



# Building an End-to-End Supply Chain with Global Standards in Ethiopia

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Ms. Heran Gerba had her first degree in Pharmacy from the Addis Ababa University and her Master's degree in Pharmaceutical Analysis and Quality Assurance from Addis Ababa University. Ms. Heran has worked in the regulatory authority in different departments as medicine quality control analyst, team leader and medicine dossier evaluation expert from 2004 to 2014. Since 2014 to date, Ms. Heran has been the Deputy Director General of EFMHACA. And since 2018 she is the Director General of the Ethiopian Food and Drug Administration (previously EFMHACA).

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Teddy is the Senior HIS Advisor for USAID/Ethiopia. In his role, he works with the Government of Ethiopia to ensure a sustainable HIS is supporting equitable access to quality health care in the Ethiopian public health system.

Teddy previously worked as a HIS consultant for various organizations, including USAID implementing partners, the private sector, his own IT company and as a professor of Information Systems and Technology. He has a Master's degree in Information Systems from the University of Addis Ababa in 2007, and Software Engineering from Florida Institute of Technology.

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## FMOH Mission

**“To promote health and wellbeing of Ethiopians by providing and regulating a comprehensive package of promotive, preventive, curative and rehabilitative health services of the highest possible quality in an equitable manner”**



## EFDA Mission

**“To promote and protect the public health by ensuring safety, efficacy and quality of health related products and services”**



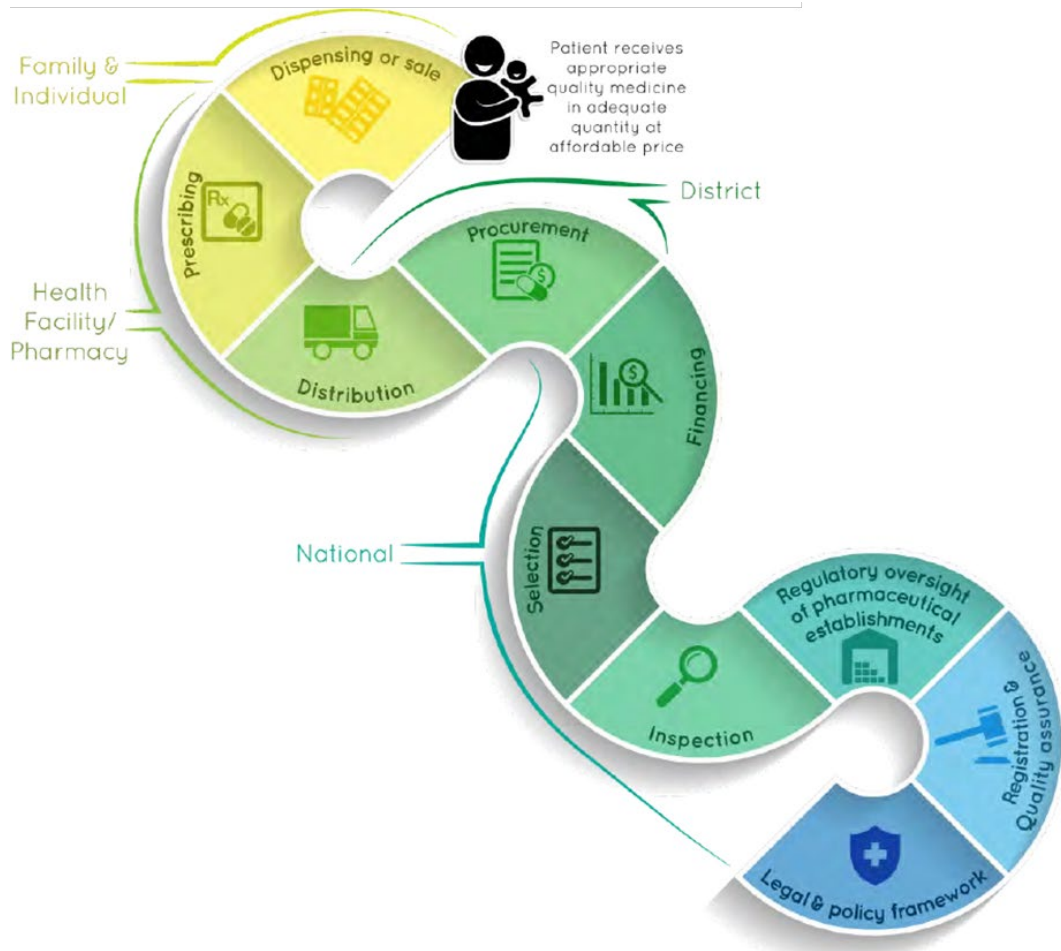
## EPSA Mission

**“To ensure uninterrupted supply of quality assured pharmaceuticals to the public at affordable prices through strengthening integrated supply chain system”**

**“Together, the FMOH, its agencies and partners are working together to ensure a continuous supply of quality assured public health commodities”**



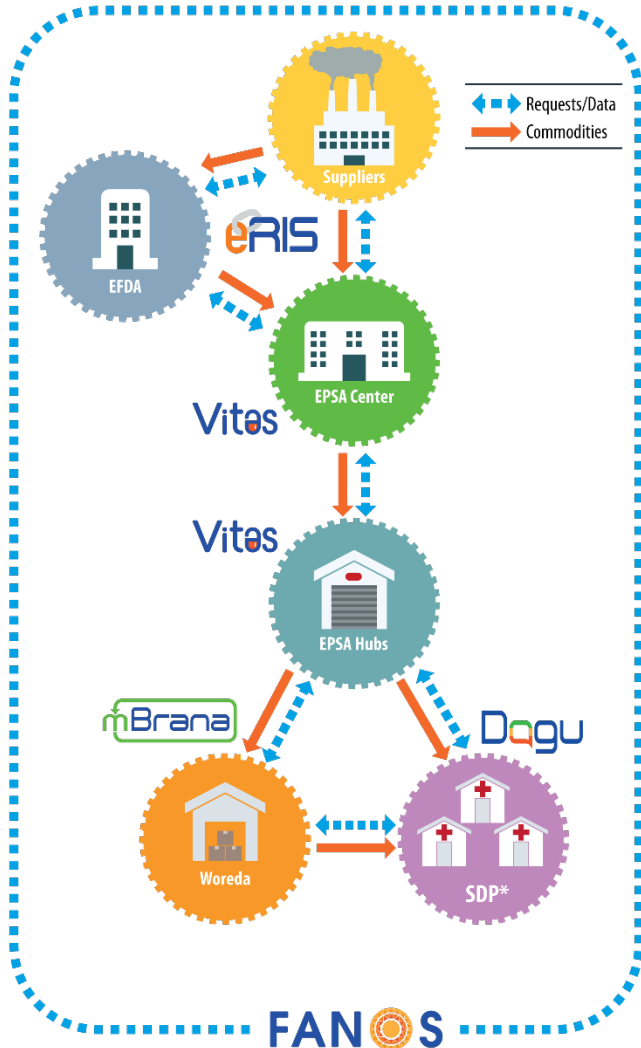
# The focus of Ethiopia's regulatory system and supply chain is to consistently get quality products to people



“Much of the [world’s] burden of **disease can be prevented or cured with known, affordable technologies.** The problem is getting **drugs, vaccines, information** and other forms of prevention, care or treatment—**on time, reliably, in sufficient quantity and at reasonable cost—to those who need them.**”



# A suite of information systems support the exchange of information throughout the supply chain



\* Service Delivery Points (hospitals, clinics, health posts)

## An overview of Ethiopia's supply chain:

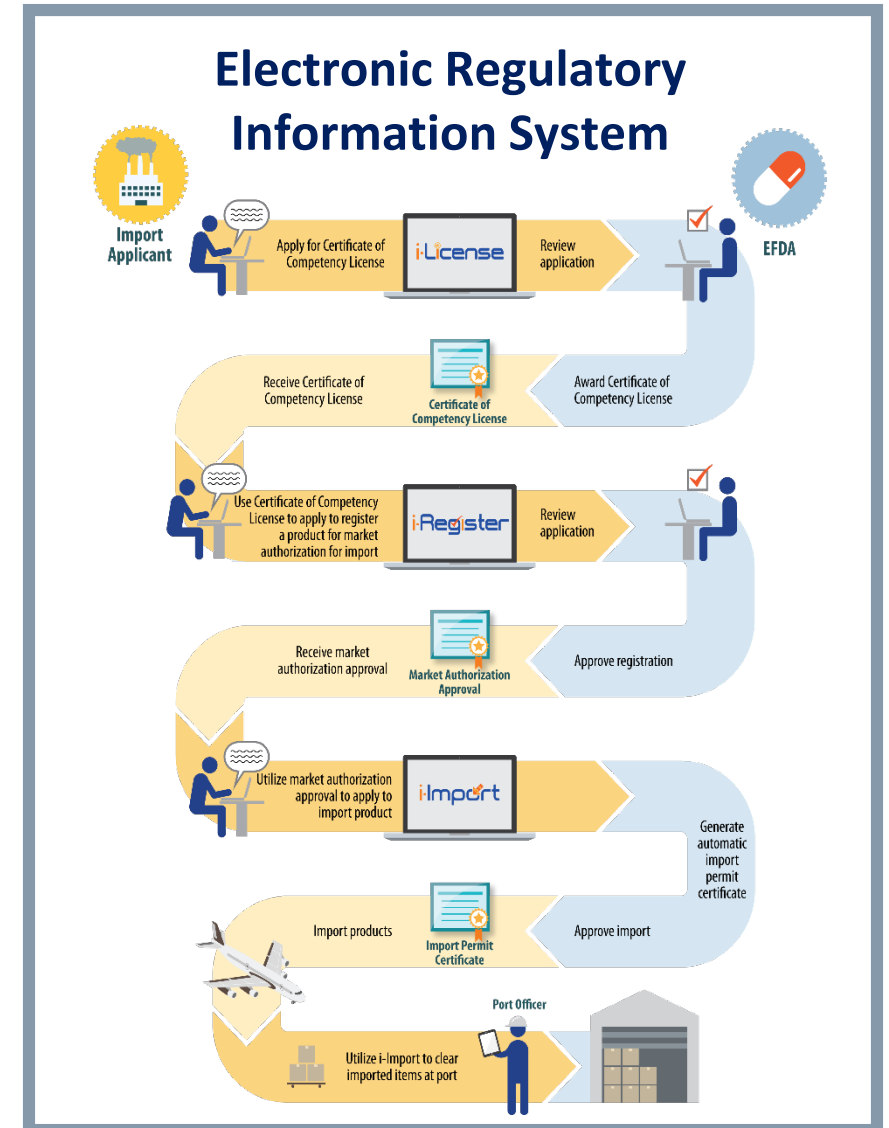
- **110+** million Ethiopians
- **21,000+** unique health commodities
- **3,900+** facilities and **18,000+** health posts
- **194+** unique importers
- **837** unique supplier license holders
- Value of drugs approved for import by local importers **USD 225,744,174**



## EFDA is leveraging technology to expedite traceability

EFDA is building a technology infrastructure with the **Electronic Regulatory Information System (eRIS)** that support end to end supply chain visibility to provide one unbroken chain of action and information:

- **i-License** – used to apply for a certificate of competency to register and import products.
- **i-Register** – used to manage the market authorization process where an applicant seeks to register a medical product.
- **i-Import** – used to manage the import process for medical products, once registered in Ethiopia.

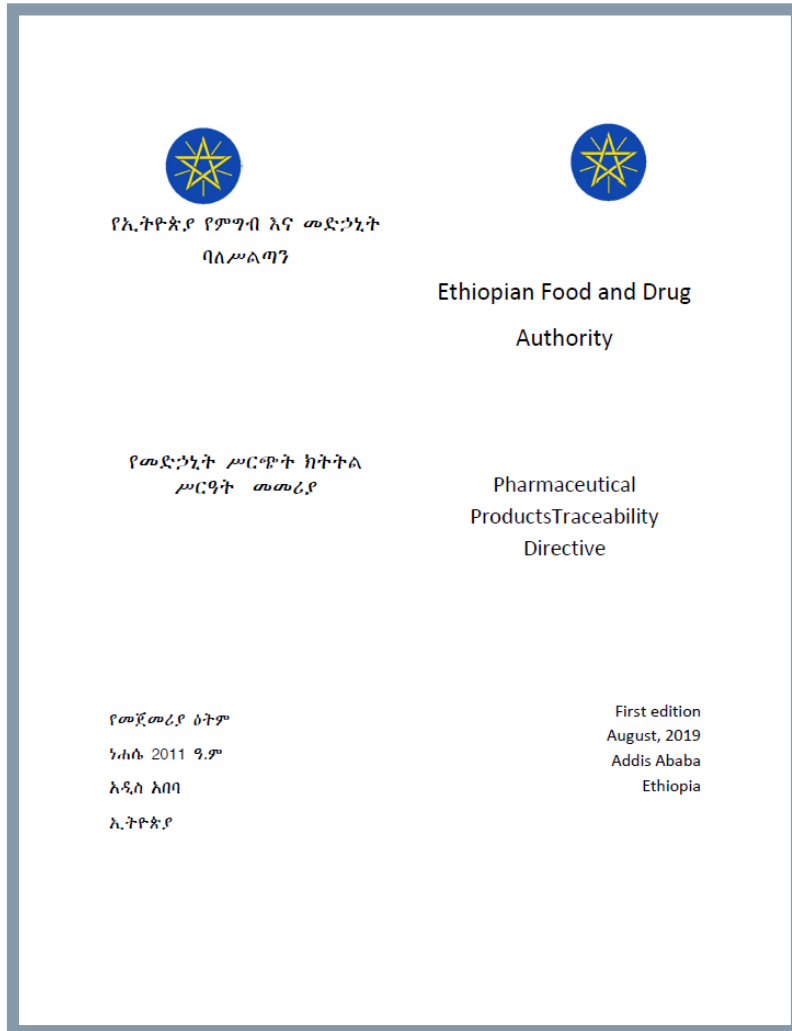




# In addition to technology, traceability is being supported by policy

## *Pharmaceutical Products Traceability Directive:*

1. To protect the public from falsified, substandard, unregistered, expired, recalled or otherwise harmful pharmaceuticals
2. To improve efficiency in the pharmaceutical supply chain regulation
3. To develop a system in which the identification, authentication and traceability of a pharmaceutical product is guaranteed from manufacturers to importers, wholesalers, healthcare providers and retail outlets, and other points of dispense, and;
4. To enforce the mandatory requirements and the implementation of identification, authentication and traceability of pharmaceutical products.









## Exemptions

- Products imported for personal use and not distributed in the official supply chain
- Non-registered pharmaceuticals ordered by hospitals for specific patients and in particular quantities
- Products manufactured and labelled prior to their unique identification compliance dates
- Products for quality analysis
- Free samples of pharmaceutical products
- Blood or blood components
- Traditional medicines
- Extemporaneous preparations
- Donations





# The *Pharmaceutical Products Traceability Directive* is being implemented in four phases

Phase 1

Unique identification (GS1) + labelling requirements



Phase 2

Share standardized master product and location data



Phase 3

Batch traceability



Phase 4

Serialization/traceability of unique items



GTIN 00314141999995  
SN 10000000234  
EXP 25 JAN 2015  
LOT 987654321GFEDCBA



# Pharmaceutical Products Traceability Directive implementation timeline

**2 years**

- All listed local manufactured pharmaceuticals GTIN for 2<sup>nd</sup> & higher packaging levels
- All listed imported pharmaceuticals GTIN + batch number + expiry date for 2<sup>nd</sup> & higher packaging levels
- Location and product master data for listed supply chain actors and pharmaceutical products and their packaging levels respectively shall be shared with the Authority

**3 years**

Local manufactured pharmaceuticals GTIN + batch number + expiry date for 2<sup>nd</sup> & higher packaging levels including SSCC on logistic items

**4 years**

Manufacturer, wholesaler and healthcare provider shall comply with batch traceability for listed pharmaceutical secondary packages and their higher packaging levels

**5 years**

All supply chain actors shall comply with batch traceability for listed pharmaceutical 2<sup>nd</sup> and their higher packaging levels

**5.5 years**

All listed 2<sup>nd</sup> & higher packaging levels distributed in the country shall be identified with GTIN + batch number + expiry date + serial number

**7.5 years**

All supply chain actors shall comply with traceability of unique items for listed pharmaceutical 2<sup>nd</sup> and their higher packaging levels



# Pharmaceutical Products Traceability Directive Implementation

## Progress

### Policies

- Approved the *Food and Medicine Administration and Control Proclamation* No. 1112/2019 (Article 53 (5))
- Issued the *Pharmaceutical Traceability Strategic Plan*
- Issued the pharmaceutical products *Traceability Directive*
- Conducted an assessment of existing infrastructure

### Tools

- Completed draft barcode guideline (under review)
- Issued informational brochures (Amharic & English version)
- Developed Master Data guideline and tool for pharmaceutical products traceability

### Processes

- Established national alliances to support implementation of traceability (NSC & TWG)



## The *Master Data Management Policy* will support information exchange with manufacturers, facilitated by the eRIS

1. The manufacturer shall share product master data with the Authority for trade items and logistics items within the scope of this Directive.
2. All supply chain actors within scope of this Directive shall share legal, functional and location master data with the Authority.
3. All supply chain actors within the scope of this Directive shall obtain a Global Location Number (GLN), to identify their organizations and important locations, including:
  - A. Location where items are manufactured.
  - B. Location where orders are received.
  - C. Locations where orders are distributed.
4. Guideline will be issued by the Authority to provide the product and location master data requirements.
5. The data elements of the Global Location Number shall be according to the GS1 Healthcare GLN Guideline.





## Next steps for implementing the *Master Data Management Policy*

### Policies

- Incorporate mgt. committee comments and finalize the directive
- Publish final *Pharmaceutical Products Traceability Directive*

### Tools

- Develop support material and guidelines under the directive
- Familiarization of the directive and guidelines to the supply chain actors and stakeholders
- Awareness creation for stakeholders, healthcare providers, and public
- Provide technical support for supply chain actors

### Processes

- Work on traceability system + pilot functionalities:
  - Test current and required capabilities
  - Improve and update technical requirements



## Communicating the *Master Data Management Policy*

- Conferences (national and international)
- Meeting with stakeholders, manufacturers, importers healthcare providers, professional associations, EFDA and EPSA management committees
- Stakeholder readiness assessment and awareness creations (manufacturers + one private hospital)
- Media communications (website, publications)







# Implementation challenges and mitigation strategies

The EFDA has responded to four key challenges in the implementation process:

## Challenges

**Fragmented information systems**

**Manufacturer engagement**

**Building stakeholder capacity**

**Sustaining momentum**

## Mitigation Strategies

Mature the eRIS to meet all master data requirements and ensure full automation of information exchange up-to facility level

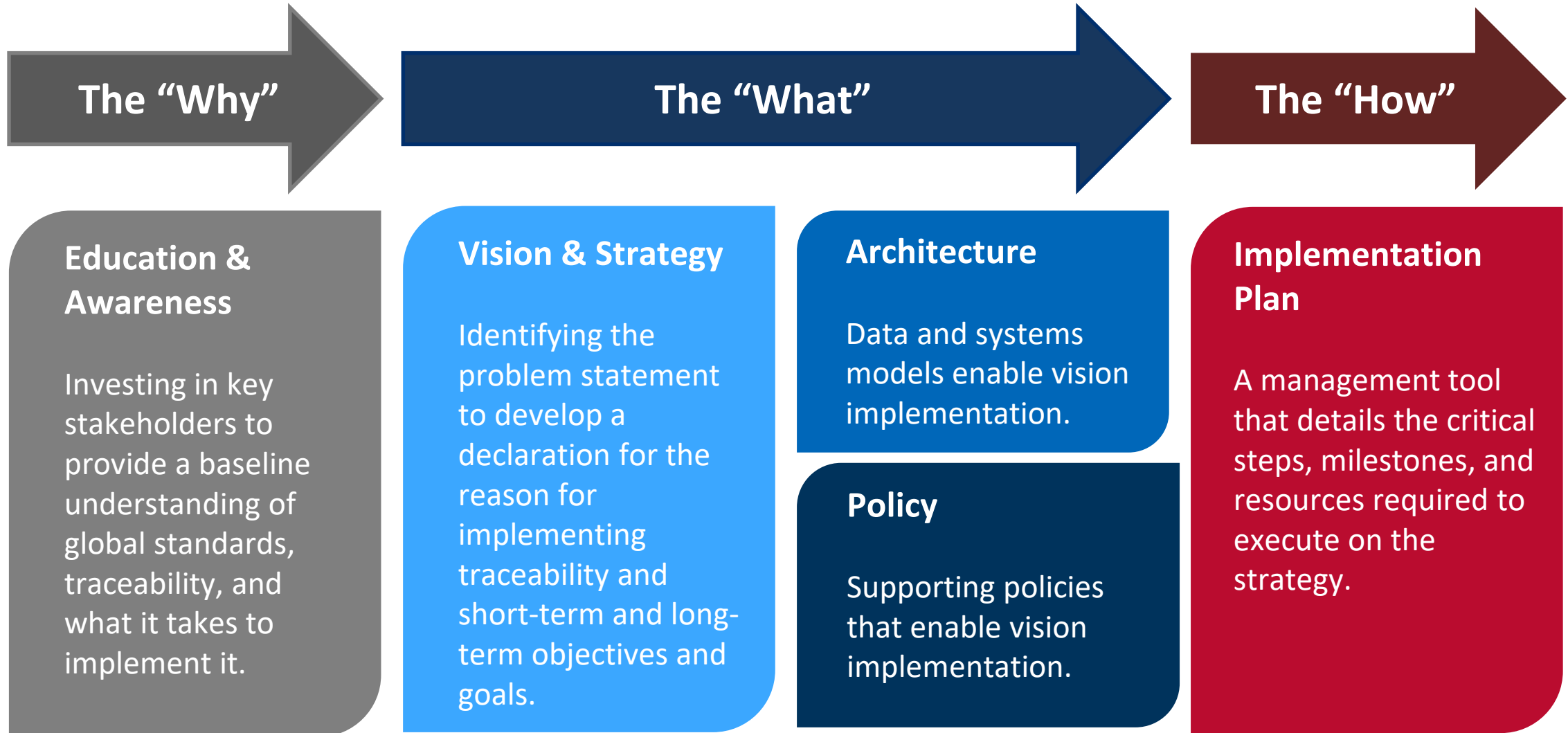
Establish appropriate fora for manufacturer engagement and ensure all procurement contracts mandate the use of the standard

Expand capacity building efforts by engaging additional government agencies and knowledge sharing approaches

A strong, well-staffed and trained Traceability Office is key to maintaining the momentum during this journey



# Lessons learned from the implementation process





Thank you for your attention!

We remember GS1's words:

**“It's a marathon, not a sprint!”**

