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Pharmaceutical Products Traceability Master Data Guideline

2nd Edition

January 2022
Addis Ababa, Ethiopia

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Contents

Foreword

Medicine plays an indispensable role in the provision of health services. Since 1993, Ethiopia has been putting tremendous efforts to implement the National Drug Policy, and has made huge strides to improve access to safe, quality and efficacious medicines to the public while promoting their rational use. The political commitment and good leadership as well as community mobilization, collaboration and partnership has remarkably improved the health system.

Assuring the safety, quality and efficacy of medicines is a global challenge. As a result, there is a tremendous surge in demand by healthcare providers to exchange information regarding medicine quality and traceability within the supply chain system, and with the various sites and departments within their institutions. In response, many institutions and healthcare facilities are developing their own solutions without agreement of common basic principles and globally accepted standards that would enable them to track and trace products from the source to the patient and back to the source, through the supply chain system.

This uncoordinated and fragmented approach makes the supply chain system inefficient and the data collected inaccurate. This incurs cost and confusion in the healthcare business, thereby compromising the quality of care and patient safety. Therefore, it is crucial to develop global standards which provide simplicity and consistency by promoting universal applicability and optimal functionality across the globe for all industry sectors.

Recognizing this, the government of Ethiopia has launched an initiative to implement global standards on identification, data capturing and exchange in the pharmaceutical supply chain system. As part of this effort, the Ethiopian Food and Drug Authority (EFDA) has developed Traceability Strategic Plan and Directives, and Systems. Furthermore, the Pharmaceutical Products Traceability Master Data Guideline is developed to facilitate the implementation of a traceability system in the country.

I hope that the Master Data Guideline will serve as a useful guide to the supply chain actors and stakeholders to share master data through standardization of data attributes. It gives me great pleasure to introduce this edition to all beneficiaries, which is the fruit of the joint effort of the staff of the EFDA and partners.

EFDA would like to appreciate and thank all development partners and individuals who have been involved in the preparation of this valuable document. I also would like to thank the National Steering Committee and Traceability Technical Working Group members and other participants from different governmental and private sectors for their valuable contribution and comments during the preparation of the guideline.

Finally, I would like to take this opportunity to acknowledge and express my appreciation to the United States Agency for International Development (USAID)/Digital Health Activity (DHA) for the financial and technical support and to all those experts who have directly or indirectly extended their helping hands in the preparation of this guideline. I call upon health professionals and interested parties to continue their usual support in reviewing the guideline by forwarding comments and suggestions to the EFDA.

Heran Gerba

Director General, EFDA

Acknowledgments

The Ethiopian Food and Drug Authority (EFDA) would like to acknowledge and express its appreciation to the United States Agency for International Development (USAID)/Digital Health Activity (DHA) for the financial and technical support delivered in producing the Master Data Guideline.

The Authority would also like to thank the members of the National Traceability Steering Committee and Technical Working Group for their commitment and contribution in developing this guideline. Last but not least, the Authority would like to give special acknowledgements to those who were involved in the preparation of the guideline, for their invaluable contributions in scrutinizing and seeing it through to completion.

Acronyms and Abbreviations

API	Application Programming Interface
ATC	Anatomical Therapeutic Chemical
EFDA	Ethiopia Food and Drug Authority
EPSA	Ethiopian Pharmaceutical Supply Agency
DHA	Digital Health Activity
GLN	Global Location Number
GTIN	Global Trade Item Number
GUI	Graphic User Interface
MOH	Ministry of Health
USAID	U.S. Agency for International Development
XML	Extensible Markup Language

1. Introduction

Ethiopia has made great strides to improve access to safe, quality and efficacious pharmaceutical products to the public. The EFDA is responsible for ensuring the safety, quality and efficacy of pharmaceutical products circulating in the market. The availability of substandard and falsified (SF), and illegally circulating medicine with unknown sources negatively impacts patient safety. In addition, the inefficient recall system, and lack of visibility in pharmaceutical products movement among the pharmaceutical supply chain actors and within organizations, hinders the supply chain from functioning efficiently. This has forced the government to implement a system that ensures traceability of pharmaceutical products that spans from manufacturer to end-users.

To exchange traceability information and enhance supply chain efficiency, ensuring proper sharing of master data is vital to all stakeholders. Master Data is description attribute information about products and locations that serve as an identifier. These data attributes are generally fairly static and will not change on a transaction-by-transaction basis. These attributes include, but are not limited to: product name, shelf-life, quantity, description, dimension, size, color, ingredients of the product; and name, address and sites for the location entity. However, there are variations in data sharing among supply chain actors. Among the main challenges of master data sharing are data errors, unit of measure confusion/misuse, duplications, missing information, incomplete descriptions, varying methods of communication and varying descriptions and levels of detail of product attributes. The discrepancies of product and location attributes are common in the healthcare setting.

Deploying a proper master data management platform and assuring the availability of standardized master data lists, help to create a single point of reference among the supply chain actors. This will also ensure effective sharing of data between supply chain actors to facilitate interoperability through standardization of data attributes, and enable accurate information and visibility about products and locations.

The EFDA, cognizant of this, and in collaboration with its partners, has devised an initiative to introduce a pharmaceutical products traceability system in the country. As part of this, the Authority is committed to implement a system for proper pharmaceutical products' and locations' master data sharing among the supply chain actors that ensures the provision of a single source of truth, attribute consistency and traceability. The synchronization of product data with pharmaceutical supply chain actors for both new and existing items will have a significant contribution in improving the supply chain data quality and management. It also improves overall supply chain efficiency and effectiveness.

According to article 14 of the Pharmaceutical Products Traceability Directive No. 43/2019, all supply chain actors including manufacturers shall share the master data about pharmaceutical products and locations with the Authority and among themselves, as appropriate.

This document is developed to set requirements and provide guidance in the process and methodology to be used by the Authority, manufacturers, importers, wholesalers and other supply chain actors in achieving the goal of master data sharing. The guideline describes the master data requirements, master data sharing modality, steps to synchronize master data and, roles and responsibilities of key stakeholders.

2. Scope

This guideline applies to all master data attributes for both product and location information to be used within the pharmaceutical supply chain system.

3. Objective

The objective of this guideline is to set master data requirements which will guide the sharing and exchange of master data among the supply chain actors and/or EFDA; and to implement practical and efficient standards and procedures which are consistent with pharmaceutical regulations.

4. Definition

Without prejudice to the definitions provided in Proclamation No. 1112/2019 and Pharmaceutical Products Traceability Directive No. 43/2019, in this guideline, unless the context otherwise requires:

1. **"Attribute"** means an element string that provides additional information about an entity identified with a GS1 identification key, such as batch number associated with a Global Trade Item Number (GTIN). Attributes are characteristics of a product that distinguish it from other similar concepts or commodities.

2. **"Authority"** means the Food and Drug Authority of Ethiopia.

3. **"Element string"** means the combination of a GS1 Application Identifier and GS1 Application Identifier data field.

4. **"GS1" means** a neutral, not-for-profit, global Organization that develops and maintains the most widely used supply chain standards in the world.

5. **"GS1 Application Identifier"** means the field of two or more digits at the beginning of an element string that uniquely defines its format and meaning.

6. **"GS1 identification key"** means a unique identifier for a class of objects (e.g., a trade item) or an instance of an object (e.g., a logistic unit).

7. **"Master Data"** means attributes of a real-world entity that are static (unchanging throughout the life of the entity) or nearly so.

8. **"Supply chain actor"** means any person in the supply chain to manufacture, import, distribute, transport, store or dispense pharmaceutical products or is involved in related activities.

9. **"Product"** means an object with a defined set of attributes or characteristics. In this guideline, the word 'product' signifies for medicine or pharmaceuticals.

10. In this guideline, the word medicine (s) and pharmaceutical (s) are used interchangeably.

5. Master Data Requirements

Availing appropriate master data requirements is a necessary condition to ensure master data consistency, uniformity, accuracy, trust and proper flow of data, thereby enabling establishment of a traceability system. The requirements are also important to ensure accountability of the supply chain actors' officially shared master data assets.

The attributes are classified depending on their significance for master data exchange as "Mandatory (M)" and "Suggested (S)". The "Mandatory" attributes are necessary for the master data exchange while the "Suggested" attributes are highly recommended to be submitted to the Authority. If some of the suggested attributes are not immediately available, share the available attributes and follow the remaining ones. The list of product and location attributes are listed in Table 1 and Table 2 respectively. For each attribute, the list provides the attributes' name, data type, a brief definition and significance.

This guideline is intended for gathering and sharing master data of products and locations. It is complementary to but not a substitute of the existing drug registration and licensing processes and procedures.

5.1. Product Master Data

Product master data is a reliable record of basic information about product attributes such as name, dosage form, strength, indication and unique identifications (which are used in the supply chain to identify the trade item). One trade item can have multiple product parameters including size, weight, color and shape - which require their own unique identifiers.

Besides the particular product master data required in this guideline, all other product master data shall be in line with the information required during regulatory submission stated in the medicine registration guidelines and all parties, especially manufacturers, need to ensure that their data meet the below requirements.

Global Trade Item Number:

Each and every trade item shall be identified by using the global trade item number (GTIN). The GTIN is the globally unique GS1 identification number used to identify trade items (i.e. items that may be priced, ordered, or invoiced). GTIN is an umbrella term for all GS1 "trade item" identification numbers. GTINs are assigned by the brand owner of the item and are used to identify items as they move through the supply chain to the point of dispense or ultimately to the end users. There are different types of GTIN's; GTIN-14 is more common for healthcare. These digits of GTIN consist of the Packaging Level Indicator, GS1 Company Prefix, Item Reference and a calculated Check Digit. Refer to Figure 1 for an example of 14 digit GTIN.

GS1 Application identifier	Global Trade Item Number (GTIN)													
	GS1 Company Prefix →									Item Reference ←			Check digit	
01	N1	N2	N3	N4	N5	N6	N7	N8	N9	N10	N11	N12	N13	N14

Figure 1: Example for 14 digit GTIN.

The trade item shall also have specific descriptions, which are not ambiguous. Items shall be specified with a unit of measure of trade item about their Depth, Height, Width, Net Weight, Gross Weight, Volume etc. For more information on how to generate and maintain a GTIN, please refer to the EFDA GTIN allocation rule guideline and GS1 General Specifications. Table 1 depicts the required attributes to exchange the product master data.

Table 1: Product Attribute Requirements

Category	Attributes	Description	Example	Significance
General item information	GTIN	The GTIN is the standard 14-digit number used to identify the medicines.	65410013107231	M
	Hierarchy Level	Describes the hierarchical level of the trade item such as unit of use, each, case or pallet. This may also be referred to as the packaging hierarchy.	Base unit, case, each	M
	Brand Name	The recognizable name used by a brand owner to uniquely identify the medicine. This is recognizable by the consumer.	Panadol	M
	Generic Name	The non-proprietary name of the medicine.	Paracetamol	M
	Functional Name	Describes the use of the medicine by the consumer. It should help to clarify the product classification associated with the GTIN. It answers the question: What does the product do?	Non-steroidal Anti-inflammatory Drugs (NSAIDs)	M
	Country of Origin	The country in which the medicines have been produced or manufactured.	Ethiopia	M

Pharmaceutical information	Dosage Form	A dosage form is the physical form of a medication that identifies the form of the pharmaceutical item.	Tablet, Capsule	M
	Dosage Unit	The unit of measurement	mg	M
	Dosage Strength	The content of the active substances expressed quantitatively per dosage unit, per unit of volume or weight according to the dosage form.	25	M
	Dosage Recommendation	Information pertaining to the dosage of medicines that should be taken/ administered per dose. This is not based upon prescribed dosage, but recommended dosage by the manufacturer. This may be pre-labeled on product or need to be labeled per target market regulations.	Take one tablet three times a day before meals. Take 2 tablets every 4 hours, Take one teaspoon daily, etc.	S
	Dosage Restriction Limits	Information pertaining to the dosage of medicine that should be taken/ administered in a limited quantity. This is not based upon prescribed dosage, but recommended restrictions by the manufacturer. This may be pre-labeled on product or need to be labeled per target market regulations.	Do not exceed no more than three tablets per day.	S
	Product Description	An understandable and usable description of a medicine using brand and other descriptors. It is the brand owner's description of the product. This information will help further to detail what the item is. Includes color, fragrance, shape etc.	Acyclovir, Suspension, 40 mg/ml, 125ml	M
	Pack Size	The amount of product in a pack or container.	Pack size of 5 vials of 10 ml	M
	Route of Administration Description	The description for the method(s) of administering the medicine. i.e. the path by which a medicine is brought into contact with the body.	Oral, inhalational, buccal, sublingual, nasal,	M
	ATC Category	WHO classification system that divides the drugs into different groups according to the organ or system on which they act and according to their chemical, pharmacological and therapeutic properties.	Antimalarials	S
	ATC Code	Code specifying a product category according to the WHO ATC.	X03AC03	S
	Controlled Substance Indicator	Indicates whether the item contains substances that are regulated under law as narcotics, psychotropic and chemicals used in the illicit production of controlled substances.	Yes	M
	Controlled Substance Name	The name of a specific controlled substance the item contains that is regulated under law as narcotics, psychotropic and chemicals used in the illicit production of controlled substances.	Diazepam	M

Hierarchy	Child Item GTIN (Lower Level Item)	Unique product identification number (GTIN) for a child item with a higher-level trade item (parent) in a product hierarchy. This item may repeat in the case of a combination pack (multiple GTINs in lower level).	87999999999995	S
	Total Quantity of Next Lower Level Trade Item	This represents the total quantity of next lower level trade items that this trade item contains.	15	S
Pallet and logistic units	Shipping Container Type Code	Type and size of the container in which the trade items composing the standard transport load (identified by a unique GTIN) are shipped in by the consignor for international transport. This code refers to the type of container and not the items inside.		M
Storage, handling and shelf life	Shelf Life from Production	The period of days, guaranteed by the manufacturer, before the expiration date of the product, based on the production.	720 days	M
	Minimum Storage Temperature	The minimum temperature that a trade item can be held without affecting product safety or quality (as defined by the manufacturer).		S
	Minimum Storage Temperature Unit of Measurement	It is the unit measurement of the minimum storage temperature	^{O}C / ^{O}F	S
	Maximum Storage Temperature	The maximum temperature that a Trade Item can be held without affecting product safety or quality (as defined by the manufacturer).		S
	Maximum Storage Temperature Unit of Measurement	It is the unit measurement of the minimum storage temperature	^{O}C / ^{O}F	S
Market Authorization	Market Authorization Number	Identification of the license given by the regulatory agency/authority.		M
	Market Authorization Start Date	The start date on which the Market Authorization permit is effective.		M
	Market Authorization End Date	The date on which the Market Authorization permit expires.		M
	Market Authorization Status Description	Description information for the status of marketing authorization (e.g., active; expired; etc.)		S

Note: The manufacturer can add other information associated with the product which are not stated here.

5.2. Location Master Data

Locations are used to describe physical, functional and legal entity locations of the supply chain actors. It typically represents a manufacturer, importer, wholesaler and point of dispense such as health care facilities, medicine retail outlets etc. A location can be hierarchical, for example, warehouse or storage locations that belong to manufacturers and distributors or an importer (which is a parent location).

The use of standards-based location identifiers enables supply chain actors to maintain and manage precise location specific information. Moreover, the use of globally standardized and accepted location identifiers provide a common language to identify, capture and share location information among supply chain actors.

Location master data contains a record of each pharmaceutical supply chain actor's (e.g. manufacturers, importers, wholesalers, hospitals, medicine retail outlets etc.) information such as location, unique identifier, name, address, country code, contact information and business type. Inconsistent naming and location identification of supply chain actors results in an error-prone, inefficient approach to location identification that weakens patient safety and overall supply chain management.

A Global Location Number (GLN) is used to uniquely identify a company or organization. A GLN acts as a database key that references location-specific information stored in a data repository, maintained by an organization (e.g. drug regulatory information system). A GLN can also be used to number delivery places, invoicing addresses, workplaces and branches as well as functions or roles, such as goods recipient or authorized purchasers, if any.

A GLN consists of 13 digits. GLN is created using a GS1 Company Prefix, a sequence number and a Check Digit.

- A GS1 Company Prefix consists of 6-9 digits.
- The sequence number (location reference) consists of a different number of digits depending on the length of the company prefix.
- The check digit prevents substitution errors.

The GLN can be constructed as follows, using a GS1 Company Prefix:

Global Location Number (GLN)												
GS1 Company Prefix →							← Location Reference					Check digit
N1	N2	N3	N4	N5	N6	N7	N8	N9	N10	N11	N12	N13

Figure 2: Example for 13 digit GLN (7350053850019)

If the company prefix has less than nine digits, you create the location number in the same way but the sequence number will be more than three digits.

The supply chain actors shall obtain their unique location identifiers from the GS1 offices located to the nearest of them.

Table 2: Location Attribute Requirements

Category	Attributes	Description	Example	Significance
Location/contact / role information	Brand Owner GLN	The Global Location Number used to identify the organization that owns the brand, the legal entity.	8712345012502	M
	Brand Owner Name	The legal name of the brand owner of the medicine.	Ethio Pharma	M
	Manufacturer Name	The legal name of the manufacturer of the medicines.	Ethio Pharma	M
	Manufacturer GLN	The Global Location Number used to identify the manufacturer that manufactures the medicine.	8712345012502	M
	Manufacturer Address	The registered address associated with the manufacturer. The address may include country, city, province, street, Phone, postal code etc.	Cherkos sub-city, district #2, Africa avenue, Addis Ababa, Ethiopia	M
	Information Provider Name	The legal name of the information provider of the medicine expressed in text	XXX	M
	Information Provider GLN	Populate this field with the GLN of the entity responsible for the validity of the item information entered into your Data Pool. The original manufacturer, importer, distributor, retailer or designated agent.	8712345012502	S
	Information provider address	The address associated with the information provider. The address may include country, city, province, street, Phone, postal code etc.	PO Box 123 Africa avenue, Addis Ababa	S
	Importers, wholesalers, medicine retail outlets, Healthcare facilities name	The respective legal name of the these institutions		M
	Importers, wholesalers, medicine retail outlets, Healthcare facilities GLN	The Global Location Number used to identify the institutions	6712245412509	M
	Importers, wholesalers, medicine retail outlets, Healthcare facilities address	The registered address associated with these institutions. The address may include country, city, province, street, Phone, postal code etc.		M

Note: if there are any GLN associated functional or physical location identifiers of a legal entity, the associated information such as unique identifiers, names, and address of the functional or physical location shall be submitted.

6. Master Data Exchange

Master data exchange is a system used to gather, clean, analyze and manage master data to allow it to become a useful data asset among supply chain actors allowing data synchronization and electronic transfer of product and location information between trading partners and the continuous exchange of that data over time. It provides management, coordination, and technology for the process to prepare and validate master data to maintain high-quality data.

6.1. Methods for Master Data Exchange

The EFDA will create a system to synchronize master data of pharmaceutical products and locations by allowing options for how to exchange master data. Master data exchange can be made through web Graphic User Interface (GUI) (manually enter or import the data), Extensible Markup Language (XML) exchange and Application Programming Interface (API).

6.2. Master Data Quality

Data quality answers questions regarding completeness, validity, uniqueness, consistency, logical, timeliness and accuracy of master data for easy access, documentation and clear quality criteria. Without sufficient data quality, data is practically useless and sometimes even dangerous.

In data-driven environments, uniform and consistent data is necessary to allow systems to talk to each other. Poor data quality will lead to false facts and bad decision-making. Duplicate and redundant data copies are expensive to clean up and lead to inconsistencies and data error.

Supply chain actors shall have procedures to ensure the quality of their master data and ensure that it's complete, consistent, accurate, time stamped and standards-based. A series of documented and periodically reviewed procedures shall be implemented to maintain and support the production of good-quality data. Data quality strategy (planning), data quality audits (assurance), and data quality validation rules and reasonability checks (control) shall be considered as part of the master data quality management program.

6.3. Master Data Security

Data security is the confidentiality, availability and integrity of data. It is all about the practices and processes established to ensure data is not used or accessed by unauthorized individuals or parties. The EFDA will create procedures to maintain data security that are shared to the national repository or central database. In addition, the supply chain actors are responsible to secure the master data they develop and share. The Authority and the supply chain actors shall follow the national laws and standards in assuring the master data security.

6.4. Workflow in the master data exchange

Manufacturers, importers, wholesalers or other pharmaceutical institutions who need to place pharmaceutical products in the market shall follow the authorized processes. The local manufacturers, importers and wholesalers shall have a certificate of competence and the pharmaceutical products shall be registered or authorized for importation as per the Food and Medicine Administration Proclamation No. 1112/2019 and its subsequent regulations, directives and guidelines.

During the registration process, manufacturers are required to submit the medicine master data as per the requirements stated in medicine registration and licensing guidelines. Master data including unique identifiers that are not submitted during registration of the product shall be submitted as per this guideline. Master data can be submitted by the manufacturers or its scientific office/representative located in Ethiopia or a local agent available in Ethiopia. The Authority will respond to receiving the product master data and will review, validate and accept or reject the information.

After reviewing the master data, the Authority may request additional information or clarification on attributes of the master data and notify the applicant of the deficiencies or missing requirements with the necessary recommendations. The applicant shall then resolve and submit the required information to the Authority.

If the submitted data is valid, the product will be recorded in the master data repository and the Authority will notify the acceptance of the master data. If the data submitted is not valid, the shared data will be rejected and the applicant will be notified. The workflow of the master data exchange is depicted in figure 3.

In addition to the product master data, all supply chain actors shall share their location master data with the EFDA's national central database and all actors shall make sure that the data is of acceptable quality and standards.

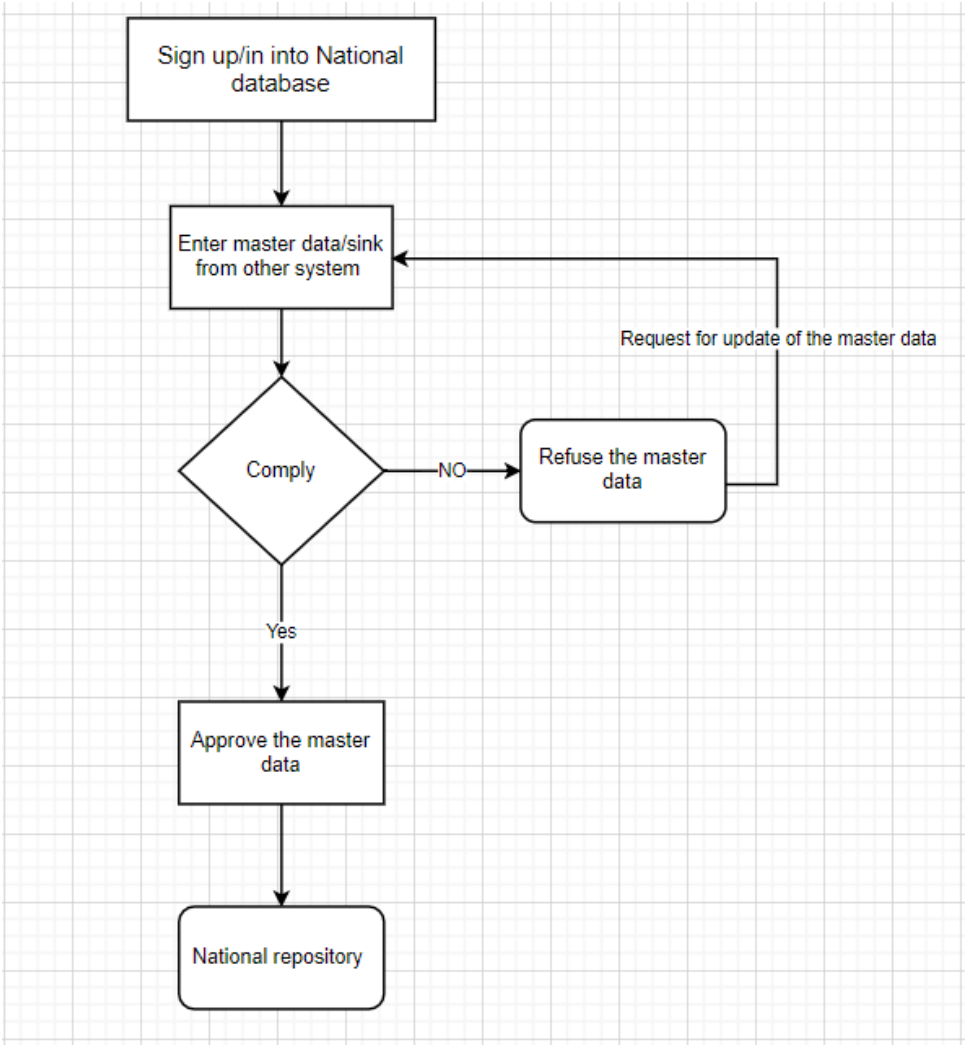

Figure 3: Master data exchange workflow

7. Synchronization of Master Data with the EFDA's traceability system

The EFDA will create a national repository or central database to enable the supply chain actors to share reliable master data as the basis of product catalogue. In addition, every company must have a database filled with master data about the products they make, sell, or buy and their locations. When appropriate, the national database will integrate with certified international systems or networks so as to connect trading partners via a network of interoperable certified data pools. Furthermore, the EFDA will create a portal with user manuals on how to share the master data.

8. Roles and Responsibilities of Supply Chain Stakeholders

Table 3: Roles and responsibilities of supply chain actors/stakeholders

Institution	Role and Responsibility
EFDA	a. Define and develop requirements of master data; b. Develop a centralized master data repository that manages the master data; c. Review the submitted master data and provide feedbacks accordingly; d. Periodically review and maintain master data attributes of the master data repository; e. Provide a reliable data import and synchronization mechanisms; f. Provide capacity building on master data for traceability; g. Ensure master data quality and security; h. Enforce the supply chain actors to share their master data to the central repository; i. Mobilize adequate resources to continually develop and strengthen the traceability system; j. Update the Master Data Guideline as necessary to accommodate changes.
Manufacturers	a. Comply with the requirements of this guideline; b. Identify products and locations master data required under this guideline; c. Gather and share the master data with EFDA master data repository; d. Establish a system that enables them to keep their own master data up-to-date and share product and location attributes to the Authority; e. Develop a procedure for identifying, capturing and sharing master data; f. Obtain GTIN from GS1 and assign to each product and level of packaging hierarchy; g. Obtain GLN from GS1 and assign it to each location; h. Establish a system to handle and provide confirmation to requests from the Authority; i. Submit any changes to the master data elements to the Authority.
Importer, wholesaler, retail outlet and healthcare facilities	a. Comply with the requirements of this guideline; b. Gather and share the location and packaging related master data with EFDA master data repository; c. Establish a system that enables them to keep their own master data up-to-date and submit location and packaging attributes to the Authority; d. Develop a procedure for identifying, capturing and sharing master data for locations and packaging, if any; e. Obtain GLN from GS1 and assign it for each location; f. Establish a system to handle and provide confirmation to requests from the Authority; g. Submit any changes to the master data elements to the Authority.
Ministry of Health (MOH)	a. Support healthcare service providers in the implementation of requirements set under this guideline; b. Ensure the communication with different sectoral offices to support the implementation of master data; c. Provide resources to the regulatory sector to appropriately implement the master data guideline; d. Oversee and support implementation of this guideline at the national level.
GS1	a. Provide technical support on master data implementation; b. Support in establishing system to provide unique identifiers for both products and locations data to supply chain actors.
Partners	Provide technical and financial support on master data implementation.

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DISCLAIMER:

The USAID DHA works with the Government of Ethiopia (GOE) to build sustainable, resilient, and interoperable health information system (HIS) that ensure the entire health sector has the data, analytics, and skills necessary to improve the health and well-being of all Ethiopians.

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