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

Ethiopia's commitment to implementation of global standards

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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**

* 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.

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

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)

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."

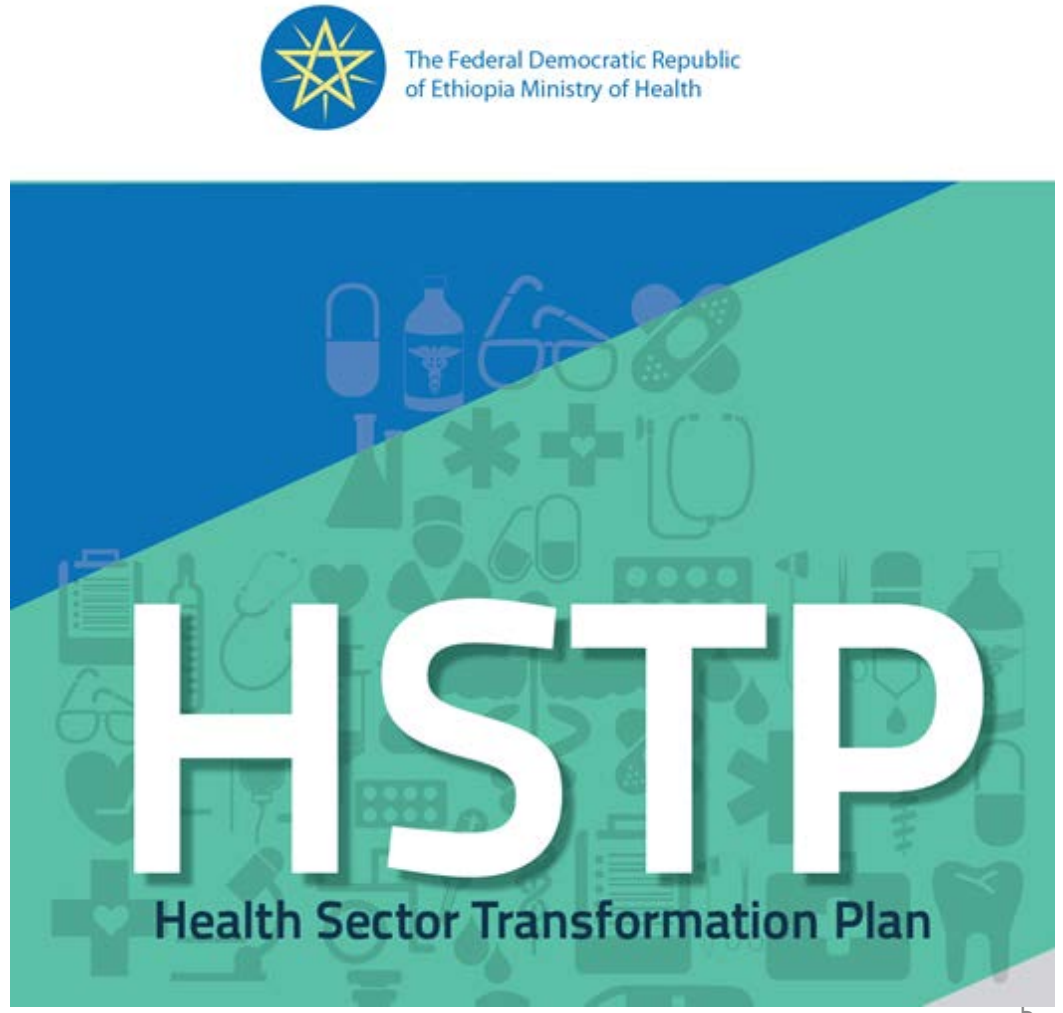
- **Vision:**

"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

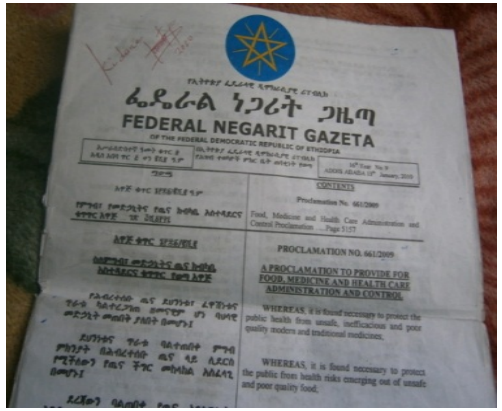
- **The way forward**
  - Health Sector Transformation Plan
  - Information Revolution



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

What we regulate

Premises

- Food Establishments
- Pharmaceutical Establishments
- Health & Health related Facilities
- Entry and exit ports

Professionals

- All type of Health professionals
  - — Lower level
  - — Middle level
  - — Higher level

Practices

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

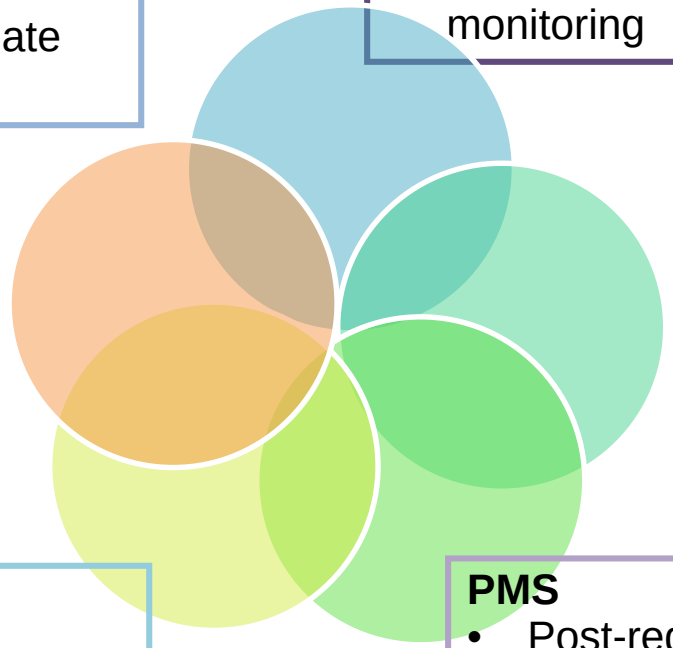
Products

- Food products
- Medicines
- Medical devices and supplies
- Laboratory reagents
- Cosmetics etc.

What we regulate

Education
- Community Mobilization
- Free toll information dissemination
- Online information access
- Education material disseminate
- Alert systems

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



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

Vigilance
- ADE monitoring
- Quality defect
- Medical error

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

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

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

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.

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.

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. All stakeholders will be informed and trained on the importance of standards through workshops, (social) media and one-on-one meetings.

Roadmap

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

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.

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.

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.

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.

Verification pilot

Malaria medication

- **Why Malaria**

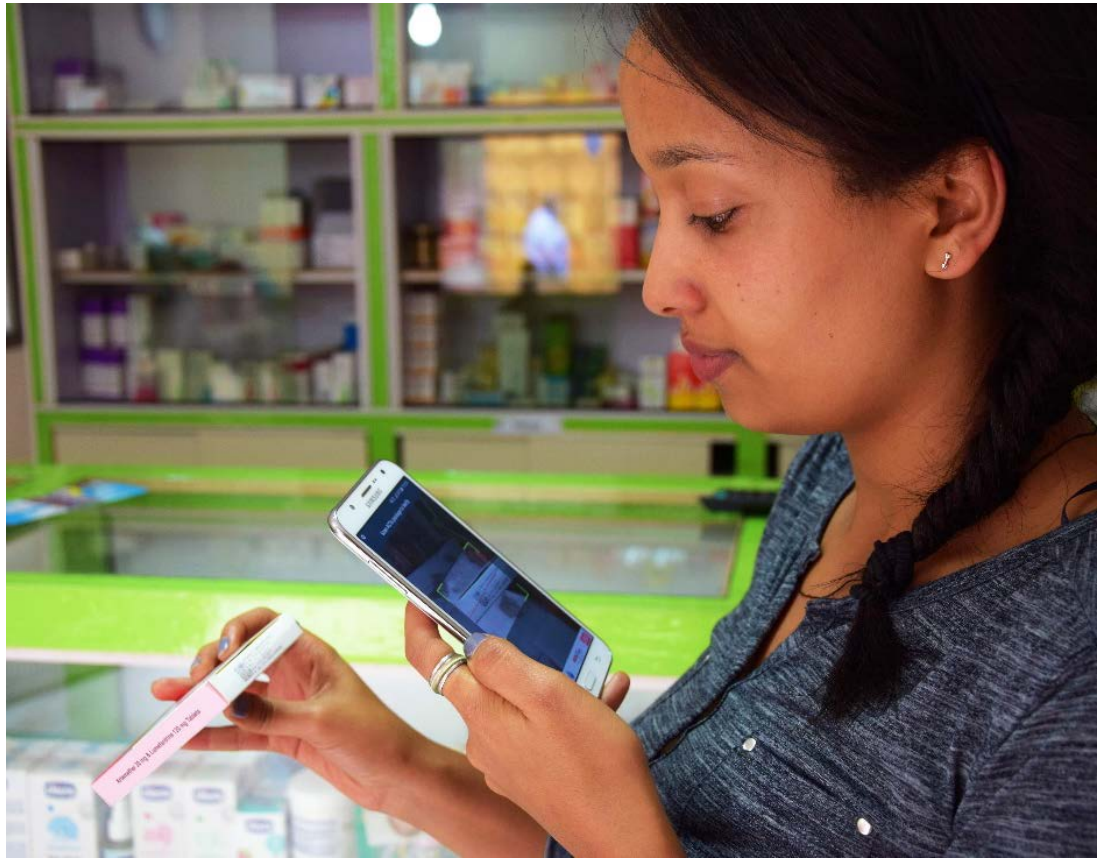
  ~ 6.5 million cases per year.

  Counterfeits have been detected in the past.

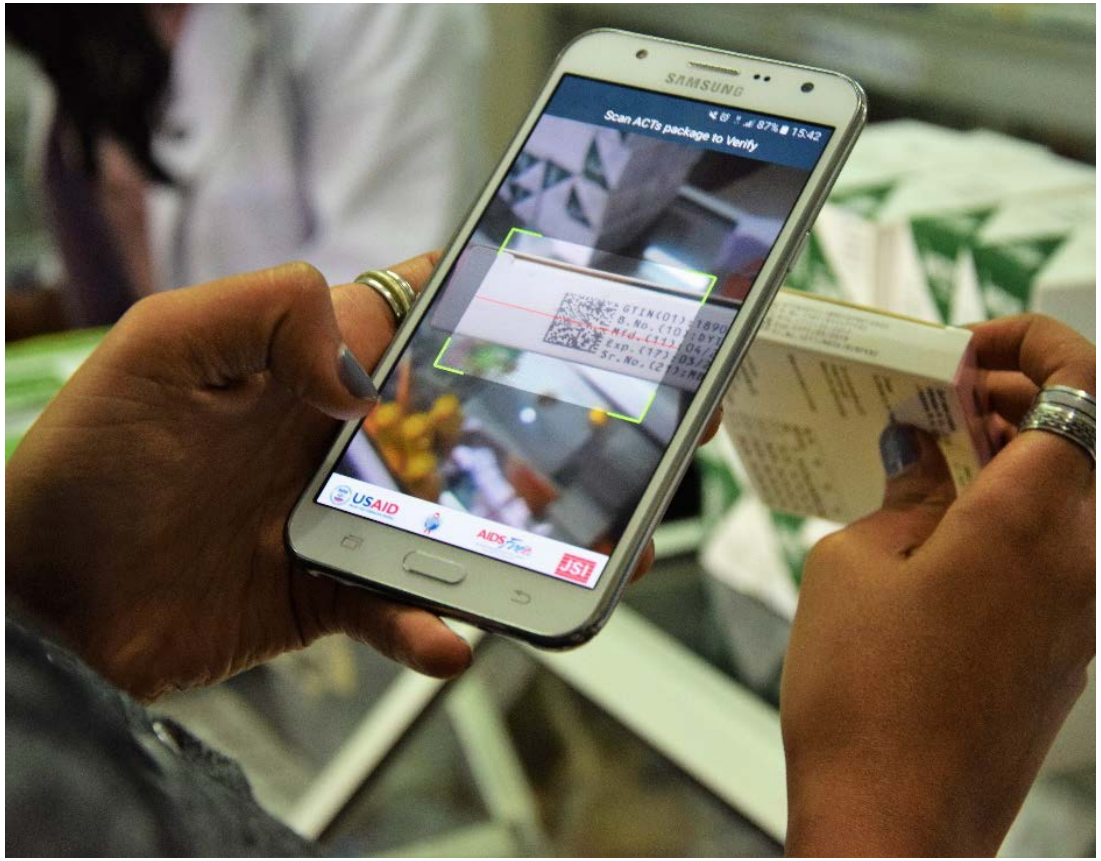
- **Purpose**

  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

Phase I:

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

(01)09504000059101
(21)19067811811
(10)563GS1
(17)200331

Example: Use of GS1 standards for the identification of products using a GS1 DataMatrix

GTIN: (01)09504000059101

S/N: (21)19067811811

Batch / lot: (10) 563GS1

Expiry: (17) 200331

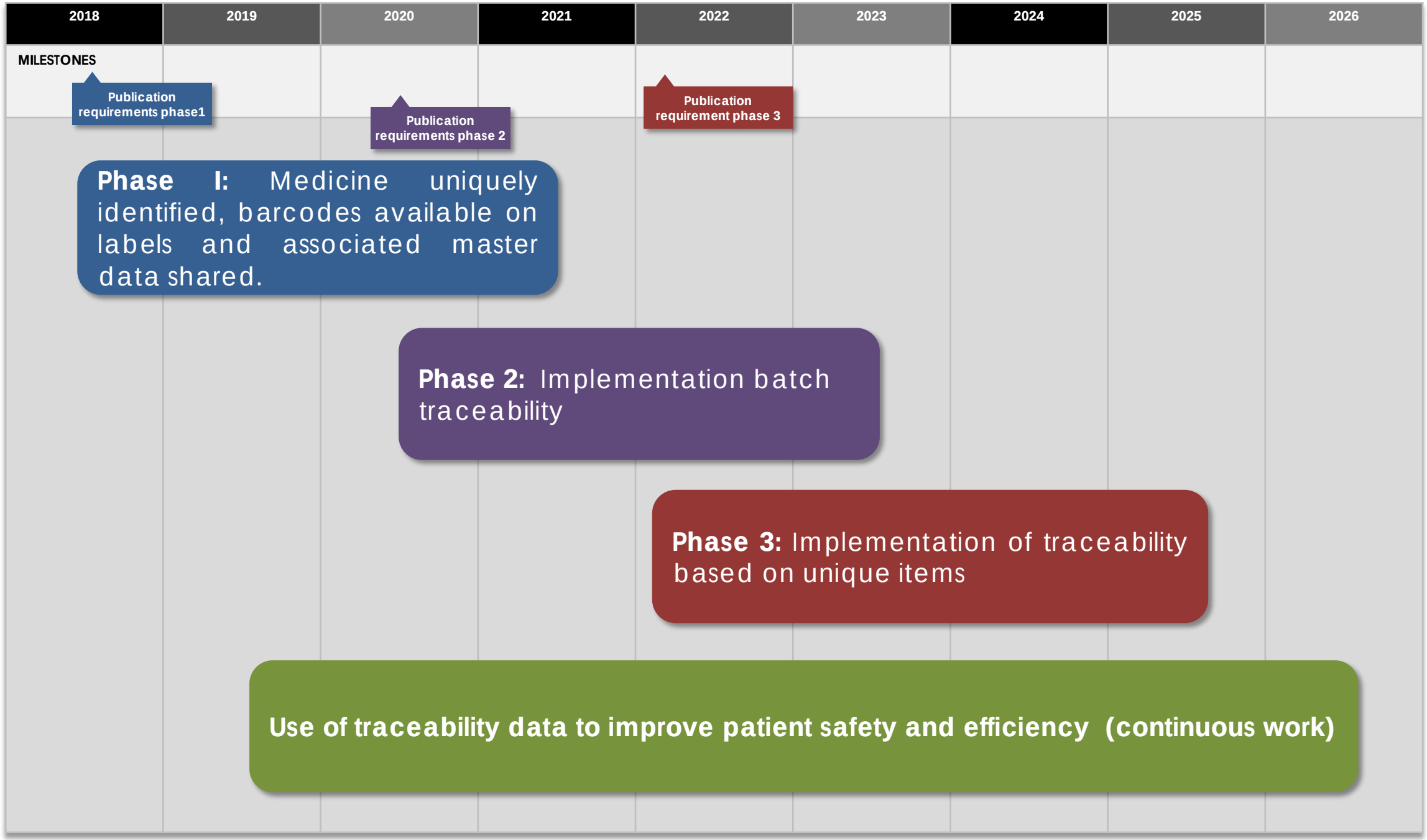
GS1 Barcode

- **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

Source: GS1 DataMatrix: https://www.gs1.org/sites/default/files/gs1_datamatrix-final_approved.pdf

Proposed timeline for implementation regulatory requirements (draft)



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**!

We need regulatory alignment

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!”

Thank you for your attention!

We would like to thank our partners for their support.