USAID GLOBAL HEALTH SUPPLY CHAIN PROGRAM

Procurement and Supply Management

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| Guideline for Pharmaceutical Product and Location Master Data  *Template and Guidance*  Version 1.0, January 2024 |

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**

Th*e 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]](#footnote-1)* and the *Guideline for Identification and Labelling of Pharmaceutical Products Template and Guidance*.[[2]](#footnote-2) The model directive helps countries develop traceability 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**. It also assumes that the entity using this template is not using the GS1 Global Data Synchronization Network (GDSN) as a means of synchronizing data at a starting point. If an NPC is not in scope or the GDSN is 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 approach for the hosting and managing 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 in consultation with national stakeholders. 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 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 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 unique instance of the generic product that is manufacturer specific and can be priced, ordered, invoiced, or marketed at any point in the supply chain.

**Key Considerations**

| Focus Area | Consideration | Template Section |
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| Introduction | * 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 | * 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 | * 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 Sharing Master Data | * 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 template and indicates a future update will be made with guidance on direct submission to an NPC. * Update this section based on specific requirements on master data sharing for the country’s NPC if applicable. | Section 4 |
| Master Data Management Resources | * 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 *Guideline for Pharmaceutical Product Identification and Labelling* to these resources and remove resources as appropriate for the context. | Section 5 |
| Product Master Data Attributes | * 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 |

1. Available: https://www.ghsupplychain.org/index.php/TraceabilityModelDirective [↑](#footnote-ref-1)
2. Available: https://www.ghsupplychain.org/ProdIdentificationLabellingGuidance [↑](#footnote-ref-2)