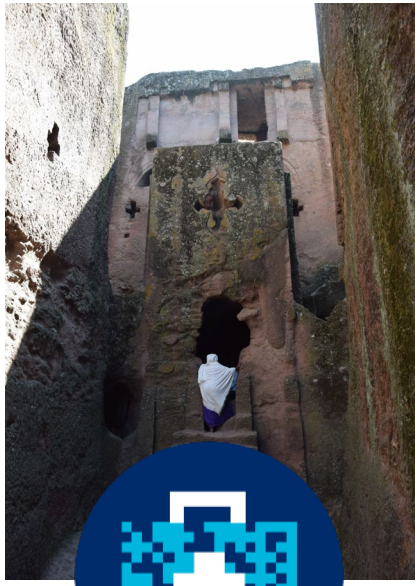
The New Traceability Regulation in Ethiopia



Ms. Heran Gerba
Director General, Ethiopian Food and Drug Authority
GS1 Healthcare Conference, Noordwijk, the Netherlands

About EFDA

- **Mission:**

"To promote and protect the public health by ensuring safety, efficacy and quality of health and health-related products and services through product quality assessment and registration; licensing and inspection of health professionals, health institutions, pharmaceutical and food establishments, and provision of up-to-date regulatory information while promoting proper use of health and health-related products and services including proper use of medicines."

- **Vision:**

"Quality health services and products to all citizens."

About Ethiopia

- **110+ million** Ethiopians
- **21,000+** health commodities
- **10,953+** healthcare facilities and 18,000+ health posts
- **14** Manufacturers, **383+** Importers, **489** Wholesalers, **1078+** Pharmacies, **4056+** Drug shops, **618+** Drug venders
- Value of drugs approved for import by local importers **6,539,797,428 Birr**

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"

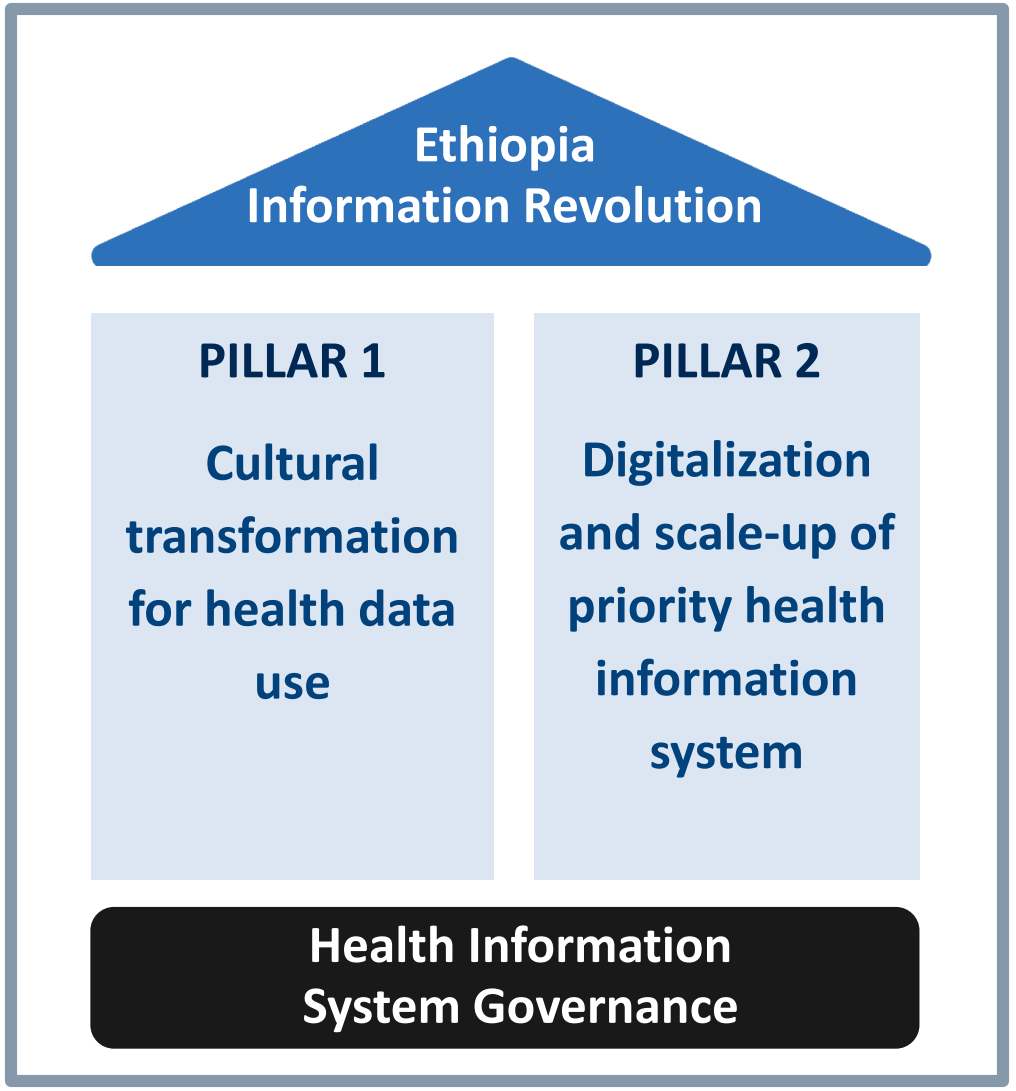
"Together, the FMOH, its agencies and partners are working together to ensure a continuous supply of quality assured public health commodities"

Technology and information

Health Sector Transformation Plan:

- A national health strategy promoting quality and equitable distribution of health care for all
- Built on 4 transformation agendas:
    1. Transformation in equity and quality of care
    2. Information revolution
    3. Woreda transformation
    4. Caring, respectful and compassionate health workforce

FMOH, EFDA, and EPSA are using technology as an enabler to realize this strategy.



GS1 Healthcare Conference, Addis Ababa

- First African GS1 Healthcare Conference
- EFDA proud co-host
- Huge commitment from all healthcare stakeholders, especially **regulators 30%**
- **Over 75%** of participants from **Africa**

AFRICAN GS1 Healthcare Conference

Traceability Implementation

Plenary Session DAY 2 MAY 8

END TO END SUPPLY CHAIN DATA VISIBILITY through GLOBAL STANDARDS with Ramy Guirguis

availability of data for decision-making

CHALLENGES on the DONOR'S SIDE...

- non-core commodities
- global supplier base
- wholesalers
- business resources needed and technology dependent
- Legacy technology and infrastructure

What do we mean by "End to End"?

TRENDS...

- Growing complexity of information systems
- Only one component of larger Digital Health interventions
- Increasing need for Visibility and Analytic Networks (VAN)

SUPPLY PLANNING

STOCK in HAND

BATCH LEVEL DATA

SERIAL-IZATION

most advanced

CHALLENGES...

- Master data management
- Data quality
- Interoperability

we need a new FOUNDATION that allows us to ...

- IDENTIFY → product master
- CAPTURE → barcodes
- SHARE

growing complexity

Ultimately, PATIENT is the end point and Patient Safety!

Tbusch@usaid.gov

Illustration by Tobey Busch, USAID

Currently: implementing roadmap

Phase I: Strengthen environment

Strengthen regulatory framework

- Traceability Office
- Traceability Directive
- Barcode and master data guidelines

Build and sustain technical infrastructure

- Analysis on current infrastructure
- Development track & trace architecture
  - GTIN repository
  - GLN repository
  - Centralised
  - Phased
- Building on existing systems (ERIS)

Build stakeholder's capacity

- Implement strategies to improve stakeholder capacity

Strengthen knowledge, communication and collaboration

- Ethiopian Standard Agency
- Communication professional
- Steering Committees and Working Groups
- Material: guidelines, website and other
- Training

Note: this is not an exhaustive list and work in progress!

The Food and Medicine Administration Proclamation 1112/2019

- Definition (Article 2)
    - “barcode” means a machine-readable code in the form of numbers and a pattern of parallel lines printed on and identifying a product for the purpose of monitoring by the manufacturer or executive organ;

- Mandatory Labeling requirements (Article 54)

    - No person may import or place into use of any medicine or medical device unless its labelling contains a barcode
    - Detail requirement will be provided in other subsidiary laws (regulation or directive) to be adopted to implement Proclamation 1112/2019

- Effectiveness Date (Article 74)
    - The mandatory barcode requirement will come it to effect at the eighteenth month from February 5, 2019

- Enforcement
    - Strong administrative measures on non-compliance including license revocation
    - Civil money penalties against regulated entities
    - Strong criminal penalties

Traceability Directive lays down specifics

(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

- For identified products, secondary package:
  GS1 DataMatrix
  - GTIN
  - Batch number
  - Expiry date

  Includes tertiary packages and logistic items
- Second phase includes serial number

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

Phase II: implementation roadmap

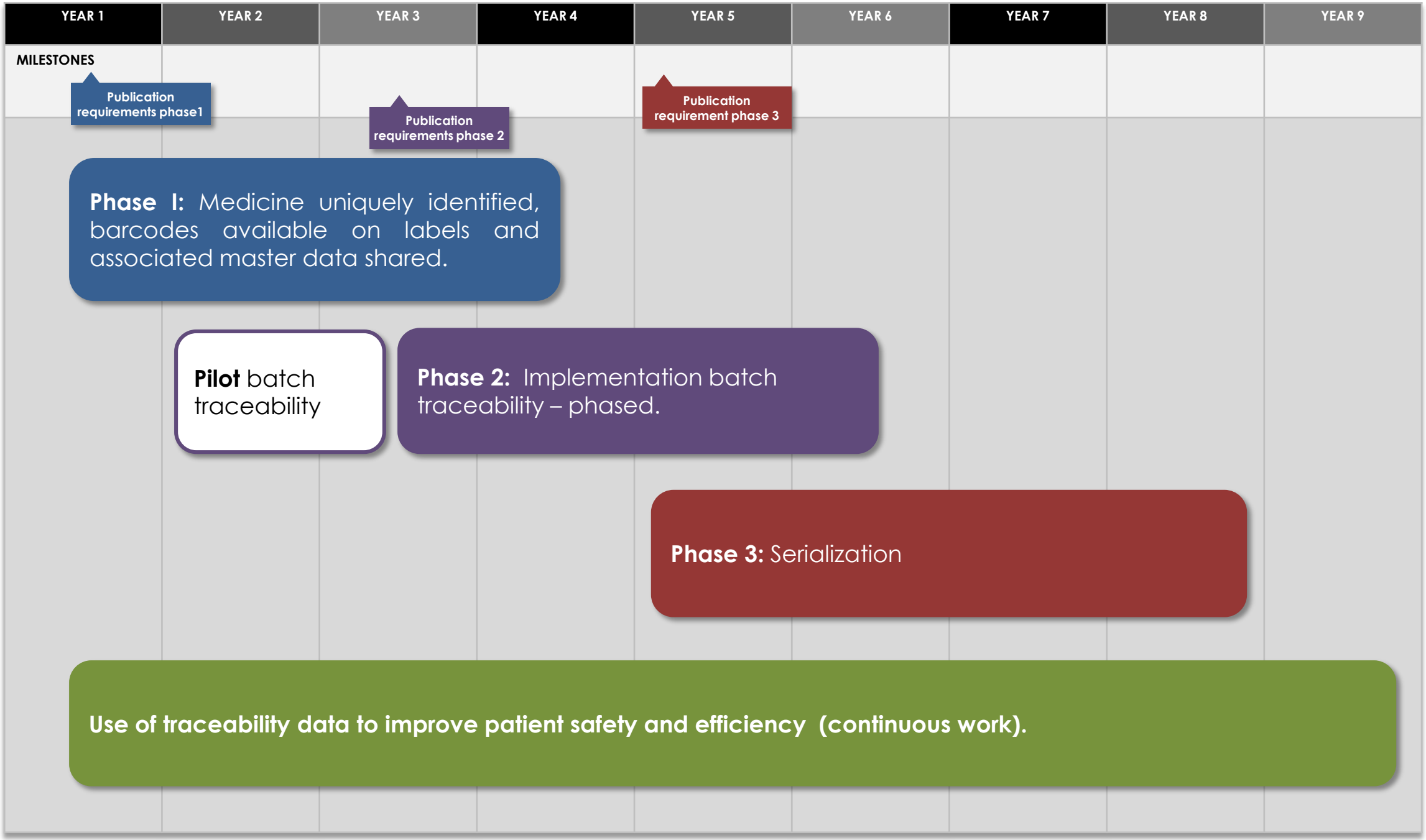
Create visibility in the supply chain

Phase I:	Phase I:	Phase II:	Phase III:
Unique identification (GS1) + labelling requirements	Share standardized master product and location data	Batch traceability	Serialization / traceability of unique items

Use traceability data to improve **patient safety** and **efficiency**: verification, traceability, detection, notification and **ACTION*** by the governmental body

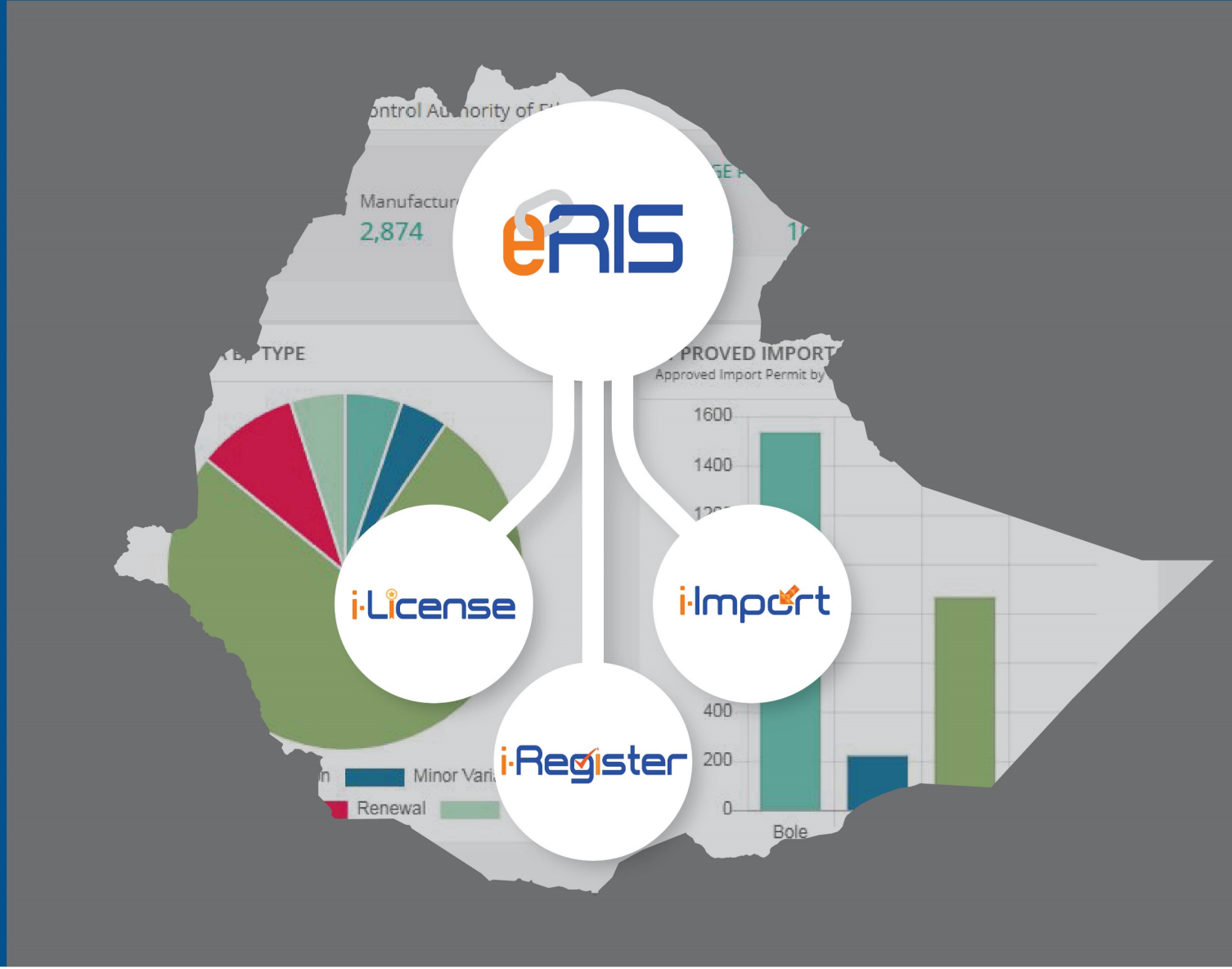
* Without action no improvement

High level timeline for implementation regulatory requirements (draft)



The Electronic Regulatory Information System:

Digitizing Ethiopia's Food and Drug Regulatory System

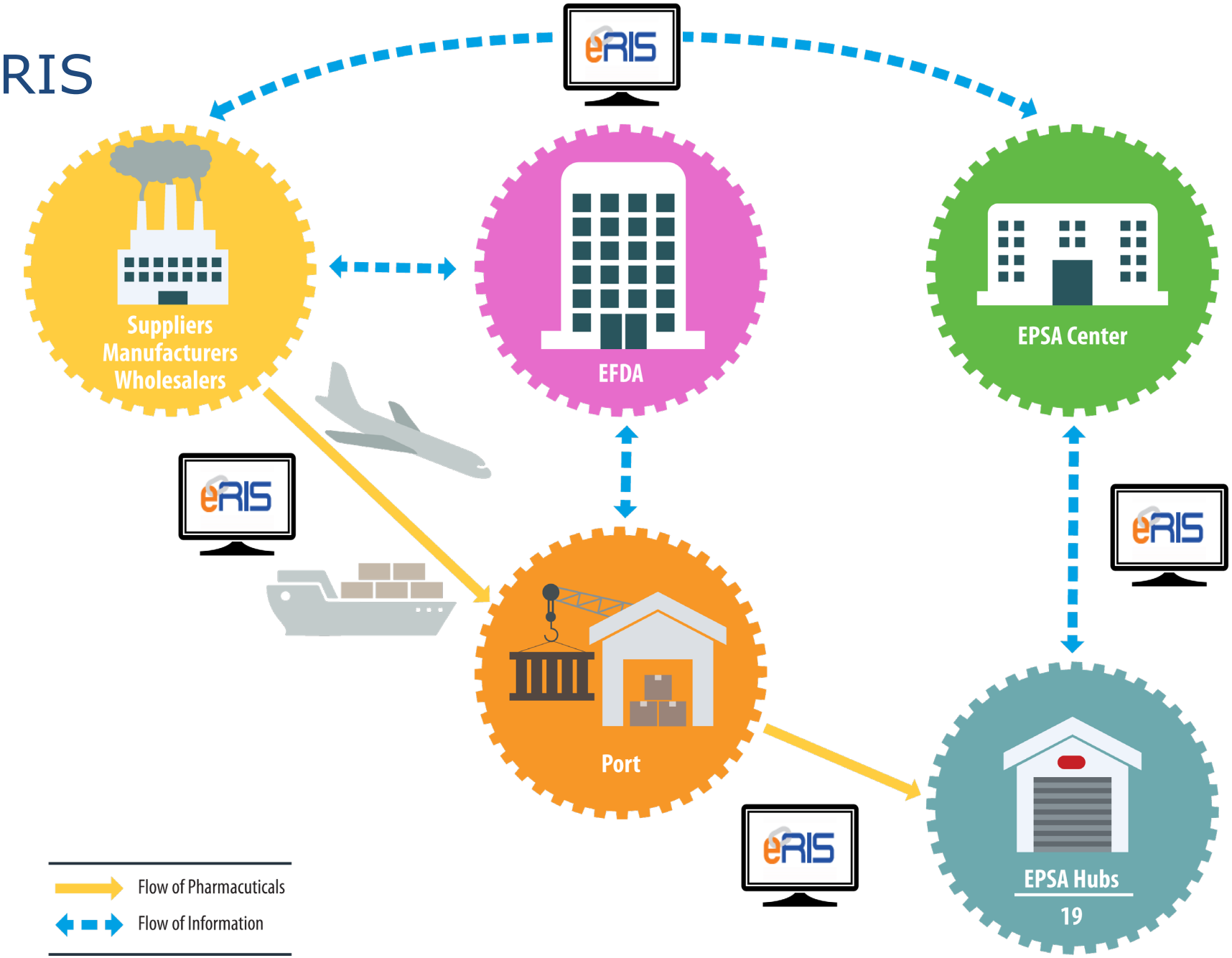


USAID
FROM THE AMERICAN PEOPLE

PEPFAR
U.S. President's Emergency Plan for AIDS Relief

AIDSFree
Strengthening High Impact Interventions for an AIDS-free Generation

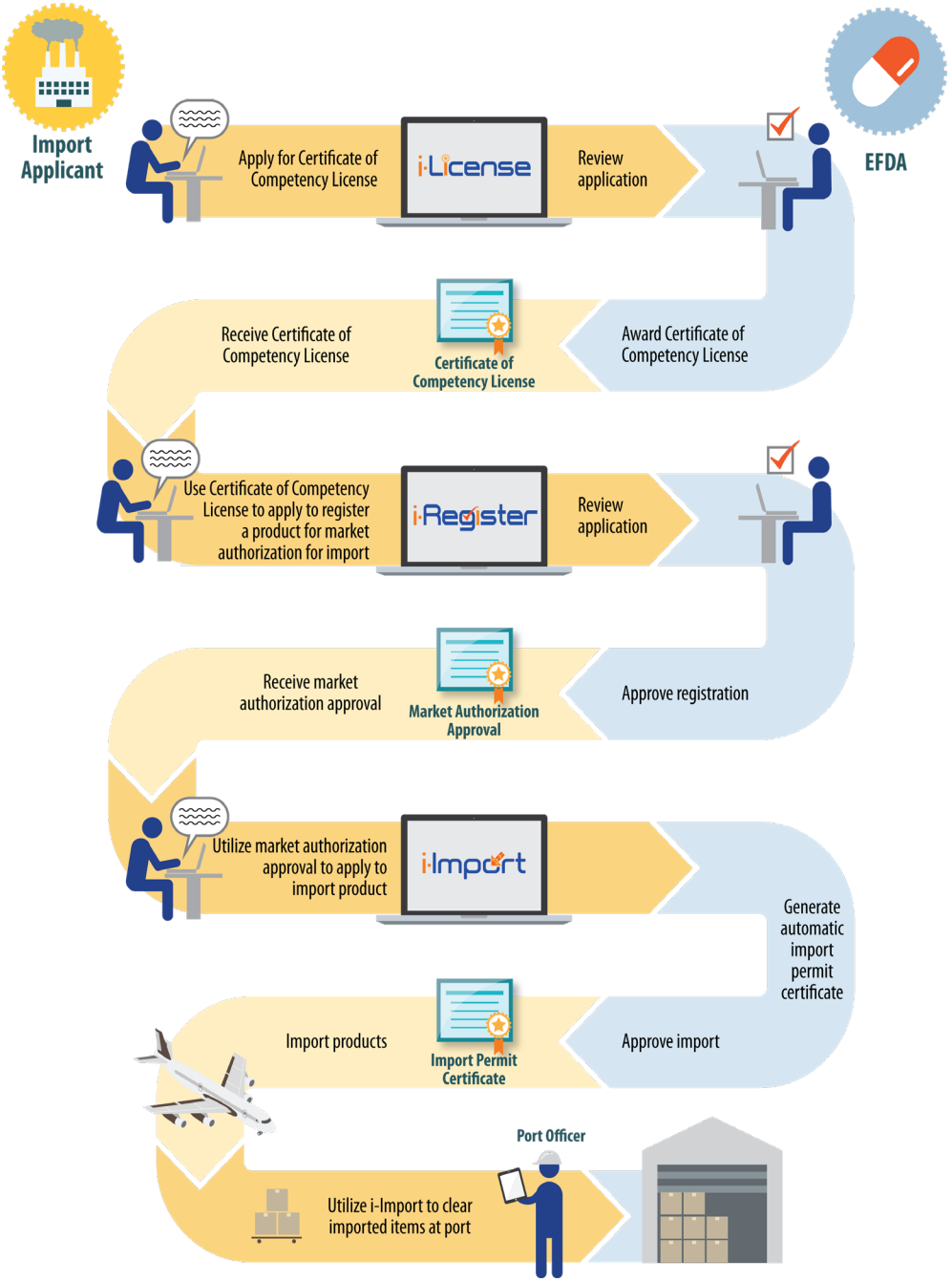
ERIS


eRIS
Suppliers
Manufacturers
Wholesalers
EFDA
EPSA Center
eRIS
eRIS
Port
eRIS
EPSA Hubs
19
Flow of Pharmaceuticals
Flow of Information

ERIS

EFDA creates

- Increased transparency
- Improved efficiency
- More effective communication with EPSA through EPSA MIS interoperability
- More accurate and timely access to data
- Improved decision-making through facile and robust reporting
- Traceability



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***

Thank you for your attention!