

Guideline for Pharmaceutical Product and Location Master Data

Template and Guidance

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The USAID Global Health Supply Chain Program-Procurement and Supply Management (GHSC-PSM) project is funded under USAID Contract No. AID-OAA-I-15-0004. GHSC-PSM connects technical solutions and proven commercial processes to promote efficient and cost-effective health supply chains worldwide. Our goal is to ensure uninterrupted supplies of health commodities to save lives and create a healthier future for all. The project purchases and delivers health commodities, offers comprehensive technical assistance to strengthen national supply chain systems, and provides global supply chain leadership.

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Introduction

The *Guideline for Pharmaceutical Product and Location Master Data Sharing Template and Guidance* is intended for use by ministries of health (MoHs) and/or national drug regulatory authorities (NDRAs). Its purpose is to support implementation of existing regulation and statutory instruments governing sharing of product and associated locations master data for pharmaceutical products authorized to be distributed in the market. A guideline for pharmaceutical products and location master data sharing should provide regulated marketing authorization holders (MAHs) or other relevant trading partners subject to an overarching regulation the information required to effectively comply. Where such instruments do not exist, the NDRA should determine the applicable country framework to enforce this document.

This resource may be used alongside the *Model Directive for Traceability Regulation Template and Guidance*¹ and the *Guideline for Identification and Labelling of Pharmaceutical Products Template and Guidance*.² The model directive helps countries develop regulation. It includes guidance on how to identify gaps and recognize areas of enhancement to support the traceability implementation process. The identification and labelling guideline informs trading partners on how to assign trade item identifiers and label their packages accordingly. Together, these three instruments are designed to provide guidance for policy implementation to support the country's traceability strategy.

This resource assumes that the entity using this template and guidance has or intends to deploy a national product catalog (NPC) as a tool to manage product and associated location master data, and introduces this concept in Section 2, "Background," of the template. If an NPC is not in scope at the time of using this template to develop a guideline, this content should be updated and replaced with a description of the system that will host and manage the master data described within.

How to Use this Document

The document includes two sections: guidance and template. The guidance section provides key considerations that authorities should use as decision points to aid in applying the template to the country context.

The template provides a structure and illustrative text that can be adapted and adopted to define and convey product and identification guidelines, as they relate to GS1 global standards, for pharmaceutical manufacturers and suppliers, and other stakeholders, such as marketing authorization holders, donors, and care providers. The user will need to change the structure and content of the template to reflect context-specific requirements. If the language is adopted as is, the fields denoted in **blue** within brackets will need to be updated to reflect context-specific information. When illustrative text or examples are included, they are depicted in *blue italics*; you will need to adapt these to reflect context-specific information.

This template and guidance document is intended for use by MoHs and/or NDRAs that have developed requirements or regulations mandating master data sharing among trading partners. The current status and readiness of the local market should be assessed in conjunction with using this tool to inform a) the existence and/or maturity of new or existing systems to manage master data, b) the existence or

¹ Available: <https://www.ghsupplychain.org/index.php/TraceabilityModelDirective>

² Available: <https://www.ghsupplychain.org/ProdIdentificationLabellingGuidance>

creation of governance structures required to support oversight, management, and maintenance of the master data submission process and associated data quality management, c) the minimum set of data required by the country to manage pharmaceutical products within the health sector, d) market readiness to comply with the requirements detailed in the guideline, and e) any gaps that may exist in certain market segments (e.g., domestic manufacturing, specialized goods) that may require alternative implementation timelines.

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 product master data, which may encompass product/trade item hierarchies. The term “trade item” is used when referring to a manufacturer-specific form of the generic product that can be priced, ordered, invoiced, or marketed at any point in the supply chain.

Key Considerations

Focus Area	Consideration	Template Section
Introduction	<ul style="list-style-type: none"> • Provide regulatory framework for applying the guideline. • Introduce the document and its rationale, purpose, and scope. • Ensure the rationale and purpose of the document are aligned with the country’s intention. • Ensure the scope of products affected by the guideline is aligned with the scope described in the legal framework. 	Section 1
Background	<ul style="list-style-type: none"> • Provide information on master data and its importance in the country context and in achieving the country’s national traceability strategy (or other relevant strategy) goals. • Describe the overall NPC initiative and how it is envisioned to advance the country’s supply chain and health objectives. 	Section 2
Master Data Requirement	<ul style="list-style-type: none"> • Summarize attribute significance (i.e., the number of mandatory and optional attributes); note that this table will need to be updated based on the final determination of attributes in Appendix 1. • Summarize attribute groupings (i.e., the types of master data that is being requested); note that this table may need to be updated or expanded based on the final determination of attributes in Appendix 1. 	Section 3
Steps for Synchronizing Master Data	<ul style="list-style-type: none"> • Outline the steps required for the MAH or other information provider (to be adjusted) to share master data with the NDRA. • This section currently assumes email submission in an Excel 	Section 4

Focus Area	Consideration	Template Section
	<p>template and indicates a future update will be made with guidance on direct submission to an NPC.</p> <ul style="list-style-type: none"> Update this section based on specific requirements on master data sharing for the country's NPC if applicable. 	
Synchronization Resources	<ul style="list-style-type: none"> This section provides additional information, including links to specific GS1 documentation and tools where the reader can get further knowledge and guidance. Add other country-specific information, such as a link to the statutory instrument and/or <i>Guideline for Pharmaceutical Product Identification and Labelling</i> to these resources and remove resources as appropriate for the context. 	Section 5
Product Master Data Attributes	<ul style="list-style-type: none"> An illustrative list of mandatory and optional master data attributes with associated descriptions has been included in an Excel spreadsheet (Tab 1) This document should be reviewed and updated to ensure that the attributes requested align with the data needs of NPC users and/or supply chain stakeholders. Attributes that will ultimately be determined to be mandatory or optional should reflect traceability and business process requirements, market readiness, and the mechanism for master data exchange and storage that is elected to be implemented (Tab 1, Column G). An example for populating each attribute should be provided for guidance (Tab 1, Column F). A template for populating the product master data against each attribute is provided, assuming manual population and submission (Tab 2). The template includes a column for each attribute in Tab 1. Mandatory attributes are in red font. If Tab 1 is updated by adding or removing attributes, Tab 2 should be updated accordingly as well. 	Appendix A

Guideline for Pharmaceutical Product and Location Master Data Sharing

Government of [Country]

Reference Regulation: No. of /.... /2021

For Inquiries: [INSERT CONTACT INFORMATION]

For the latest updates, please visit the [NDRA] website: [INSERT WEBSITE]

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Template

Acronyms

GDD	Global Data Dictionary
GDSN	Global Data Synchronization Network
GLN	Global Location Number
GPC	Global Product Classification
GTIN	Global Trade Item Number
MAH	marketing authorization holder
NPC	national product catalogue

Template

Revision History

Version	Author	Date	Comments

Template

1. Introduction

The *Guideline for Pharmaceutical Product and Location Master Data Sharing* document outlines implementation requirements for those stakeholders in scope for meeting the master data sharing provisions outlined in the [NAME OF STATUTORY INSTRUMENT].

[NAME OF STATUTORY INSTRUMENT] is established under the [ACT], whose main mandate *[for example: is to ensure that all medicines and allied substances being made available to the country citizens consistently meet the set standards of quality, safety, and efficacy]*. With this mandate comes a need to provide guidance for complying with this [ACT] leveraging global standards to share pharmaceutical product and location master data to enable use of product and location identifiers, specifically when encoded in a data carrier and labeled on a pharmaceutical product, in the national public health supply chain.

1.1. Rationale

The [NDRA] is establishing a national product catalogue (NPC) with the intention of collecting and managing product and associated location master data related to products authorized to be distributed in the [COUNTRY] market. The information in this guideline is informed by the minimum set of master data required to manage the product lifecycle in the national public health supply chain, existing good practices, and GS1 global standards for product master data.

1.2. Purpose

This document is intended to provide trading partners subject to [ACT] with further information on how to implement [NDRA] regulations on sharing master data for pharmaceutical products.

1.3. Scope

This document applies to all products that fall within the definition of pharmaceutical products per [NAME OF STATUTORY INSTRUMENT]. This guideline provides information on master data attributes and location information that must be exchanged for any entity subject to [NAME OF STATUTORY INSTRUMENT], when this information must be exchanged, and how it must be submitted. This document is not intended to address sharing of associated transaction and event or traceability data. More direction will be provided on these topics through additional guidance in the future.

2. Background

Product master data are 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 underpin regulation and commerce and are used daily among trading partners to execute transactions in the supply chain and by a broader value chain of health sector stakeholders, such as regulators, to manage marketing authorization. The [NDRA] requires that [MARKETING AUTHORIZATION HOLDERS (MAHs)] share master data attributes about its product(s) and location(s) with the Authority for their use. Therefore, this specification documents the guiding requirements for product and location master data to support fulfillment of this mandate.

A critical element of the [COUNTRY TRACEABILITY STRATEGY OR OTHER REFERENCE DOCUMENT] 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 and supporting attributes for reference by trading partners in the national supply chain and across the health sector, [MOH and/or NDRA] are implementing an NPC, which consists of a system and processes that will organize and manage product and trade item master data in a manner that aligns with and facilitates the adoption of GS1 standards.

The NPC will be the authoritative system to collect and organize product and GS1-based trade item master data, including Global Trade Item Numbers (GTINs) and relevant Global Location Numbers (GLNs) for health commodities procured and supplied to the [COUNTRY] market. The NPC will facilitate efficient and effective product master data management, will enable linkages between global and national product identification numbers (e.g., marketing authorization numbers), and will enable access to and sharing of these data across all supply chain and health information systems in [COUNTRY]. The NPC will: *for example:*

- *Facilitate the scanning and use of GTINs on GS1-compliant data carriers as mandated by the [NDRA] to increase operational efficiency, data accuracy, and data integrity for products authorized for use in the health sector.*
- *Improve interoperability across health systems by sharing standardized trade item master data across all systems.*
- *Be a key step toward implementing health commodity traceability using standardized identifiers across all supply chain levels and relevant information systems in [COUNTRY].*

3. Master Data Requirement

The [\[NDRA\] Product and Location Master Data Attribute Guide](#) (see Appendix A) is the primary reference document to be used for complying with [\[NDRA\]](#) master data attribute requirements. Attributes refer to the characteristics of a product, trade item, location, or legal entity that differentiate it from other similar concepts. It includes all initial priority attributes to be provided as relevant on trade items marketed in [\[COUNTRY\]](#). For each attribute, the guide provides the category, attribute name, description, and an example.

3.1. Attribute Significance

Attribute Requirement	No. of attributes
Mandatory Attributes that must be populated to share with the [NDRA]	[XX]
Optional Attributes that should be populated if available, but not yet mandatory for the [NDRA]	[XX]
Total attributes	[XX]

3.2. Attribute Groupings

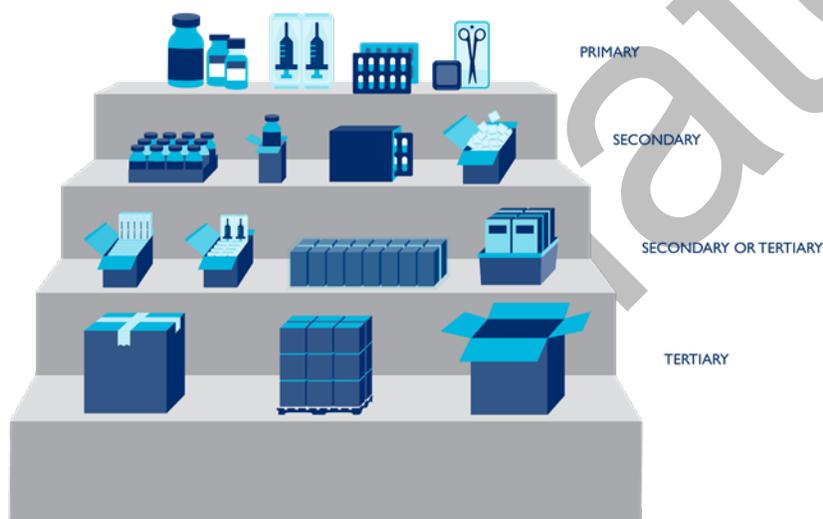
Attribute Grouping	Description
General Item Information	General information about the trade item
Product Description	Supplier product descriptions and other descriptive information
Unit Indicators	Information on the trade item packaging level and the processes in which the item can be used (e.g., consumed, shipped, invoiced, or ordered)
Dimensions	Trade item dimensions, weights, and measures
Contact/Role Information	GLNs of the brand owner, manufacturer, and information provider (i.e., MAH), including contact information
Pharmaceutical Information	Information on dosage and route of administration
Hierarchy	Trade item information of the next level (child) trade item
Storage, Handling, and Shelf Life	Information and processes needed to safely handle the trade item
Product Classifications	Information classifying similar groups of products based on a global classification structure (e.g., UNSPSC, GPC)
Dangerous/Hazardous Goods Information	Information on dangerous and hazardous goods and waste classification
Referenced Trade Item Identification	Attributes that support identification of substitute or alternate trade items from the same brand owner

4. Steps for Synchronizing Master Data

To synchronize data with [NDRA], [MAHs] are to undertake the following actions:

1. Assign a GLN³ for each of the relevant locations or legal entities, including brand owner, manufacturing location, and information provider (i.e., [MAH]).
2. Assign a GTIN to each level of the trade item packaging hierarchy (e.g., each, inner, case, pallet).⁴ An example of a trade item packaging hierarchy in the healthcare context is:

Figure 1. Identification at healthcare levels of packaging⁵



3. Gather the product and location attribute data on each trade item packaging hierarchy level, per the [NDRA] *Product and Location Master Data Attribute Guide* (Appendix A). Note that these attributes are based on the GS1 Global Data Synchronization Network (GDSN) standard.
4. Populate the [NDRA] *Product and Location Master Data Submission Form* (Appendix A) in Excel format and submit with the marketing authorization application. If submitting an ad hoc request for master data from the [NDRA] or providing an update to data submitted through the marketing authorization process, email your form to [EMAIL ADDRESS].
5. Ensure that the master data provided for registered products is maintained and updated as necessary. If the master data provided on your products or relevant locations have any changes, send an updated template to [NDRA] within [30] days of implementing the change.

[If applicable: Please note that [NDRA] seeks to enable direct submission of product and location master data to the NPC over time, either through direct entry or a form of electronic data exchange. This guideline will be updated as those capabilities are developed, tested, and deployed.]

³ For more information on the GLN, please refer to the GS1 website: <https://www.gs1.org/gln>

⁴ For more information on definitions and assigning GTINs in the healthcare context, please reference the GS1 Healthcare GTIN Allocation Rules, available at: <https://www.gs1.org/1/gtinrules/en/healthcare>

⁵ "Primary packaging" is usually the unit of use. "Tertiary packaging" in this context refers only to trade items and not to logistic units.

5. Data Synchronization Resources

GS1 Healthcare GTIN Allocation Rules

This voluntary guideline is developed and maintained by GS1 Healthcare so that, when and where product identification is required, use of data structures is consistent worldwide. The guideline also covers specific point-of-sale requirements, which are essential for prescription and non-prescription healthcare items.

The GS1 Healthcare GTIN Allocation Rules guideline is available at:

https://www.gs1.org/docs/gsmf/healthcare/GS1_Healthcare_GTIN_Allocation_Rules.pdf

GS1 Global Data Dictionary (GDD)

The 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 GDSN.

The GDD is available at: <http://apps.gs1.org/GDD/SitePages/Home.aspx>

GS1 Global Product Classification (GPC) Browser

With the 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 languages.

The GPC Browser is available at: <https://www.gs1.org/services/gpc-browser>

GS1 Attribute Explorer

This tool is designed to help users search, filter, and view standardized attributes as defined in the GS1 GDD. It contains attributes, code list values, and definitions.

The GS1 Attribute Explorer is available at: <http://ae.gs1.org/>

GS1 Package Measurement Rules Standard and Implementation Guide

This standard establishes rules for the global, unambiguous definition of nominal measurement attributes for product packaging. The 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 at:

http://www.gs1.org/docs/gdsn/3.1/GS1_Package_Measurement_Rules.pdf

**Appendix A. [NDRA] Product and Location Master Data
Attribute Guide and Submission Form**

Template