Strengthening the pharmaceutical supply chain to deliver quality medicines in Ethiopia and across Africa

Ethiopia’s commitment to implementation of global standards

Ms. Heran Gerba
Deputy Director General
Ethiopian Food, Medicine and Healthcare Administration and Control Authority
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About Ethiopia

- > 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**

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

14 local pharmaceutical manufacturers, supply only 20% of the market*

328 medicine and medical device importers and 285 wholesalers

~ 313 hospitals, 3200 health centres, 16000 health posts

~ 13400 physicians, 6300 pharmacists

About EFMHACA

• **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.”
About EFMHACA

• **Objectives**
  – Food safety and quality
  – Safety, efficacy, quality and proper use of medicines
  – Competence and ethics of health professionals
  – The standards of health institution and
  – The hygiene and environmental health protection suitability for individuals and community health

• **The way forward**
  – Health Sector Transformation Plan
  – Information Revolution
Overview on History of Regulation in Ethiopia

- 1941: Early period and beyond
- 1947: Pharmacopoeia for the Maintenance and Administration of Medicine
- 1950: Public Health Regulation (water, food, hygiene)
- 1964: Pharmacy and Laboratory Department at Ministry of Health
- 1999: Drug Administration and Control Authority
- 2000: Public Health Authority
- 2010: Food, Medicine and Healthcare Administration and Control Authority
Establishment of EFMHACA

- Organized regulation started since 1960s
- Health Sector Reform [in 2008]; which scrutinizes all regulatory components together
- Mandate were divided into [in 2009)
  - Federal regulatory body
  - Regional regulatory bodies
- EFMHACA Comes into picture [in 2010]
  - Foods, Medicines, Medical Devices, Cosmetics, Health services, Health professionals, Other health products
- EFMHACA is a federal science based law enforcement authority mandated to protect the public health and safety
  - Established by Council of Ministers Regulation No. 189/2010
  - Established as an autonomous government office having its own legal personality
  - Accountable to Ministry of Health
  - Head office at Addis Ababa and may have branch office else where
<table>
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<tr>
<th>What we regulate</th>
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**Premises**
- Food Establishments
- Pharmaceutical Establishments
- Health & Health related Facilities
- Entry and exit ports

**Practices**
- Healthcare service at all levels
- Quarantine services at port of entry & exit

**Professionals**
- All type of Health professionals
  - Lower level
  - Middle level
  - Higher level

**Products**
- Food products
- Medicines
- Medical devices and supplies
- Laboratory reagents
- Cosmetics etc.
What we regulate

Registration
- Pre-market evaluation and registration
- Re-registration approval
- Variation evaluation & approval
- Clinical trial authorization and monitoring

Vigilance
- ADE monitoring
- Quality defect
- Medical error

PMS
- Post-registration market surveillance
- Collect samples
- Samples lab testing

Analysis
- Analysis of samples
- Pre- and post-registration products
- Testing of complaint cases
- Post market testing

Licensing and inspection
- Inspect premises like factory
- Licensing of Manufacturers, Importers & Wholesalers
- Market survey

Education
- Community Mobilization
- Free toll information dissemination
- Online information access
- Education material disseminate
- Alert systems
Challenges in the healthcare sector

Inefficiencies & patient safety

• Lack of product visibility in supply chain
• Availability issues: supply can not keep up with demand
• Presence of counterfeit medicines, illegal trade
• Weak border control to secure supply chain
• Limited number of verification capabilities (such as laboratories and technological solutions)
• Waste and expiry

→ All negatively affect patient safety

→ We understand that we need to align with global standard implementation to address challenges!
Global standards implementation

The challenges

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

The opportunities

- Government commitment and stakeholder engagement 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

Development industrial park provides opportunities for growth pharmaceutical industry, improvement availability of medication, provides jobs and export.
Ethiopia’s journey toward traceability for patient safety and efficiency in the healthcare supply chain

What have we done so far?

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) field 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 a stakeholder that promotes, funds, and supports traceability systems. Stakeholders and members of the forensic medicine association will be informed and trained on the importance of standards through workshops, seminars, 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 to identify the roadmap for Ethiopia to implement global standards in the healthcare sector.

Roadmap
A roadmap for the implementation of global standards in the healthcare sector will include: (1) the identification of the current state and the necessary improvements, (2) the implementation of the roadmap, and (3) the evaluation of the implementation of the roadmap.

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

Efficiency
Greater visibility, traceability and transparency can improve efficiency of global standards and align quality and safety expectations with the application of these standards. The implementation of these standards enables organizations to develop effective information systems for electronic record management and will eliminate waste and inefficiencies in the supply chain.

Patient safety
Global standards in healthcare help support the five patient rights: right patient, right drug, right dose, right route, and right time. 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 including the medical product to the patient.

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 ensure 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.
Malaria medication

• **Why Malaria**
  ~ 6.5 million cases per year.
  Counterfeits have been detected in the past.

• **Purpose**
  To develop a GS1 Verification Platform for the public to validate malaria commodities. Implementation of full traceability is a complex and time taking process, so this is one step to give practical solution towards achieving the goal.
Verification of malaria medication

• **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**
  Enabling the public by developing a tool that uses global standards to verify malaria commodities.
  Learn from the implementation for scale up to other categories of commodities.
Currently: implementing strategic plan

Phase I: Strengthen environment

Strengthen regulatory framework
- Establish Traceability Office
- Draft regulation which lays down requirements and timelines
  - Proclamation
  - Regulation
  - Directives
  - Guidelines

Build and sustain technical infrastructure
- Analysis on current infrastructure
- Development T&T Architecture, including
  - GTIN repository
  - GLN repository

Build stakeholder’s capacity
- Analysis on current stakeholder capabilities
- Implement strategies to improve stakeholder capacity, including use of software and hardware

Strengthen knowledge, communication and collaboration
- Ethiopian Standard Agency
- Communication professional
- Steering Committees and Working Groups
- Material: guidelines, website and other
- Training
Currently: implementing strategic plan

Phase II: Create visibility in the supply chain

Phase I:
- Unique identification (GS1) + labelling requirements
- Share standardized master product and location data

Phase II:
- Batch traceability

Phase III:
- Serialization / traceability of unique items

Use traceability data to improve **patient safety** and **efficiency**: verification, traceability, detection, notification and **action** by the governmental body.
First: Unique identification & master data

GS1 Barcode

- **18 months** after publication Proclamation, for identified products:
  - GS1 DataMatrix
    - GTIN
    - Batch number
    - Expiry date
  - Second phase includes (deadline tbc):
    - Include serial number

- Provide more time for local manufacturers
- Focus on good **quality** barcodes
- Focus on good **quality** associated product and location master data

### Proposed timeline for implementation regulatory requirements (draft)

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<td>Phase 3: Implementation of traceability based on unique items</td>
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**Use of traceability data to improve patient safety and efficiency (continuous work)**
Important during implementation

- **Use of global standards (GS1)**
- **National traceability system (centralized)** to track and trace identified pharmaceuticals
  - Product and traceability information (transactional and event data) is being captured for product movement from manufacturer until the healthcare provider
- **Phased implementation**
  - Start with high risk, often counterfeited, prescribed medication and other important products
  - Start with traceability of batches, move forward with serialization
- **Pilot phase** to test
  - Regulatory requirements with stakeholder readiness and capability
  - Technical infrastructure
  
  → Pilot phase will provide **learnings** for the next implementation phase

→ Continuous **engagement** and **support** for local stakeholders!
Our lessons learned

• **Engage** your **stakeholders**: supply chain partners (manufacturers, wholesalers, importers, healthcare providers, etc.), standard organizations, governmental bodies, solution providers, etc.

• **Learn** from international developments: look at implementations in markets that have **similar challenges** as yours.

• Engage **experts** on global standards and traceability.

• **Be bold**, but manage **expectations**: implementation is **complex** and takes time.

• As a regulatory body, take the **lead**!
Important

- Understanding of *challenges*, we can’t do it alone!

- Supply chains are *global* and require a global approach

- Need for *interoperability* to avoid complexity, inefficiency and costs

- No *re-invention* of the wheel or *duplication* of effort

- Make our manufacturing industry *ready* for global *competition*
We remember GS1’s words:
“It’s a marathon, not a sprint!”
We would like to thank our partners for their support.