RWANDA FDA
Rwanda Food and Drugs Authority

GUIDELINES FOR PRODUCT AND LOCATION MASTER DATA SHARING

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FOREWORD

Rwanda Food and Drugs Authority (Rwanda FDA) is a regulatory body established by the Law N° 003/2018 of 09/02/2018 with the mandate to ensure the quality, safety and efficacy of the pharmaceutical products to support the implementation of various public health programs, improve the health status of the population and the socio-economic development of the Country.

Reference to the Regulations No. DFAR/HMDAR/TRG/003 Governing the Implementation of Identification, Data Capture, and Data Sharing for Traceability of Pharmaceutical Products and the Rwanda National Vision & Strategy for Pharmaceutical Traceability Leveraging GS1 Global Standards;

Rwanda FDA has developed these guidelines for Product and Location Master Data Sharing to document requirements for product and location master data to be shared to support the implementation of the traceability of pharmaceutical products.

The Authority acknowledges all the efforts of key stakeholders who participated in the development and validation of these guidelines.

Dr. Emile BIENVENU
Director General

GUIDELINES DEVELOPMENT HISTORY

DRAFT ZERO	29/03/2021
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STAKEHOLDERS CONSULTATION	07- 10/03/2022
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Document Revision History

Date of revision	Revision number	Changes made and/or reasons for revision
05/07/2022	Rev_0	First version

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ACRONYMS AND ABBREVIATIONS

FDA	Food and Drug Authority
GDD	Global Data Dictionary
GDSN	GS1 Global Data Synchronization Network
GLN	Global Location Number
GPC	Global Product Classification
GTIN	Global Trade Item Number
MAH	marketing authorization holder
MOH	Ministry of Health
NPC	National Product Catalogue
SF	substandard and falsified

1. INTRODUCTION

The Ministry of Health (MOH) is undertaking a number of supply chain and health information system investments and governance interventions to improve efficiency in sharing data across the supply chain and in the health sector, strengthen data quality, extend data visibility, and reduce costs of data capture and transformation. In a time where the country seeks to achieve greater health benefits and reduced operational costs, implementation of global standards serves as an enabler in achieving these goals through ensuring consistency in how health commodities are identified, how data can be captured about these commodities as they move through the supply chain, and how this data can be shared across disparate systems in a consistent and streamlined manner across industries, countries, and trading partners. These interventions together create an enabling environment for pharmaceutical traceability, which aims to:

a) Decrease the presence of substandard and falsified (SF) medications
b) Ensure the quality and desired efficacy of pharmaceutical products
c) Promote trust in the pharmaceutical sector and healthcare system
d) Provide visibility of product status across the supply chain
e) Create supply chain efficiencies from manufacturers to the end consumer
f) Increase patient safety

As mandated by Rwanda FDA Regulations CBD/TRG/030 Governing the Implementation of Identification, Data Capture, and Data Sharing for Traceability of Pharmaceutical Products especially in its Article 12, these guidelines apply to the sharing of product and location master data as it relates to pharmaceutical products. This document is not intended to address sharing of associated transaction and event or traceability data.

1.0 BACKGROUND

Product master data is core information about "what" is being traded in the supply chain. The "what" is identifying information about a given trade item, such as name, brand, manufacturer, description, size, color, and unique identification number. These data are used daily among trading partners to execute transactions in the supply chain and also by a broader value chain of health sector stakeholders including regulators. Rwanda FDA requires that marketing authorization holders (MAH) share master data attributes about their products and location with the Authority for their use. Therefore, these guidelines document requirements for product and location master data to be shared to support fulfillment of this mandate.

A critical element of the *Rwanda National Vision & Strategy for Pharmaceutical Traceability* is identifying pharmaceutical products leveraging a globally standardized approach. The standards referenced within this document are largely supported by GS1, a standards organization that enables

unique identification, data capture, and data sharing among trading partners so that anyone in the supply chain who requires that information can interpret it in the same manner. To collect and manage trade item identifiers for reference by trading partners in the national supply chain and across

the health sector, the Ministry of Health is implementing a National Product Catalogue (NPC), which focuses on system and processes that will organize and manage trade item master data in a manner that aligns with and facilitates the adoption of GS1 standards.

NPC will be the authoritative system to collect and organize GS1 based trade item master data, including Global Trade Item Numbers (GTIN) and relevant Global Location Numbers (GLN) for pharmaceutical products procured and supplied to the Rwandan market. NPC will facilitate efficient and effective product master data management. It will also enable linkages between global and national product identification numbers (e.g., marketing authorization numbers), access to and sharing of this data across all supply chain and health information systems in Rwanda. The NPC will:

a) Facilitate the scanning and use of GTINs on GS1-compliant data carriers as mandated by Rwanda FDA to increase operational efficiency, data accuracy, and data integrity for products authorized for use in the health sector.
b) Improve interoperability across health systems by sharing standardized trade item master data.
c) Be a key step towards implementation of health commodity traceability through the use of standardized identifiers across all supply chain levels and relevant information systems in Rwanda.

2. MASTER DATA ATTRIBUTE REQUIREMENTS

The Attribute List (see Appendix 1) is the primary reference document for trading partners regarding the master data attribute requirements. It includes all initial priority attributes to be provided as relevant on trade items supplied in Rwanda. For each attribute, the guidelines provide the category, attribute name, description, and an example.

Table 1: Attribute Significance

Attribute Requirement	No. of attributes
Mandatory Attributes that must be populated and shared with Rwanda FDA	13
Optional Attributes that should be populated if available, but not yet mandatory for Rwanda FDA	51
Total attributes	64

Table 2: Attribute Groupings

Attribute Grouping	Description
General Item Information	General information about the trade item
Product Description Information	Supplier product descriptions and other descriptive information
Unit Indicators	Supply chain characteristics
Dimensions	Trade item dimensions, weights and measures
Contact/Role Information	Manufacturer, supplier and information provider contact information (name, address and contact method)
Pharmaceutical Information	Information on dosage and route of administration
Hierarchy	Trade item hierarchy (packaging levels) information
Storage, Handling & Shelf Life	Defines the information and processes needed to safely handle the trade item.
Product Classifications	Product classification details
Dangerous/Hazardous Goods Information	Information on dangerous and hazardous goods and waste classification
Referenced Trade Item Identification	These attributes support identification of substitute or alternate trade items from the same brand owner.

3. STEPS FOR SYNCHRONIZING MASTER DATA

To synchronize data, trading partners are advised to undertake the following actions:

a) Assign a GLN[1] for each of the relevant locations or legal entities, including Brand Owner, manufacturing location, and MAH.

b) Assign a GTIN to each level of the trade item packaging hierarchy (e.g., each, inner, case, pallet).[2] An example of a trade item packaging hierarchy in the healthcare context is:

[1] For more information on the GLN, please refer to the GS1 website: https://www.gs1.org/gln
[2] For more information on definitions and assigning GTINs in the healthcare context, please reference the GS1 Healthcare GTIN Allocation Rules available: https://www.gs1.org/1/gtinrules/en/healthcare

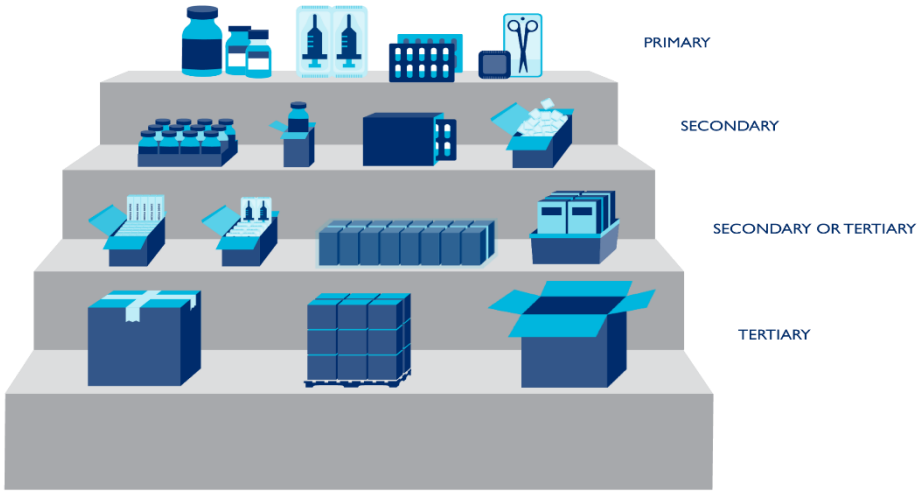

Figure 1. Identification at healthcare trade item levels of packaging[3]

c) Gather the product and location attribute data on each trade item packaging hierarchy level, per Product and Location Master Data Attribute form (Appendix A). Note that these attributes are based on the GS1 Global Data Synchronization Network (GDSN) standard.

d) Populate Product and Location Master Data Attribute Form (Appendix A) for Submission in Excel format along with marketing authorization application. If submitting an ad hoc request for master data form or providing an update to data submitted through the marketing authorization process, email your form to *info@rwandafda.gov.rw*

e) MAHs are expected to ensure that the master data provided for registered products is maintained and updated as necessary. If there are any changes to the master data provided on your products or relevant locations, send an updated template to Rwanda FDA within 30 days of implementing the change.

Rwanda FDA seeks to enable direct submission of product and location master data to the NPC over time, either via direct entry or a form of electronic data exchange. These guidelines will be updated as those capabilities are developed, tested, and deployed.

4. DATA SYNCHRONIZATION RESOURCES

GS1 GTIN healthcare allocation rules

The GS1 Healthcare GTIN Allocation Rules voluntary guideline is developed and maintained by the GS1 Healthcare so that, when and where product identification is required, use of data structures is consistent worldwide. The guidelines also cover specific Point-of-Sale requirements, which are essential for prescription and non-prescription healthcare items.

[3] "Primary packaging" is usually also the unit of use. "Tertiary packaging" in this context refers only to trade items and not to logistic units.

The GS1 Healthcare GTIN Allocation Rules is available:
https://www.gs1.org/docs/gsmp/healthcare/GS1_Healthcare_GTIN_Allocation_Rules.pdf

GS1 Global Data Dictionary

The GS1 Global Data Dictionary (GDD) is a repository of the data elements defined across all GS1 Standards. Attributes in the GDD are described using data types, some of which may contain code lists. Each GS1 Standard is represented in the GDD, sorted by the type of data exchange standard, including Global Data Synchronization Network (GDSN).
The GDD is available: http://apps.gs1.org/GDD/SitePages/Home.aspx

GS1 Global Product Classification Browser

With the GS1 Global Product Classification (GPC) Browser, you can search all components (Segment, Family, Class, Brick and Attribute) of the published GPC schemas. The GPC has been translated into more than 20 different languages.
The GPC Browser is available: https://www.gs1.org/services/gpc-browser
GS1 Attribute Explorer

The GS1 Attribute Explorer is designed to help users search, filter and view standardized attributes as defined in the GS1 GDD. The tool contains attributes, code list values, and definitions.
The GS1 Attribute Explorer is available: http://ae.gs1.org/

GS1 Package Measurement Rules Standard and Implementation Guide

The GS1 Package Measurement Rules Standard establishes rules for the global, unambiguous definition of nominal measurement attributes for product packaging. These rules are designed to facilitate communication of these attributes for retail and nonretail products from the consumer unit to the case level and all intermediate packaging levels in between.

The GS1 Package Measurement Rules Standard is available http://www.gs1.org/docs/gdsn/3.1/GS1_Package_Measurement_Rules.pdf
GS1 GDSN
Additional information on the GS1 GDSN can be found here: https://www.gs1.org/standards/gdsn

ENDORSEMENT OF THE GUIDELINES

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APPENDIX A: PRODUCT AND LOCATION MASTER DATA ATTRIBUTE FORM AVAILABLE ON RWANDA FDA WEBSITE