USAID GLOBAL HEALTH SUPPLY CHAIN PROGRAM

Procurement and Supply Management

ETHIOPIA NATIONAL TRACK & TRACE SYSTEM – A TECHNICAL ARCHITECTURE DOCUMENT

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1.INTRODUCTION

1.1 DOCUMENT PURPOSE

Track and trace is a business process that enables various participants like manufacturers, suppliers, distribution centers, consumers, in a supply chain to follow items as they move from the source of production into consumers hand. A combination of hardware and software technologies, business processes and overt or covert item identifiers enables auditable record-keeping of the physical movement of the item.

This document is a technical architectural guide for FMHACA to implement a national level traceability system to track and trace the movement of pharmaceutical commodities in In-Country supply chain. The technical design recommended in this document are based on
1. GS1 global standards for supply chain management and product identification.
2. Track and trace features that are most likely to make a deployment effective.
3. Ability to impact and meet the goals of mitigating counterfeits and diversions, providing supply chain security, data transparency and ease of product recall

The purpose of this document is to provide the technical teams with
1. High level principles and concepts relating to track and trace,
2. Implementation of a modular and scalable solution and
3. Guidance and approach to enable various capabilities for an effective and sustainable deployment.

1.2 DOCUMENT AUDIENCE

This document is intended for technical architects and developers who will be implementing the track and trace solution or providing necessary data from various supporting systems at FMHACA, PFSA and with 3rd party suppliers.

1.3 ACRONYMNS USED

Term	Description
FMHACA	Food, Medicine and Health Care Administration and Control Authority of Ethiopia
PFSA	Pharmaceuticals Fund and Supply Agency
USAID	United State Agency for International Development
GS1	Global Standards
GTIN	Global Trade Item Number
GLN	Global Location Number
SSCC	Serial Shipping Container Code
HCMIS	Health Commodity Management Information System
MRIS	Medical Registration Information System
FMOH	Federal Ministry of Health

2 PROJECT VISION AND SCOPE

Ethiopia, located in the North East part of Africa is the oldest independent and second most populous (99 million)[1] country in Africa. The FMOH (Federal Ministry of Health) is responsible for the accessibility of quality health care service to all citizens throughout the country.

One of the most complex and challenging problems facing FMOH is securing the integrity and safety of its pharmaceutical commodities supply chain.

- Counterfeit, fake and illegal drugs impact patient safety and dangers public health.
- Diversions, thefts undermine public and private investments in health care besides causing life-threats due to stock-outs or lack of medicines at the right time in the patient's hands.
- Recall of pharmacheautical products in a timely and effective manner

Achieving End to End visibility into its pharmaceutical commodities supply chain is of critical importance as by enhancing the ability to track and trace the products, it will

1. Become harder to divert items
2. Insert counterfeit, illegal or unauthorized items
3. Easier to ensure high levels of quality and safety
4. Verify and authenticate the item
5. Enable targeted recalls
6. Provide transparency and visibility into the movement of the item
7. And increase supply chain efficiencies.

As part of this goal FMOH established multiple health sector reform initiatives, starting with setup of a regulatory body FMHACA (Food, Medicine and Health Care Administration and Control Authority) to regulate the 4 Ps – Practice, Premises, Professionals and Products. FMHACA is developing and rolling out MRIS- Medicines Registration Information System an integrated system to manage key functions and responsibilities of FMHACA.

Another key and central entity PFSA (Pharmaceuticals Fund and Supply Agency) plays a critical role in quantification, procurement, inventory management and distribution of pharmaceuticals commodities within Ethiopia. It uses the Health Commodity Management Information System (HCMIS) inventory management, warehouse and logistics information management system version in PFSA central and branch warehouses. HCMIS automates facility, warehouse and cold room transactions from goods receipt to issuing, with additional features including location tracking and pricing and vaccine specific features such as volumetric analysis. HCMIS includes dashboards for PFSA managers allowing them to visualize data including stock on hand and generate reports. It is a complex system with an enterprise architecture and broad functionality across a variety of business processes. HCMIS inventory management system is also used in health facilities.

HCMIS is integral to the various business processes of the Ethiopian public sector healthcare supply chain and is likely to remain so for the near and medium term future.

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[1] Wikipedia - https://en.wikipedia.org/wiki/Ethiopia

Though there have been substantial investments by USAID mission and Gates Foundation in Ethiopia's eLMIS (Electronic Logistics Management Information Systems), there is still a lack of good end to end data visibility due to fragmented systems (both in-country and among procurement agencies), lack of standards-based identification, and heavy reliance on manual data exchange. Establishing a National Pharmaceutical Traceability System (NPTS) that is integrated with HCMIS and MRIS is of critical importance to FMHACA

The overall scope and goal of this document is to provide a framework for FMHACA to implement a system that supports the need for strengthening the cooperation and exchange of information between various stakeholders with the goal of adopting cost effective, interoperable and efficient technology standards and systems. The document outlines:

- A high-level architecture for establishing and implementing a NPTS
- Integration of HCMIS, MRIS and other 3rd Party LMIS systems with NPTS,
- Sharing current industry best practices, track and trace innovations and thought leadership around supply chain traceability.
- Recommended roadmap to streamline the software development towards achieving complete supply chain traceability.

Section No.
3 TRACK & TRACE OVERVIEW

3.1 WHY TRACK AND TRACE

In order to combat the spread of counterfeiting, some countries like Turkey, Argentina. EU have enacted traceability directives in certain value chains like pharmaceutical, explosives and tobacco for companies to report traceability data to government databases. This traceability data serve scenarios for process compliance, logistical supply chain visibility and item traceability for compliance and recall.

Per GS1 Global Traceability Standards (GST), "Traceability is 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". A traceable item can be:

1. A product or traded item (e.g. case or carton or single unit of consumer item)
2. A Logistic Unit (e.g. package, bin, container, pallet)
3. A process (e.g. procure to cash lifecycle, order to cash lifecycle)

There must be an agreement between all trading partners on what the traceable item is. This ensures that all partners are tracking the same thing. All traceable items must be uniquely identified. And all supply chain parties must systematically link the physical flow of products with the flow of information about them. Otherwise the traceability link will be broken.

In case of Ethiopia's In-Country track and trace the capability will be built for traded product traceability, using the framework and guidelines provided by GS1 Global Traceability Standards For Healthcare (GTSH) published in 2013.

Per GS12, the term "Traceability" includes the sub-processes of "Tracking", "Tracing", "Authentication" and "Recall"

3.1.1 Definitions

1. Tracking is the ability to record information about the movement of the item along the supply chain.
2. Tracing is the ability of operators, controlling authorities and, in many cases, final consumers, to access all the tracking information associated with the given item in order to understand its properties and the path taken for it to arrive at a given location
3. Product authentication is the capability to check that that product is genuine, and not counterfeited. The product authentication may be carried out by a nominated party, controlling authority or even the consumer. The process of authentication can take many forms:- overt, covert and forensic.
    a. Overt solutions are obvious to the naked eye and enable instant authentication through visual inspection, such as serialization, barcodes, holographic images and color-shift inks.

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[2] www.gs1.org

b. Covert solutions often require specialist equipment to identify their presence, such as microtext and UV fluorescent inks.

c. Forensic solutions include using intrinsic features within packaging to create a unique signature or molecular markers that can only be identified using laboratory equipment.

4. Recall is the ability to send an upstream or downstream trace request to right supply chain partner to uniquely identify specific items that may have a problem.

3.1.2   Role of Serialization and Aggregation

While tracking can be done at batch number or serial number level, in order to achieve full and effective track and trace abilities, it is important to adopt serialization of an item, where each item has a unique identifier.

A batch number tracing allows small number of units that have same properties like same manufacturing run, 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. Serialization will provide a better control over counterfeit, monitoring of smuggling and diversions.

Per GS1 standards an item must be identified by GTIN, Batch Number, Expiration Date and Serial Number. This data is physically represented on the item as a 1D/ 2D barcode/ RFID or human readable form. This way whenever the item is scanned, the unique information of each item can be stored in the track and trace database.

While batch number tracking provides the granuarlity

Aggregation of serialized information makes tracing of serialized items operationally effective and sustainable. Aggregation is the process of building packaging hierarchies and storing this relationship in a database.

If, for example single products get packed in a carton and these cartons get packed on a pallet, this relationship has to be recognized and stored in a database using scanning processes. Each new packing level, e.g. cartons or pallets, also requires a unique serialized identifier. Once the packaging hierarchy is built and stored in a database, only the highest-level identifier (e.g. pallet) has to be scanned   and all associated packed items and their attributes, in the hierarchy will automatically be known. This process makes it much easier to follow the items through the supply chain, as not every single item needs to be scanned at different intervals in the supply chain.

3.1.3   EPCIS Guidelines

EPCIS is a GS1 Standard for sharing real-time information about physical events in the supply chain between trading partners. With the visibility provided by EPCIS, trading partners in a supply chain can improve their inventory management by real-time tracking of their products, they can see where their shipments are stuck and if they have been delivered, they can combat counterfeiting by identifying where products came from, etc.

EPCIS provides information about physical events concerning products and other assets in the supply chain. It allows organizations to share data about the location of products or assets within their company and across multiple stakeholders, making it possible for all to understand what actually happened in the physical world as products and other assets were handled during operations taking place in factories, warehouses, retail stores, and other facilities.

EPCIS data comprises a series of real-life "events". Each event documents at business-level something that happened in the physical supply chain.

EPCIS   defines the structure and meaning of physical visibility data, the interfaces for the secure sharing of EPCIS events between business applications and between trading partners.

The EPCIS Capture interface specifies a standard way for business applications that generate visibility data to communicate that data to applications that wish to consume it.
The EPCIS Query interface specifies a standard way for internal and external systems to request business events from repositories and other sources of EPCIS data.
EPCIS events are designed such that they are by any business application, without the application needing to know how the process took place or how the data was captured. This ensures that all parties who exchange EPCIS data have a common and consistent understanding of the semantic meaning of that information.
The EPCIS standard provides a way to share high volume, very fine grain information about material movement and status among cooperating partners. EPCIS does not address processes such as purchasing, forecasts, bidding, billing, etc. that are typically exchanged via EDI in a business transaction between two parties.
A company implementing EPCIS can use the authenticated identity of a trading partner in conjunction with pre-defined business rules to determine which information is made available to that partner.

Each EPCIS event has four dimensions of information:
- WHAT (object identified by a GS1 Key)
- WHERE (event location identified by an SGLN)
- WHEN (date & time of event)
- WHY (business context and object status)

1. WHAT - Product : It is possible to include any unique identity in the EPC (Electronic Product Code) field. The EPC is designed as a universal identifier that provides a unique identity for every physical object anywhere in the world, for all time. Its structure is defined in the EPCGlobal Tag Data Standard, which is an open standard. To ensure that an EPC always uniquely identifies an individual physical object, in the case of GTIN, the EPC is constructed as a serialized GTIN (sGTIN) by combining a GTIN product identifier with a unique serial number.
2. WHERE - Location : this indicates the "Business location" where an event took place and what was the "read point". Example Distribution center X (business location) conveyor belt Y (read point)
3. WHEN - Time : "Event Time" field indicates the time an event tool place. "Record time" indicates when the event was received and recorded via Events Capture Interface
4. Why - Business Step and Status : 'Business Step' indicates what business operation was taking place at the time of the event – e.g.: Receiving, Picking, Loading, Shipping. 'Disposition' describes the status of the product immediately after the event occurs – e.g.: Sellable, In Progress, Non Sellable, Destroyed

3.2   TRACK & TRACE SYSTEM BENEFITS

With the right data model, a traceability system can become an enabler for complete item visibility across a value chain from raw material to the point of consumption, provide supply risk management, supply chain security, real-time complex supply chain orchestration and provide real-time data intelligence. Traceability can help in providing the visibility and intelligence of both global market opportunity as well as risk, in an effective and speedy manner. The list below gives potential advantages of Track and Trace implementation:
1. Ensures patient safety
   a. By mitigating counterfeit and illegal medical products

b. Ensuring quality products in supply chain and thereby decreasing adverse health effects, lack of response to treatments and need for alternative treatments

c. Ensure timely availability of medical products thereby decreasing number of hospitalization days and even death

d. It helps to ensure that medical products circulate only through the authorized health supply chain

e. Avoid consumption of recalled or expired medicines

2. Prevents diversions

a. Prevents the circulation of stolen and smuggled products

b. Prevent the distribution and/or dispensation of expired, prohibited or recalled products

c. Ensure free medical products samples are properly delivered

d. Allows identification of the right custodian of item at any point till the consumption of the product

3. It favors efficient, fast and safe market recalls

4. Efficient supply chain management and operations through accurate forecasting, planning and optimized fulfillment

5. Better inventory management especially for products nearing expiration dates

6. Transportation cost reduction by managing waste and expired products upstream in the supply chain

7. Visibility into delayed shipments and its alerting to downstream partners

8. Brand protection for all involved stakeholders

9. Real-time visibility into all attributes of the product.

10. Prevents insurance, reimbursement and tax frauds

11. It enables the collection of meaningful data and development of specific marketing, growth and consumer management strategies as well as assess the effects of pharmaceutical products in effective treatment of medical conditions in each geography

3.3   TRACK AND TRACE SYSTEM CAPABILITIES

An effective track and trace system should offer following capabilities:

1. Keeps an electronic record of each transaction that results a change of ownership of an item, from sale by a manufacturer, through acquisition(s) and sale(s) by one or more wholesalers, manufacturers, or pharmacies, until final sale to the dispenser.

2. Clearly identifies chain of custody at any point in time, product's status, alerts and recalls

3. Can exchange event data per EPCIS standards as XML files or other forms with supply chain partners

4. Allows ease of integration with variety of ERP/ MES, WMS and eLMIS systems

5. Supports data types such as GTIN, SGTIN, SSCC as per GS1 and EPCIS standards

6. Supports serialization and aggregation of units into bundle, cases or pallets.

7. Supports creation or changes to parent/child relationship in aggregation process and disassociates a parent serial number from its child when necessary

8. Supports verification of items, its attributes and serialization

9. Support participant validation

10. Provides data security and data access per authorization

11. Be a modular, flexible and scalable application

12. Supports exception management, communication and notification to appropriate parties

13. Has flexible database management with secure and full audit trail of all transactions

14. Supports analytics and reporting

4 TRACEABILITY MODELS

There are several emerging models for traceability in the pharmaceuticals industry, the choice of which depends on market and country specific characteristics.

The "one-up, one-down" model is perhaps the most basic traceability model. In this model each firm in the supply chain keeps a record containing the product identifiers and characteristics, from whom the product was received, and to whom it was sent.
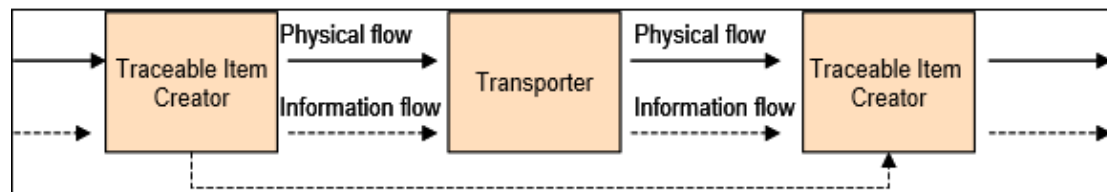
Although it is possible for the product to be traced throughout the entire supply chain using this model, the fact that there is no single repository for tracing information means that the speed at which products may be traced is often not as fast as other more comprehensive approaches.

The "pedigree" model for traceability requires that a record containing information on product identification, characteristics, and any change of ownership accompanies the product (either physically or electronically) throughout the supply chain.
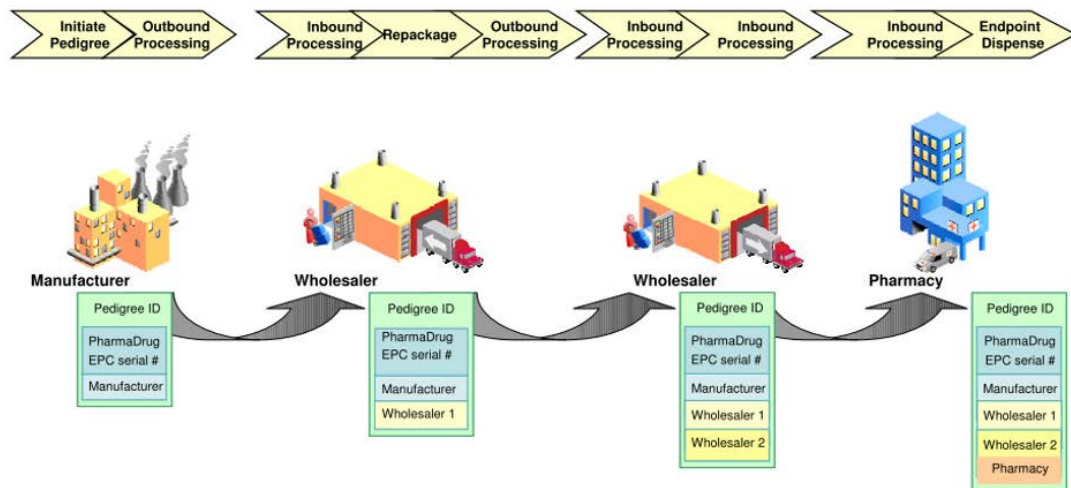

Figure 1 Pedigree Model

For example, the California e-Pedigree Law, which came into effect in 2015, requires an electronic pedigree to accompany all prescription drug distributions in California starting from the manufacturer up to the point of sale. A pedigree in this case is an electronic record of all transactions that result in a change of ownership, and the law requires that these records be maintained using an interoperable, electronic system that ensures compatibility at all stages of the supply chain .

The "point of dispense authentication" model is a process that determines whether a product is actually what it purports to be at the point of sale. For example, Turkish law requires drug manufacturers to uniquely identify their products using (GTINs) and lot/batch numbers, and to upload a list of these numbers to a central government database. The drugs are then authenticated at the point of sale by checking human- and machine-readable

identifications on product packaging against the central database . See section 4.2 for further details

The "distributed network track and trace" model requires that all firms who produce, buy, sell, store, or otherwise impact a product in the supply chain publish key data that are accessible to other authorized parties in the supply chain as well as government regulator.
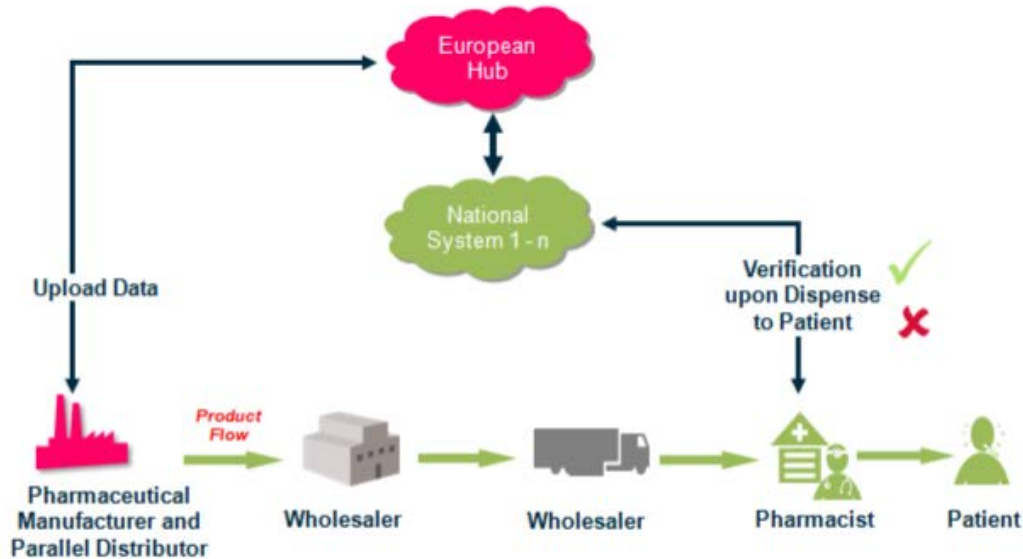

Figure 2 Authentication Model

Information is published to a "cloud" and permissions are granted by the owners of the data to determine who has access. This model is perhaps the most advanced traceability architecture but also the most complex to implement

4.1 SAMPLE IMPLEMENTATIONS - ARGENTINA

- Issue
- Receipt
- Return

Transaction Upload
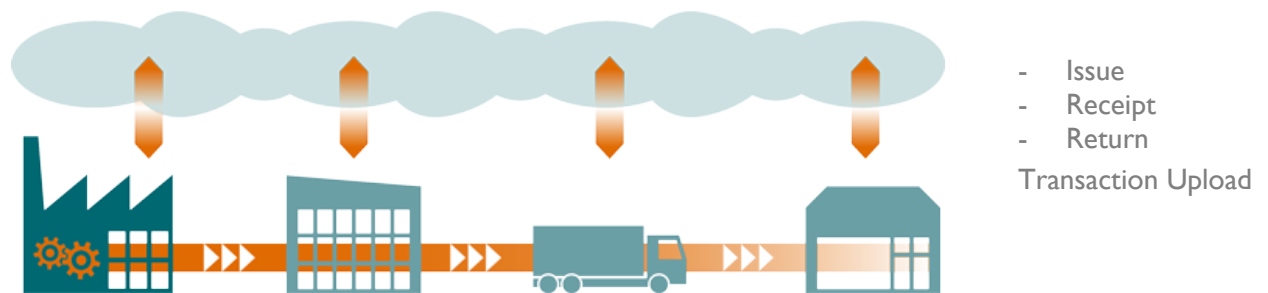
Figure 3 National Level Track and Trace Database

All current drugs and samples that contain an Active Pharmaceutical Ingredient (API) on the lists published by the Argentina Health Authority (ANMAT) are subject to serialization regulations, plus all new drugs which are introduced to the market.

In the Argentina model the data captured by each supply chain member is uploaded to the central database in a specific file format. The centralized system is developed and operated by ANMAT, and no data retention requirements exist for supply chain members.

All changes of ownership must be recorded by the corresponding supply chain participant in the central government database. Many types of transactions are also required to be

captured, including ship, receive, return, dispense, recalled, etc. Data captured includes timestamp,

4.2 SAMPLE IMPLEMENTATIONS - TURKEY

The Turkish "Pharmaceutical Track and Trace System" (abbreviated as İTS) defines the infrastructure constructed to track and trace all units belonging to each pharmaceutical product in Turkey. İTS is the first successful and unique application of "Pharmaceutical Track and Trace System" in the world. İTS is designed to track the location of every drug unit to ensure the reliable supply of drugs to patients. The serialization providing the uniqueness of the units is ensured by the DataMatrix code instead of formerly used barcode. The ability to track each drug unit is provided by gathering the information of each unit in every single step and action; and traceability is provided by its pedigree. Therefore, all the drugs on the market are traced by notifications in all phases from production to consumption. Thus; the sale of fraudulent drugs, drug theft and barcode scams are prevented. In addition, if required, drugs can easily be recalled due to traceability of stocks.
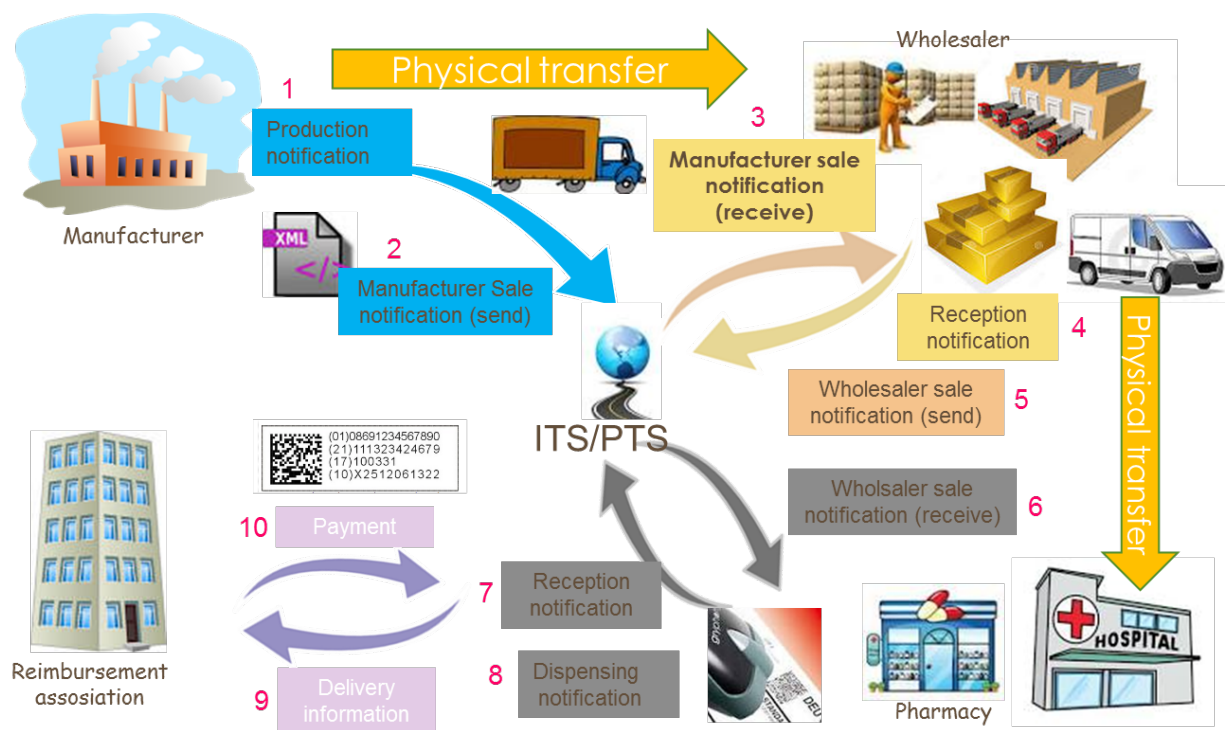

Figure 4 Central Governance Track and Trace Model

4.3   EXAMPLES OF AVAILABLE COTS SOLUTIONS

There are many software vendors that offer commercial serialization and track and trace solutions. The nature and feature function of the solutions depends on the user of the solution. The users can be raw material supplier, manufacturing plant, brands, wholesalers, retailers, hospitals, consumers or regulatory bodies.

The capabilities and feature function required from a COTS solution depends on the function the user is trying to address. For example if a manufacturer is trying to comply with a regularoty body's serialization reporting requirements, then they may end up using an EPCIS compliant ERP system like SAP to monitor the movement of serialized item throught their supply chain.

Some of the COTS solutions currently available in the market are

1. Tracelink – (www.tracelink.com) - TraceLink's Life Sciences Cloud solution provides pharmaceutical and their supply chain partners, a platform to enable serialization and exchange of track and trace data required for regulated and government compliance needs. TraceLink provides tailor-made solutions for regulatory requirements in countries around the world, including the United States, China, Brazil, India, South Korea, the European Union, and more. The TraceLink Life Sciences Cloud is built on Amazon Web Services' native cloud architecture with a network-tenant platform to deliver scalability, performance, and business-to business connectivity. A single point and click connection to the Life Sciences Cloud allows any company to gain complete global connectivity with all of their trading partners.

2. Frequentz – (www. frequentz.com) – Similar to Tracelink, Frequentz provides pharmaceutical companies the ability to extract necessary event data that is captured in their IRIS repository and repurposed to meet specific country reporting standards. Their solutions are GS1 certified and are built to comply with country reporting anywhere around the globe. The solution is deployable through a hosted private cloud, an on-premise database, or a hybrid of each.

3. Fosstrak EPCIS – (http://fosstrak.github.io/epcis/index.html) - Fosstrak is an open source application that provides an EPCglobal-certified EPCIS Repository as well as Query and Capture clients. This opensource application can be
- Embedded into your own applications to add an EPCIS interface to it
- Interactively explore any EPCIS Repository using the graphical EPCIS Query Application
- Use the EPCIS accessing applications as a blueprint to build your own EPCIS Capture or Query Application

5 CURRENT STATE

This section describes the movement of pharmaceutical commodities in Ethiopia, within the public sector supply chain, from a manufacturer's warehouse into a patient's hand. The intent of this section is to provide an overview of the business process and various systems that are currently track the flow of information to match with the flow of good. It description is in the context of necessary functions and information required to achieve an end to end in-country track and trace. The section will not describe each and every state or touch point for the item or each and every function carried out by a current application in use.

5.1 CURRENT PUBLIC SECTOR SUPPLY CHAIN SYSTEMS LANDSCAPE

This section provides a quick review of existing supply chain applications that are used to manage and maintain pharmaceutical commodities in Ethiopia's public suply chain system
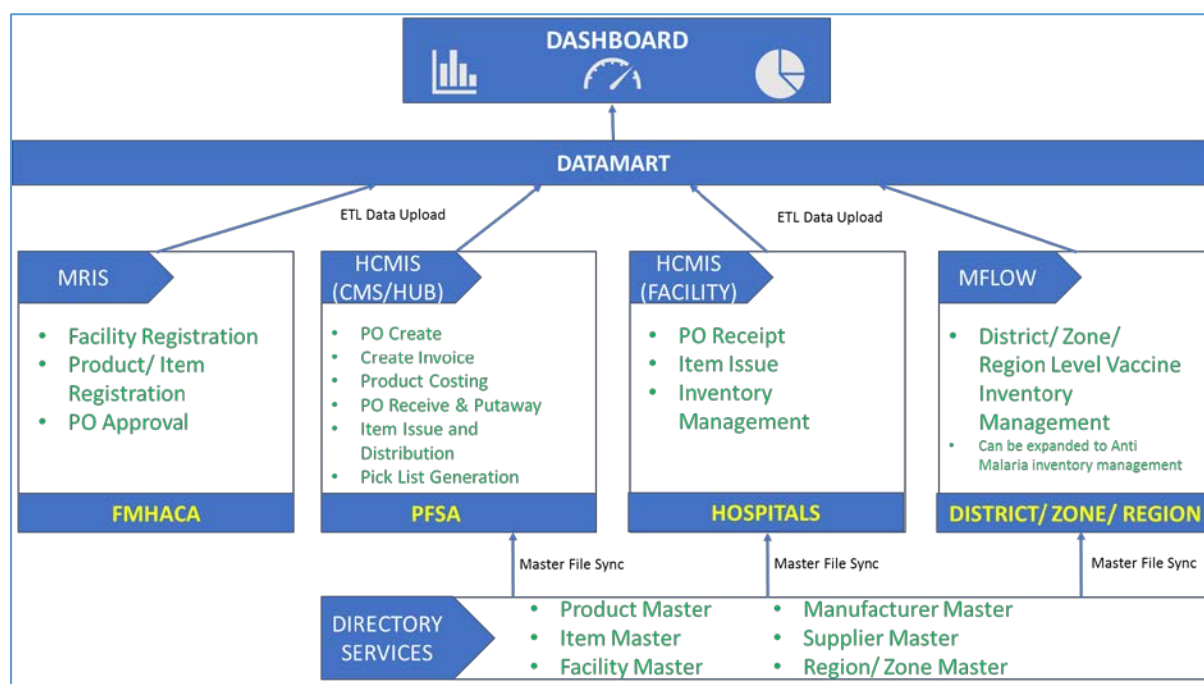
Figure 5 Current As-Is Systems

1. MRIS – Is the application used by FMHACA to manage the registration and approvals of products, pharmaceutical manufacturers, suppliers, hospitals and other service provides that wish to do business in Ethiopia. It is also the system that captures and approves all Request for PO requistions before a purchase order can be placed with a manufacturer or supplier to import any product into the country

2. Directory Services – This is a master data maintenance application that is owned an operated by PFSA. This is a central application that manages and maintain all product, item, facility, supplier, manufacturer, region and zone masters. Once a new master record is captured or updated in this system, the data is synchronized to all instances of HCMIS and MFLOW application using the master file sync process.

3. HCMIS – Is a Windows based procurement, inventory, replenishment, warehouse and forecast management application used in Central medical store and the 18 hubs of PFSA. Each location has its own instance of the application. It downloads the master data from Directory Services application. And it uploads all completed transactions to a central Datamart using ETL processes

4. HCMIS (Facility Edition) – HCMIS Facility Edition is an abridged version for inventory management, receipt and issue process at the Facilities.

5. MFLOW – Is a lightweight mobile / desktop application to manage vaccine inventory at district, region, zone level. While the application is currently only being used for vaccines, it can easily be extended to manage limited number of products (say under 10) in other programs like Anti-Malaria / ACT program

6. Datamart – This is a central data repository that collects transactional data from all the above applications. Period ETL processes extract and update the data from MRIS, HCMIS and MFLOW applications. It serves as a single view or single source of truth of information for various users at MOH, FMHACA, PFSA, etc

7. Dashboard – This is a data visualization application that provides various snapshots and metrics into the public sector pharmaceutical supply chain. The dashboards and reports are built on top of the Datamart data

5.2   CURRENT PUBLIC SECTOR SUPPLY CHAIN PROCESS OVERVIEW

Following are the major players in the public supply chain process :
1. Brand or Manufacturer of pharmaceutical goods
2. Supplier in Ethiopia - entity that places an order to bring the goods into the country
3. FMHACA - Ministry of Heath's regulatory body that regulates the quality and quantity of health related provisions, including pharmaceutical goods, available in the market
4. PFSA - is another agency that that is the sole distributor of pharmaceutical goods for suppliers in the public sector supply chain. Majority of the products purchased or donated for imports are handled by PFSA
5. PFSA buys 75% plus of all commodities into Ethiopia with PSM, UNFPA, UNICEF also providing procurement services
6. Customs and border control - entity that regulates import or export of goods in Ethiopia
7. CMS - is the central medical store or the central warehouse where all imported pharmaceutical goods are inventoried and distributed from
8. Branch or Hub - regional locations that store and distribute goods to the health facilities
9. Health Facility - hospitals, clinics or dispensaries / health centers

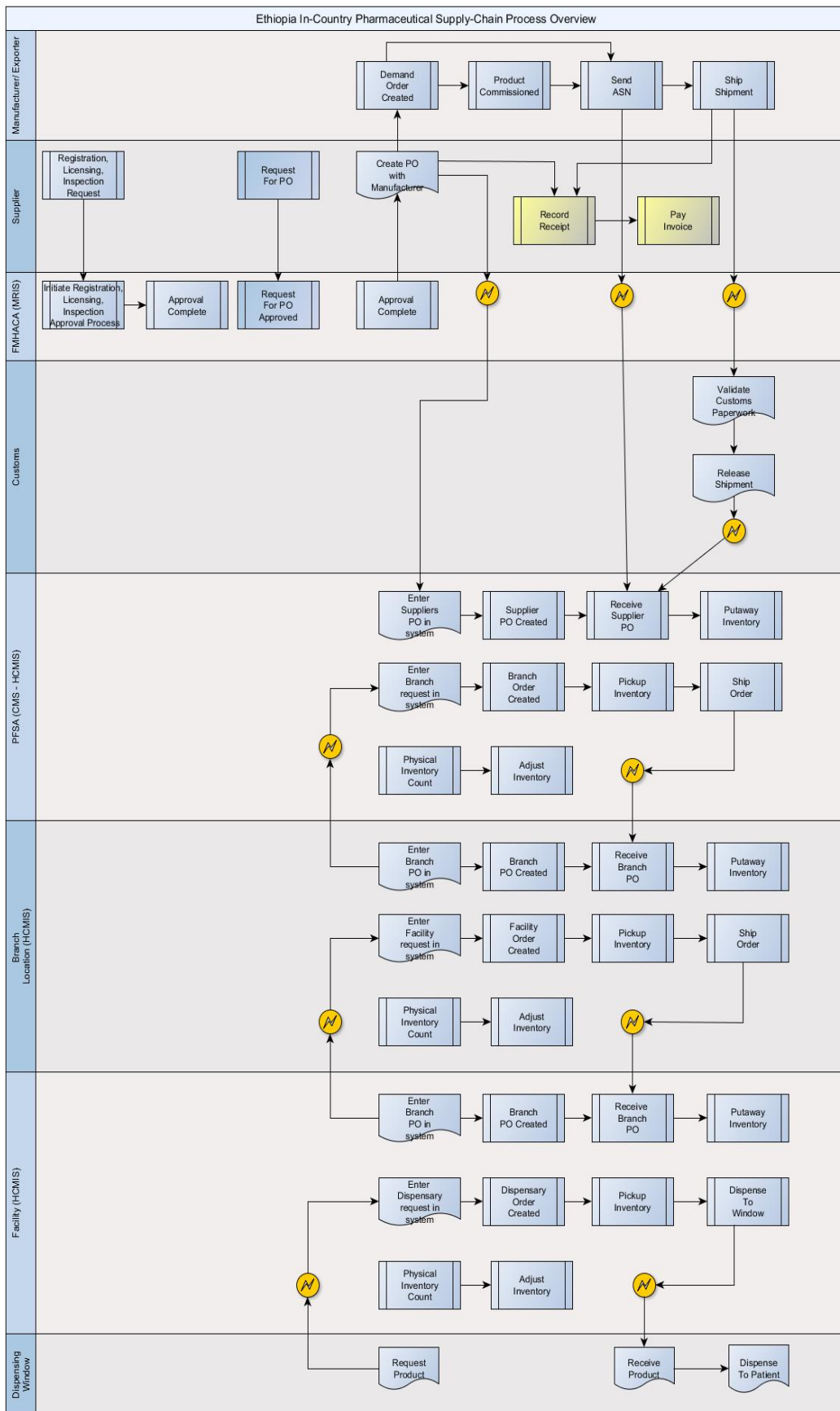The diagram below provides a high level overview of In-Country Pharmaceutical Public Sector Supply Chain in Ethiopia.

Figure 6 Current As-Is Public Supply Chain Business Process Flow

1. When a new practice, facility (premises , product or professional wishes to conduct business in Ethiopia, they undergo a registration, inspection and licensing process with FMHACA.
   a. FMHACA uses MRIS - Medicines Registration Information System for this purpose.
   b. Upon approval of a practice, premises, product or professional the MRIS has established the necessary information about the entity. For example in case of a product the MRIS will have the product id, description, formulation, manufacturing facility, country of manufacturing etc as part of its master data
   c. Once the registration and licensing process is complete, the supplier puts in a "Request for PO" for the products to be imported. The supplier can initiate multiple "Request for PO" anytime they wish to import products. The "Request for PO" is submitted and approved in MRIS system
   d. When PFSA is the procurer of goods, they can seek an exception to procure an unregistered product and procure without a "Request for PO"
2. After the "Request for PO" is approved, the supplier utilizes the approved physical documentation to place a purchase order in their ERP/ procurement system. For example if GHSC-PSM is the supplier they will use ARTMIS to place the purchase order with the manufacturer say Pfizer. The purchase order information can be submitted to a manufacturer as an email, fax or other electronic forms like EDI, manufacturer's portal. (Note: Currently there is no systematic linkage between MRIS and HCMIS systems. If in future should there be an integration between the "Request for PO" and actual POs placed, there will be better visibility into demand planning)
3. The manufacturer fulfills the PO and ships the products to Ethiopia. Depending on supplier's capabilities, they may send an Advanced Shipment Notice (ASN) to the supplier. FMHACA or PFSA currently do not receive any ASN information.
4. In all cases the goods shipped by manufacturer are accompanied with necessary documents like BOL for import and movement within the country. Currently, not all manufacturers have ability to provide GTINs and serialization on products being imported. And none of the manufacturers are currently sending any serialization data to any agency in Ethiopia
5. Once the goods are received at the borders, they undergo an inspection and border control before they are moved to CMS which is operated by PFSA. Currently Ethiopia's Customs and Border control do not have a systematic/ digitized way to verify and approve the import documentations. It's based on visual inspection and approval of the accompanying paperwork
6. Upon clearance from customs all goods marked for public sector are received at CMS. CMS uses HCMIS (Healthcare Management Information System) for recording the receipt of goods. Currently CMS does not utilize barcode scanning in any of its warehousing operations. Most of the warehousing functions are combination of paper and manual data entry into the HCMIS system. The key data element for identifications is HCMIS assigned item id. GTINs are not in use today
7. HCMIS also serves as a system of record for purchase order management, inventory control (inventory adjustments, disposition, physical inventory count), warehouse management, forecasting and demand planning, requisition/ replenishment/ demand management and shipment of goods.
8. HCMIS is a stand-alone instance at CMS. Similar instances - HCMIS Hub Edition and HCMIS Facilities Edition are also deployed at hub and facilities to manage warehousing and inventory control functions. All instances of HCMIS share common master data like item master, supplier master that is managed by "Directory Systems". The master data is downloaded into HCMIS instances through periodic sync process

9. CMS delivers the products to the Hubs, where the hubs receive before shipping it to the facility.
10. The facilities are the last stage in the supply chain cycle where the physical movement of the product is recorded. The facilities receive the product sent by the hubs and issue to the dispensing window.
11. All transactional data across multiple instances of HCMIS are synced up to a datamart/ data warehouse.

6 TRACK & TRACE ARCHITECTURE

As seen in section 5, Ethiopia FMOH has many IT systems - MRIS, HCMIS, MFLOW, Datamart, Dashboard and Directory Services, in place to manage the operations within the four walls of an organization. But when the regulatory body FMHACA has to track an item say that entered the borders to a specific hub, then there is information linkages and visibility challenges as the information about the item spans across at least 2 separate agencies and 3 different systems, which do not have any correlation amongst themselves

Thus implementing a track and trace solution transcending organizational boundaries and system silos will allow building of interlinkages between the information islands to track or trace an item end to end in the supply chain.

This track and trace solution will be efficient and effective when all stakeholders in the ecosystem adhere to common way of identifying items (GTIN), locations (GLN) and instance of an item (serialization). Our recommendation is to adopt GS1 Standards for Healthcare and EPCIS standards for collecting and collating event specific data in a common data repository.

Inserting a new solution in the current systems landscape will ensure that the existing systems do not have to endure the burden of providing capabilities that is expected to be a common platform offering common data visibility to all participating stakeholders. This also helps in ensuring that the current systems continue to provide the logistics and operational management capabilities that were built for.

In short FMHACA should implement a new track and trace solution that is independent of current systems like MRIS or HCMIS, that interfaces and integrates with other systems in the overall supply chain.

6.1   RECOMMENDED TO-BE SOLUTION ARCHITECTURE

The section below describes the conceptual architecture of the new Track and Trace solution.

The diagram below depicts that FMHACA will own the systems and components required to support national level track and trace system.
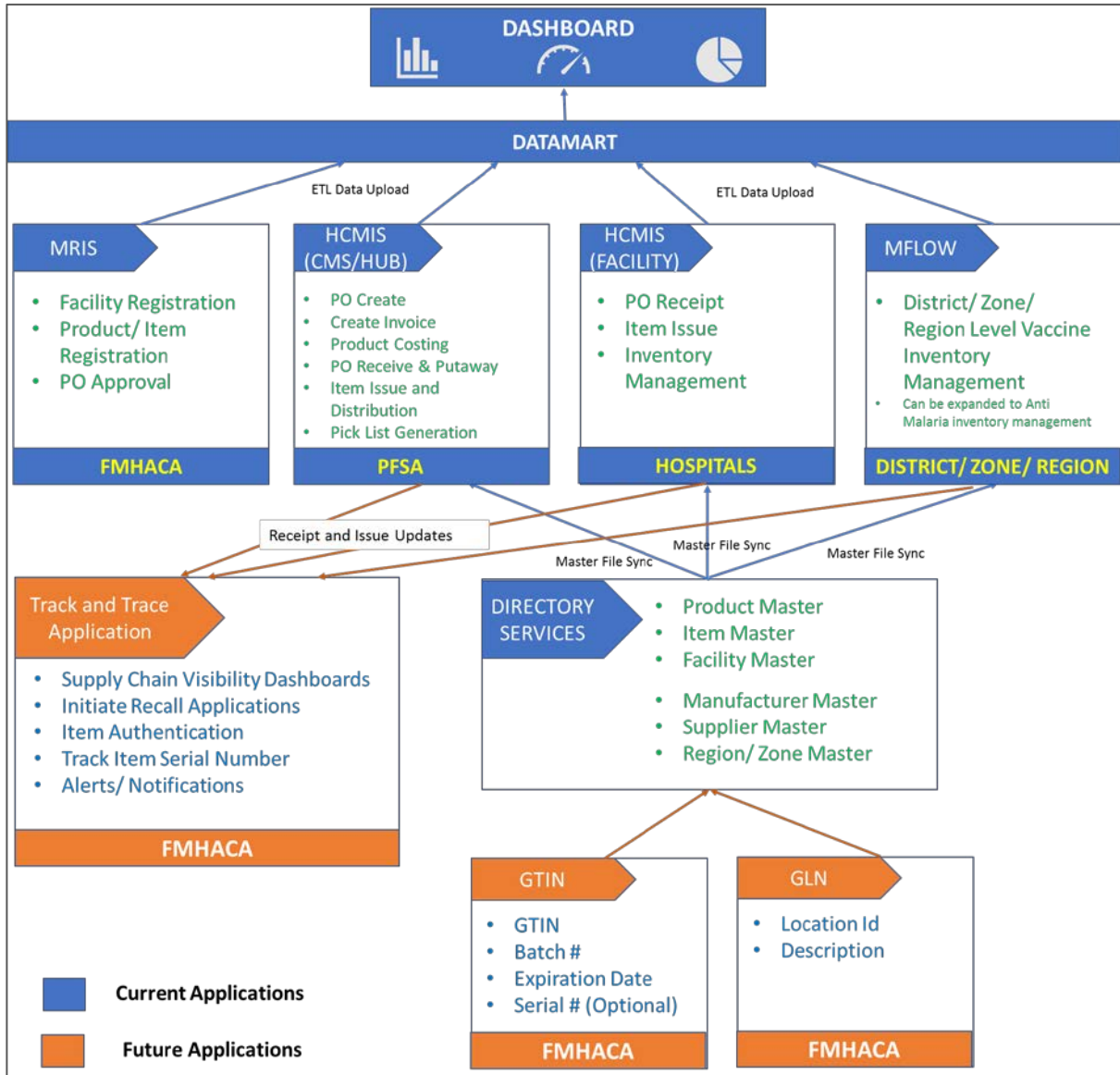

Figure 7 Future To-Be Ssytems Landscape

The track and trace solution will be a central repository, owned and hosted by FMHACA. The solution will primarily be for regulating the public sector supply chain with the potential to extend it to the private sector too. Only GS1 compliant manufacturers can participate in this program. The system will support both serialized and unserialized products. The three major application that will be owned by FMHACA, besides MRIS are

1. GTIN/ S-GTIN Database – This database contains information of all the approved and legal GTINs with or without serial numbers that are imported in the country

2. GLN Database – This database contains GS1 standard way of identifying the location of each physical stop of the item during its movement in the supply chain

3. Track and Trace Repository – This database contains a record of all events associated with an item as it moves through various stages in the supply chain
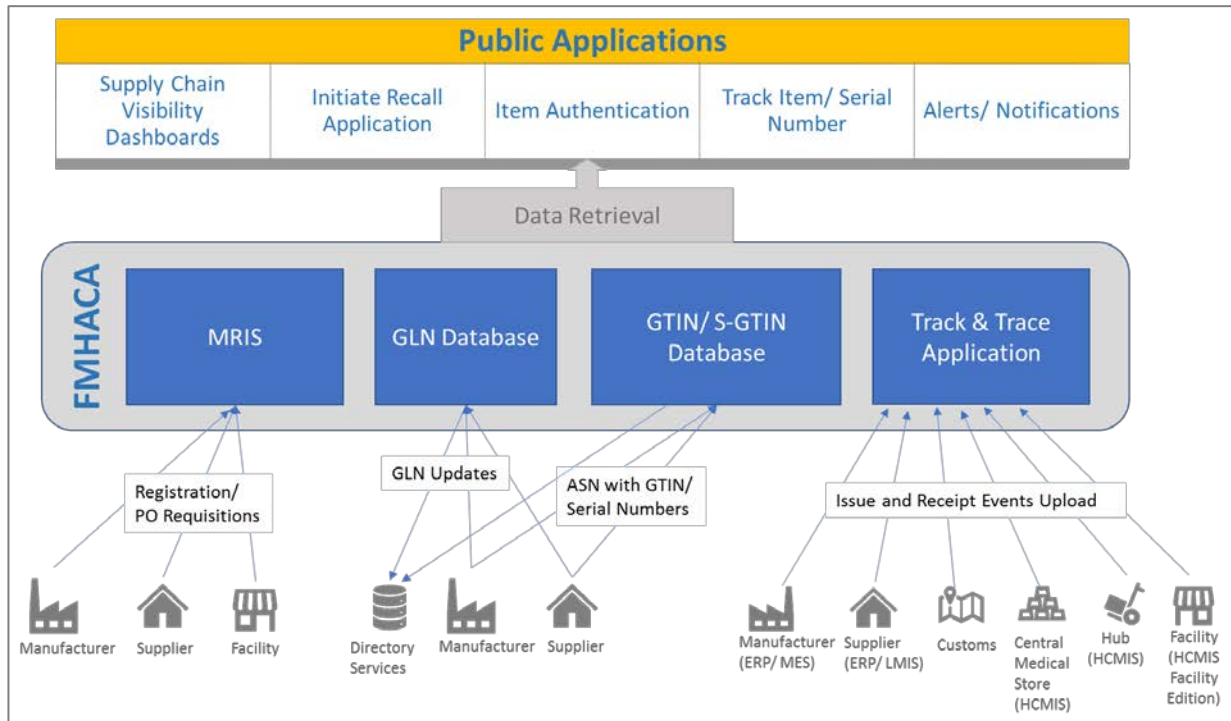
Figure 8 Application Governance Model

These three modules will expose various public APIs on which application modules like "Initiate product recall" can be built. Some of the identified business applications are:

1. Supply Chain Visibility Dashboards
2. Initiate Recall
3. Item Authentication
4. Track Item Serial Number
5. Diversion Alert / Notifications

The owner of above five applications can be any agengy like FMHACA or PFSA as they are building the application on the data exposed by the national level respositories.

6.2 BUSINESS PROCESS ARCHITECTURE

The diagram below describes the high level To-Be track and track business process flow. It has leveraged the in-country supply chain process flow described in section 4, to identify the critical events to track and their sequencing the the process lifecycle..
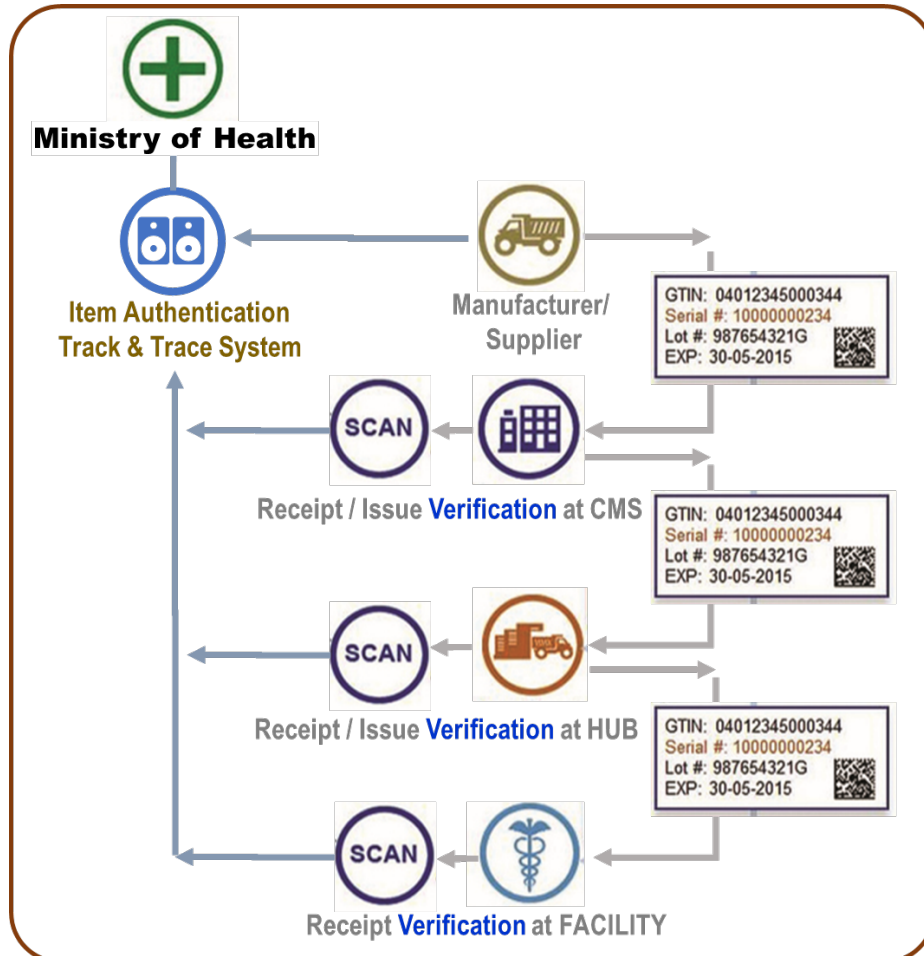
Here's a detailed process flowchart describing the **end-state** activities and events in a step by step manner
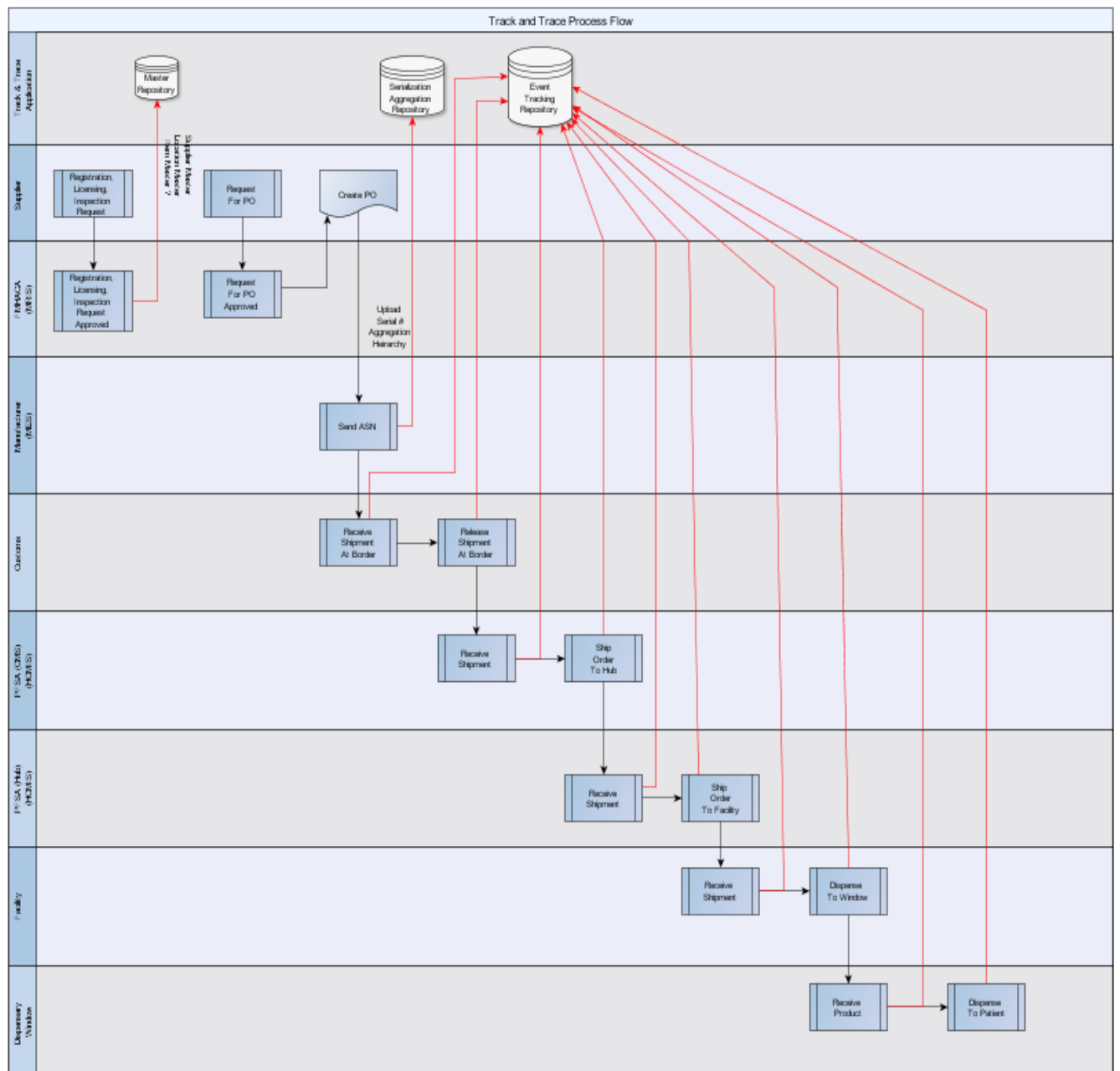
Figure 9 Track and Trace Data Upload Flow

1. When FMHACA approves the registration of a product or facility the associated master data is created in the Track and Trace system.
   a. For product master, GTIN is a mandatory requirement
   b. For facility, GLN definition is a mandatory requirement
2. When the manufacturer ships the supplier's order for import into Ethiopia, the manufacturer sends two sets of data to track and trace system
   a. product hierarchy with all serialization information in the shipment
   b. Shipping data that includes information related to Who, What, Where, When and Why (shipping event)

3. Once the shipment arrives at the Customs and Border Control, the SSCC code is scanned and the "Receipt" information per EPCIS guidelines is sent to Track and Trace database

4. The shipment is released to be received by CMS. The shipment release event is sent the the Track and trace system and the electronic shipment file is sent to CMS (HCMIS)

5. CMS carries out the receipt verification in the HCMIS system. The receiver uses barcode reader to receive the shipment by SSCC code or GTIN and record all the serial number which received in the shipment. On receipt confirmation, the receipt event along with received serial numbers are uploaded in Track and trace system.

6. CMS builds shipment to ship to the Hub. The picker uses barcode to scan all the serial numbers on Tertiary pack or SSCC code (for unbroken logistic unit) going to the hub. Once the shipment is marked shipped in HCMIS, the event data and serial number information is sent to the track and trace system. An electronic receipt file is generated from CMS-HCMIS to Hub-HCMIS

7. The above process of receipts and issues is recorded as the goods move from CMS to Hub to facilities, until it is dispensed to the dispensary window or a patient.

8. Each receipt and shipping process uses a barcode reader to read the GTIN or SSCC code on the Shipment/ pallet/ case/ item either received or shipped from the facility

6.3 SOFTWARE COMPONENT ARCHITECTURE

This section describes the various modules and components that define and complete the Track and Trace solution. The component architecture depicted below is the end state solution. It does not describe the changes or updates to existing LMIS application. The implementation and realization details are mentioned in the next section. The roadmap to achieve this end state in a phased manner is described in Section 7.

The software component architecture does not focus on whether the solution is custom built or a commercial package. But it focuses on identifying all the critical building blocks, each block's core capabilities and their inter-relationship and interdependence to achieve the end goal. The actual implementation and solution can be a combination of commercial and custom built solution. For example the "Event repository" module can be custom and "Analytics" module can be commercial or visa versa

There are 5 major components that are part of the track and trace architecture:
1. Data Store Layer
2. Platform/ API Services Layer
3. Interoperability Layer
4. Functional Application Layer
5. Analytics Layer

The data store, platform and interoperability layer for the heart of the overall solution. Other applications, analytics, extensions will be built off these core layers

6.3.1 Data Store Layer

The data store layer stores master and transactional data across all trading partners. There will be 3 core data stores to manage and maintain the track and trace data
1. GTIN/ S-GTIN Master Data :This repository will at a minimum will contain all GTIN, product description, batch number and expiration date of the products coming into Ethiopia's supply chain. This master will also store the Serial number where present for given GTINs
2. GLN Master Data : This will contain the global location identifier of all the locations through which the product could move. This includes manufacturer/ supplier facility, PFSA warehouses and hub locations. Facilities (hospitals, health care centers and dispensing locations)

3. Event Data : This repository will keep a record of each and every event sent in by a trading partner. The 2 core events that most partners are expected to provide are
    a. Shipping/ Issue or Dispatch Event
    b. Receipt Event

6.3.2 Platform/ API Service Layer

Figure 10 Software Component Model
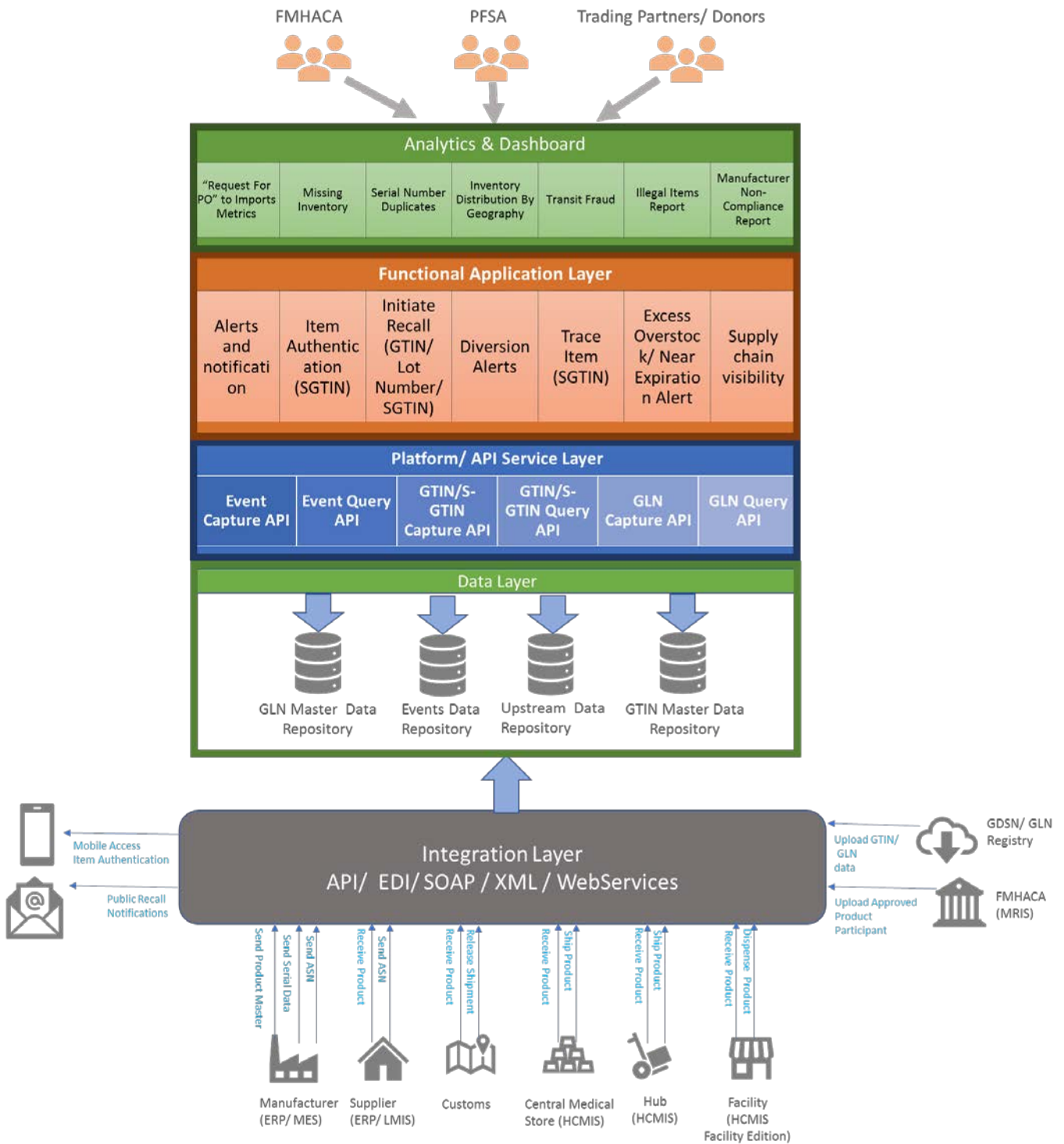
The platform layer will consist of core infrastructure engine and business logic layer. This layer will also provide external applications ability to access track and trace related data to apply for various functional use.

The two core service each component will provide is

1. Capture services
2. Query/ Share services

Capture Services : - The capture service allows data and events from various sources to be captured seamlessly in a consistent format per GS1 standards. As part of capture it is also important to identifiy various source and formats of data. For example a user may scan a barcode that represents GTIN-BatchNumber-ExpirationDate or GTIN-BatchNumber-

ProductionDateExpirationDate or an SSCC code. The capture interface must be able to distinguish between various types of barcodes. Or the capture interface must be able to read data file as provided from external data capture systems

Query/ Share Services :- The query service allows internal and external applications to reterive the data in the the track and trace database. Using these interfaces various applications like "Initiate recall", "Broadcast overstock/ near expiration item" etc can be build. Abstracting the query from application layer, helps in building modular applications in a phased and / or parallel manner

At a minimum the Platform layer should provide following capture and query services
1. Capture API/ Service
    a. Event Capture API/ Service
    b. SGTIN/ GTIN Capture API/ Service
    c. GLN Capture API/ Service
2. Query API/ Service
    a. Event Query API/ Service
    b. SGTIN/ GTIN Query API/ Service
    c. GLN Query API/ Service

Besides the query and capture interface the platform layer can also include following modules
1. Subscription/ Security management – In order to manage access, the subscription/ security module allows partipants to register and have access to authorized query interfaces. This module authenticates the trading partner and the users who can use the Query services.
2. Exception management - This module provides the framework to manage data validation and system errors that may occur in the system

6.3.3   Interoperability Layer

The interoperability layer provides the capabilities to integrate with external 3rd party systems. This layer will provide various formats and protocols for data exchange. EPCIS standards recommend XML format for EPCIS events capture and retrieval. The others like master data can be EDI, flat file etc.. This layer may be a candidate for COTS application

6.3.4   Functional Application Layer
The functional layer applies the captured data to serve various use cases. The applications in this layer can be owned and developed by any entity that is authorized to have access to the Query API from the Platform layer.
The modules below are listed in no particular order. These modules can be developed in a phased manner in order to realize the investments faster.
1. Alerts and notification - This module allows setup of monitors that will trigger notifications if the defined threshold or data conditions are met.
2. Item Authentication (SGTIN) : This module will allow a patient or any user to scan or enter the serial number and validate that the said item entered the country legally.
3. Initiate Recall (GTIN/ Lot Number/ SGTIN) : This module will allow the user to enter a GTIN or SGTIN, Lot or Batch Number to initiate a product recall. If the user provides a GTIN, it will show all the items in the supply chain which are available in a form that it can be recalled. For example the GTIN may be stored in CMS, a particular hub and say four facilities. This visibility will allow user to initiate targeted recall operations. Similarly if the GTIN and Batch or Lot number are provided, it'll function the same way but with a smaller quantity set - limited to specific batch number(s)

4. Diversion Alerts - This module raises an alert if the a specific serial number destined for location X but is received in location Y. or never shows up at location X say after a specified time period
5. Trace Item (SGTIN) - This feature will allow a user to enter a serial number and be able to see all the points through which it passed to reach the current location
6. Excess Overstock/ Near Expiration Alert – This module can be used to alert other facilities and health care centers of overstock items or products which are nearing expiration, but can be used elsewhere
7. Supply chain visibility
8. Other possibilities for future modules
   a. Insurance reimbursement
   b. Refund claims
   c. Tax and duties payments (hopefully far off in the future)

6.3.5 **Analytics Layer**

The analytics layer will allow generation of various supply chain visibility reports from the transactional data collected in the database. This component may be a candidate for a COTS application

6.4 INTEGRATION ARCHITECTURE
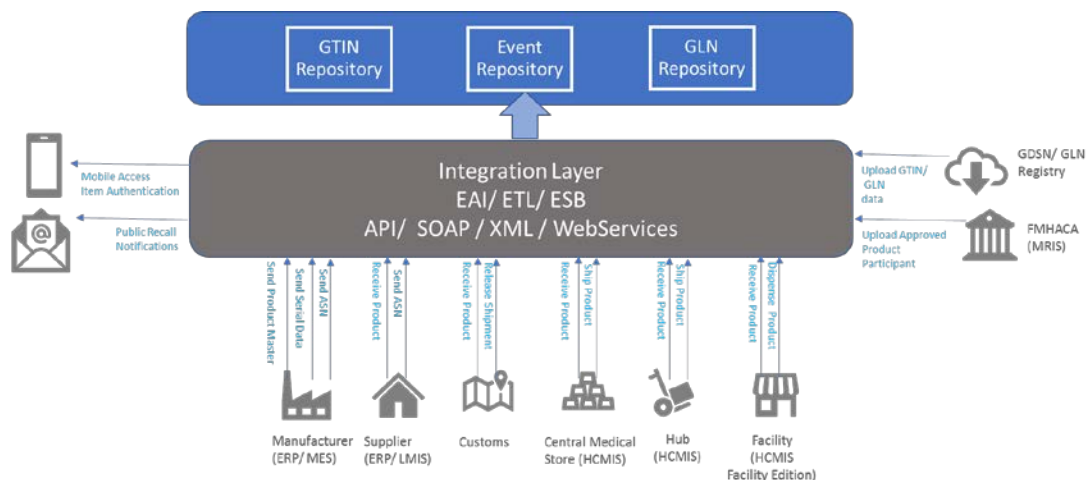
The diagram above represents the integration architecture. There are various options to integrate the data from source system like HCMIS to the event repository. One can chose an ETL or an ESB application.
For details on data exchange please see section 7.1.1

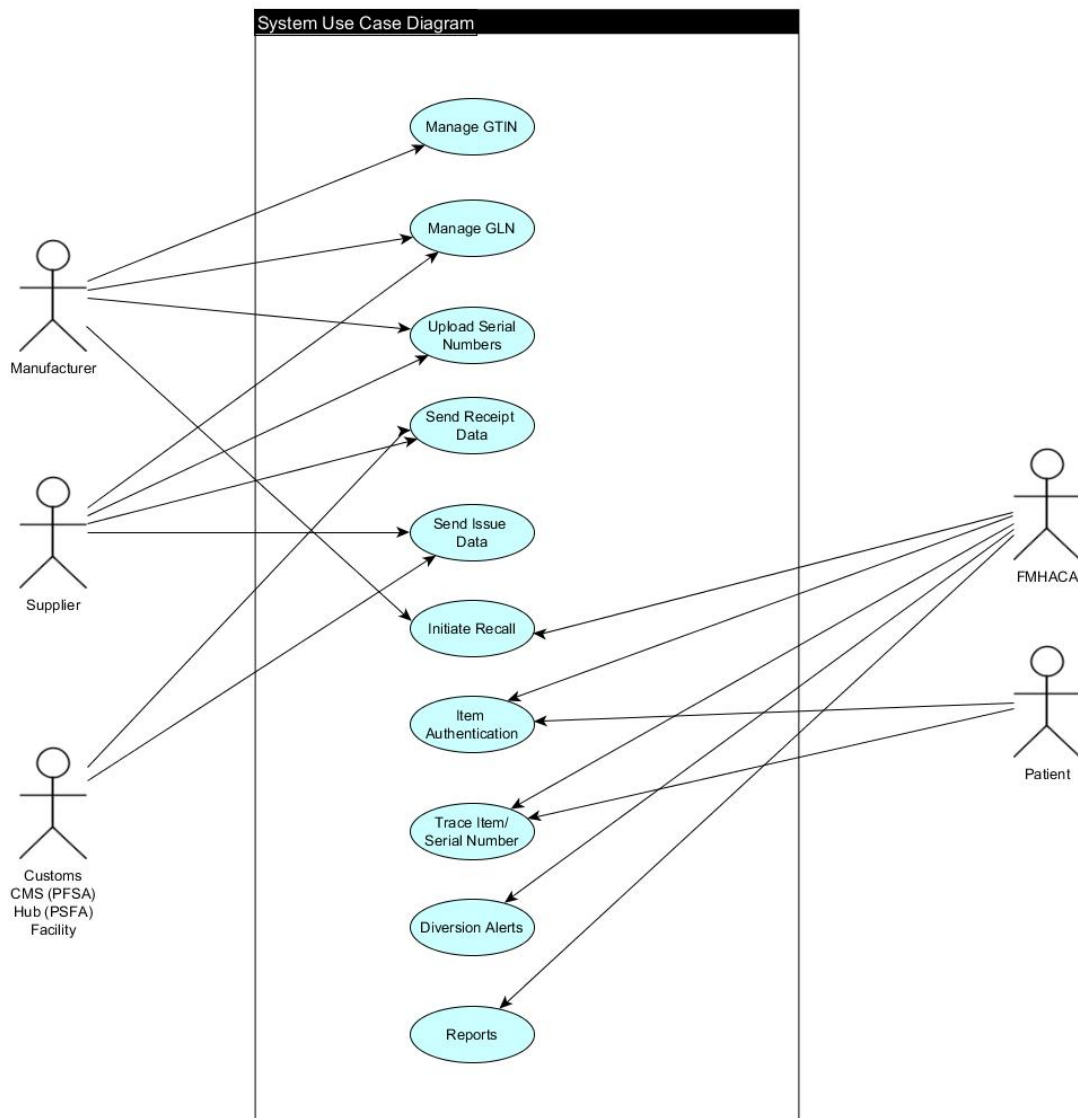## 6.5 SYSTEM USE CASE DIAGRAM

Figure 11 System Use Case Diagram

Use Case List
1. Manage GTIN
2. Manage GLN
3. Upload Serial Number, Batch Number, Expiration Date
4. Send Issue Data
5. Send Receipt Data
6. Initiate Recall
7. Item Authentication
8. Trace Item or Serial number
9. Diversion Alert
10. Reports

1.	**Use Case Name:** Manage GTIN

1. Use Case Name: Manage GTIN		
Actors: Manufacturer Supplier FMHACA		
Main Path: The manufacturer or supplier will register every new GTIN they wish to sell. GTIN will be a unique identifier used to identify a tradeable . This function is to promote code harmonization and central repository of GLNs for supply chain parties		
Inputs GTIN Item Id Item Description	**Trigger(s)** • Initial registration • New tradable packaging of the same formulation • Formulation or manufacturing process change	**Usage Frequency** Once at initial registration and whenever information changes
Pre-Conditions Obtain GS1 company prefix, if not yet done Note: The same GS1 company prefix can be used for creating GTIN, GLN, SSCC, etc.		**Post Conditions** A valid GTIN gets defined in the system

2. Use Case Name: Manage GLN		
Actors: Manufacturer Supplier PFSA (CMS, Hub) Facility (Hospital, Pharmacy) FMHACA		
Main Path: GLN will be a unique identifier used to identify the physical location where the item is. This function is to promote code harmonization and central repository of GLNs for supply chain parties. The supply chain parties with register the GLN in FMHACA's central database		
Inputs GLN of Organization Company Organization/Company Name Functional Role Address or PO Box City Postal Code Country Is Active? Start Date End Date Last Update Date	**Trigger(s)** • Initial registration • New location/company entity • Mergers & Acquisitions	**Usage Frequency** Once at initial registration and whenever information changes
Pre-Conditions Obtain GS1 company prefix, if not yet done Note: The same GS1 company prefix can be used for creating GTIN, GLN, SSCC, etc.		**Post Conditions** A valid GLN is defined for one or more entities

3. Use Case Name: Upload Batch Number/ Serial Number

3.	**Use Case Name:** Upload Batch Number/ Serial Number	

Actors:
Manufacturer
Supplier
FMHACA

Main Path:
The manufacturer or supplier will provide the upstream data containing the GTIN, batch number, expiration date and serial number where applicable, everytime they ship the products for Ethiopia. This information will become the item verification and authentication database and allow various sstakeholders to check the authenticity of the products in their hand

Inputs	Trigger(s)	Usage Frequency
GTIN Item Id Item Description Batch Number Expiration Serial Number (Optional)	• Shipment from manufacturer or supplier location	Everytime an ASN transaction is created
Pre-Conditions		**Post Conditions**
Creation of ASN		GTIN with or without serialization is registered in the database

4.	**Use Case Name:** Send Issue Data	

Actors:
Manufacturer
Supplier
PFSA (CMS, Hub)
Facility
FMHACA

Main Path:
Whenever an inventory location, carries out the activity of shipping out the product to another location, the actor will send the shipping data to National track and trace system.

Inputs	Trigger(s)	Usage Frequency
● Notification Type (Shipment) ● Shipment Date ● Seller Name ● Seller GLN ● Buyer Name ● Buyer GLN ● Ship-To Name ● Ship-To GLN ● Document Identifier (Eg PO#, Invoice#) ● GTIN ● Batch Number ● Expiration Date ● Serial Number ● SSCC code	• GTIN products are picked, packed and ready to ship	Everytime an ASN transaction is created
Pre-Conditions		**Post Conditions**
Creation of ASN for products with GTIN, batch number, expiration date and serial number Stamping of SSCC code on the logistic unit like a pallet		Record and reporting of item movement in National track and trace database

5. Use Case Name: Send Receipt Data		
Actors: Manufacturer Supplier PFSA (CMS, Hub) Facility FMHACA **Main Path:** Whenever an inventory location, records receipt of shipment from another location, the actor will send the receipt data to National track and trace system.		
Inputs ● Notification Type (Receipt) ● Receipt Date ● Seller Name ● Seller GLN ● Buyer Name ● Buyer GLN ● Ship-To Name ● Ship-To GLN ● Document Identifier (Eg PO#, Invoice#) ● GTIN ● Serial Number ● Batch Number ● Expiration Date ● SSCC	**Trigger(s)** • ASN receipt and GTIN products are phycially received at the inventory location	**Usage Frequency** Everytime inventory products are received
Pre-Conditions Shipment of products with GTIN, batch number, expiration date and serial number from another location		**Post Conditions** Record and reporting of item receipt in National track and trace database

6. Use Case Name: Initiate Recall		
Actors: Manufacturer Supplier FMHACA **Main Path:** Specify the GTIN, batch number(s), expiration date and serial number(s) to be recalled from the supply chain.		
Inputs ● GTIN to recall ● Serial Number ● Batch Number ● Expiration Date ● Recall Request Date ● Manufacturer Name	**Trigger(s)** • Manufacturer, Supplier or FMHACA determine there is a patient safety issue with certain batch of products	**Usage Frequency** As needed
Pre-Conditions The GTIN for recall has entered the country The manfaturer or supplier are registered owner of the GTIN		**Post Conditions** Successful recording of recalled items

7. **Use Case Name:** Item Authentication		
Actors: FMHACA Patient **Main Path:** Allow patients and FMHACA to scan a serialization barcode to authenticate an item.		
Inputs ● 14 digit GTIN ● Serial Number	**Trigger(s)** • Patient or FMHACA suspects a fraudulent product	**Usage Frequency** As needed
Pre-Conditions Availability of access to serialization database Serialization barcode is present on item packaging for actor to scan		**Post Conditions** The system returns a positive on the GTIN or serial number scan. The system indicates the item is not authentic

8. **Use Case Name:** Trace Item or Serial Number		
Actors: Manufacturer Supplier PSFA (CMS, Hub) Facility FMHACA **Main Path:** Any of the supply chain partners can specify the GTIN, batch number(s), and/ or serial number(s) to trace the path it's traversed in the supply chain.		
Inputs ● GTIN to trace ● Serial Number ● Batch Number	**Trigger(s)** • Manufacturer, Supplier, PFSA, Facility or FMHACA wish to verify the series of custodians for the item or identify an adverse event like fraudulent insertion into the supply chain or repeated failure to comply with event reporting	**Usage Frequency** As needed
Pre-Conditions Atleast one track record (with GTIN and GLN information) exists for the item in the National track and trace database.		**Post Conditions** Successful recording of recalled items

9. **Use Case Name:** Diversion Alert		
Actors: FMHACA **Main Path:** When an outbound shipment is not received by the intended location within "X" days from the intended receipt date, then the system will raise an alert of a potential exception.		

9. **Use Case Name:** Diversion Alert		
Inputs ● GTIN ● ASN/ PO # ● Receipt Date ● Alert Notification Period Range	**Trigger(s)** • System does not detect an intended receipt or cancellation transaction record "X" days after getting the shipment record	**Usage Frequency** As needed
Pre-Conditions A shipment tracking record with expected receipt date has been recorded in the Track and trace system. No receipt record has been received "X" days after the expected receipt date		**Post Conditions** An alert with GTIN, shipment information and quantity is sent to FMHACA

10. **Use Case Name:** Reports		
Actors: FMHACA		
Main Path: Since FMHACA will have access to all traceabiity data they can generate various types of reports like inventory count in the supply chain network, items nearing expiration, overstocls etc.		
Inputs ● GTIN ● Date Range ● Supply Chain Participant	**Trigger(s)** • On-adhoc basis	**Usage Frequency** As needed
Pre-Conditions Master data like GTIN, GLN and transactional data like serial number, tracking data exists in the database		**Post Conditions** Successful report generation

7 TECHNICAL IMPLEMENTATION ROADMAP

7.1 RECOMMENDED IMPLEMENTATION PHASES

Step 1 – Enable sending and receiving of electronic receipt of data files like ASN through out the supply chain systems like various instances of HCMIS. Minimize as much manual data entry as possible

Step 2 – Enable barcode reading / verification during issue and receipt process. Barcodes will capture GS1 standards code, thus eliminating manual verification and data entry

Step 3 – Conduct the Pilot as Two-Phase approach to enable capture of Serialization data and achieve the end state architecture. There will be 3 development tracks to support the 2 pilot phases. Development track 1 and 2 will run in parallel. Development track 3 will be initiated after completion of pilot phase1.

7.1.1 Development Track 1

This track will create the new event and master repository for the track and trace system. Below are basic minimum attributes that should be captured in the given repositories

1) GTIN/ SGTIN Repository
   a) GTIN (Mandatory)
   b) Product Description (Mandatory)
   c) Packaging level – (Tertiary/ Secondary/ Primary)
   d) Batch Number – (Optional)
   e) Expiration Date - (Optional)
   f) Serial Number - (Optional)
   g) Country of Origin – (Optional)
   h) Unit of Measure – (Mandatory)

2) GLN Repository
   a) GLN (Mandatory)
   b) Company Name (Mandatory)
   c) Location Name (Mandatory

3) Events Repository
   This respository will capture 4 core elements
   a) What
   b) Where
   c) When
   d) Why

   The detailed attributes are as follows
   a) Event id
   b) What:
      i) GTIN,
      ii) Lot or Batch level,
      iii) Serial Number,
      iv) Quantity,
      v) UOM
      vi) Serial Number
   c) Where:
      i) Business Location,

ii) Read point (example Dock door #3) - Optional

iii) Physical Reader Id, Logical Reader Id (Example barcode reader) - Optional

d) When:

i) Event time,

ii) Event time zone,

iii) Record time (optional)

e) Why:

i) Business step (example shipping),

ii) Disposition (example good),

iii) Disposition qty,

iv) Business transaction type (example "PO"),

v) Business transaction id (PO number),

vi) Source type (source/ destination),

vii) Source id (name of the shipping destination)

7.1.2   **Development Track 2**

This track will modify and update the HCMIS application to enable barcode reader based verification of the issue and receipt activities.

Today all receipts and issues are done on the basis of the human readable label as shown in the picture below. The label contains batch number, expiration date, item description, quantity and PO# or Tender number.

Figure 12 Sample Label on Tertiary Packaging

As part of receiving and issue process, the receiver/ picker currently uses the printed documents as shown below.

Good Receiving Notification Form

Stock Transfer Voucher

In order to enable track and trace as well as adoption of GS1 standards, the receipt and issue process will be driven by scanning of barcodes.

HCMIS already has barcodes on the "Goods receiving notification form" and "Issue Order List". These reports have to be updated to include barcodes to represent GTIN instead of current product id number. See section 7.1.3 for details of pilot phase implementation. Once the receipt or issues data have been verified and captured, HCMIS will create an event file to upload the event data into the event repository.

7.1.3 Pilot Phase 1 Implementation Guiding Principles

In order to enable a successful track and trace implementation, with reasonable data accuracy, it is important to introduce barcode reader based receipt and issuing process. Our initial thoughts are as follows

Phase 1 – Pilot Phase Activities
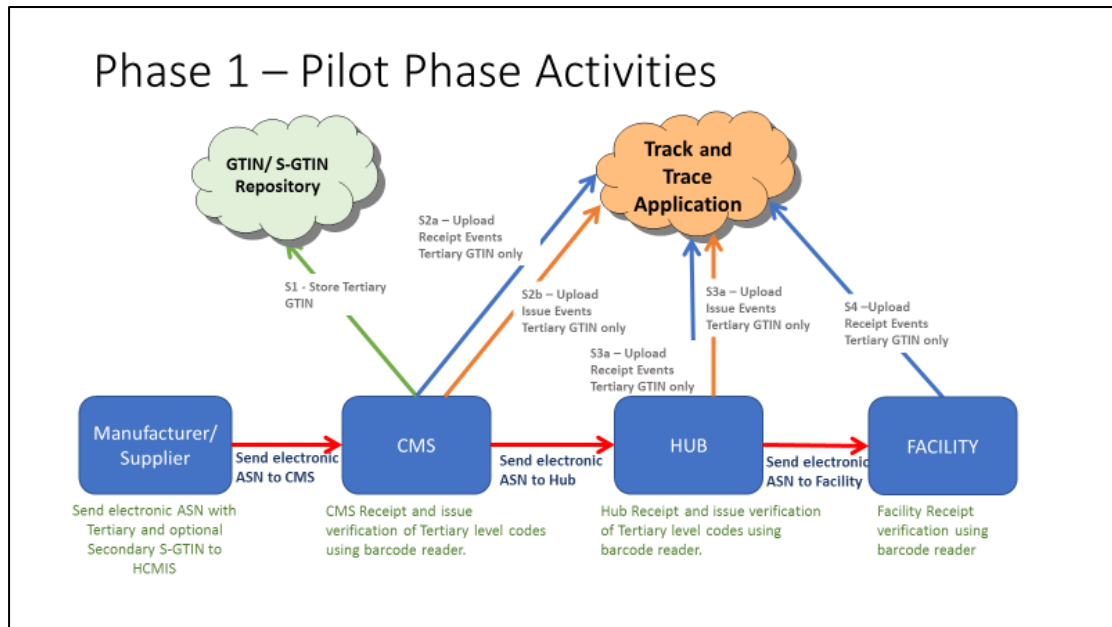
1. Phase 1, Step 1& 2.a –
    a. Receive electronic ASNs with Tertiary level GTIN information from suppliers/ manufacturers. The supplier will also apply Tertiary level GTIN barcode label on Tertiary cases.
    b. CM will place a separate PO for items with GTIN during the pilot. This will help with seggragating the receiving process operationally for GTIN products during the pilot.
    c. The supplier who is chosen for the pilot will be asked to send two separate shipments if the PO has GTIN vs non-GTIN items
    d. The system will print two separate versions of the receving report. The curret report as is for regular products and the modified report with barcodes for items with GTINs
   e. Rationale for Tertiary level GTIN only
        i. We believe bar-code scanning and verification is the first step to a successful implementation. Trying to validate receiving at secondary level in stage 1 will be too cumbersome. Thus for this reason secondary level GTIN, serial number or SSCC code are nice to have but not a requirement.
        ii. We believe if the receipt verification process using barcode readers it successful, then it will encourage a barcode reader based picking process. The picking process will be successful if the issue and pick is done only at the case level. That is no opening of cases and issuing items at individual unit level
        iii. The reason to start with Tertiary level GTIN is cause this will be most practical, where the level of change from current process of reading human readable label on Tertiary pack will be replaced with barcodes. This is the first delta step in process and change management
        iv. The above operational process of receipt and issue should be implemented at Central medical store.
    f. Serialization of Tertiary level packaging, GTIN at secondary level packaging or SSCC code is not necessary for this phase.

g. The goods receiving notification form will be updated to print the Tertiary GTIN barcode.
h. When the receiver receives the goods, s/he will scan the barcode on the receiving document and then the label on the case.
i. On successful verification, the system will update the receipt quantity.
j. On completion of receipt transaction, a nightly ETL job will upload the EPCIS compliant receipt transaction into the Track and Trace database
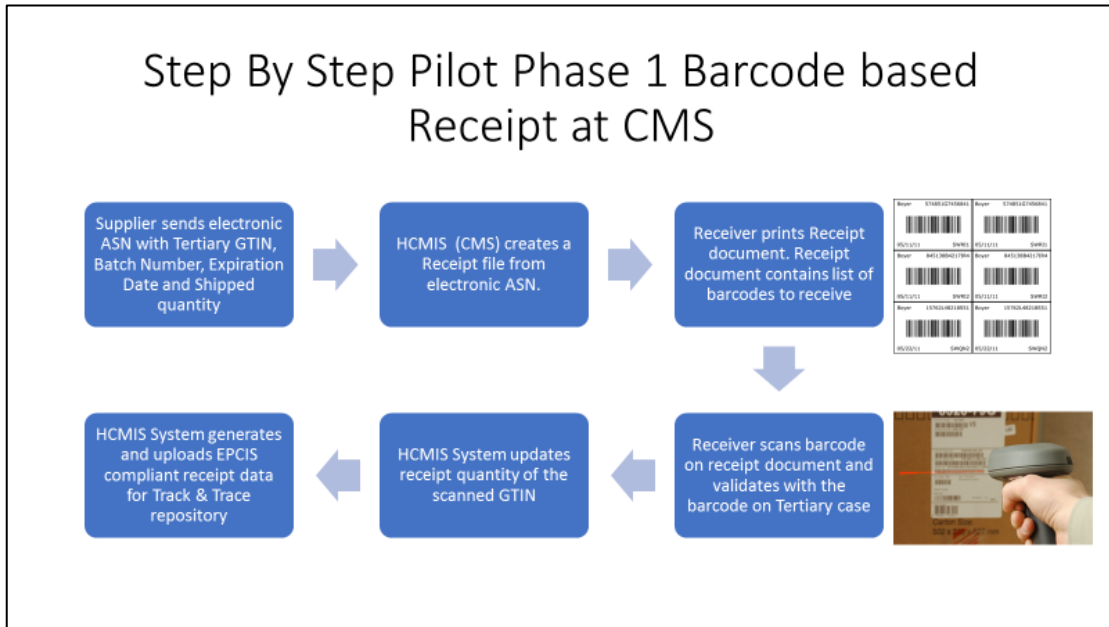
2. Phase 1, Step 2.b and 3.a –
   a. Once barcode based issue of Tertiary GTIN at CMS is successful, the same data can be treated as a receipt file at the Hubs. The hub can then use the same barcode reader process to do receipt verifications, similar to the receipt process at the CMS.
   b. As far as issues go, most of Hubs issues are at secondary package level. Thus barcode based issue is optional and limited to tertiary cases issues only.
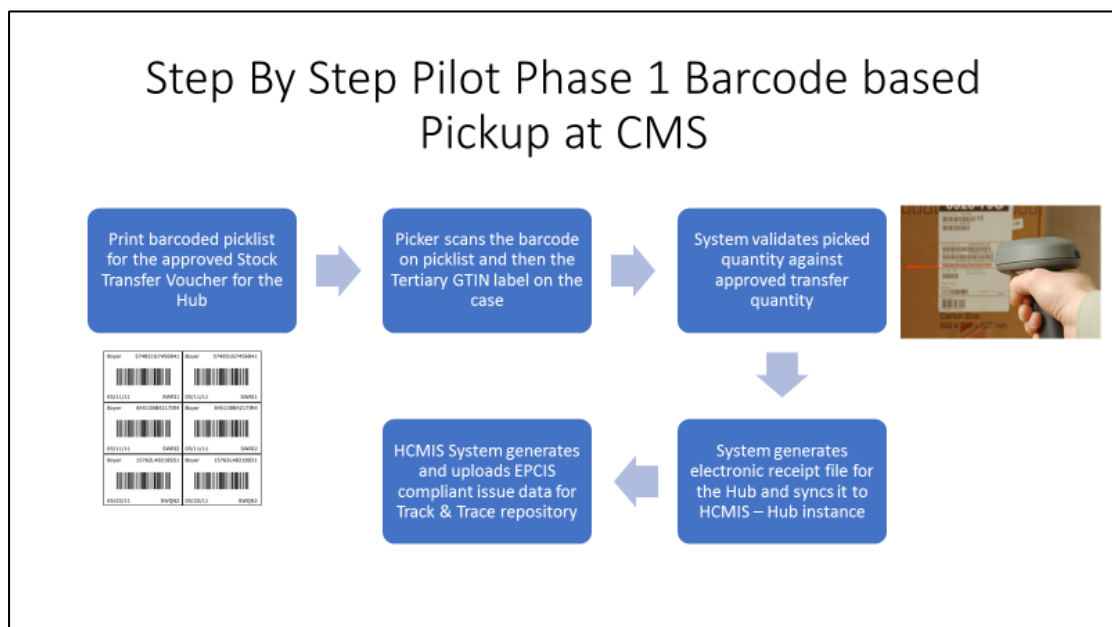
3. Phase 1, Step 3.b and 4 –
   a. Though a little ambitious, but the same process can be replicated at the facilities for receipt operations. The key guiding principle is that the receipt is done at a Tertiary packaging level.

7.1.4 **Pilot Phase 2 Implementation Guiding Principles**

The phase 2 of the pilot will include serialization and SSCC code on the pallets and Tertiary packaging. It will follow the same process as Phase 1 except that instead of scanning for just the Tertiary GTIN, the receiver or picker will scan the unique SSCC code at the pallet or Tertiary packaging level, which in turn is going to translate to set of serial numbers at a secondary packaging level. The receipt and issue reports will be modified to contain the SSCC code

1. Pilot Phase 2 will capture and track secondary level GTIN and serial numbers through the supply chain. In order to enable the same following operational processes will require enhancements
2. Suppliers provide unique SSCC barcoded label on each pallet and tertiary case.
3. GTIN and corresponding barcodes are available at Tertiary and Secondary level. Secondary level packaging has serialization
4. Supplier ASN contains the aggregation hierarchy – ie Pallet SSCC code contains all the Tertiary SSCC code and GTIN. Each Tertiary SSCC Code in turn contains the list of all Secondary level GTIN and serial numbers.
5. The receiver at CMS scans the pallet SSCC code to complete 1-step receipt process.
6. In case of exceptions – example the pallet was broken/ opened, then the receiver scans the Tertiary level SSCC code to complete the receiving process. Since the receivers were already doing Tertiary case receipt, this will be a minor shift in their operations.
7. The guiding principle for the Issue process is to issue at "unbroken' pallet or tertiary case level only. At facilities where volumes are low, scanning of secondary pack serial number for issues will be enabled
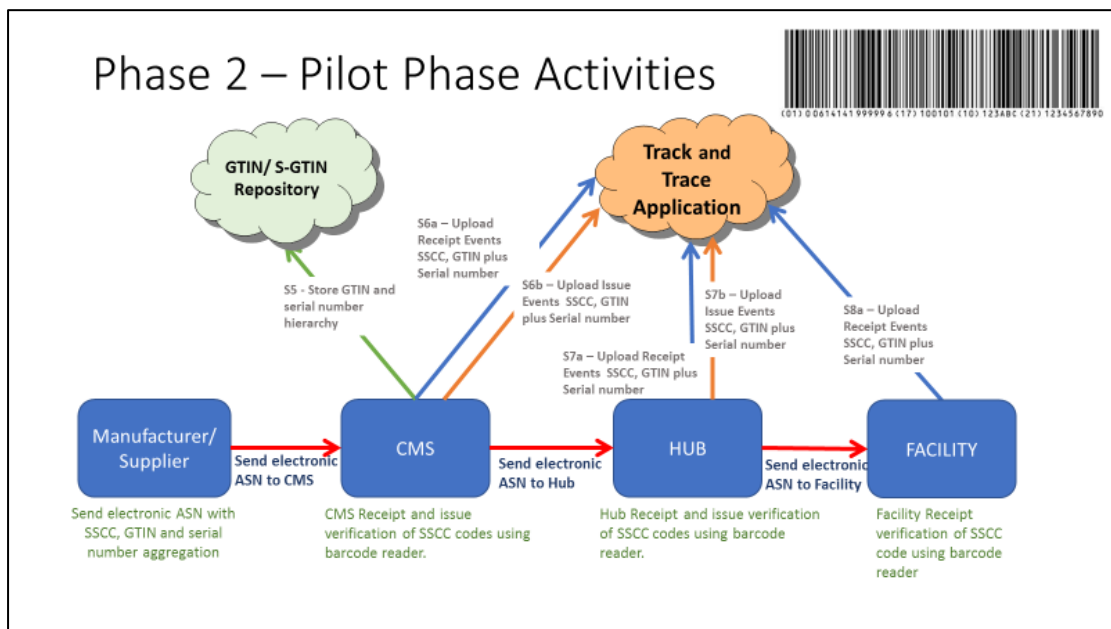
Pilot Phase Timeline

	ACTIVITY	MONTHS																		
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19
	Pilot Phase 1																			
	Development Track																			
1	Create Track & Trace Application, GTIN Master, GLN Master																			
2	Update HCMIS Receiving and Issue Activity and Report																			
3	Update HCMIS (Facility Edition) Receiving Activity and Report																			
4	Buy Barcode readers																			
5	Build Tracking Dashboard																			
	Implementation Track																			
6	Identify Suppliers and products for Pilot Phase 1																			
7	Place PSM purchase orders																			
8	Receive ASN and products at CMS warehouse																			
9	Issue Inventory to Hub; Receive inventory at Hub																			
10	Issue Inventory to Facility; Receive inventory at Facility																			
11	Monitor Results/ Pilot Phase 1 Complete																			
	Pilot Phase 2																			
	Development Track																			
1	Update HCMIS Receiving and Issue Report For SSCC																			
2	Update HCMIS (Facility Edition) Receiving Report For SSCC																			
3	Build Various Application																			
4	Enhance Dashboard																			
5	Build Reports																			
	Implementation Track																			
6	Define MOH Policy and Regulations For Suppliers																			
7	Define GS1 standards and labeling guidelines																			
8	Place PFSA Purchase Orders																			
9	Receive ASN and products at CMS warehouse																			
10	Issue Inventory to Hub; Receive inventory at Hub																			
11	Issue Inventory to Facility; Receive inventory at Facility																			
12	Monitor Results/ Pilot Phase 1 Complete																			

7.2 PROJECT TIMELINES AND MILESTONES

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