



The Global Language of Business

Early learnings from policy work on implementation of global standards

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Strengthening the pharmaceutical supply chain to deliver quality medicines

Ethiopia's commitment to implementation of global standards

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Ethiopia, the country



- Horn of Africa
- Land of origins
- > 90 million inhabitants
- > 80 ethnic groups
- 1,104,300 square kilometres
- Average annual economic growth 10.8% in the last eleven years (2016)
- Pharmaceutical market:
 - Growth rate: 25% per annum*
 - Could reach just under US\$ 1 billion in 2018**

* WHO (2015), National Strategy and Plan of Action for Pharmaceutical Manufacturing Development in Ethiopia (2015-2025)

** Naidoo, S. High growth rates expected for the Ethiopian pharmaceutical market, but it's not all smooth sailing – Unpacking the challenges.



Ethiopia, the healthcare sector



- 12 local pharmaceutical manufacturers supply only 20% of the market*
- 328 medicine and medical device importers and 285 wholesalers
- ~ 313 hospitals, 3200 health centers, 16000 health posts
- ~ 13400 physicians, 6300 pharmacists



Source: Ministry of Health: Health and Health Related Indicators (2015) & WHO (2015), National Strategy and Plan of Action for Pharmaceutical Manufacturing Development in Ethiopia (2015-2025)



Health Sector Transformation Agendas



Information revolution



The Federal Democratic Republic
of Ethiopia Ministry of Health





About EFMHACA



- Establishment of Proc. No. 661/2009 and Reg. No.189/2010
- **Mission:**
“To promote and protect the public health by ensuring the safety and quality of health services and products through registration, licensing and inspection of Health professionals, pharmaceuticals, food establishments, and health and health related institutions and provision of up-to-date regulatory information while Promoting rational medicines use.”
- **Vision:**
“Quality health services and products to all citizens.”



Inefficiency & patient safety



Inefficiencies in the supply chain

- Lack of visibility
- Availability issues: supply cannot keep up with growing demand
- Counterfeit, illegal trade
- Weak border controls
- Limited number of verification capabilities (such as laboratories and technological solutions)
- Waste and expiry

→ All negatively affect **patient safety**



Ethiopia's journey toward traceability

for patient safety and efficiency in the healthcare supply chain

Traceability pilot
 During the course of a year, the Traceability Working Group is testing verification and traceability capabilities in Ethiopia's pharmaceutical supply chain through four pilots: (1) End user verification of product authenticity; (2) Verification if a product entered the country legally; (3) Product recall from the facility level and (4) Product recall from the patient level.

Awareness
 Implementation is impossible without all stakeholders in the supply chain fully understanding and endorsing the use of standards. Awareness creation is therefore very important. Stakeholders will be informed and trained on the importance of standards through workshops, (social) media and one-on-one meetings.

Assessment
 An assessment will help us understand the current landscape in terms of stakeholder awareness, gaps in legislation, and technology platforms needed for the implementation of global standards. The result of the assessment will be used as an input for a roadmap for Ethiopia to implement global standards in the healthcare sector.

Roadmap
 A roadmap for the implementation of traceability from manufacturer to the patient will be developed. The document will discuss policy recommendations, time lines, roles and responsibilities.

Information revolution
 This is one of the four transformation agendas of the Ethiopian Federal Ministry of Health. The ministry and its specialized agencies have embarked on initiatives critical to build information systems fit for the purpose of ensuring patient safety and efficiency. Implementation of global standards is one such undertaking.

Patient safety
 Global standards in healthcare help support the five patient rights: right patient, right drug or device, right time, right dose and right route. Supply chain visibility with improved traceability and transparency will help fight counterfeit medication. Finally, the use of global standards will improve the recall process by linking the medical product to the patient.

Efficiency
 Greater visibility, traceability and transparency through the use of global standards will improve efficiency in the healthcare supply chain. The implementation of standards enables organizations to develop effective information systems for electronic record management and will eliminate waste and inefficiencies in the supply chain.

GS1 standards
 GS1 standards ensure globally unique identification and enable cross-border compatibility of supply chain solutions. This means all stakeholders can efficiently and effectively comply with various local and global requirements, and achieve interoperability and compatibility within their organization, between organizations and across borders.



100 million inhabitants, one of the oldest nations in the world, over 82 languages, more than 79 ethnicities and home to Lucy, a human fossil believed to have existed over 3 million years ago.



About 20 percent of pharmaceuticals are locally manufactured. This number is expected to grow significantly in the coming years. The public sector has approximately 340 hospitals, 3,500 health centers and 16,000 health posts providing health services.



Important stakeholders including the government, manufacturers, and healthcare providers are supporters of the initiative to develop a roadmap for the implementation of global standards.



Following GS1 recommendations



Define clear objectives

- Our **objective** is to strengthen the pharmaceutical regulatory system's ability to deliver **quality** medicines and create **visibility** in the pharmaceutical supply chain to improve **patient safety** and **efficiency**.

Collaborate with stakeholders

- Our **Traceability Steering Committee** includes the **Ministry of Health, Local Pharmaceutical Manufacturers Association, Pharmaceutical importers and Distributors Association**, healthcare **providers**, **donor** organizations and many other stakeholders.

Use global data standards

- Global data standards for product identification and data exchange will form the basis for implementation of **product verification** and **full traceability** in the Ethiopian supply chain.





Global standards implementation



The challenges

- **Awareness, human resource and capacity**
- Network **infrastructure**
- **Technological** limitations
- **Supporting industries**, including packaging, printing, software and hardware

The opportunities

- **Government commitment** and **stakeholder engagement**, including the Pharmaceutical Fund and Supply Agency, for implementation of global standards
- Global standards provide '**simple**' and **realistic** solution for many of the **challenges**
- **Global** and regional developments
- Growing **mobile** network and use

The development of a **pharmaceutical industrial park** provides **opportunities** for growth of the industry, improved availability of medication, generates jobs and creates **export** potential.



Roadmap implementation



Strategic objectives

1. Strengthen pharmaceutical regulatory system
2. Develop awareness, knowledge and human resources
3. Build capacity for stakeholders to ease implementation
4. Verification of pharmaceuticals to check authenticity
5. Create visibility by implementation of full traceability
6. Use traceability data to improve patient safety and supply chain efficiency

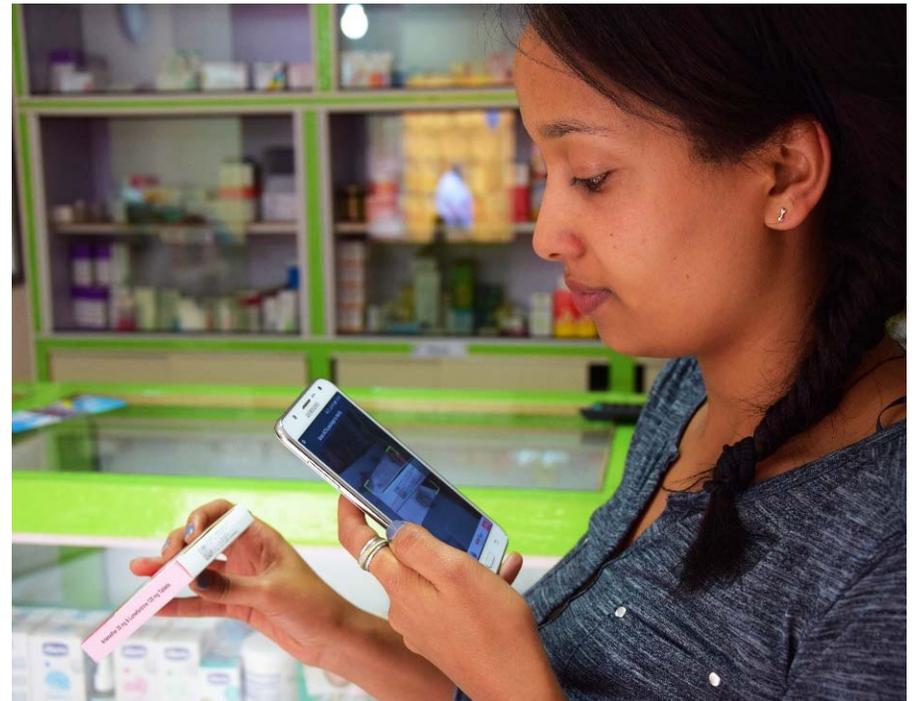


Verification pilot



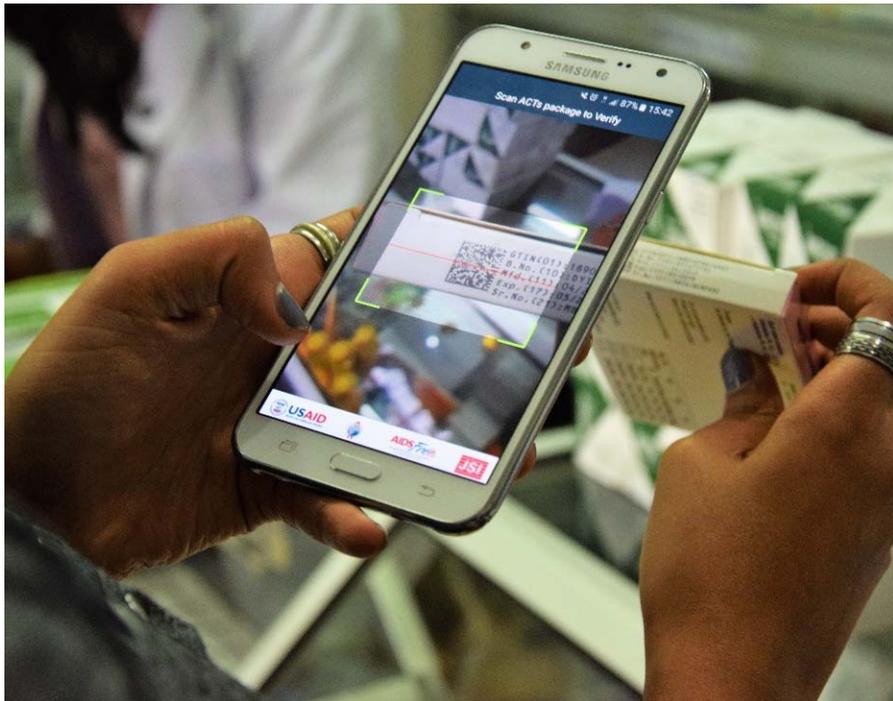
Malaria medication

- **Why Malaria**
 - ~ 6.5 million cases per year.
 - Evidence of counterfeit products in the market.
- **Purpose**
 - To develop a GS1 Verification Platform for the public to validate malaria commodities.
 - Implementation of full traceability is a complex and time consuming process, so this is one step to give practical solution towards achieving the goal.





Verification pilot



- **What it does?**

Manufacturers of ACTs provide serialized GTINs for the products that are shipped to Ethiopia.

By using this app the public can scan the ACT package and verify that this product is procured by PFSA.
- **Outcome**

Consumers can verify the origin of malaria commodities using global standards.

Learn from pilot implementation to scale up to other categories of commodities.



We keep GS1's comment in mind:
"It's a marathon, not a sprint!"





Our partners



We would like to thank our partners for their support.





Questions?



Don't hesitate to contact us.

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