Food, Medicine and Healthcare Administration and Control Authority

PHARMACEUTICAL TRACEABILITY STRATEGIC PLAN

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The Ethiopian Food, Medicine and Healthcare Administration and Control Authority (EFMHACA) would like to extend its sincere appreciation to USAID, UNFPA, and AIDSFree/Joh Snow Inc. for the support of the development of the Pharmaceutical Traceability Strategic Plan. We would also like to give special acknowledgement to the members of the National Traceability Steering Committee, National Traceability Technical Working Group & EFMHACA Traceability Technical Working Group, Ministry of Health, PFSA, USAID, AIDSFree/JSI, Bill & Melinda Gates Foundation, UNFPA, Ethiopia Medical Association, Ethiopian Pharmaceutical Association, UNICEF, St. Paul Millennium Medical College, Ethiopian Standard Agency, Myungsung Christian Medical Hospital, Ministry of Communication and Information Technology, Information Network Security Agency and USP/PQM for their unreserved effort to bring this document to reality.

Background

Before establishment of this document was possible EFMHACA, with support from partners took a long road. It all started in 2014 when collaboration between USAID and UNFPA started to address interoperability and data visibility and the first pilots to test the use of GS1 standards in the Ethiopian healthcare supply chain started. In 2015, collaboration for standards adoption led by USAID, UNFPA and GAVI was introduced at the Interagency Supply Chain Group. USAID and UNFPA founded the RH Global Traceability Advisory Group (RH GTAG). In 2016 EFMHACA got involved and participated, together with important partners in the supply chain like the Pharmaceutical Fund and Supply Agency in the GS1 Healthcare Conference to learn about the importance of global standards for improvement of patient safety and efficiency in the healthcare sector. A National Consultative Workshop was conducted to educate and engage local stakeholders. Also, the National Traceability Steering Committee and Technical Working Group were established. In 2017 a consultant was hired to work on creation of awareness, to assess stakeholders' capabilities and develop a roadmap for implementation of traceability in the pharmaceutical supply chain.

FOREWORD

The Ethiopian Government with continued support and collaboration from the development partners achieved a lot towards improving the health status of its citizens.

The safety, quality and efficacy of health commodities is a challenging issue at global level. As a result, there is a tremendous surge in demand by healthcare providers to exchange information regarding medical products quality and traceability within their supply chain, and with the various sites and departments within their institutions. In response, many institutions and healthcare facilities are developing their own solutions without common basic principles and globally accepted standards that enables them to track and trace product delivery from the source to the patient and back through the supply chain.

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

Hence, FMOH and EFMHACA 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 Traceability Steering Committee, National Traceability Technical Working Group and EFMHACA Traceability Technical Working Group members for their valuable contribution and comments during the preparation of the document.

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EXECUTIVE SUMMARY

Falsified medicine negatively impacts patient safety in the Ethiopian pharmaceutical supply chain. In addition to this, threats to patient safety, the lack of visibility in product movement between trading partners and within organizations highlight many supply chain inefficiencies.

Because of this, the Ministry of Health and its specialized agencies, particularly the Ethiopian Food, Medicine and Healthcare Administration and Authority (EFMHACA) and the Pharmaceuticals Fund and Supply Agency (PFSA) have embarked on initiatives critical to building information systems fit for ensuring patient safety, modernizing regulatory functions and improving supply chain efficiency.

One of these initiatives is the implementation of global standards for product identification and data exchange to support the implementation of traceability in the pharmaceutical supply chain. The implementation of traceability will help to **improve patient safety** by making sure patients aren't exposed to falsified, expired, recalled or other otherwise harmful pharmaceuticals and **improve supply chain efficiency** by ensuring the visibility of pharmaceutical product movement.

EFMHACA developed this Pharmaceutical Traceability Strategic Plan to describe the strategic objectives and supporting activities the Ethiopian government will need to undertake to implement traceability in the pharmaceutical supply chain, taking the different weaknesses and challenges in the current landscape into account. The strategic objectives are:

1. Strengthen regulatory system to enable implementation of traceability of pharmaceuticals.
2. Build and sustain technical infrastructure to support implementation of traceability.
3. Build stakeholder's capacity to ease implementation of traceability.
4. Strengthen knowledge, communication and collaboration to ease implementation of traceability.
5. Create visibility in the pharmaceutical supply chain by implementation of traceability.
6. Improve patient safety and efficiency in the pharmaceutical supply chain by use of traceability data.

To create visibility in the pharmaceutical supply chain the introduction of global standards will be executed in phases to give all stakeholders enough time for the implementation. This will also provide the opportunity to use the experience from each phase in the phase that will follow.

1. The first regulatory publication will require manufacturers to uniquely identify their products and share standardized master data with supply chain actors, including the government.
2. The second phase will require implementation of traceability of product batches.
3. The third phase will require traceability of unique item.
4. During each phase, information captured in the traceability system will be used to improve patient safety and efficiency in the pharmaceutical supply chain and will provide input for decision making by the government and supply chain actors.

To successfully achieve the objectives this strategic plan will require ownership from all stakeholders in the supply chain, including governmental bodies. Monitoring and reporting on progress of implementation will be done between the Traceability Office working on the execution of this strategic plan, EMFHACA management and the National Steering Committee providing guidance for the implementation.

GLOSSARY OF TERMS

API	Active Pharmaceutical Ingredient
ANMAT	National Administration of Drugs, Food and Medical Devices,
DSCSA	Drug Supply Chain Security Act
EFMHACA	Food, Medicine and Health Care Administration and Control Authority
EPCIS	Electronic Product Code Information Services
FMD	Falsified Medicine Directive
FMOH	Federal Ministry of Health
GDSN	Global Data Synchronization Network
GLN	Global Location Number
GS1	Global Standards 1
GTIN	Global Trade Item Number
GTSH	Global Traceability Standard for Healthcare
HSDP	Health Sector Development Program
HCMIS	Health Commodity Management Information System
HSTP	Health Sector Transformation Plan
iTS	Pharmaceutical Track & Trace System
JSI	John Snow, Inc.
MO	Member Organization
MRIS	Medical Registration Information System
OTC	Over the Counter
PFSA	Pharmaceuticals Fund and Supply Agency
PTSP	Pharmaceutical Traceability Strategic Plan
POP	Prescription Drugs
PSM	Procurement and Supply Management
SSCC	Serial Shipping Container Code
TO	Traceability Office
TWG	Technical Working Group
UNFPA	United Nations Population Fund
UI	Unique Identifier
USAID	United States Agency for International Development
WHO	World Health Organization

DEFINITION OF TERMS

In this strategy, unless the context otherwise requires,

Barcode means a machine-readable code in the form of numbers and a pattern of parallel lines printed on and identifying a product for monitoring by the manufacturer or executive organ.

Counterfeiting means using in any way, the packing material, identification or trademark, trade name or any special mark thereon of an authentic product of a manufacturer and presenting such falsely labelled and packed food or pharmaceuticals as if it is manufactured by the genuine manufacturer or altering content and properties of food or pharmaceuticals that cause health hazards to humans.

Distributor means any natural or legal person in the supply chain who, on his own behalf, furthers the availability of a medical device to the end user.

Falsified pharmaceutical or medicine means medicine that deliberately or fraudulently misrepresent their identity, composition or source.

Importer means any natural or legal person in the supply chain who is the first in a supply chain to make a medical device, manufactured in another country or jurisdiction, available in the country or jurisdiction where it is to be marketed.

Label means any material which is printed or affixed to a packing material which provides the necessary information about a food or medicine and includes an insert.

Manufacturer means any natural or legal person with responsibility for design and/or manufacture of a medical device with the intention of making the medical device available for use, under his name; whether such a medical device is designed and/or manufactured by that person himself or on his behalf by another person(s).

Manufacturing means processing of raw materials into finished goods using tools and processes.

Medicine or **pharmaceutical** means any substance or mixture of substance:

a. used in the diagnosis, treatment, mitigation or prevention of human disease, disorder, abnormal physical or mental state, or the symptoms thereof;
b. used in restoring, correcting or beneficial modification of organic or mental functions in humans;
c. which are articles other than food, intended to affect the structure or any function of the body of humans; and
d. which includes articles intended for use as a component of any articles specified in clause (a), (b) or (c).

Supply chain means a network between a company and its suppliers to produce and distribute a specific product. The supply chain represents the steps it takes to get the product or service to the customer.

Traceability means according to GS1's Global Healthcare Standard, 'the ability to track forward the movement through specified stage(s) of the extended supply chain and trace backward the history, application or location of that which is under consideration'.

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1 Introduction

Ethiopia has one of the fastest growing economies in the world. However, production capacity, technological developments, creation of employment opportunities and investments in the healthcare sector are behind on other sectors (HSTP, 2015), while at the same time due to population growth and longer life expectancy the Federal Ministry of Health is expecting an increase in demand of medication. This forms a threat to one of the biggest issues in the healthcare sector: the existence of falsified products in the legitimate pharmaceutical supply chain.

Falsified pharmaceuticals negatively impact patient safety. They can cause harm, might lead to loss of lives, but also will have economic impact and will result in less trust in the healthcare system. Many governments have limited resources to have adequate counterfeit control. Currently, anti-malarials and antibiotics are amongst the most commonly reported falsified pharmaceuticals worldwide (WHO, 2017). The WHO estimates that 1 in 10 medical products in low- and middle-income countries is substandard or falsified (WHO, 2017).

In addition to threats to patient safety, the lack of visibility in product movement between trading partners and within organizations uncovers much inefficiency in the Ethiopian pharmaceutical supply chain. According to the recent medical products supply process reengineering exercise conducted by the Pharmaceuticals Fund and Supply Agency (PFSA) one of the major problems identified is inefficiency in the public-sector supply chain mainly attributed to lack of logistics data visibility (PFSA, 2017). Gaps in forecasting and distribution have resulted in limited availability of key pharmaceuticals in hospitals, long procurement lead time, problems in record-keeping, low data quality, untimely requisition and consumption reporting, no real-time stock status information at national level, wastage due to expiry and damage, theft and an inefficient recall system (HSTP, 2015).

In the past decades, the government of Ethiopia has invested a lot in health system strengthening to improve the quality and equity of health services to the public. Maintaining accountability, responsiveness, informed decision, traceability and good governance in pharmaceutical regulation and the supply chain are key milestones that the authority is striving to ensure.

The government is actively implementing national policies and transformation plans including the National Growth and Transformation Plan II (2016/16-2019/20) (NGTP, 2016) to ensure that pharmaceutical regulations are streamlined, effective, efficient and accessible to the community. Also, Information Revolution is a key transformation agenda set by the Ethiopian Ministry of Health within the five-year Health Sector Transformation Plan (2015/16-2019/20). Information revolution will reform the methods and practice of collecting, analysing, presenting and disseminating information. It is a radical shift from the traditional way of data utilization to an information management system. It includes improving the data collection, aggregation,

reporting and analysis practice; promoting the culture of information use, harnessing ICT, improving data visibility and access as well as strengthening verification and feedback systems.

Moreover, the "National Strategy and Plan of Action for Pharmaceutical Manufacturing Development in Ethiopia (2015-2025)" jointly endorsed by both the Ministry of Health and the Ministry of Industry, aims to assist local pharmaceutical companies and to create a conducive environment for the growth of the pharmaceutical industry which is believed to attain national resilience in providing access to essential medicine.

Even though the efforts of the Ethiopian Ministry of Health have yielded significant progress and political commitment, good leadership, community mobilization and ownership, the additional organized support from development partners has resulted in improved health of the citizens of Ethiopia in the last two decades; many of the challenges in the pharmaceutical supply chain mentioned remain.

As a result, the Ministry and its specialized agencies, particularly the Ethiopian Food, Medicine and Healthcare Administration and Authority (EFMHACA) and the Pharmaceuticals Fund and Supply Agency (PFSA) have embarked on initiatives critical to building information systems fit for ensuring patient safety, modernizing regulatory functions and improving supply chain efficiency.

One of these initiatives is the implementation of global standards for product identification and data exchange to support the implementation of traceability in the pharmaceutical supply chain. The implementation of traceability in the pharmaceutical supply chain will help to **improve patient safety** by making sure patients aren't exposed to falsified, expired, recalled other otherwise harmful pharmaceuticals and **improve supply chain efficiency** by ensuring the visibility of pharmaceutical product movement.

Global identification and serialization standards for the healthcare supply chain have been implemented or are in the process of being implemented in more than 40 countries worldwide and have received attention from globally operating organizations such as the World Health Organization. The WHO (2015) states that, to build an interconnected world which is cost-effective in terms of health, the pharmaceutical industry should be motivated to implement traceability measures by means of adopting a single set of global standards.

Application worldwide has shown the great benefits of implementing standards but has also expressed the importance of governmental involvement. For Ethiopia this is equally important. Many stakeholders in Ethiopia's healthcare sector understand the importance of global standards. They however also recognize the duplication of efforts and lack of integration among the various actors in both public and private sectors, which affirmed the need for an inter-sectoral collaboration. Without governmental involvement, implementation will take many years, and will further endanger patient safety.

Building on the lessons learned from implementing the earlier regulatory plans, other countries' experience in regulation as well as the desire to respond the current socioeconomic landscape of

the country, the government of Ethiopia has developed this Pharmaceutical Traceability Strategic Plan (PTSP) as part of the Health Sector Transformation Plan (HSTP). This plan will allow the implementation of global standards to support traceability in the pharmaceutical supply chain.

The Pharmaceutical Traceability Strategic Plan describes the strategic direction which will guide EFMHACA to improve patient safety and efficiency in the pharmaceutical supply chain by implementing global standards for product identification and data exchange. This document describes the strategic objectives and activities with time lines and responsibilities that must be undertaken within the coming years to implement traceability.

1.1 Mission

The Pharmaceutical Traceability Strategic Plan has been drafted by the Ethiopian Food, Medicine, Health Care Administration and Control Authority. In accordance with Food, Medicine and Health Care Administration and Control Proclamation No. 661/2009, the Authority is provided with a mandate to regulate the 4Ps (Practice, Premises, Professionals and Products). Its mission is "To promote and protect the public health by ensuring safety and quality of products and health service through registration, licensing and inspection of health professionals, pharmaceuticals, food establishments and health institutions and provision of up-to-date regulatory information while promoting rational medicine use."

Therefore, the mission of this strategic plan contributes to the broader mission of the health service regulatory body to facilitate the availability of safe, quality and efficacy pharmaceuticals through implementation of a pharmaceutical traceability system by using modern technology; providing safe medicine for all Ethiopians, at the time they need them. Important core values for achieving this mission include having and developing transparency and accountability between trading partners in the supply chain.

1.2 Vision

The vision of this strategy is to see availability of safe pharmaceuticals to all inhabitants of Ethiopia.

2 Traceability

Traceability systems keep electronic records of transactions that result in a change of ownership or location of an item and could include all trading partners in the supply chain, from manufacturer until the dispenser, and in some cases even the patient.

2.1 Advantages

A traceability system can be an enabler for visibility of product movement in a supply chain. The potential advantages of traceability implementation include ensuring patient safety by mitigating falsified and illegal medical products; ensures timely availability and authentication of pharmaceuticals and thereby decreasing the number of hospitalization days and even death; ensures that pharmaceuticals only circulate through the authorized health supply chain and avoids the distribution and usage of recalled or expired medicine.

Implementation of traceability will improve efficiency by favouring an efficient, fast and safe recall procedure; enables accurate inventory management, forecasting and planning; managing waste and expired products; provides visibility into delayed shipments; provides brand protection; creates real-time visibility into product attributes; prevents insurance, reimbursement and tax fraud and enables the collection of meaningful product and usage data (USAID, 2017; GTSH, 2009).

2.2 Traceability models

Several models for traceability in the pharmaceutical industry are currently implemented or in the process of being implemented and serve as an example for Ethiopia's roadmap. Depending on the specific challenges in their pharmaceutical supply chains the scope or phases of implementations worldwide could differ.

The WHO (2015) identifies a 'point of dispensing check', 'full track and trace' or a 'mixed' traceability system. The advantage of a 'point of a dispensing check' in which products are being authenticated at the point of dispensing is that it's an easier implementation than a 'full track and trace' implementation. A 'full track and trace' system however provides visibility of the whole product supply chain; makes it possible to in real time detect irregularities; help improve the recall process; enhance inventory management and provides the possibility of conducting epidemiological studies and adopting focused health-related measures in any step of the supply chain. It however is more complex, a higher number of agents is involved, and could possibly slowdown logistic processes.

Turkey

ITS, the Turkish Pharmaceutical Track and Trace System defines the infrastructure constructed to track and trace all units belonging to each pharmaceutical product in Turkey. The regulation requires every pharmaceutical, reimbursable food supplement and reimbursable borderline product to be identified with a serialized GS1 DataMatrix. The serial numbers are being captured

in a centralized database owned by the government. All pharmaceuticals on the market are traced by notifications in all the phases in the supply chain, from production to consumption.

The requirements in Turkey have evolved over the years, requiring more data to be recorded at more points along the supply chain. In 2010 the first phase was the application of a serialized 2D barcode. Through the years more applications have been added, including tracking and tracing of individual items (ITS Management Guideline, 2012).

Argentina

In 2011 Argentina's National Administration of Drugs, Foods, Medical Devices (ANMAT) developed the National Pharmaceuticals Traceability System which requires all secondary packages with a certain Active Pharmaceutical Ingredient (API) to be uniquely identified with the Commercial Product Code, the GTIN and a serial number. The pharmaceuticals listed are recorded in real time in a centralized database managed by ANMAT. The system captures each movement of the drug. Some of the transactions that are required to be captured are issue, receipt and return. The traceability system can guarantee that the drug when reaching the patient has never abandoned the legal path of production and distribution.

Some of the objectives ANMAT wishes to achieve are detection of product duplication, improved efficiency, reduction of costs of health systems, minimize wrong supply, provide quality and safety for patients, facilitate effective product recalls and evaluate the consumption of each drug type (Derecho, Sànchez, 2014).

European Union

The European Commission published the Falsified Medicine Directive (FMD) to improve the protection of public health. The measure includes safety features on the outer packaging of medicinal products subject to prescription and strengthened record-keeping requirements for wholesale distributors. A unique identifier should be placed in a 2D barcode and contain the product code, batch number, expiry date and a serial number. The authentication of the medication should be guaranteed by an end-to-end verification system - "The authenticity of each pack is verified by (i) entering its identifier number into a repository system at the time of manufacture, and (ii) checking the unique identifier against its entry in the repository system at one or more points in the supply chain." - supplemented by risk-based verification by wholesalers.

As a rule, the decommissioning of the UI takes place at the time the medicinal product is supplied to the public. As an exception, hospitals can decommission the UI at any time the medicinal product is in their physical possession. When only part of a pack is supplied, the UI should be verified and decommissioned when the pack is opened for the first time (Tosetti, 2016).

The United States of America

The Drug Supply Chain Security Act (DSCSA) in the U.S.A. outlines critical steps to build an electronic, interoperable system by November 27, 2023, which will identify and trace certain prescription drugs as they are distributed within the United States. A unique product identifier must be placed on certain prescription drug packages (in human and machine-readable format).

The system will facilitate the exchange of information by trading partners at the individual package level; improve efficiency of recalls; enable prompt response to suspect and illegitimate products when found and create transparency and accountability in the drug supply chain.

The US FDA has a phased approach for implementation of DSCSA. The first phase requires that supply chain participants share chain-of-ownership data. The second phase, requires that pharmaceutical products be marked with a National Drug Code, serial number, lot number and expiration date in both machine-readable and human-readable format. The third phase of DSCSA requires trading partners to share chain-of-ownership data to enable serialized item traceability back to the product origin, which usually is the manufacturer (GS1 US, 2016).

2.3 Global standards that support traceability

Even though scope and implementation phases could differ, the one thing these implementations have in common is that the foundation of the traceability implementation is built on global standards for product identification and data exchange. This means that trading partner in scope need to be able to document and produce the following:

- Products must be uniquely identified.
- Product and location master data must be shared.
- Transactional data needs to be captured (business transactions to capture information about the movement of the products).
- Event data needs to be captured (item specific data, product specific variable data – e.g. batch/lot/serial number, expiration date) (GTSH, 2009).

2.3.1 Product and location identification

Products in scope and locations must be globally uniquely identified. Unique product identification is about assigning data attributes to a product, which could include unique identification number for the product or package and other data attributes, like expiry data, lot/batch number and serial number. Unique product identification provides an additional identification feature to more accurately identify a package and enables authentication of the package.

Data capture refers to the methods of automatically entering the data attributes directly into computerized systems without human involvement. Identification keys unlock access to information held in computer files, information about companies, locations, packages, products and price (gs1.org/healthcare).

Note: unique product identification alone does not ensure the contents are genuine. It must be used with additional processes, security features and measures.

2.3.2 Master, transactional and event data transactions

When products and locations are uniquely identified, information about these products and locations should be shared across the supply chain: Three types of data that need to be shared are identified: master data, transactional data and event data.

Master data refers to data that is associated with the product and mostly remains unchanged, e.g. the product description. Global data synchronization enables healthcare trading partners to share trusted product master data, locally and globally, in an automatic and efficient way. This enables reduction in errors and increased efficiency.

Inconsistent, inaccurate and outdated product information makes it, for example, nearly impossible for hospitals to conduct effective supply chain procurement. This can have a ripple effect across all other processes and systems in a hospital which require accurate and correct product information, ultimately affecting patient safety.

Transactional data refers to data that is shared between two trading partners in the sale/purchase process (Electronic Data Interchange), e.g. purchase order, delivery note, invoice, payment.

Event data refers to activities that a product goes through as it moves through the supply chain. An event has four dimensions:

- What physical objects were involved (e.g. serialised product identifier in a data carrier)?
- When took the event place (e.g. timestamp)?
- Where took the event place (e.g. location identifier)?
- Why: what business process step was being carried out (e.g. receiving, shipping)?

(GTSH, 2009)

3 Situational analysis for global standards implementation

To understand Ethiopia's readiness for implementation of traceability an analysis has been done to understand the different strengths, weaknesses, opportunities and threats to consider while deciding on the strategic framework. The assessment has been conducted via workshops, face-to-face discussions, site visits and a questionnaire with different stakeholders.

3.1 Strengths

Strengths are identified from an internal governmental perspective, identifying the current strengths that will help standards implementation, and that need to be cherished.

Strong governmental commitment

The Federal Ministry of Health has strong commitment to lead the implementation of traceability in the pharmaceutical supply chain. EFMHACA is the governmental body currently overseeing regulating the pharmaceutical supply chain, with support from the Ethiopian Ministry of Health.

Availability of regulatory tools

EFMHACA has the right tools to implement a regulatory framework to make implementation happen. Also, different supply chain tools to support product registration are currently being developed by EFMHACA and PFSA, including the Medicine Registration Information System.

Government commitment to replace Proclamation 661/2009

The government is committed to replace the current Proclamation with a Proclamation that will make it possible to create the regulatory framework to make standard implementation mandatory.

3.2 Weaknesses

Weaknesses are identified from an internal governmental perspective.

Absence of structure to implement global standards

Currently, the regulatory framework to support implementation of global standards is not in place: There is no dedicated team working on standard implementation at the regulatory body, thus human resource needs to be improved; EFMHACA processes aren't adjusted to global standards implementation and there is no regulation for global standard implementation in place yet.

Limited knowledge & awareness

In general, the implementation of global standards for product identification and data exchange is a new concept, not only in the pharmaceutical supply chain, but also in other sectors. Unfortunately, most stakeholders in the supply chain, including the governmental bodies, do not have any or limited experience with using global standards for product identification and data exchange in their processes and are not aware of the importance of these standards.

Limited coordination and communication among stakeholders

Implementation of traceability will require stakeholders in the supply chain to actively communicate with the government offices working on the topic and other supply chain actors. Currently communication between stakeholders is not sufficient for the implementation of global standards.

3.3 Opportunities

There are different opportunities that can be identified in Ethiopia's current pharmaceutical supply chain and worldwide that provide a good environment for implementation of global standards.

Availability of global experience

The use of global standards in the pharmaceutical industry is implemented or in the process of being implemented in more than 40 countries worldwide. Many of the learnings from these implementations will be taken into account while moving forward in Ethiopia, including, making patient safety our primary objective, involvement of stakeholders, make actors in the supply chain aware of the challenges that need to be addressed, consider reasonable timeframes for implementation, don't underestimate the complexity and resources that will be needed for implementation, provide constant training and support and make sure to keep global and technological developments into account.

Presence of global standards and expertise

With growing implementation worldwide, and a globalizing world, more stakeholders present in the Ethiopian pharmaceutical supply chain (especially international manufacturers) will use global standards for product identification and data exchange.

Understanding importance of implementation by actors in the supply chain

Even though local manufacturers, wholesalers and importers, just like healthcare providers or PFSA and FMHACA in Addis Ababa and around the country have little to no experience with the implementation of standards they all seem to understand the importance of implementation for patient safety and improvement of supply chain efficiencies. As one manufacturer mentioned: "In the end, it's also our family that at some point might require reliable medication."

But also, the benefits for improved efficiency are very much understood. Many stakeholders mention that with the help of the standards they can improve inventory management, data quality and, for example reduce waste. Another important opportunity mentioned by many stakeholders is getting data visibility not just for their own organization, but for the entire supply chain. Implementation of global standards will for example help all the parties get information about national consumption.

One of the improvements healthcare providers also hope implementation will bring is improved and greater visibility in suppliers' stock levels. Now, healthcare providers can't rely on availability

of products and must implement complicated strategies to address unavailability of products or can't treat patients as they need to.

Investments in pharmaceutical manufacturing sector

The government has endorsed a National Strategy and Plan of Action for Pharmaceutical Manufacturing Development in Ethiopia (2015-2025). This strategy aims to assist local pharmaceutical companies and to create a conducive environment for the growth of the pharmaceutical industry which is believed to attain national resilience in essential medicine access to the public.

For the future, with the current focus of the Ethiopian government on product export, the implementation of global standards makes it possible for Ethiopian manufacturers to enter the global market. International requirements regarding product identification and data exchange will be easily met.

Focus on Information Revolution

Information Revolution is a key transformation agenda set by Ethiopian Ministry of Health as one of the transformation agendas of the five-year Health Sector Transformation Plan (2015/16-2019/20). Information revolution will reform the methods and practice of collecting, analysing, presenting and disseminating information. It is a radical shift from traditional way of data utilization to a systematic information management. It includes advancing the data collection, aggregation, reporting and analysis practice; promoting the culture of information use at place of generation; harnessing ICT; improving data visibility and access; and strengthening verification and feedback systems (HSTP, 2015).

Support from stakeholders

The health sector currently works with many stakeholders on the implementation of global standards, including the Ministry of Health, Ethiopian Standard Agency, Manufacturing organization, healthcare providers and other. Many organizations have communicated their support for this initiative.

3.4 Threats

Threats are identified as external challenges that must be considered while moving forward. These are more difficult to influence than internal challenges, and therefore even more important.

Limited readiness of stakeholders to implement global standards

There is no known use of global standards in the pharmaceutical supply chain. No local manufacturer uses barcodes to uniquely identify their products, no wholesaler or importer receiving products from abroad use the barcodes that are already on products and there is no standardized way of master or event data exchange.

Even though many international manufacturers do have experience with implementation of global standards for product identification, unfortunately a lot of issues regarding good quality barcodes and data quality remain.

Limited resources: technology, human capacity and finances

A great challenge named by many stakeholders is having enough resources, in money, time and people at all the different levels of the supply chain, starting at the regulatory bodies.

Manufacturers will have to make sure that a project team will be developed, which includes many departments of their organization, for example, ICT, regulatory, logistics, artwork and labelling. Once global standards have been implemented and it can be transitioned to 'business as usual' less capacity is needed.

Even though deviation from global standards will come at greater costs an initial investment must be made by supply chain actors. Some of these investments include: GS1 subscription for product identification and data exchange, printers, scanners and software. The costs will depend on the scope and implementation phases of the regulation, status of current implementation for that stakeholder and revenue.

Also, one of the challenges identified by different organizations, but especially by the manufacturers, is the lack of a strong supporting industry with quality services and products like printing, labelling, packaging, inventory management software and verification industry. For good quality barcodes good printers, good quality ink and paper are necessary. Quality data and data exchange will rely on appropriate software applications. Especially a good quality packaging industry is mentioned as one of the biggest challenges.

Absence of GS1 office in Ethiopia

One of the requirements for proper support for all the parties in the supply chain, including the government is the existence of a GS1 Member Organization (MO). Unfortunately, there is no office in Ethiopia yet. In Africa, there are a couple of MO's, with closest GS1 Kenya, GS1 Egypt, GS1 Nigeria and GS1 Tanzania. Even though support from these MO's and GS1 Global Office can be expected, it is important to have support from GS1 staff knowledgeable about Ethiopia's specific context and challenges.

Limited technological capabilities

Some stakeholders mentioned concerns about the technological capabilities of Ethiopia's healthcare sector for the implementation of global standards. Concerns about connectivity,

especially in the areas outside Addis Ababa, reliability of internet, data security, confidentiality and the availability of back-up systems have been raised.

Availability of technology is important to consider, not only for manufacturers. Also, even though the growth of the use of smart phones and mobile health applications in Africa is enormous, still a large group of people can't afford a smart phone or don't have access to a data network. This is the main challenge for one of the end goals, verification of a product by the patient.

Dependency of stakeholders on other parties

The implementation of global standards requires cooperation of the entire supply chain. If a manufacturer doesn't understand implement the standards (correctly), doesn't provide good quality data, all the parties down the supply chain will be influenced. The manufacturer is the source of the unique identifier and the associated master data.

Currently, the Ministry of Health, EFMHACA and PFSA depend for a great deal on technical and financial support from development organizations: USAID, UNFPA and JSI. Even though this support provides a lot of opportunities for the government to achieve the goals set in their Health Sector Transformation Plan (2015), with global developments and new US government continued support might be at risk.

4 Strategic objectives

Achievement of the goal; improve patient safety and supply chain efficiency in the pharmaceutical supply chain by implementation of traceability supported by global standards; requires several measures and creation of an environment in which implementation is possible, taking the strengths, weaknesses, opportunities and threats of the healthcare sector for implementation of global standards in Ethiopia into account.

The strategy sets out the details of the different objectives and activities to be undertaken in the coming years and identifies two phases.

(1) Creation of an environment in which implementation is possible.

The current healthcare sector is not ready for implementation of global standards. The first four objectives will provide a regulatory framework, build and sustain the technical infrastructure to support traceability, strengthen stakeholder's capacity for standard implementation and build and improve communication and collaboration between stakeholders.

(2) Implementation of global standards for traceability to improve patient safety and efficiency in the pharmaceutical supply chain.

While working on building an environment in which standards implementation can be achieved, EFMHACA will need to work on the regulatory framework to enforce implementation of the standards. The strategic objectives will focus on the actual creation of visibility in the pharmaceutical supply chain and the use of traceability data to improve patient safety and efficiency.

A description of the different activities to achieve the objectives, including time lines and responsibilities can be found in Annex 1 Action Plan.

1. Strengthen regulatory system to enable implementation of traceability of pharmaceuticals

Currently, the pharmaceutical regulatory framework (including regulatory documentation) and systems are not equipped to enforce and support implementation of global standards. Different activities will be undertaken to strengthen the regulatory system to be able to publish regulatory documentation and successfully implement traceability of pharmaceuticals.

Activities

1.1 Develop required strategic plan for implementation of traceability system for pharmaceuticals.

The Pharmaceutical Traceability Strategic Plan describes the strategic direction which will guide EFMHACA to improve patient safety and efficiency in the pharmaceutical supply chain by implementation of global standards for product identification and data exchange. This document describes the traceability approach, relevant standards, a short summary of the assessment done to assess stakeholders' readiness for standard implementation and the

strategic objectives, including activities with time lines and responsibilities that will have to be undertaken over the coming years.

1.2 Establish Traceability Office at EFMHACA.

A well-resourced, effectively functioning national pharmaceutical regulatory authority is a prerequisite for implementation of traceability, therefore there is the need to establish a Traceability Office responsible for all the different activities around implementation of global standards. Because knowledge about global standards is currently limited within the different governmental bodies, human capacity and resources will have to be built.

1.3 Establish national alliance to support implementation of traceability.

Next to establishing the Traceability Office, stakeholders need continuous involvement via different means, including a National Traceability Steering Committee and Technical Working Groups. The National Steering Committee consists of important stakeholders, such as Ministries, development partners, and other stakeholders. Technical Working Groups will be established to support implementation by addressing specific challenges that arise.

1.4 Conduct assessment on internal and external regulatory processes.

An assessment must be done to know the impact of standard implementation on regulatory processes and documentation. Based on the assessment actions will be undertaken to make processes fit for implementation.

1.5 Prepare and enforce regulatory documentation.

New regulatory documents, such as Regulations, Directives and Guidelines will have to be prepared and existing documentation will have to be revised for implementation of product identification and data exchange to support traceability. These documentation will be developed with help of the EMFHACA TWG with expertise from different directorates including Registration, Legal and Inspection.

2. Build and sustain technical infrastructure to support implementation of traceability

The technical infrastructure to support a national traceability system to capture product movement and detect irregularities in the supply chain must be developed. A combination of hardware and software technologies, business processes and over or covert item identifiers enables auditable recordkeeping of the physical movement of the item.

Activities

2.1 Conduct traceability technical infrastructure gap analysis.

The technical infrastructure gap analysis will describe the current technical infrastructure, technical requirements and the different activities to undertake, including timelines and

responsibilities to achieve the required technical infrastructure to implement traceability of pharmaceuticals taking the challenges in the supply chain (e.g. network reliability) and objectives for improvement of patient safety and efficiency into account.

The infrastructure will be built on global GS1 standards for product identification and data exchange, track and trace features and the ability to impact and meet the goal of mitigating falsified medicine, providing supply chain security, visibility and ease of product recall. Also, in case relevant new technological and standard developments will be taken into account.

2.2 Develop and sustain technical infrastructure.

After description of the desired technical infrastructure, actions will have to be undertaken to build and pilot the technical infrastructure. Also, a system will have to be set into place to monitor performance of the system, monitor incidents, provide an escalation process and support to stakeholders with technical requirements or questions.

3. Build stakeholder's capacity to ease implementation of traceability

Currently no stakeholder in the Ethiopian pharmaceutical supply chain uses global standards for product identification or data exchange which provides risk for a successful implementation. The outcome of this strategic objective is building stakeholder's capacity and ease implement global standards.

3.1 Conduct gap analysis for stakeholder readiness.

A gap analysis will have to be conducted in terms of technology and human resources to understand stakeholders' capabilities concerning the standard implementation. This analysis will describe the needs of the industry and suggests how to best improve the capabilities of stakeholders to comply with the regulatory requirements.

EFMHACA will have to define the minimum requirements for manufacturers, supporting industries (such as packaging, printing, labelling soft- and hardware), healthcare providers and other organizations involved in implementation of global standards.

3.2 Undertake support activities for capacity building.

Based on the gap analysis, EFMHACA will have to undertake activities to support local manufacturing industry, supporting industries and other stakeholders like the Ethiopian Standards Agency and Universities with implementation of the standards.

4. Strengthen knowledge, communication and collaboration to ease implementation of traceability

Implementation of global standards is a very new concept in Ethiopia's healthcare sector. Currently there is lack of awareness, knowledge and human resources at all stakeholders. The outcome of this strategic objective is improvement of knowledge for all stakeholders, a strengthened communication and collaboration with and between stakeholders in the supply chain to ease implementation.

Activities

4.1 Develop communication and collaboration plan.

A communication plan must be drafted describing, among other, the knowledge that needs to be shared (per stakeholder) the message that needs to be communicated, and how.

4.2 Create communication and collaboration material.

Support material for awareness creation, knowledge building, communication and training will have to be developed, including documentation, website, presentations and other.

4.3 Provide continuous communication and collaboration.

Awareness creation, training and support is a continuous activity which must be undertaken by EFMHACA to make sure stakeholders are up-to-date on developments throughout the implementation phases and after. This can be done through:

- Public workshops and meetings
- Professional conference participation
- Calls and webinars
- Website
- Checklists, guidance and implementation documentation

Next to support, EFMHACA will collaborate with stakeholders via Strategic and Technical Working Groups.

5. Create visibility in the pharmaceutical supply chain by implementation of traceability.

The activities undertaken while implementing strategic objective five will enforce use of the standards to implement traceability of pharmaceuticals. The outcome of this strategic objective is the implementation of global standards to create traceability in the pharmaceutical supply chain. Even though this implementation occurs in phases, each activity already provides benefits.

Activities

Activity 5.1: Enforce presence of unique identification of distributed pharmaceuticals in Ethiopia.

The first step is to make sure all distributed pharmaceuticals in scope in Ethiopia are uniquely identified and that this unique identification number is captured in a data symbol on the label of the different packages that can be electronically captured through scanning.

Activity 5.2: Enforce stakeholders to share standardized product and location master data.

The next step is to have standardized product and location master data available. Location and master data is associated with the unique identifier and is captured in a centralized data base. The unique identifier serves as the 'key' to access this information by different actors.

Activity 5.3: Enforce implementation of batch traceability.

The next step is to make sure all stakeholders in the supply chain register product movement (e.g. receipt, distribution, expired) in the national traceability system. Implementation of traceability will be done in phases, starting with traceability of items and packages based on batches.

Activity 5.4: Enforce implementation of traceability based on serialized pharmaceuticals.

Learning from batch traceability will give input to implementation of traceability for identified unique distributed items in the country. A pilot phase before batch traceability and traceability based on unique items will be implemented prior to actual implementation.

6. Improve patient safety and efficiency in the pharmaceutical supply chain by use of traceability data

Implementation of traceability will provide data; product movement has been captured in a national traceability system. This data will have to be efficiently managed, analyzed and most importantly used to improve patient safety and efficiency in the supply chain.

Implementation of this strategic objective will make it possible to detect falsified or illegal pharmaceuticals in the supply chain. The responsible body will have the processes in place to act upon detection of these irregularities. The data captured in the supply chain will also provide input for improvement of efficiency: recalls can be executed more effective and it will support efficient inventory management.

Activities

Activity 6.1: Identify what kind of information to monitor and data to capture to achieve the objectives.

An analysis will have to be made to decide what kind of supply chain information will have to be captured and monitored to enable detection, notification and response to issues in the supply chain to improve patient safety and efficiency.

Activity 6.2: Implement systems and processes to capture data.

The data that will be captured will have to be translated in understandable dashboards and reports and will serve as input for management teams of different organizations.

Activity 6.3: Act based on captured data

Processes will have to be implemented to detect falsified or illegal pharmaceuticals and notify the responsible authority (EFMHACA and/or the Ministry of Health). The responsible authority will have to take actions to investigate the suspected pharmaceuticals.

5 Stakeholder roles and responsibilities

Implementation of this strategy and traceability approach is the responsibility of the Ethiopian Government. Counterfeit and illegal production and circulation of pharmaceuticals is a multi-sectoral problem which calls for multi-sectoral cooperation, a coordinating structure that will serve as an umbrella body for coordination of the roles and responsibilities of all stakeholders, framing institutions to bring about an effective and efficient product traceability system is very important.

5.1 Defining roles of the key stakeholders

Effective implementation requires defining the role of the key stakeholders that are involved in reaching the identified objectives.

The Community

The community needs access to genuine pharmaceuticals, health information and service. In the end, the public needs to be able to rely on the healthcare sector to provide genuine pharmaceuticals at any time they need it.

The Government

Organization	Role
Parliament, Council of Ministers	The Parliament and Council of Ministers will ratify the relevant Proclamation and Regulation. In addition, they will give direction for the implementation of traceability and follow up on progress.
EFMHACA	EFMHACA will • prepare and ratify the appropriate Guidelines and Directives; • oversee and evaluate enforcement of implementation of the legal framework; • allocate adequate budget for implementation of the regulatory documentation; • coordinate the implementation of traceability; • implement, monitor and evaluate; • serve as information center for traceability related information and data; • generate and collect evidence on pharmaceutical traceability.
Ministry of Health	The Ministry of Health will • mobilize resource for implementation; • follow up implementation status of the strategy.
Ministry of Finance and Economic Cooperation	The Ministry will allocate the necessary budget and introduce efficient ways of utilizing resource for the implementation of global standards.

Ministry of Trade	As a Ministry with the power to work towards promotion and development of the country's export trade, provision of commercial registration and business licensing service, prohibition of import and export of goods that do not conform with required standards, the Ministry of Trade may encourage (through licensing and the like) organizations who have implemented global standards to start trading in or with Ethiopia, and shall work towards the implementation of global standards in collaboration with the concerned government bodies.
Ministry of Industry	The Ministry shall support local manufacturing industry with the implementation of traceability.
Ministry of Education	The Ministry of Education shall incorporate global standards in University's supply chain and regulatory science curriculum (Regulatory and other related BSC, MSC or PHD programs) to support knowledge building of stakeholder's employees.
Ministry of Science and Technology	The Ministry shall register technology transfers and cooperate with other stakeholders on implementation of the global standard. The Ministry is responsible for keeping track of innovative developments which could benefit implementation of traceability of pharmaceuticals.
Ministry of Communication and Information Technology	The Ministry shall provide general consultation regarding relevant software and hardware necessary for the implementation of global standard and will provide the necessary network infrastructure to support implementation of traceability.
Communication Affairs Office (Government)	The office should collaborate in advocating and creation of awareness regarding implementation of traceability.

Supply Chain Partners

Organization	Role
Associations	The associations need to collaborate in the implementation of traceability. They will inform their members on traceability system accordingly and will be available to provide feedback to EFMHACA. These include e.g. Manufacturer Association, Importers and Wholesalers Association, Ethiopian Pharmaceutical Association, Medical Association, and their members.
Manufacturers	International and local manufacturers must implement required legislation related to traceability. The Manufacturer Association will be informed about regulatory requirements and will asked for feedback on regulatory developments.
Pharmaceutical Fund and Supply Agency (PFSA)	The majority or the products purchased or donated for import are handled by PFSA. PFSA buys 75% plus of all commodities into Ethiopia with PSM, UNFPA, UNICEF also providing procurement

	services. PFSA will need to comply with regulatory requirements regarding product identification and data exchange.
Importers, wholesalers, distributors	Importers, wholesalers and distributors must implement required legislation related to traceability. Their association will be informed about regulatory requirements and will asked for feedback on regulatory developments.
Healthcare providers	Healthcare providers include hospitals, pharmacies, healthcare facilities and other organizations or persons that provide health services to the public from the public and private sector. They will need to comply with regulatory requirements.

Other organizations

Organization	Role
Ethiopian Standard Agency (ESA)	The ESA will need to accept the GS1 standard as a national standard and possibly support users and implementers in training and technical support.
Ethiopian Pharmaceutical Development Institute	The Institute shall build capacity of local manufacturers for implementation of global standards.
Information Network Security Agency (INSA)	The Ethiopian Information Network Security shall ensure data security and quality of the traceability system.
Ethiopian Revenue and Customs Authority (ERCA)	ERCA shall cooperate with stakeholders to detect irregularities in the traceability system and take appropriate measures.
Trade Practice and Consumer Protection Authority (TPCPA)	The TPCPA shall collaborate with stakeholders to detect irregularities in the traceability system and take appropriate measures.
Donor Agencies	Different Donor Agencies currently support the pharmaceutical supply chain via mobilization of resources and funding. These organizations include USAID, UNFPA and the Bill and Melinda Gates Foundation. Their support will need to be present the coming years for a successful implementation but will need to be phased out so all responsibilities lie with the government and their supply chain partners.
Implementing Partners	Implementing Partners will need to provide technical support during the implementation. These organizations currently include John Snow Inc., PQM and PSM. Their support will need to be present the coming years for a successful implementation but will need to be phased out so all responsibilities lie with the government and their supply chain partners.

6 Implementation approach

This chapter describes important consideration for implementation of traceability.

6.1 Scope of traceability system

The objectives of implementation can be met by the implementation of a traceability system to identify and track and trace pharmaceuticals. Records of organizations, entities and/or locations that have had and/or currently have physical possession of the products needs to be captured. This means that every movement of products in the supply chain needs to be captured, from manufacturer until the healthcare provider.

6.1.1 Traceability system requirements

To achieve this, the traceability system needs to support the following:

- The security and authenticity of pharmaceuticals needs to be validated at each step of the supply chain.
- Information needs to be digitized, eliminating the need for manual documentation.
- Information needs to be reliable and updated in real-time.
- Records of information blocks about product movement need to be stored in a centralized database, for authorised parties to view this information, including patients at the end of the supply chain.
- This centralized database needs to be able to produce alerts and notifications, including authentication of items, initiate a recall, perform diversion alerts (a specific item isn't received), trace items, detect extensive stock or near expiry.
- The system needs to be flexible to have the possibility to in the future add extra features (like detection insurance reimbursement fraud).
- The traceability system will have to be independent of current existing systems but must be easy to integrate by actors in the supply chain.
- The traceability system must consider stakeholder privacy and data security.

6.1.2 Use of global standards

Global standards for product identification and data exchange will be used to support implementation of the traceability system. Global standards provide homogeneity in multinational companies' production, including Ethiopian pharmaceutical manufacturers; provide the possibility of information exchange at global level; are often already set in many countries and makes implementation easier for countries with a large volume of imported products. Also, no local standards for product identification and data exchange are currently in use in the Ethiopian pharmaceutical supply chain that could support implementation of traceability in a sustainable manner.

6.2 Phased implementation

Because implementation of serialization of products and traceability of unique items will require a lot from all stakeholders in the supply chain a phased implementation will be executed. During the implementation of these phases, time will be incorporated to integrate learnings from that phase, including learnings from pilots, and use of each implementation to drive momentum and promote success.

Please see Annex 3 for a suggested timeline of implementation of the different phases.

6.2.1 Phase 1: Product identification and location and product master data

6.2.1.1 Products in scope

To protect the public from falsified pharmaceuticals, not just in the hospital but also when receiving medication from a private pharmacy, all pharmaceuticals distributed in Ethiopia should be subject to implementation, subscribed and non-subscribed medication.

Implementation of all distributed pharmaceuticals in the country at once however is too complicated, therefore, to do implementation in phases, product groups have been prioritized:

1. Products often falsified or illegal in Ethiopia
2. Program items, including TBC, HIV, malaria and vaccines
3. Prescribed pharmaceuticals
4. Other pharmaceuticals distributed

Note: Implementation of traceability of medical devices often requires different specification and timelines, therefore the focus is only on traceability of pharmaceuticals.

6.2.1.2 Packaging levels

To achieve full and effective track and trace abilities it is important to adopt serialization, where each item has a unique identifier assigned by the manufacturer. Serialization will provide control that authorized medical products circulate only in the legal supply chain; prevents entry and circulation of stolen and smuggled products; prevents distribution of expired or recalled products; helps ensure an efficient and safe recall; enables collection of pharmacoepidemiologic data; enables efficient supplies management and contributes to reducing the expenditure in the healthcare sector (WHO, 2015).

Effective traceability of the unit of sale can only be achieved by involving all higher packaging levels. The tertiary package and the logistic units, up to the pallet level will therefore also be in scope of the regulation. A relationship between these different packaging levels will have to be built in the system. Aggregation, the process of registration of the unique items contained in unique packaging levels (this means that the different packaging levels also needs to be serialized) moving between organizations makes tracing of serialized items operationally effective and sustainable.

Because serialization of unique items, especially for the local manufacturers requires many investments, the first focus will be on traceability of batches. Batch number tracing allows small

number of units that have same properties, e.g. manufacturing run or expiration date, whereas serialization is a one to one relationship and a unique identifier for a specific unit. While batches can be traced to specific sets of locations, a serial number provides an instant update on which specific location a specific item is at.

Note: Serialization of primary or immediate packaging (unit of dispensation) will give greater advantage for patient safety at the hospital, especially because also at the hospital pharmacy often the smallest level is given to patients, instead of the secondary package (or unit of sale), but will require a lot more in terms of investments and complexity from all stakeholders in the supply chain, but especially from manufacturers. For specific products, this however could be an option for the future. Authentication of the secondary package can be done by the healthcare provider before splitting the package.

6.2.1.3 Regulatory requirement

During the first phase products needs to be uniquely identified and product and location master data needs to be shared by supply chain actors.

During this phase EFMHACA will provide regulation that lies down:

- the characteristics and technical specifications of the unique identifier that enables the full traceability and authentication of individual packages;
- printing and labelling specifications;
- master data requirements;
- A list of medicinal products and product categories subject to the regulation with timelines for implementation.

Simplified, during this phase the following will be required from supply chain partners:

- All secondary packages and higher homogenous packaging levels of identified distributed pharmaceuticals in the country must be identified with a global unique identifier (GTIN), including batch number an expiry date on the label.
- For some product only a GTIN will be required on the label.
- For secondary packages, this information needs to be captured in a GS1 Data Matrix.
  For tertiary packages, this information needs to be captured in a GS1 Data Matrix and/or GS1-128.
  Logistic units must be identified with a Serial Shipping Container Code.
- Associated location and product master data must be shared by the manufacturer, including building a package hierarchy between the secondary package and all higher packaging levels.

EFMHACA will provide:

- the possibility of an easy upload of product and location master data (web interface or use of the Global Data Synchronization Network);
- validation of the quality of the GS1 Data Matrix and GS1-128 on the labels;

- data quality process to test and improve master and location data quality.

Implementation of this phase will benefit the pharmaceutical supply chain because:

- standardized master data with the manufacturer as a source will provide reliability, quality and up-to-date master data;
- presence of the GS1 Data Matrix and GS1-128 on the labels of the different package levels will provide supply chain actors with the possibility to electronically capture product information (instead of manual registration);
- It enables improved receipt and dispense processes and;
- It enables improved inventory management.

6.2.2 Phase 2: Batch traceability

The second phase will focus on implementation of batch traceability which will make it possible to track complete manufacturer batches from manufacturer until the healthcare provider.

6.2.2.1 Regulatory requirements

During this phase EFMHACA will provide regulation that lies down:

- Event and transactional data requirements for all actors in the supply chain, including aggregation of packages based on batches and verification of batches by barcode scanning.

During this phase from supply chain partners it will be required that:

- Physical movement of each pharmaceutical batch in scope needs to be in real-time captured in the traceability system.

During this phase EFMHACA will provide:

- The traceability system to capture batch product movement.

Implementation of this phase will benefit the pharmaceutical supply chain because:

- batch traceability allows for tracking and tracing small number of units;
- it enables an efficient recall processes;
- it enables efficient receipt and dispense processes and;
- It provides learnings before implementation of a more complex traceability of serialized items.

6.2.3 Phase 3: Serialization and traceability of unique items

As a third phase serialization of pharmaceutical packages and traceability of serialized pharmaceuticals will be required.

6.2.3.1 Regulatory requirements

During this phase EFMHACA will provide regulation that lies down:

- Event and transactional data requirements for all actors in the supply chain, including aggregation of packages based on unique items and verification of the unique items by barcode scanning.

During this phase from supply chain partners it will be required that:

- Physical movement of each unique pharmaceutical package in scope needs to be in real-time captured in the traceability system.

During this phase EFMHACA will provide:

- The traceability system to capture unique product movement.

Implementation of this phase will benefit the pharmaceutical supply chain because:

- serialization allows for tracking and tracing of unique items;
- It will provide better control that authorized medical products circulate only in the legal supply chain;
- It prevents entry and circulation of stolen and smuggled products;
- It prevents distribution of expired or recalled products;
- It helps ensure an efficient and safe recall;
- It enables collection of pharmacoepidemiologic data.

6.2.4 Phase 4: Use traceability data to improve patient safety and efficiency

During implementation of phase 1, 2 and 3 EFMHACA will also work on using the traceability data generated by the system to improve patient safety and efficiency.

The implementation of the traceability system will provide enormous amounts of data that will be very beneficial for improvement of patient safety and efficiency. Data needs to be gathered, analysed, understood, reported and shared. Decisions by the regulatory bodies and supply chain actors will have to be made on this data.

During this phase EFMHACA will provide regulation that lies down

- The requirements for actions to take by stakeholders when irregularities are being detected in the supply chain, including possible falsification, expiry or recalled pharmaceuticals (notification).

During this phase required from supply chain partners will be:

- Notification of irregularities to EFMHACA.

During this phase EFMHACA will provide:

- A process or system for the notification of irregularities in the supply chain;
- A process for response to these irregularities.

Implementation of this phase will benefit the pharmaceutical supply chain because:

- Irregularities, including falsified, expired or recalled products will be detected;
- Actions will be undertaken to remove these irregularities from the supply chain;
- Data will be gathered to improve patient safety and supply chain efficiency.

7 Monitoring and evaluation

7.1 Responsible body

7.1.1 Traceability Office

EFMHACA's Traceability Office will have the responsibilities for implementation of the strategic objectives and activities described in this document. The Traceability Office will develop a framework in which performance against set targets is measured and shared with stakeholders via reporting and meetings. Continuous monitoring and evaluation of set performance indicators will be performed to identify challenges, work on solutions, improve efficiency and where necessary adjust work planning or find extra resources.

The responsible Manager of the Traceability Office will communicate with the EFMHACA Management and the National Steering Committee that includes all stakeholders about progress of the implementation.

He or she will:

- write annual implementation plans;
- inform stakeholders on progress, challenges and actions based on challenges;
- communicate with other governmental departments to ensure congruence of institutional, department, project and other work plans with the strategic plan;
- ensure that a framework for effective coordination of strategy implementation is adhered to at all levels;
- establish mechanisms to coordinate intra-departmental linkages;
- organize strategy performance review meetings;
- develop guidelines and reporting formats to support strategy implementation and;
- Keep track of international developments and review EFMHACA's progress and activities based on international developments.

Available information about progress needs to be disseminated in a timely manner and used for strategic decision making at all levels.

7.1.2 EFMHACA Management Committee

The EFMHACA Management Committee will be informed on a quarterly basis about progress of the implementation.

7.1.3 National Steering Committee

The National Steering Committee will be informed on a quarterly basis about progress of the implementation.

7.1.4 Forum for the National Alliance

At national level, yearly a forum for the national alliance working on traceability will be organized to evaluate the process. The Manager of the Traceability Office will be responsible for an annual report and presentation describing the status of traceability implementation.

7.2 Reporting

During monitoring the Traceability Office will monitor detailed progress of different strategic objectives and activities. This will be discussed during weekly meetings between team members and Traceability Office Director, including the responsible EFMHACA Management person. Progress will be registered in a shared management file which will provide input for monthly, quarterly and yearly reports.

Evaluation will be done between team members and the Traceability Office management on a monthly, quarterly and yearly basis. Evaluation between TO management and EFMHACA Director and the National Steering Committee will be done through quarterly and yearly reporting via documentation and meetings.

7.3 Information source

Different information sources will be used for monitoring and evaluation. Monitoring and evaluation information will be gathered through regular meetings between Traceability Office members and stakeholders, assessments, field visits, interviews, surveys, data analysis and other means of information collection.

For specific implementations or evaluation of performance of processes and implementation external evaluators could be hired.

7.4 Indicators

A list of inputs, outputs, outcomes and indicators can be found in Annex 2. Indicators will help ensure that resources are properly mobilized, equitably distributed and efficiently utilized.

Once the Traceability Office is operational, these indicators will be evaluated and more extensively described in the M&E framework and Annual Plans.

7.5 Assumptions

Success of the implementation will depend on the following:

- A functioning responsible team at EFMHACA dedicated to working on implementation of the strategic plan,
- the necessary budget for implementation will be available;
- effective annual planning and commitment of resources;
- continuous support from EFMHACA Management;
- develop and maintenance of the technical infrastructure;
- support from funding organizations for specific knowledge not existent at EFMHACA;

External

- GS1 standards remain the globally accepted standard for product identification and data exchange;
- stakeholders will cooperate with EFMHACA in making implementation a success;
- network reliability and capabilities in Ethiopia will improve tremendously in the coming 10 years.

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ANNEX 1 ACTION PLAN

#		Objectives and activities	FY2017-2025									Deadline	Responsible	Budget
			17	18	19	20	21	22	23	24	25			
1	**Strategic objective 1: Strengthen regulatory system to enable implementation of traceability of pharmaceuticals**													
	Activity 1.1: Develop required strategic plan for implementation of traceability system for pharmaceuticals													
	a	Develop strategic plan	x											
	b	Receive approval from high level officials	x	x										
	c	Approval for approach from higher officials is received	x	x									EFMHACA	
	d	**Publication strategic document**		x								July-18	TWG	N/A
	Activity 1.2: Establish Traceability Office at EFMHACA													
	a	Describe roles and responsibilities	x											
	b	Hire professionals	x	x										
	c	Train professionals on global standards implementation	x	x										
	d	Official Traceability Office started		x										
	e	Traceability Office working on implementation of strategic plan		x	x	x	x	x	x	x	x	Continuous activity	EFMHACA Management	To be allocated
	Activity 1.3: Establish national alliance to support implement of traceability													
	a	Establish National Steering Committee and Technical Working Groups to support implementation	x	x	x	x	x	x	x	x	x			To be allocated
	b	Train participants on global standards	x	x	x	x	x	x	x	x	x		Traceability	Organizati
	c	Organize meetings to discuss challenges and opportunities	x	x	x	x	x	x	x	x	x	Continuous activity	Office (TO): Management	on meetings + training
	Activity 1.4 Conduct assessment on internal and external regulatory processes													

	a	Conduct gap analysis on regulatory framework	x	x								Aug-18	TO: Legal Advisor	N/A
1.5	***Activity 1.5: Prepare and enforce regulatory documentation***													
	a	Draft regulatory documentation	x	x	x	x	x	x	x	x	x	Continuous activity	TO: Legal Advisor	N/A
	b	Publish policies and procedures	x	x	x	x	x	x	x	x	x			
2	**Strategic objective 2: Build and sustain technical infrastructure to support implementation of traceability**													
2.1	***Activity 2.1: Conduct traceability technical infrastructure gap analysis***													
	a	Describe current situation		x								Dec-18	TO: Technical Advisor	To be allocated Technical specialist
	b	Identify gaps for desired technical infrastructure		x										
	c	Develop roadmap for development technical infrastructure		x										
2.2	***Activity 2.2: Develop and sustain technical infrastructure***													
	a	Develop technical infrastructure		x	x							Jun-19	TO: Technical Advisor	To be allocated Development technical infrastructure
	b	Monitor performance of the technical infrastructure		x	x									
	c	Take action for continuous improvement		x	x									
3	**Strategic objective 3: Build stakeholder's capacity to ease implementation of traceability**													
3.1	***Activity 3.1: Conduct gap analysis for stakeholder readiness for implementation of traceability***													
	a	Define minimum requirements to comply with regulatory requirement		x								Jul-19	TO: Supply Chain Advisor	To be allocated
	b	Research stakeholders		x	x									
	c	Identify gaps		x	x									
	d	Write gap analysis report		x	x									
3.2	***Activity 3.2: Undertake support activities for capacity building (see also activity 4.3)***													

	a	Undertake support activities for capacity building	x	x	x	x	x	x	x	x	x	Continuous activity	TO: Supply Chain Advisor	To be allocated
4	**Strategic objective 4: Strengthen knowledge, communication and collaboration to ease implementation of traceability**													
4.1	***Activity 4.1: Develop communication and collaboration plan***													
	a	Identify stakeholders, what to communicate, how to communicate and when		x									TO: Communication Advisor	N/A
	b	Write communication and collaboration plan		x								Sept-18		
4.2	***Activity 4.2: Develop communication and collaboration material***													
	a	Develop communication and collaboration material		x	x	x	x	x	x	x	x	Continuous activity	TO: Communication Advisor	To be allocated
4.3	***Activity 4.3 Provide continuous communication and collaboration***													
	a	Continuous communication and collaboration		x	x	x	x	x	x	x	x	Continuous activity	TO: Communication Advisor, Account Management, Management	To be allocated
5	**Strategic objective 5: Creation of visibility in the pharmaceutical supply chain**													
5.1	***Activity 5.1: Enforce presence of unique identification of distributed pharmaceuticals in the supply chain***													
	a	Enforce presence of unique identification (batch) of distributed pharmaceuticals		x	x	x	x					Publication 2018. Implementation 2021.	TO: Legal Advisor, Management and other	To be allocated
	b	Implement barcode verification process		x	x	x	x							
5.2	***Activity 5.2: Enforce stakeholders to share standardized product and location master data***													

	a	Enforce stakeholders to share standardized product and location master data		x	x	x						Publication 2018 (depending on new Proclamation), Implementation 2021.	TO: Legal Advisor, Management and other	To be allocated
	b	Implement data quality processes		x	x	x								
5.3	***Activity 5.3: Enforce implementation of batch traceability***													
	a	Conduct pilot phase			x	x						Publication June 2020 (depending on new Proclamation), implementation June 2023	TO: Legal Advisor, Management and other	To be allocated
	b	Enforce batch traceability				x	x	x	x					
5.4	***Activity 5.4: Enforce implementation of traceability based on serialized pharmaceuticals***													
	a	Conduct pilot phase						x	x			Publication Jan 2022, implementation Jan 2026	TO: Legal Advisor, Management and other	To be allocated
	b	Enforce serialization						x	x	x				
	c	Enforce serialized traceability							x	x				
6	**Objective 6: Improve patient safety and efficiency in the pharmaceutical supply chain by use of traceability data**													
6.1	***Activity 6.1: Identify what kind of information to monitor and data to capture to achieve the objectives***													
	a	Identify irregularities in the supply chain (e.g. counterfeit/waste and other)				x	x	x	x	x	x	Continuous activity	TO: Management, Supply Chain Advisor and other	To be allocated
	b	Decide on information needed to fight irregularity				x	x	x	x	x	x			
	c	Describe detection and notification process for stakeholders to implement				x	x	x	x	x	x			

	d	Decide on actions to take by regulatory bodies in case of identified irregularities				x	x	x	x	x	x			
6.2	***Activity 6.2: Implement systems and processes to capture data***													
	a	Implement detection, notification and monitoring processes and systems				x	x	x	x	x	x	Continuous activity	TO: Management, Supply Chain Advisor and other	To be allocated
6.3	***Activity 6.3: Regulatory measures taken based on captured data***													
	a	Detect irregularities (from stakeholders or in systems)				x							TO: Management, Supply Chain Advisor, Legal Advisor and other	
	b	Regulatory actions by regulatory body to improve patient safety and efficiency				x	x	x	x	x	x			
	c	Actions taken by supply chain partners to improve patient safety and efficiency										Continuous activity		To be allocated

ANNEX 2 MONITORING AND EVALUATION

Please note that a detailed description of the different inputs, outputs, outcomes, indicators and impact will be developed by the Traceability Office.

#		Objectives and activities	Input	Output	Outcome	Indicators	Impact
1		**Strategic objective 1: Strengthen regulatory system to enable implementation of traceability of pharmaceuticals**					
Activity 1.1: Develop required strategic plan for implementation of traceability system for pharmaceuticals							
	a	Develop strategic plan	Meetings, literature research, site visits and other resources.	Strategic plan	Strengthened regulatory system is capable to enforce traceability.	Approved strategic plan. Functional Traceability Office. Establishment NSC and TWG. Number of meeting per year of NSC and TWG. Availability of policies and procedures.	A strong regulatory body will enable not just initial regulatory publication and implementation of the traceability system, but will also make it possible to have a continuous improvement of the system.
	b	Receive approval from high level officials					
	c	**Approval for approach from higher officials is received**					
Activity 1.2: Establish Traceability Office at EFMHACA							
	a	Describe roles and responsibilities	Human, financial and material resources.	Established Traceability Office			
	b	Hire professionals					
	c	Train Professional on global standards implémentation					
	d	Official Traceability Office started					
	e	Traceability Office working on implementation of strategic plan					
Activity 1.3: Establish national alliance to support implement of traceability							
	a	Establish National Steering Committee and Technical Working Groups to support implementation	Identified stakeholders. Financial and	Established NSC and TWG.			

	b	Train participants on global standards	material resources.				
	c	Organize meetings to discuss challenges and opportunities					
Activity 1.4 Conduct assessment on internal and external regulatory processes							
	a	Conduct gap analysis on regulatory framework	Human, financial and material resources, including regulatory processes and documentation.	Assessment report			
Activity 1.5: Prepare and enforce regulatory documentation							
	a	Draft regulatory documentation	Human, financial and material resources, including reference material.				
	b	Publish policies and procedures		Regulatory documentation published			
2	**Strategic objective 2: Build and sustain technical infrastructure to support implementation of traceability**						
Activity 2.1: Conduct traceability technical infrastructure gap analysis					Technical infrastructure to enable implementation of traceability established and process in place to maintain.	Technical infrastructure present # GTINs and GLNs in master data repository	A good functioning technical infrastructure will make it possible to have visibility in the supply
	a	Describe current situation	Current technical infrastructure, traceability requirements, assessment tools global				
	b	Identify gaps for desired technical infrastructure					
	c	Develop roadmap for development technical infrastructure		Traceability technical infrastructure gap analysis report			

			experience and resources.			% of distributed pharmaceuticals captured in traceability system. Minimum 90% master data quality	chain and improve patient safety and efficiency by using data produced by the system.
Activity 2.2: Develop and sustain technical infrastructure							
	a	Develop technical infrastructure	Traceability gap analysis report, global experience, resources.	Traceability infrastructure			
	b	Monitor performance of the technical infrastructure					
	c	Take action for continuous improvement					
	Strategic objective 3: Build stakeholder's capacity to ease implementation of traceability						
Activity 3.1: Conduct gap analysis for stakeholder readiness for implementation of traceability							
	a	Define minimum requirements to comply with regulatory requirement	Traceability requirements, identified stakeholders, assessment tools, resources.	Stakeholder gap assessment report		**To be identified in gap analysis** Number of training conducted Number of stakeholders trained	Built capacity will enable successful and smooth implementation within set timeframes, including good quality barcodes, quality master data and reliable traceability data captured in systems.
	b	Research stakeholders					
	c	Identify gaps					
	d	Write gap analysis report					
Activity 3.2: Undertake support activities for capacity building (see also activity 4.3)							
	a	Undertake support activities for capacity building	Identified gaps described in stakeholder gap assessment report, resources.	Support activities performed	Capacitated stakeholders to implement global standards.		
4	**Strategic objective 4: Strengthen knowledge, communication and collaboration to ease implementation of traceability**						
Activity 4.1: Develop communication and collaboration plan							

	a	Identify stakeholders, what to communicate, how to communicate and when	Regulatory documentation, infrastructure and stakeholder gap assessment report, stakeholder requests.		Strengthened knowledge, communication and collaboration will ease implementation of traceability	**To be identified in communication plan** Number of communication material developed Number of stakeholders trained Number of training sessions held Communication infrastructure developed	Strengthened knowledge, communication and collaboration will provide support from stakeholders, they know the advantages for the healthcare supply chain and patients and support implementation.
	b	Write communication and collaboration plan		Communication and collaboration plan			
Activity 4.2: Develop communication and collaboration material							
	a	Develop communication and collaboration material	Communication and collaboration plan	Communication material			
Activity 4.3 Provide continuous communication and collaboration							
	a	Continuous communication and collaboration	Communication and collaboration plan and stakeholder requests	Training and communication			
5	**Strategic objective 5: Creation of visibility in the pharmaceutical supply chain**						
Activity 5.1: Enforce presence of unique identification of distributed pharmaceuticals in the supply chain						Know where a product is at any given moment and why. % of registered pharmaceuticals uniquely identified	Visibility in the supply chain provides data that can be used to improve patient safety and efficiency
	a	Enforce presence of unique identification (batch) of distributed pharmaceuticals	Published regulatory requirements, technical infrastructure, training & communication		Visibility in product movement in the supply chain.		
	b	Implement barcode verification process		Uniquely identified pharmaceuticals distributed in the market			

Activity 5.2: Enforce the supply chain actors to share standardized product and location master data					% of registered pharmaceuticals traced in the supply chain	
	a	Enforce stakeholders to share standardized product and location master data	Published regulatory requirements, technical infrastructure, training & communication	Product and location master data available.		
	b	Implement data quality processes				
Activity 5.3: Enforce implementation of batch traceability						
	a	Conduct pilot phase	Published regulatory requirements, technical infrastructure, training & communication	Batch traceability implemented		
	b	Enforce batch traceability				
Activity 5.3: Enforce implementation of traceability based on serialized pharmaceuticals						
	a	Conduct pilot phase	Published regulatory requirements, technical infrastructure, training & communication	Traceability based on unique items.		
	b	Enforce serialization				
	c	Enforce serialized traceability				
6	**Objective 6: Improve patient safety and efficiency in the pharmaceutical supply chain by use of traceability data**					
Activity 6.1: Identify what kind of information to monitor and data to capture to achieve the objectives					Data for improvement	Improve supply chain efficiency:	Improved efficiency and

	a	Identify irregularities in the supply chain (e.g. counterfeit/waste and other)			patient safety and efficiency is captured. Data is reliable and is used for decision making. Regulatory measures are taken based on data.	% decrease of pharmaceutical waste % decrease recall time Reduce procurement lead-time Improve patient safety: % less irregularities Increase availability of pharmaceuticals to 100%	patient safety result in less deaths, improved trust in the healthcare system, brand protection, cost and time saving which can be spend on improvement of the healthcare sector
	b	Decide on information needed to fight irregularity					
	c	Describe detection and notification process for stakeholders to implement					
	d	Decide on actions to take by regulatory bodies in case of identified irregularities	Technical infrastructure, resources	Identified information and data to be captured			
Activity 6.2: Implement systems and processes to capture data							
	a	Implement detection, notification and monitoring processes and systems	Identified information and data to be captured	Systems and processes to capture data			
Activity 6.3: Regulatory measures taken based on captured data							
	a	Detect irregularities (from stakeholders or in systems)					
	b	Regulatory actions by regulatory body to improve patient safety and efficiency					
	c	Actions taken by supply chain partners to improve patient safety and efficiency	Traceability data	Regulatory and stakeholder measures			

ANNEX 3 SUGGESTED PHASED APPROACH FOR IMPLEMENTATION

NB: note that the details and timelines of these phases could change in time.