The Global Language of Business

GS1 Healthcare Newsletter

GS1 Healthcare Africa

May 19, 2021

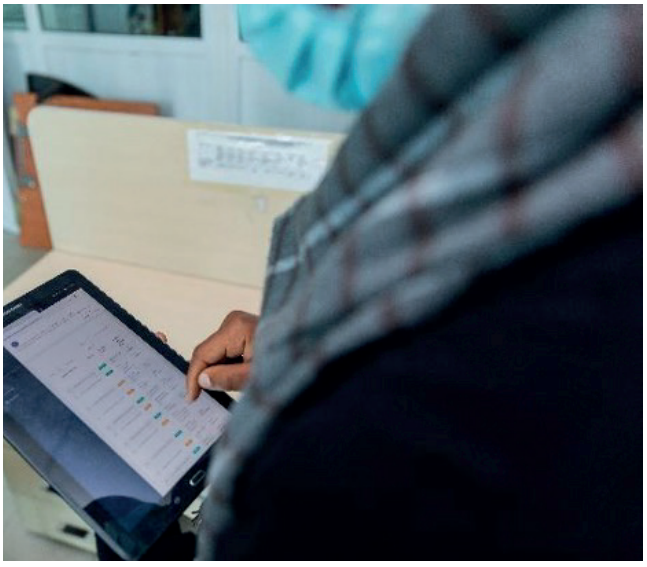
Pharmaceutical Products Traceability in Ethiopia

The Ethiopian pharmaceutical supply chain system has faced challenges, including substandard and falsified products, ineffective product recalls, medication errors, and supply chain inefficiencies and limited visibility. To address these concerns, in 2019 Ethiopia became the first country in Sub-Saharan Africa to issue regulations drawing on global standards to strengthen pharmaceutical products traceability. The regulations strengthen supply chain integrity, combat counterfeit medicines, and improve patient safety by providing visibility across the value chain.

Mandated to ensure the safety, quality, efficacy and rational use of medicines, the Ethiopian Food and Drug Authority (EFDA) plays a crucial role in pharmaceutical products traceability efforts. A national steering committee was established with representatives from the EFDA, government agencies, professional associations, development partners, and supply chain stakeholders. The committee, chaired by Ms. Heran Gerba, the Director General of the EFDA, drives traceability activities and oversees implementation of the initiative.

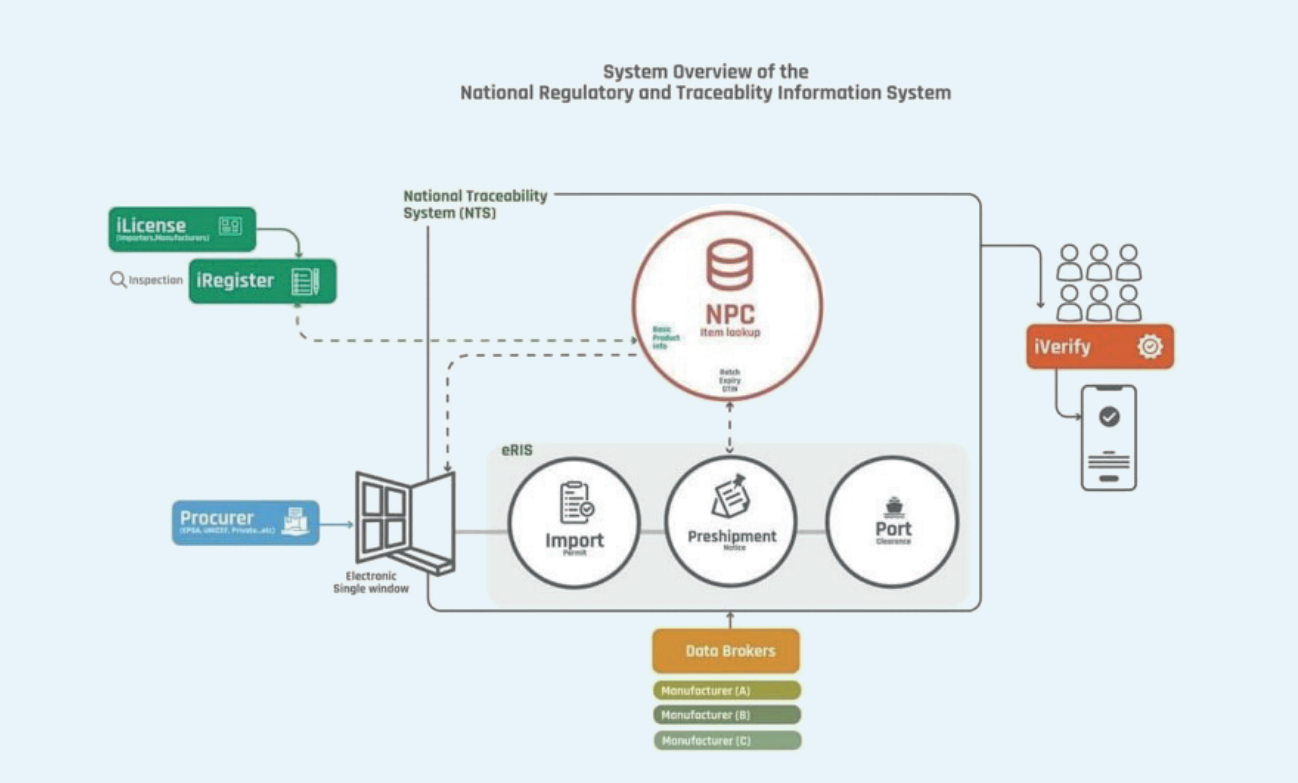
Over the past few years, Ethiopia has made significant strides in paving the way for pharmaceutical products traceability, including developing planning and implementation strategies and publishing a legislation, defining relevant digital technologies, creating formal governance structures, undertaking capacity-building activities, and conducting communication and advocacy efforts.

In this issue



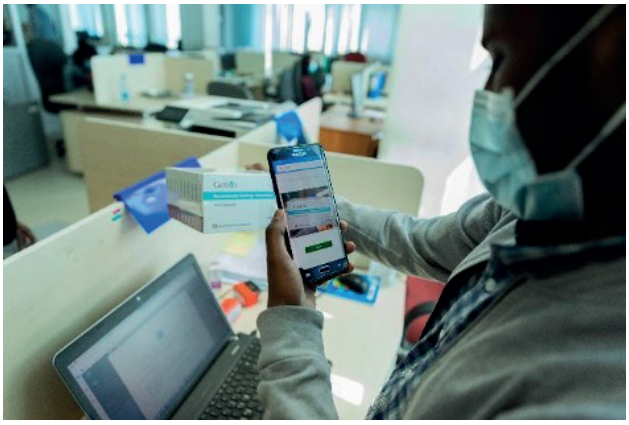
In March 2021, the EFDA published the Pharmaceutical Products Traceability Master Data Guideline, which supports the legislation and serves as a guide for supply chain actors and stakeholders to share master data using standardized data attributes. The EFDA is now developing a Barcoding Guideline, which is expected to be published before the end of 2021. This will be followed by additional guidelines on Global Trade Item Number (GTIN) allocation rules, Global Location Number (GLN) allocation rules, and National Product Catalogue (NPC) management.

To ensure that appropriate systems are in place, the EFDA, with support from the USAID Digital Health Activity (DHA), is developing a suite of systems to support traceability initiatives, including an NPC tool with an associated mobile application. The tool, designed as an information repository for managing master data, acts as a single source of information. Manufacturers and other pharmaceutical supply chain stakeholders will be able to share master data on the platform, and other systems in the country will use the tool to ensure standardization in product nomenclature. The NPC tool is integrated with existing electronic regulatory information systems such as i-Import and i-Register, which will automatically feed information about drugs approved by the EFDA into the NPC. Currently, the Authority is enforcing that manufacturers share their products' information, including GTIN. The system overview of the national regulatory and traceability information system is depicted in the figure below.



Another system under development is i-Clear, which will be used to manage the clearance of pharmaceuticals from the port of entry. I-Clear will enable manufacturers to share pre-shipment information, including GTIN, expiry date, batch/lot numbers, and serial numbers and will make this information available to supply chain stakeholders prior to the arrival of the product in Ethiopia.

Because public awareness is believed to be an important enabler for the successful implementation of traceability systems, the EFDA is working to raise public awareness about pharmaceutical products traceability through activities such as organizing a series of traceability discussions featuring manufacturers and importers. The Authority is also disseminating information about traceability to its stakeholders via its website, social media platforms, and print media. For instance, when the i-Verify app was released providing regulators and the public with real-time visibility into the movement of health commodities, including pharmaceuticals, a YouTube video was used to explain how to use the app and how to report information about defective and unsafe pharmaceuticals to the EFDA.



As a result of the 2019 legislation, in mid-2021, the EFDA expects to begin receiving products barcoded according to GS1 global standards. The EFDA will also continue to develop and issue additional guidelines, provide training to stakeholders, strengthen existing technologies, and develop new ones. The Authority will enforce the policies and legislation associated with the traceability system.

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And check the **EFDA website** to stay abreast of traceability developments.

Email questions to **traceability@efda.gov.et** or **infodha@et.jsi.com**.

WHO policy paper on traceability of medical products

In March 2021, the World Health Organization (WHO) issued a policy paper on traceability of medical products. The policy paper outlines the features of existing traceability systems and provides guidance on developing workable traceability regulation. Member States are encouraged to establish a suitable governance process for their traceability system and include a costing analysis as well as a sustainability mechanism in their traceability system planning. **This paper includes an unprecedented explicit reference to the benefits of the use of GS1 global standards** for product identification, production identification, automatic identification and data capture as well as data exchange to reduce set-up and operating system costs and maximize national and international interoperability.

GS1 Learn: Master data – What it is and why it is important?

Master data is an important foundation for any health information system as it provides defining information about the item. In the case of products, master data helps determine the product name, its strength, measurements, who manufactured it and much more; in fact, there are more than 3000 different attributes in the GS1 Global Data Dictionary that can define product master data.

In traceability, master data is an important foundation without which traceability cannot occur, you cannot trace what you do not know. Standardised master data is the foundation of interoperability across traceability systems. Every partner in the supply chain has a version of “their data” kept in silo systems or, in some cases, data exists only in hardcopy form.

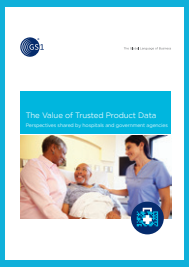
The multitude of health information systems that address various needs in many health supply chains in Africa, as is the case all over the world, has resulted in each system having their ‘own master data’. This means that as soon as there is a need to exchange data between the various systems, the first step would be to redefine and match how the products are named, for instance. The need for interoperability and connectivity of these systems in a seamless manner has never been more evident, thus resulting in wasted time in comparing the data and process inefficiencies.

Centralised master data management helps ensure a single source of truth when the product information comes from the source and is accessible to all actors in the supply chain. For this to happen you need to have one way of communicating about

product data and one way of describing products, while making sure that the data is accurate and of high quality.

Many studies show that when the data is trusted and integrated into processes, costs decrease, efficiency increases and consumers and patients are more satisfied with the brand.

Read more about the value of trusted product data



Quality master data along the supply chain will eventually result in visibility and insights into product movement and use. Additionally, this will reduce the time and cost to gather and verify data, allow easy access to and more reliable product information, provide better brand and counterfeit protection and ultimately improved patient safety and care outcomes because the healthcare provider has access to good quality data, minimising the need for manual data entry, and preventing medication mistakes.

It is important to note the differences between master data and transactional data. Transactional data is used in orders, invoices and shipments and provides information about the products being moved between multiple entities in the supply chain. Examples of transactional data include “quantities” on order, or “shipped” status.
To read more about the role of master data in the traceability system, read the Regulatory roadmap: Traceability of medicinal products.

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To learn more about the various initiatives related to master contact a GS1 Member Organization near you or refer **this page** on the GS1 website. You can also reach out to **healthcare@gs1.org** to learn more.

Co-Creation Workshop: Sharing Product Master Data

The 2021 Co-Creation Workshop: Sharing Product Master Data was hosted virtually on May 5-6, 2021, by Digital Square, GS1, and VillageReach, with support from USAID. The purpose of this two-day workshop was to focus on data challenges in making product data easily available to any organization planning to adopt GS1 standards for product identification, as well as to discuss the governance aspects required to establish National Product Catalogues (NPCs).

Experienced implementers from Ethiopia, Malawi, and Rwanda as well as the Global Family Planning Visibility Analytics Network (GFPVAN) presented both the challenges and best practices in establishing a GS1-based product master catalogue. Through dynamic panels, participants learned how global and national systems suffer from fragmentation, duplication, and lack of interoperability. Ethiopia, Malawi, and Rwanda are solving this by standardizing product master data and implementing policies required as part of procurement. It is clear that the use of global standards is essential for product identification, automatic identification, data capture, and data exchange.

The second day featured a call for contribution on VillageReach’s open data set, which was created to speed up adoption of GS1 standard identifiers and facilitate their adoption through national public health supply chains. Instructions for contributions are available here with a public open data set to be published by the end of 2021.

The 100+ workshop participants examined the need for a global product catalogue (GPC) and how to create and maintain one. To accelerate master data collection and quality, the participants plan to lean into those who have already gone through the process, seek pooled funding from multiple donors to maintain core functionality, focus on priority commodities, provide guidance on roles and responsibilities, and demonstrate to suppliers the importance of supplying core data attributes to the GPC. To learn more about this initiative, contact one of the workshop co-hosts. You can also reach out to healthcare@gs1.org to learn more.

Rolling out the National Product Catalogue to Rwanda and Malawi

USAID's flagship project, Global Health Supply Chain – Procurement and Supply Management (GHSC-PSM) has been leading the effort to support conception, development and implementation of a NPC tool.

In the past year, GHSC-PSM has provided technical support to Malawi and Rwanda to implement the NPC, a tool that will help manage standardized GS1 based product master data that is a critical step in setting up pharmaceutical traceability based on international standards. In addition to Malawi and Rwanda, the team is also working with other countries in the region including Zambia to implement this NPC. The NPC is positioned as an important enabler for the efforts in these countries to set up pharmaceutical traceability.

To support the adoption and sustained utility of the NPC, GHSC-PSM has been working alongside its local counterparts in these countries to manually collect GTINs and develop Standard Operating Procedures (SOP) manuals. In both countries, the local NPC has over 200 GTINs already added.

A mobile app that helps users scan standardized GS1 barcodes and pull data from NPC was also developed and is being rolled out as part of this effort, ultimately, this app will enable the users to verify that the products existing in the supply chain are legitimate.

To learn more about the NPC, access available reading and listening resources on the **GHSC-PSM website**. To inquire about this effort, contact **GHSC-PSM-NPC@ghsc-psm.org**.

Learn about GS1 implementation stories

To-date many countries across the world, hospitals, manufacturers and solutions providers have incorporated GS1 standards into their processes. To read of the various stories, access the GS1 Healthcare reference book on the GS1 website.

The 2021 Reference book will be released late in 2021 at the same location, so look out for fresh implementation stories then, including the very first from Africa showcasing Netcare's journey to adoption of GS1 standards into their processes.

Events

A few informative sessions are planned over the next few months. Below is a rundown of some key ones this newsletters readership might find interesting:

- A third executive dialogue has been scheduled. Join in to learn about ongoing efforts in developing a verification system to reduce the risk from falsified and diverted Covid-19 Vaccines. In this iteration of the dialogue, UNICEF will share updates about the Global Trust Repository that is being developed especially for low and middle income countries. Registration is free for all on the event website. These executive dialogues were started in January, 2021 following the release of a White paper by Deloitte- Securing trust in the COVID-19 supply chain.
- From 20 – 22nd April, 2021, GS1 Healthcare held its second healthcare online summit. Attended by close to 600 attendees from over 80 countries, speakers from various countries and agencies attended and shared their GS1 implementation stories. Specifically from Africa, regulatory authorities from Nigeria, Ethiopia and Egypt shared updates about the progress in their countries. These sessions, and their recordings, are freely available for hospitals, regulatory authorities and donor organizations. Contact healthcare@gs1.org for access codes or if you have any other questions. The recordings are available on the event website.
- To learn more about upcoming events, webinars and other learning opportunities, check out the webinars and events section on the GS1 Healthcare website.

About GS1 Healthcare

GS1 Healthcare is a neutral and open community bringing together all related healthcare stakeholders to lead the successful development and implementation of global GS1 standards, enhancing patient safety, and operational and supply chain efficiencies.

The development and implementation of GS1 standards is led by the experts who use them: pharmaceutical and medical device manufacturers, wholesalers, distributors, group purchasing organisations, hospitals, pharmacies, logistics providers, solution providers, governmental and regulatory bodies, and trade associations. Evidence available from industry implementations shows that GS1 identification, data capture and data sharing standards in healthcare deliver tangible benefit to all stakeholders. Global members of GS1 Healthcare include more than 100 leading healthcare organisations worldwide.

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