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# Guideline for Pharmaceutical Product and Location Master Data Sharing

**Government of [Country]**

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

**For Inquiries:** [INSERT CONTACT INFORMATION]

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Acronyms

|  |  |
| --- | --- |
| GDM | Global Data Model |
| 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 |

Revision History

|  |  |  |  |
| --- | --- | --- | --- |
| **Version** | **Author** | **Date** | **Comments** |
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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. 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. 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. 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.

1. 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 [responsible party type (e.g., marketing authorization holder)] 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 applicable 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].*

1. 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.

* 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] |

* 1. 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 |

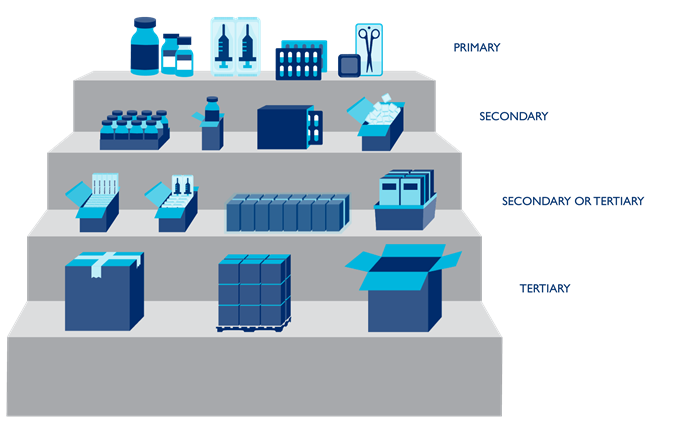
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1. Steps for Sharing Master Data

To share data with [NDRA], [responsible party type (e.g., marketing authorization holder)] are to undertake the following actions:

1. Assign a GLN[[1]](#footnote-2) for each of the relevant locations or legal entities, including brand owner, manufacturing location, and information provider (i.e., [responsible party type (e.g., marketing authorization holder)]).
2. Assign a GTIN to each level of the trade item packaging hierarchy (e.g., each, inner, case, pallet).[[2]](#footnote-3) An example of a trade item packaging hierarchy in the healthcare context is:

*Figure 1. Identification at healthcare levels of packaging[[3]](#footnote-4)*



1. 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.
2. 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].
3. 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 [XX] 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.]*

1. Master Data Management Resources

**GS1 Healthcare GTIN Allocation Rules Standard**

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 Standard is available at:

https://www.gs1.org/standards/gs1-healthcare-gtin-allocation-rules-standard/current-standard

**GS1 Global Data Model**

The GS1 Global Data Model (GDM) identifies and defines a set of foundational attributes for product master data including standard attribute names, definitions, data type, length, validation rules, code lists, and local name(s). The technology-agnostic GDM standard references other standards such as the Global Data Synchronization Network (GDSN).

The GDM can be explored using the GDM Navigator Tool available at: [**https://navigator.gs1.org/gdm**](https://navigator.gs1.org/gdm) and can be understood further through the GS1 Global Data Model Attribute Implementation Guideline available at: [**https://www.gs1.org/standards/gs1-global-data-model-attribute-implementation-guideline/current-standard**](https://www.gs1.org/standards/gs1-global-data-model-attribute-implementation-guideline/current-standard)

**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: https://www.gs1.org/standards/gs1-package-and-product-measurement-standard/current-standard.

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

1. For more information on the GLN, please refer to the GS1 website: https://[www.gs1.org/gln](http://www.gs1.org/gln) [↑](#footnote-ref-2)
2. 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](http://www.gs1.org/1/gtinrules/en/healthcare) [↑](#footnote-ref-3)
3. “Primary packaging” is usually the unit of use. “Tertiary packaging” in this context refers only to trade items and not to logistic units. [↑](#footnote-ref-4)