The New Traceability Regulation in Ethiopia

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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 vendors
- Value of drugs approved for import by local importers **6,539,797,428 Birr**
“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”

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

“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”
**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 Remy Ounougis

What do we mean by "End to End"?

SUPPLY PLANNING

STOCK IN HAND

BATCH LEVEL DATA

SERIALIZATION

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

TRENDS...

CHALLENGES...

Master data management
Data quality
Interoperability

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

IDENTIFY
CAPTURE
SHARE

Non-core Commodities
Global Supplier base
Whole sellers
Business resources needed and technology dependent
Legacy technology and infrastructure

Growing complexity
Most advanced

Patient Safety

Ultimately, PATIENT is the end point

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 into 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

- 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:
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

* Without action no improvement
## High level timeline for implementation regulatory requirements (draft)

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**Phase 1:** Medicine uniquely identified, barcodes available on labels and associated master data shared.

**Pilot batch traceability**

**Phase 2:** Implementation batch traceability – phased.

**Phase 3:** Serialization

**Use of traceability data to improve patient safety and efficiency (continuous work).**
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!

We remember GS1’s words: “It’s a marathon, not a sprint!”