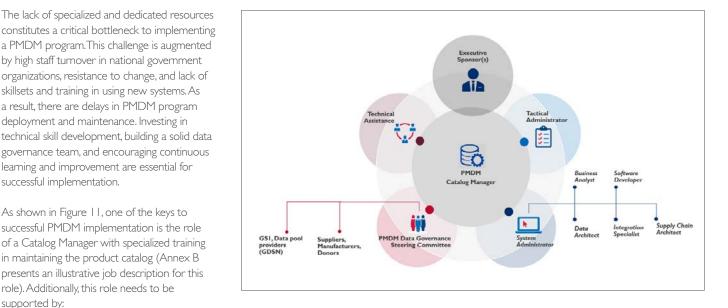
Implementing and leveraging data analytics capabilities play a significant role in informing decision making. These capabilities provide data visibility and support data quality monitoring, data compliance, and operational efficiencies within NPC/MDM operations. The MDM/NPC heavily relies on data profiling as a foundational process for understanding and effectively managing master data. Without comprehensive data visibility, countries may lack the insights necessary to fully understand their data landscape and identify areas for improvement.



Lesson 8: Empower Workforce for PMDM

Investing in technical skill development, building a solid data governance team, and encouraging continuous learning and improvement are essential for successful implementation.

FIGURE 11 PMDM Organizational Structure



successful implementation. As shown in Figure 11, one of the keys to successful PMDM implementation is the role of a Catalog Manager with specialized training in maintaining the product catalog (Annex B presents an illustrative job description for this

by high staff turnover in national government organizations, resistance to change, and lack of

skillsets and training in using new systems. As a result, there are delays in PMDM program deployment and maintenance. Investing in technical skill development, building a solid data governance team, and encouraging continuous learning and improvement are essential for

- role). Additionally, this role needs to be supported by: - Information and technology resources with
- the technical skills to install, configure, integrate, and maintain the NPC platform. Their absence results in implementation delays, configuration errors, and system instability.
- -Technical understanding in the areas of pharmacy or healthcare standards to ensure PMD is responsive to existing healthcare guidelines and supply chain management.
- A PMDM governance structure that promotes collaboration among PMD users and stakeholders to ensure responsiveness to use cases and user experience.
- Executive sponsors that formalize data ownership, stewardship, and access controls. These roles are critical for risk management, strategic direction, and resource allocation.
- SOPs are vital in enabling the role of a Catalog Manager: Similarly, clear guidelines and accountability for data creation, modification, and retirement are critical. A lack of guidelines can lead to inconsistencies and errors, impacting data quality and its use in supply chain operations. For example, in supply chain

automation, if packaging net content is not defined, the data collection tools may not be able to determine a receipt quantity accurately, and the operators will have to hand count the goods for a given transaction. The accuracy and timeliness of PMD are critical to achieving user adoption and preventing confusion about how processes work.

By leveraging the above, organizations can build a skilled and capable workforce that ensures the success of their MDM/NPC initiatives.



Lesson 9: Establish a Process for Sourcing PMD

Acquiring the initial PMD should be planned through incremental steps, identifying reliable data sources that can provide GTINs and the necessary attributes for supporting the particular use case. Building the initial data set begins with identifying the existing PMD protocols used by the country's national essential medicines list, Food and Drug Administration (FDA) regulations information systems, and supply chain operations systems such as ERP, WMS, and eLMIS. This process also requires identifying primary identification keys and all accompanying attributes in use. After that, these will be mapped to GS1 attribute definitions⁴, the data model will be enhanced to align GTINs with internal product identifiers, and the GS1 attributes that the particular use case may need will be added. The resultant is the to-be data model defined based on GS1 standards mapped to the country's internal identifiers and attributes, focusing on a minimal viable dataset that can scale over time.

Table 2

WMS Product File

SKU	SKU description	Category
ARV0002	Abacavir Suphate 300mg Tablet (60)	Anti-retroviral medicines
ARV0003	Didanosine 100mg tab (60)	Anti-retroviral medicines
ARV0004	Efavirenz 200mg tab (30)	Anti-retroviral medicines
ARV0005	Efavirenz (scored) 200mg tablet (90)	Anti-retroviral medicines
ARV0006	Efavirenz 50mg tab (30)	Anti-retroviral medicines
ARV0007	Efavirenz 600mg tablet (30)	Anti-retroviral medicines
ARV0008	Efavirenz 600mg tab (60)	Anti-retroviral medicines
ARV0009	Lamivudine 10mg/ml susp, 100ml btl (1)	Anti-retroviral medicines
ARV0011	Lamivudine I 50mg tablet (60)	Anti-retroviral medicines
ARV0016	Lamivudine/Zidovudine 150 300mg tablet (60)	Anti-retroviral medicines
ARV0018	Lopinavir/Ritonavir 200/50mg Tablet (120)	Anti-retroviral medicines
ARV0020	Lopinavir/Ritonavir 80/20mg 60ml Suspension (1)	Anti-retroviral medicines
ARV0021	Nelfinavir 50mg/g oral pwd in 144g btl (1)	Anti-retroviral medicines

4. The GS1 Navigator includes attribute definitions: https://navigator.gs1.org/

TABLE 3

Harmonized Generic Product Data in PCMT

		215 - 125 - 125 - 1								CATEGORY_OF_		LEVEL_OF_ PRESCRIBIN	PRODUCT	ROUTE_OF	AD
sku	MSL_SKU	PRODUCT_DESCRIPTION-en_US	STRENGTH	PACK_MEASURE	PACK_COUNT	GENERIC_NAME	PRODUCT_SHORT_DESCRIPTION	UNSPSC_CODE	ATC_CODE	DISTRIBUTION	FORM	G	FORM	MINISTRATE	ION VEN
P10000	ARV0002	Abacavir Suphate 300mg Tablet(60)	300mg	TABLET	64	Abacavir Suphate	Abacavir Suphate 300mg Tablet			pom	TA	ILV 1	TABLET	Oral	E
P10001	ARV0003	Didanosine 100mg tab (60)	100mg	TABLET	60	0 Didanosine	Didanosine 100mg Tablet	102029		pom	TA	ILIV 1	TABLET	Oral	E
P10002	ARV0004	Efavirenz 200mg tab (30)	200mg	TABLET	36	Efavirenz	Efavirenz 200mg Tablet	100783001		pom	DT	ILIV 1	TABLET	Oral	E
P10003	ARV0005	Efavirenz (Scored) 200mg Tablet(90)	200mg	TABLET	90	Efavirenz Scored	Efavirenz 200mg Tablet								
P10004	ARV0006	Efavirenz 50mg tab (30)	Some	TABLET	30	Efavirenz	Efavirenz 50mg Capsule	100258	J05AG03	pom	CA	ILIV (CAPSULE	Oral	Ε
P10005	ARV0007	Efavirenz 600mg Tablet(30)	600mg	TABLET	30	Efavirenz	Efavirenz 600mg Tablet	100259	105AG03	pom	TA	IL/V 1	TABLET	Oral	8
P10006	ARVOODS	Efavirenz 600mg tab (60)	600mg	TABLET	60	Efavirenz	Efavirenz 600mg Tablet	100259	105AG03	pom	TA	II_IV 1	TABLET	Oral	ε.
P10007	ARV0009	Lamivudine 10mg/ml Susp, 100ml Bottle (1)	10mg/mi/\100ml	SUSPENSION	1	Lamivudine	Lamivudine 10mg/ml Suspension, 100ml Bottle								
P10008	ARV0011	Lamivudine 150mg Tablet(60)	150mg	TABLET	64	Lamivudine	Lamivudine 150mg Tablet	104271001	105AF05	pom	TA	ILIV 1	TABLET	Oral	ε
P10009	ARV0016	Lamivudine/Zidovudine 150/300mg Tablet(60)	150/300mg	TABLET	60	Lamivudine/Zidovudine	Lamivudine/Zidovudine 150/300mg Tablet	104281001	105AR01	pom	TA	IUV 1	TABLET	Oral	ε
P10010	ARV0018	Lopinavir/Ritonavir 200/SOmg Tablet(120)	200/S0mg	TABLET	120	Copinavir/Ritonavir	Lopinavir/Ritonavir 200/50mg Tablet	104303001	J05AR10	pom	TA	ILUV 1	TABLET	Oral	E
P10011	ARV0020	Lopinavir/Ritonavir 80/20mg 60ml Suspension(1)	80/20mg 60ml	SUSPENSION	1	Lopinavir Ritonavir	Lopinavir/Ritonavir 80/20mg 60ml Suspension								
P10012	ARV0021	Nelfinavir 50mg/g oral pwd in 144g Bottle (1)	50mg/g\144g	POWDER	1	1 Nelfinavir	Nelfinavir 50mg/g oral Powder in 144g Bottle								
P10013	ARV0022	Nelfinavir 250mg Tablet (270)	250mg	TABLET	270	Nelfinavir	Nelfinavir 250mg Tablet	100533	J05AE04	pom	TA	ILV 1	TABLET	Oral	£
P10014	ARV0024	Nevirapine SOmg/Sml 100ml Suspension(1)	50mg/5ml 100ml	SUSPENSION	1	Nevirapine	Nevirapine S0mg/Sml 100ml Suspension								
P10015	ARV0025	Nevirapine 200mg Tablet (60)	200mg	TABLET	60	Nevirapine	Nevirapine 200mg Tablet	100538	J05AG01	pom	TA.	ILIV 1	TABLET	Oral	ε
P10016	ARV0027	Stavudine 15mg Tablet (60)	15mg	TABLET	60) Stavudine	Stavudine 15mg Capsule	100696	105AF04	pom	CA	ILIV I	CAPSULE	Oral	ε
P10017	ARV0028	Stavudine 20mg Tablet (60)	20mg	TABLET	60	5tavudine	Stavudine 20mg Capsule	100697	305AF04	pom	CA	ILIV I	CAPSULE	Oral	E
P10018	ARV0029	Stavudine/Lamivudine 30mg/150mg Tablet	30mg/150mg	TABLET		Stavudine/Lamivudine	Stavudine/Lamivudine 30mg/150mg Tablet	100698		pom	TA	IL_IV	TABLET	Oral	E
P10019	ARV0031	Tenofovir 300mg Tablet (30)	300mg	TABLET	30	Tenofovir Disproxitfuma	a Tenofovir DisproxilFumarate 300mg Tablet	103906		pom	TA	11_IV 1	TABLET	Oral	ε

This harmonization effort against the to-be-data model is labor-intensive and presents some challenges due to the non-standardized nature of the current data files. For example, as shown in Table 2, the generic nature of the product data does not easily lend itself to building out the logic to a more granular level of identification required to support GTIN.

Some of the challenges identified during data harmonization include:

- The manual nature of collecting GTINs from the physical products present in the warehouses. The use of handheld devices should be considered to parse out GTINs into a workbook by scanning the label present on the item.
- Existing national master data files cannot be easily harmonized, for example, due to challenges around parsing strength, pack count, and pack measures from the product description.
- Missing key information (PACK_ MEASURE, PACK_COUNT) in most product descriptions.
- Lack of pharma knowledge
 to populate missing data
 (UNSPSC_CODE, ATC_CODE,
 CATEGORY_OF_DISTRIBUTION,
 DOSAGE_FORM, GPC_CODE, LEVEL_
 OF_PRESCRIBING, PRODUCT_FORM,
 ROUTE_OF_ADMINISTRATION, VEN).

Table 3 illustrates the desired outcome of the alignment process.

The next effort is to identify reliable data sources to **build the model**. These include donor listings that contain GTINs, potentially several of the targeted attributes, and physical data collections by actively scanning packages in country warehouses to access GTINs. Tools such as the USAID GHSC-PSM-developed GTIN Data Collection Tool or Cubiscan may be leveraged to source GTINs and other critical attributes such as volumetrics that might be missing from the to-bedata model. Due to the manual nature of physical inspection, the quality of data could be compromised by challenges such as:

- Missing and incomplete data in trade item records.
- Missing hierarchy level (each, packet, case, pallet) relationship/information for most GTINs.
- Missing the next level total quantity count details from most GTINs.
- Missing/Lack of market authorization holder information.

Ongoing data sourcing can involve direct collaboration with suppliers and manufacturers for specific product details, leveraging GDSN for standardized trade item and packaging data, and partnering with donors and regulatory agencies for information on donated goods and compliance requirements. Ongoing data sourcing should be driven by regulations that mandate what PMD attributes should be shared with the authority and the format, frequency, and method of data exchange. Some countries have opted to receive this data via a flat file by email. Sourcing data directly from suppliers using email is very labor-intensive, timeconsuming, and error-prone and presents data harmonization issues such as:

- Varying data formats, structures, and quality levels across multiple suppliers makes mapping this data to the NPC PMD mode challenging. Data schema validation checks should be ensured before ingestion into the PMD instance.
- Validating and cleansing supplier data to ensure accuracy, completeness, and consistency reviews gaps in data quality is required.
- Maintaining updated PMD as product information changes is not always prioritized.
- Obtaining supplier cooperation to share
 PMD with a national authority often
 requires regulations.

Establishing direct data exchange using a Secure File Transfer Protocol or application programming interface (API) integration should be considered to address these challenges; however, this requires supplier technology capabilities and a significant level of effort to build an integration with each supplier. Leveraging GDSN may be explored as a means for countries to receive standardized PMD with their trading partners. For example, in 2022, the Zambia Ministry of Health (MOH) partnered with GS1 South Africa to conduct a pilot project to integrate the NPC tool with GDSN to source data directly from suppliers. The pilot invited 13 (antiretroviral and anti-malaria drug) suppliers to publish their trade items (GTINs) data to the MOH GDSN instance hosted by GS1 South Africa. Manual and semi-manual processes were set up to receive and upload the GTIN data to NPC. The GDSN data integration via the TrustedSource File Transfer Protocol (FTP) process received 204 GTINs, which were uploaded into PCMT. The FTP was set up to transfer files (trade item data (GTINs)) between GDSN South Africa and the PCMT server. For phase | (manual data entry), the catalog manager regularly downloaded a full copy of the trade item file from the FTP server. The trade item data was then reviewed and captured manually into PCMT. Some challenges identified during manual data collection included UOM conversion to PCMT format, API capability, and complexity in receiving delta files (recent changes only) vs. full files from GDSN. The decision of whether to use the GDSN approach should be based on careful evaluation of specific needs, budget,



Activity-based costing gives managers a new perspective on how best to utilize human and financial resources. PHOTO CREDIT: Mickael Breard | USAID GHSC-PSM

and technical expertise. Some key benefits that might be valuable to consider with the GDSN approach include:

 Improves data accuracy and consistency: Via the GS1 Navigator, the harmonized data definitions are accessible and can bring many benefits, such as significantly reducing errors and inconsistencies arising from variable data definitions. The data submission part through GDSN has a cost and can be leveraged as a second step in data exchange among trading partners.
 Standard data format: Different trading partners may use different data formats. GDSN translates and standardizes the data, ensuring everyone can access consistent information.

 Simplifies data exchange: GDSN acts as a central hub for sharing product data between all the trading partners. This eliminates the need for sending and receiving data files through email, direct supplier integrations, and/or other manual methods that could be costly and resource-intensive.



Annex A.

Product Master Data Governance Roles and Responsibilities

Role	Responsibilities
Executive Sponsor	 Accountable for the overall governance of the master data program Approves policy-level decisions regarding the priorities and implementation as presented by Data Approvers and stewards
Catalog Manager	 Responsible for day-to-day data management of product master data Manages queries/issues related to data, providing answers or validating the accuracy, completeness, or use of data within a business context Manages data quality through validation rules to identify and address anomalies in product master data Ensures adherence to the defined product master data lifecycle, including archiving and retention
PMDM Data Governance Steering Committee	- Provides strategic direction and oversees data governance policies and procedures
System Administrator	 Provides technical support and maintains PMDM system and related infrastructure Handles requests for security, including privacy, access control, and authentication Manages integrations with external systems
Tactical Administrator	- Provides logistic support, including scheduling meetings and stakeholder coordination
Technical Assistance	- Provides support and guidance in their relevant area of expertise

Annex B.

Catalog Manager Job Description

Role Overview

The Catalog Manager will be responsible for updating and maintaining a National Product Catalog that will serve as a centralized location for product data that can populate information systems and be used in processes throughout the supply chain. The ideal candidate for this position will have expert knowledge of healthcare products, namely pharmaceuticals and medical devices, and a strong understanding of data management principles. The Catalog Manager must be able to effectively coordinate between multiple stakeholders who may be either sources or users of product data. The individual in this role must demonstrate an ability to learn and implement innovative data management concepts, especially those focused on implementing global data standards for product identification and exchange. The individual must master the navigation of product information management tools. In specific contexts, this position may already exist, though it may be necessary to upskill the existing supply chain master data management specialist to support the maintenance of a product catalog and guide product identification and data exchange grounded in GS1 standards.

Expected Deliverables

- Design a holistic product master data management strategy
- Lead implementation of a product master data management program including, but not limited to, implementing processes for data governance, quality, and risk management
- Design mechanisms and processes to populate the product catalog with supplier/vendor-sourced data
- Liaise with business users and information technology team(s) to source, design, enhance, and configure

the product information management information system

- Train and/or orient catalog users and entities providing data to populate the catalog
- Establish and track key performance indicators for data quality

Technical Competencies

- Demonstrates expert understanding of data management and data science principles
- Can describe data governance roles and processes
- Experience conducting routine data quality assessments to validate the completeness and accuracy of product master data
- Ability to develop processes for enhancing, archiving, and retaining product data
- Ability to use analytics tools to monitor the use of product catalog data
- Ability to manage ad hoc requests by users of the product catalog data
- Understands how to create and maintain large data sets and complex data structures
- Ability to align product catalog structure and global product classification structures
- Knows how to navigate product information management tools
- Can describe current trends in product catalog systems and content management
- Can identify primary pharmaceutical and medical device attributes used for product identification in supply chain systems

Managerial Competencies

- Ability to drive collaboration across teams, organizational units, and external stakeholder groups
- Communicates information accurately,

concisely, and confidently verbally and in writing

- Pays attention to detail and identifies the main ideas, detects inconsistencies, and identifies missing information in documents
- Implements continuous improvement and optimization approaches in catalog management
- Exhibits a high degree of ownership and accountability
- Learns and implements new approaches in data management
- Demonstrated integrity, independent thinking, judgment, and respect for others

Skills/Training

Required

- Experience managing healthcare product data
- Comfort in navigating information technology solutions for product information management

Desired

- Degree in data science, informatics, pharmacy, or equivalent
- Certificate in pharmacy informatics or equivalent training
- Knowledge of GS1 standards with specific experience in the implementation of solutions using the Global Data Synchronization Network

Annex C.

Steps for Synchronizing National Product Master Data through GDSN

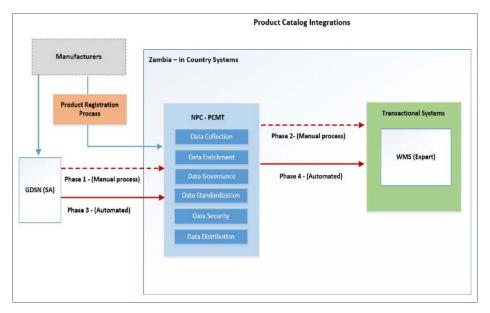
Organizations requiring product information can take advantage of GDSN by subscribing to a data pool provider. The data synchronization involves several steps, and the cost may vary depending on the chosen data pool provider, the number of trade items, and the trading partners. Here are the general steps for synchronization:

I. Acquire a GLN

The Global Location Number (GLN) plays an essential role in the GDSN setup process. It is mandatory within GDSN and used to identify data owners/information providers (suppliers, distributors, and manufacturers) and data recipient entities. For countries implementing NPC, it is recommended that the FDA or MOH acquire a GLN if they are the recipients of the product master data. For example, in Zambia, the GLN is registered under the MOH.

2. Identify and choose a GS1certified data pool provider

A data pool provider acts as an interface to the GDSN. Research and select a provider based on your requirements, budget, and compatibility with your trading partners. For example, in a pilot project in Zambia, MOH partnered with GS1 South Africa to integrate the NPC tool (PCMT) with GDSN to source data directly from the manufacturers. Suppliers are required to identify and work with their preferred data pool providers. Integration with GDSN may take a phased approach. For example, for Zambia, the integration of GDSN is being executed in four phases, starting with a manual integration of PCMT and GDSN data pool in Phase I. Phase 2 focused on integrating PMCT with the WMS, specifically configuring the WMS system to receive and capture generic products (MSL_SKU) and GTINs with different packaging hierarchies received from PCMT. Phases 3 and 4 are planned to automate the integration between the GDSN Data Pool and PCMT, and



between PCMT and WMS, respectively. (Note: Phases 3 and 4 have not been implemented yet).

3. Develop an attribute guide

Develop an attribute guide comprising data elements suppliers must submit through the GDSN. Ensure the product data attributes meet GS1 standards (GTIN, trade item packaging hierarchies, and global attributes). Use your data pool provider guidance to map your data attributes to the GDSN data model.

4. Identify trading partners

Determine which supplier, distributor, and manufacturer should provide the trade item information. Write/send communication to suppliers, distributors, and manufacturers, making them aware of the initiative to publish their product master data through the GDSN. For example, Zambia FDA (Zambia Medicines Regulatory Authority, ZAMRA) contacted antiretroviral and anti-malaria suppliers/ manufacturers for the GDSN pilot.

5. Monitor and maintain data

Once the GDSN integration is established, monitor the integration to keep the NPC data accurate and up-to-date. Use the data pool provider tools (Web UI, SFTP directory, API endpoint) to track the data exchange transactions, review synchronization logs and reports, and make follow-ups with suppliers/ manufacturers and data pool providers as needed.

Resources:

- GS1 GDSN website: https://www.gs1. org/services/gdsn

- GS1 Data Synchronization Quick Start Guide: <u>https://www.gs1.org/services/</u> gdsn

- GDM Navigator Tool: <u>https://navigator.</u> gs1.org/gdm

- GS1 Global Data Model Attribute Implementation Guideline: https://www. gs1.org/standards/gs1-global-datamodel-attribute-implementationguideline/current-standard