Government and regulatory body ThinkTank

Day 2: Discussing the possibility of regulatory alignment across Africa

GS1 Healthcare African Conference
9 May 2018, Addis Ababa, Ethiopia

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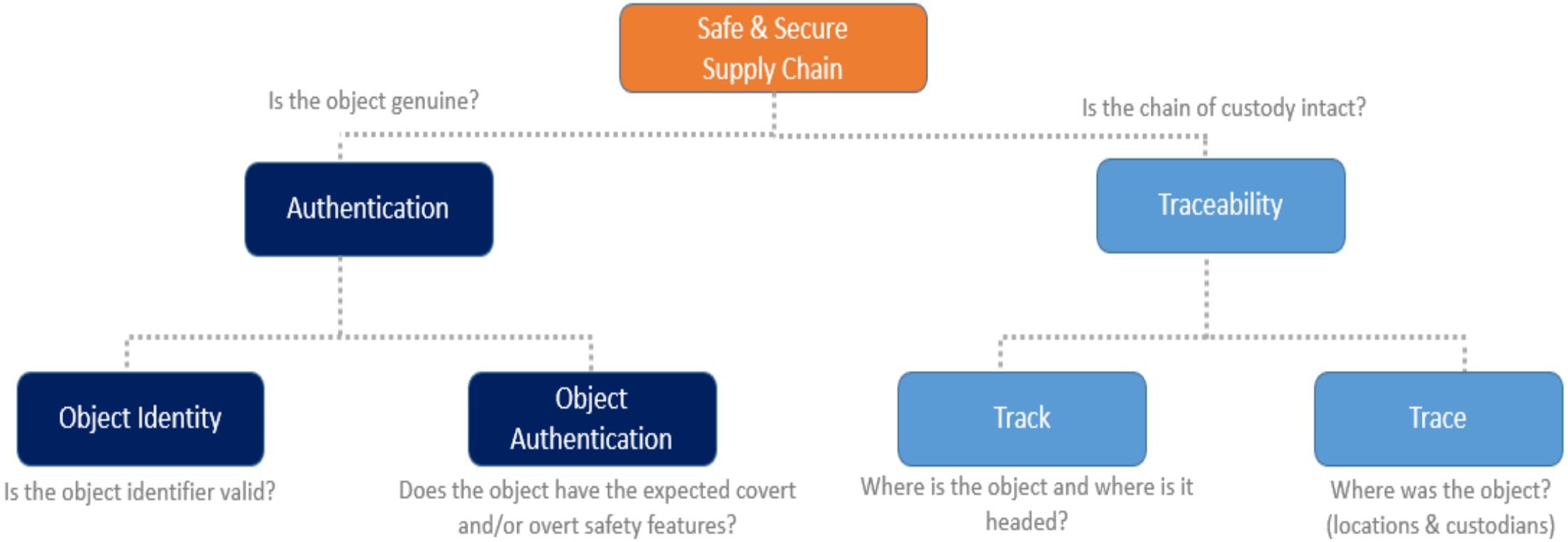
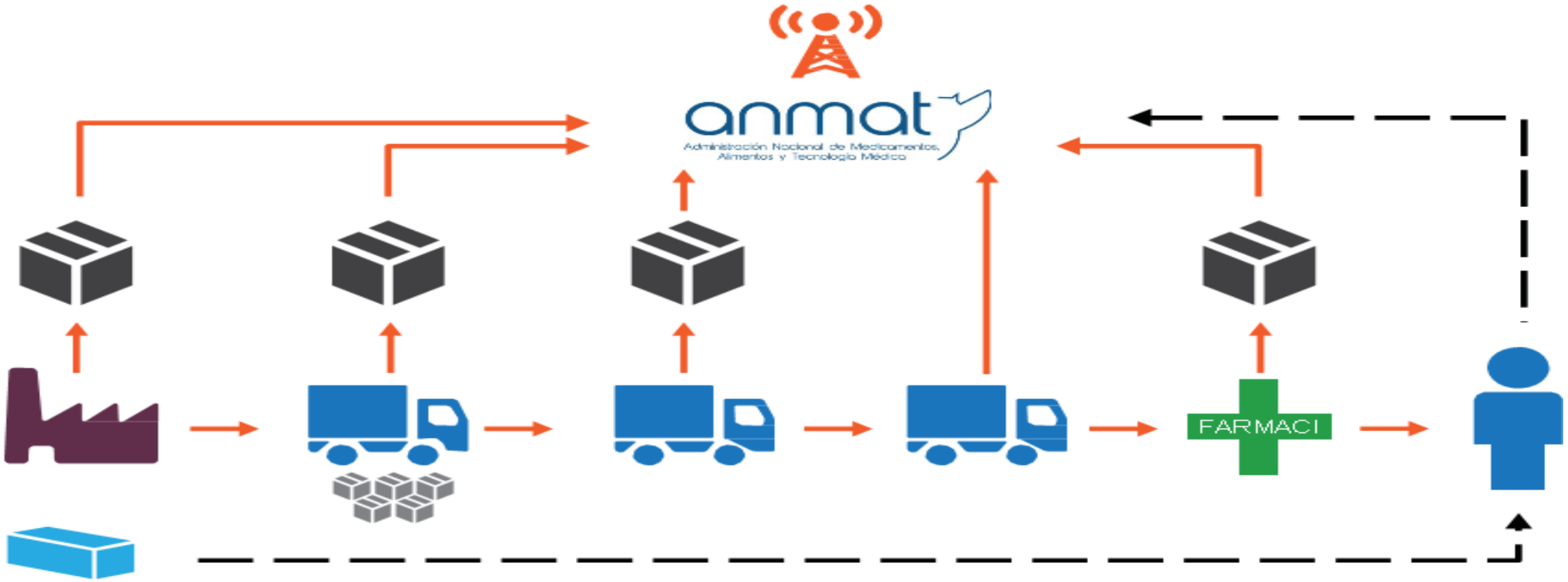
See more at: http://www.chathamhouse.org/about/chatham-house-rule#sthash.JmrtoLcU.dpuf

14.15 – 14.35 *(20 minutes)*	Opening and introduction of participants *Facilitator: Géraldine Lissalde-Bonnet, Public Policy Director, GS1 Global Office, Belgium*
14.35 – 14.50 *(15 minutes)*	EFMHACA : initiating regulatory developments for medicines traceability *Speaker: Yehulu Denekew, Director General, Food Medicine Health Care Administration and Control Authority, Ethiopia*
14.50 – 15.00 *(10 minutes)*	Discussions Facilitator: *Géraldine Lissalde-Bonnet, Public Policy Director, GS1 Global Office, Belgium*
15.00 – 15.10 *(10 minutes)*	Nigeria : working on improving medicines traceability *Speaker: Olubukola Ajayi, Head Drug and Vaccine Division, FMS Federal Ministry of Health, Nigeria*
15.10 – 15.20 *(10 minutes)*	South Africa : aligning of global framework for medicines traceability *Speaker: Ephodia Nyathi, Senior Pharmaceutical Policy Specialist, National Department of Health, South Africa*
15.20 – 15.30 *(10 minutes)*	KENYA: using global standards for medical products traceability *Speaker: Fredrick Wanyonyi, CEO Kenya Medical Supplies Authority (KEMSA)*
15.30 – 15.45 *(15 minutes)*	Discussions *Facilitator: Géraldine Lissalde-Bonnet, Public Policy Director, GS1 Global Office, Belgium*
15.45 – 16.15	Coffee Break
16.15 – 16.35 *(20 minutes)*	GSC – collaborating to improve regulatory harmonization Speaker: *Tom Woods, Chairman Global Steering Committee for Quality Assurance, World Bank, U.S.A.*
16.35 – 16.55 *(10 minutes)*	Contribution from US FDA Speaker: *Leigh Verbois, Associate Commissioner for International Programs, US FDA, U.S.A.*
16.55 – 17.15 *(30 minutes)*	Discussions Facilitator: *Géraldine Lissalde-Bonnet, Public Policy Director, GS1 Global Office, Belgium*
17.15 – 17.30 *(15 minutes)*	Next Steps *Facilitator: Géraldine Lissalde-Bonnet, Public Policy Director, GS1 Global Office, Belgium*
17.30 – 17.45 *(15 minutes)*	Closing *Facilitator: Géraldine Lissalde-Bonnet, Public Policy Director, GS1 Global Office, Belgium*

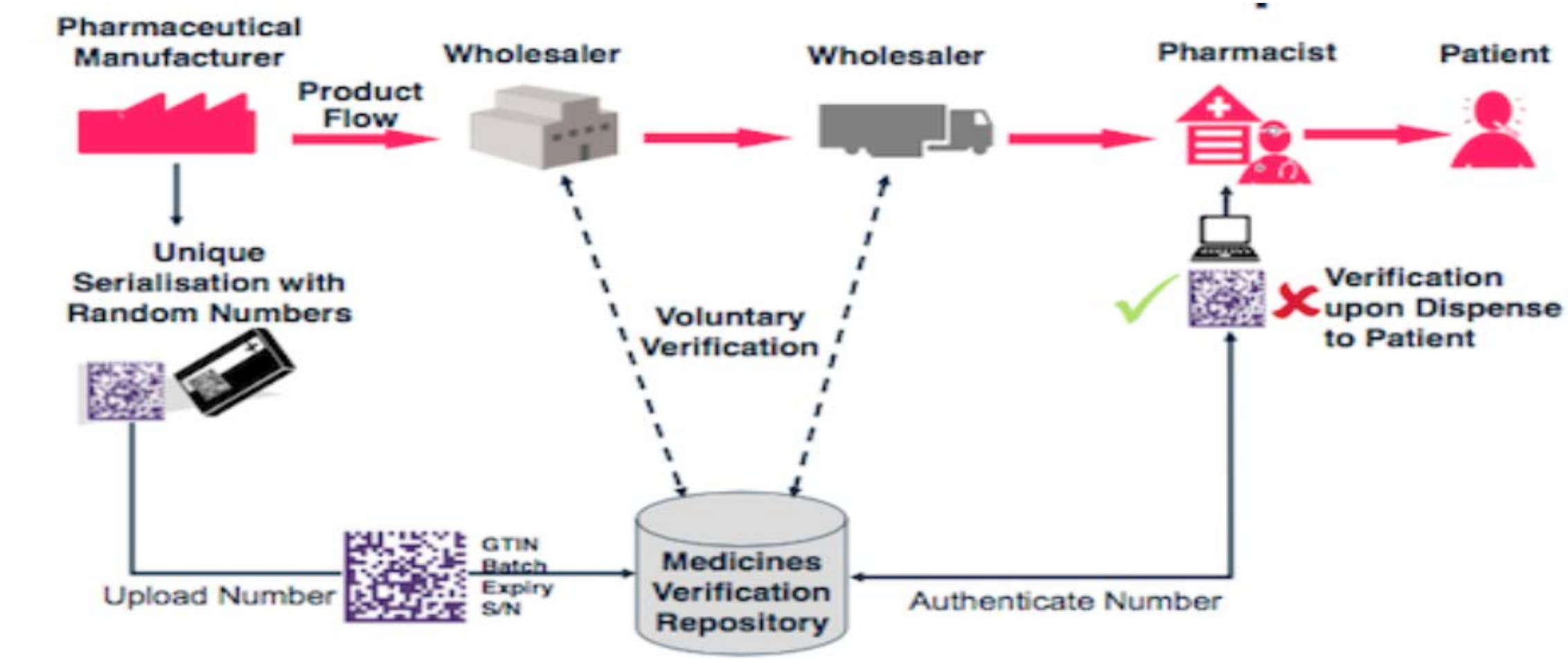
Traceability approaches



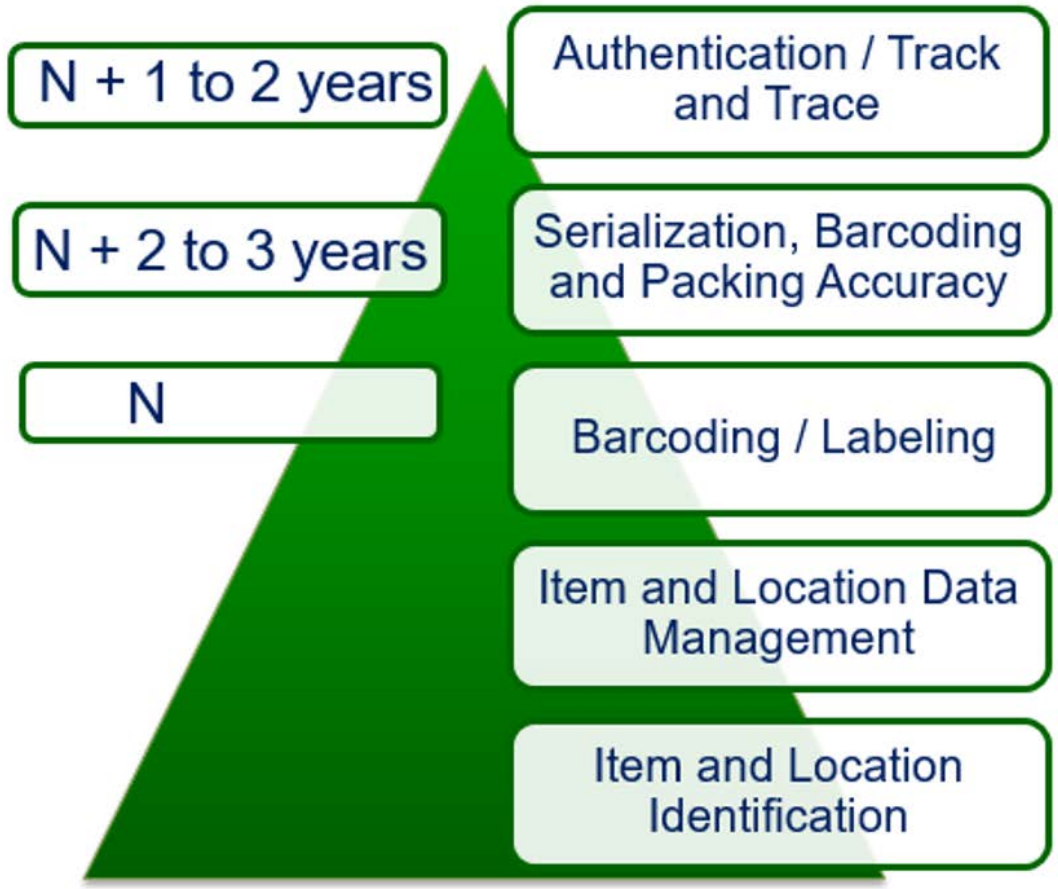
Track and Trace system – e.g. Argentina



End-to-End system – e.g. Europe



Step by step implementation



N: refers to the first date of compliance of a regulation

Government Think Thank

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

DEVELOPMENT REGULATORY REQUIREMENTS

Mr. Yehulu Denekew

Director General, Ethiopian Food, Medicine and Healthcare Administration and Control Authority

GS1 Healthcare Conference, Addis Ababa, May 2018

Initiating regulatory developments

Ethiopia's steps:

- Again, identify **challenges** and define **objectives**.
- Understand how the implementation of **traceability** could help achieve the objectives. Looking at **international developments** and countries with similar challenges helps!
- Find **support** and **experts**, also within your organization!
- Test the assumptions and receive feedback by:
  - **Engagement** and **training** of stakeholders.
  - Assessing stakeholder's **perception** on traceability and global standards.
  - Assessing stakeholder's **capabilities**.
  - Develop **pilots** to test the current **capabilities** (barcodes, technical infrastructure, etc.).

- Use all the knowledge to develop a strategic plan for the future, describing:
  - Again, challenges and objectives
  - Activities, roles, responsibilities, timelines
- **Be bold, but understand complexity of implementation!**

Ethiopia's efforts

- **Next step for Ethiopia: execution of the strategic plan, including:**
  - Keep stakeholders, including the government, engaged!
  - Develop a traceability office at the responsible governmental body
  - Actual implementation (see next slides):
    - Phase I: Strengthen environment for successful traceability implementation
    - Phase II: Implementation of traceability
    - During these phases:
      - Use of barcodes and (traceability) data to improve patient safety and efficiency.
      - Each phase provides benefits - having **quality barcodes** and **master data** is no traceability yet, but is still extremely important!

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

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

Phase II: implementation of traceability

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

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!

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***

Questions

- What are the biggest challenges for EFMHACA?
- What are the unique challenges for Ethiopia, compared to other countries?
- What approach should we take in order to achieve regulatory alignment?

What EFMHACA would like to hear from participants:

- What are other countries' experiences?
- How did you structure your governmental office working on implementation of traceability? Where did you find the expertise?

Thank you for your attention!

We remember GS1's words: "It's a marathon, not a sprint!"

African GS1 Healthcare Conference
Addis Ababa, Ethiopia

Nigerian Federal Ministry of Health Presentation to the International ThinkTank Session

BY
AJAYI OLUBUKOLA, B.Pharm,MSc,MFIP
Head,Drug and Vaccine Development Division
Department Food and Drug Services
Email: detopkeb@yhoo.com

Brief on Federal Ministry of Health, Nigeria

Established for the purpose of formulation and implementation of Federal Government policies on health matters.

The Ministry is headed by a Minister, appointed by the President, assisted by a Minister of State and a Permanent Secretary (A career civil servant)

Prof. Isaac Folorunsho Adewole is the current Minister

FMOH/NAFDAC Engagements with GS1

- Dates back to the Global GS1 Healthcare Conference in Dubai (2016), NAFDAC team led by the then Director-General, who was convinced that GS1 Standards will enhance the healthcare system in Nigeria to track and trace medicines and medical devices from the manufacturer to the patient, improve efficiency, safety, patient care. The same also applies to the Food sector with merely little modifications.
- A committee was immediately constituted and a follow-up meeting was fixed to be held in Nigeria. GS1 Nigeria and the committee drew a roadmap for the implementation. In summary, it consists of GS1 presentation to the TMC of NAFDAC, to various departments, sharing of pharmaceutical companies that were users of GS1 standards, drafting of MOU between GS1 and NAFDAC, but was not signed as it was advised to be re-routed to the Ministry of Health through the department of Food and Drugs Services under which NAFDAC is a regulatory agency.

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Progress so far (Cont)

1. GS1 Nigeria Commenced discussions with the Honourable Minister stating two major prayers:

- **The FMOH to lead a healthcare stakeholders workshop/conference for the purpose of introduction, adoption and implementation of global standards in the Nigerian healthcare sector.**
- **That consequently, the Minister to issue policy directives to the adoption and implementation of global standards.**

2. The Minister constituted a Technical Committee to develop a roadmap for possible implementation of global standards. The committee comprising of relevant FMOH departments, GS1 Nigeria, NAFDAC, SON, MAN, USAID & other key stakeholders.

Progress so far (Cond)

3. The committee headed by the Director of FDS directorate had a number of meetings which had the GS1 Senior Vice President in active participation..

4. GS1 Nigeria was also formally recognised by the Ministry of Health as an NGO in collaborative work efforts with the FMOH Nigeria following an application granted by the Department of Planning, Research and Statistics.

5. The committee has reached a conclusion to have the workshop with tentative dates and venue approved. However, funding was a challenge.

Strengths and challenges

STRENGTHS:

- **The approval of the technical committee.**
- **Attendance of officials from the Nigerian FMOH delegates to this conference.**
- **GS1 Nigeria partnering with the Nigerian Government**
- **A vibrant national supply chain management program in Nigeria.**
  - **Decentralized warehouse, logistics management coordination units across 36+1 states and in 774 LGA for data collation and transmission to the highest level for informed decision.** Managing an Automated Database of All Registered Products accessible on demand to designated Stakeholders.
  - Building of two big state of the art pharmaceutical grade warehouses at Abuja and Lagos with a modern Warehouse management system.
  - **Tracking Identifiers:**
    - **NAFDAC Reg. No (capturing NRN, BN, Manufacturing & Expiry Dates, etc), Truscan, Mobile Authentication System**
    - **CHALLENGES:**

- **Engagements of the stakeholders**

Next steps

- Engagement of wider healthcare supply chain stakeholders
- Development of a roadmap to implementation of GS1
- Mobilization of resources
- Collaborative System Building and Ownership

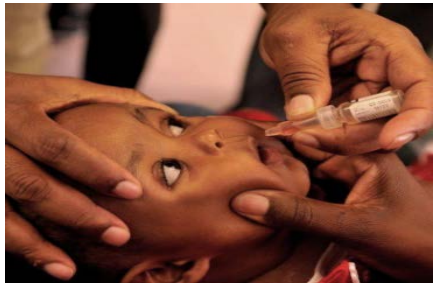
Conclusion

- When GS1 is adopted and implemented in Nigeria, the benefits are huge and would revolutionise the Nigerian healthcare system while cascading into other sectors where GS1 also supports.
- It would also be a effective platform by extension to cover the entire Sub-Saharan African regions.

- The continuous deliberate support of donor agencies will facilitate adoption and implementation.

THANK YOU

GS1 Healthcare Conference 2018
Addis Ababa, Ethiopia



Medicine Track & Traceability – Aligning with Global Frameworks

The South African Experience

Ms Ephodia Nyathi
Senior Pharmaceutical Policy Specialist
Affordable Medicines Directorate
National Department of Health – South Africa

9 May 2018

The South African Context

56.5 million

the population of South Africa

82%

% of people dependent on public health system

(46 million people)

+3,900

Healthcare establishments in the public sector

1,166

Medicines on contract with suppliers

4.2 million

Patients receiving treatment for HIV

$1.29 billion

Spent on medication in the last financial year (public sector)

Over 134 million

units of medicine delivered per annum

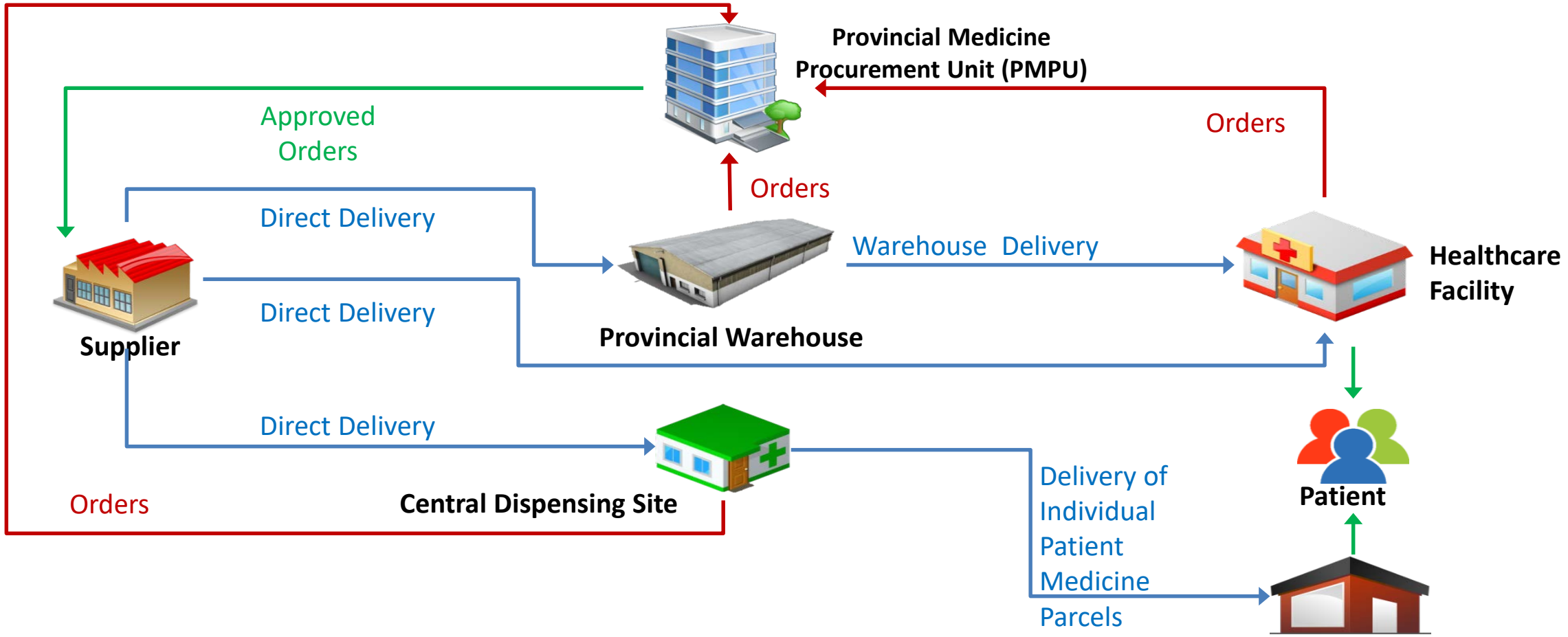
health

Department:
Health
REPUBLIC OF SOUTH AFRICA

Phila
Inspired to live

2030 NDP

Public Sector Supply Chain



*Pick-up-Points may exist within Healthcare Facilities

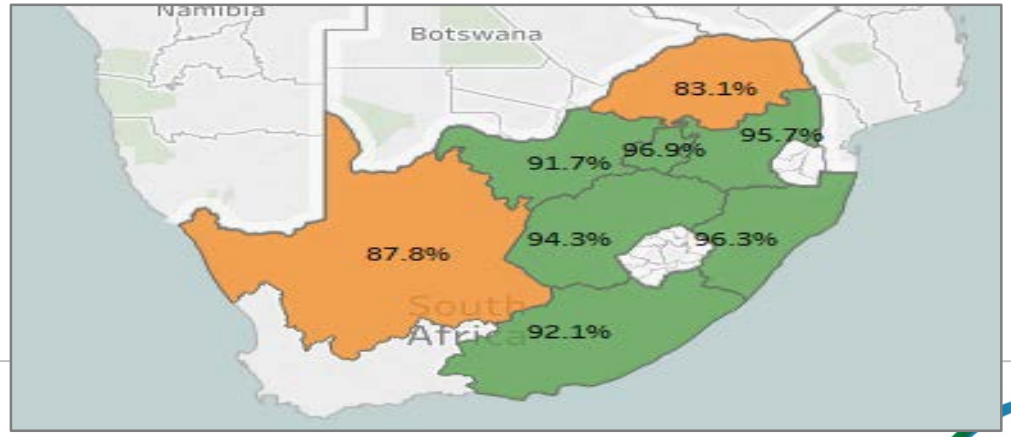
health
Department:
Health
REPUBLIC OF SOUTH AFRICA

A Global Challenge?

Patient safety, security of supply and ***medicine availability*** are of paramount importance within the health sector, and is critical to achieve the desired ***health outcomes.***

The aim is to ensure that the ***correct medicine*** of the ***correct quality*** is available at the ***correct location*** and in the ***correct quantity*** to satisfy ***patient needs***.

The success of this rests on the ability to ***uniquely identify medicines.***



Track & Traceability

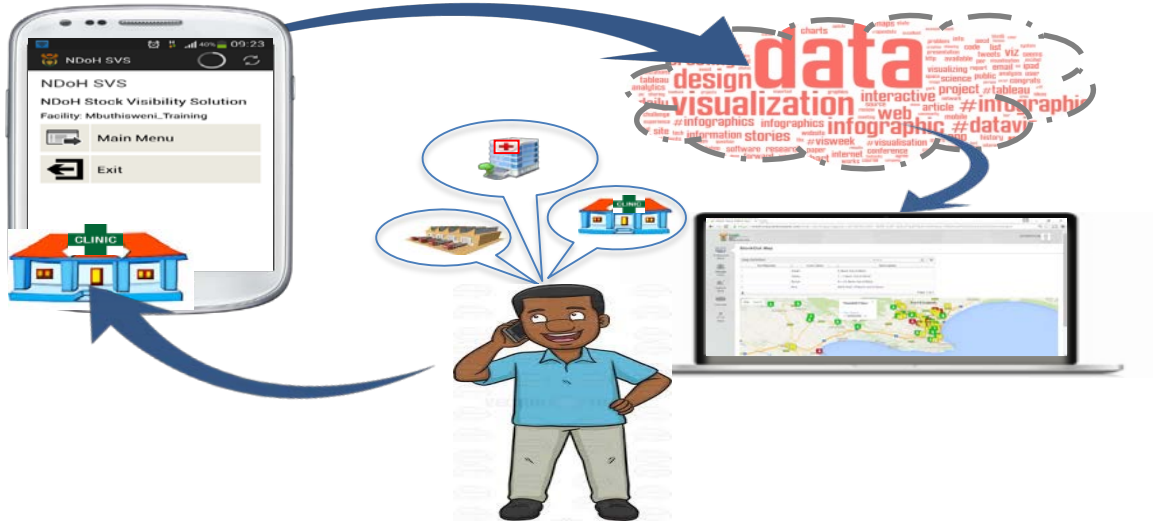
South Africa has therefore opted to improve ***track and traceability*** by:

- Improving ***efficiencies*** and ***reducing errors*** through scanning technologies
- Ensuring **supply chain security**
- Reducing ***wastage*** through batch and expiry control
- Improving ***inventory management***
- Enabling ***end-to-end supply chain visibility***
- Reducing the potential for ***fraud and corruption,*** and
- Increasing ***patient safety*** by avoiding the potential for counterfeit medicines.

NDOH Initiatives

Development of a ***master data repository*** based on single unique identifier per product.

Established a ***National Surveillance Centre (NSC)*** to monitor medicine availability across the country.



Stock Visibility System (SVS)

- A mobile and web-based ***management tool*** used at over ***3,100*** clinics.
- Uses ***barcode scanning*** to identify and then capture ***stock on hand***
- Data used to populate ***medicine availability dashboards*** and inform decision making

Aligning to Global Standards

- Changes have been made to the ***legislation w.r.t. labelling*** to support implementation
- ***Government Gazette published*** in September 2017 for stakeholder comment, detailing the proposed adoption and implementation of the GTIN and associated data matrix or barcodes.
- Changes made to the ***Special Conditions of Contract*** that govern the terms of contracting with the NDOH for the supply of medicines.
- Aligned with ***donor agencies*** including United States Agency for International Development (USAID) implementation of GS1 standards.

Current Legislative & future Contract Requirements

Regulations gazetted 25 August 2018 – Medicines and Related Substances Act (Act 101 of 1965) as amended:

LABELLING OF MEDICINES INTENDED FOR HUMAN USE

10 (1)….the immediate container of every medicine in which a medicine intended for administration to or use by humans is sold shall have a label attached to it on which the following particulars shall appear …..

(n) the lot number of the medicine;

(o) the expiry date of the medicine in a font size that makes it clearly visible;

(p) a barcode suitable for the identification and tracking of medication;

Special Conditions of Contract:

"It is mandatory that all products supplied must include a barcode (number plus symbology). All shipper, shelf and unit packs must be marked with the appropriate number and symbology. The European Article Numbering Code 13 (EAN 13) has been accepted as standard.

Suppliers are encouraged to include a 2D barcode or similar on their packaging that will include the following information:

- *Unique identifier (GTIN);*
- *Batch number;*
- *Expiry date."*

Proposed barcode standards

The NDOH has initiated processes to implement a ***product identification, labelling, and data exchange*** requirement for medicines procured in the public sector.

It is proposed that this will include:

- The use of the ***Global Trade Item Identification Number (GTIN™)*** for the unique identification of medicines, using the GS1 standards;
- The introduction of the ***data matrix or 128-linear barcodes*** on packing including the:
  - GTIN;
  - Batch or lot number;
  - Expiry date;
  - Item serial number.

(01) 07046261398572
(10) TEST5632
(17) 130331
(21) 19067811811

Proposed phased implementation

	Identifier	Phase 1	Phase 2	Phase 3
Tertiary Packaging Case/Shipper/Carton	GS1 Datamatrix GS1 128-Linear	(01) GTIN (10) Batch / Lot (17) Expiration date		(21) Serial Number
Secondary Packaging Multi-pack	GS1 Datamatrix GS1 128-Linear		(01) GTIN (10) Batch / Lot (17) Expiration date	(21) Serial Number
Secondary Packaging Multi-pack / Single-pack	GS1 Datamatrix		(01) GTIN (10) Batch / Lot (17) Expiration date	(21) Serial Number

Next Steps

- ***Finalise document*** for publication incorporating public comment and learnings from the GS1 conference

- ***Multi-stakeholder engagement*** including
  - Suppliers
  - Distributors
  - Public sector health establishments

- ***Implement changes*** to the Special Conditions of Contract

- Engage with the South African Health Products Regulatory Authority (SAHPRA) to develop a ***guidelines document*** to supplement the ***labelling regulations***

The future

Potential future initiatives

- Tracking and tracing throughout the supply chain with appropriate data interchanges and all information stored in a ***central repository***;
- Extending the requirements to incorporate ***the private sector***
- Extending the requirement to include ***medical related items including devices and surgical equipment;***
- Using data to improve the ***rational use of medicines*** and thereby improve patient safety while reducing overall cost of treatment.

In summary

South Africa has embarked on the journey ***to improve track and traceability*** of medicines and health commodities across the supply chain in an effort to improve***:***

- ***Security of supply;***
- ***Supply chain visibility;***
- ***Medicine availability, and***
- ***Patient Safety.***

KENYA MEDICAL SUPPLIES AUTHORITY

YOUR PARTNER IN HEALTHCARE

INTRODUCTION

KEMSA is a medical logistics management state corporation in the Republic of Kenya whose mandate is to Procure , Warehouse , Distribute medical commodities and offer supply chain solutions in the Kenyan health sector.

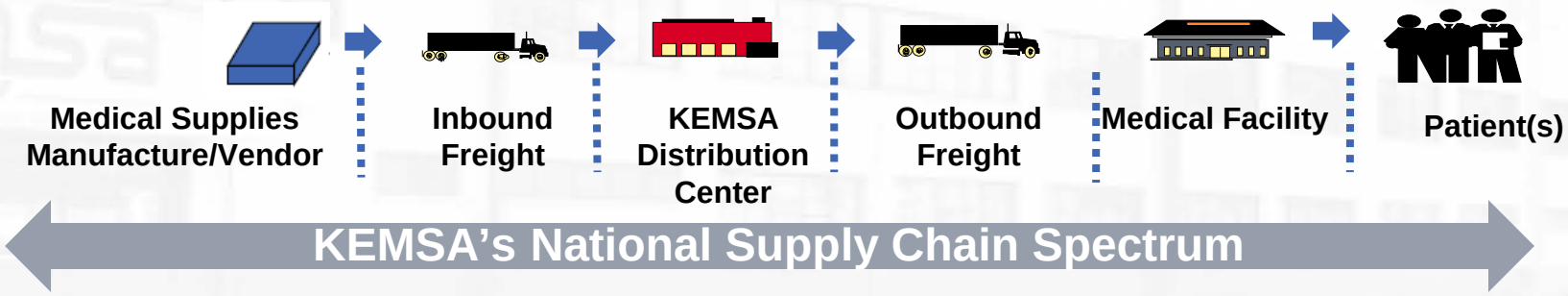
1. **PROCUREMENT**
2. **WAREHOUSING**
3. **DISTRIBUTION**
4. **SUPPLY CHAIN SERVICES**

Background

In line with its mandate, KEMSA has ensured ;

- High quality and cost effective supply of products at all the service delivery points/ health facilities
- Quality and Safety of products supplied guaranteed and thus patient safety.
- Quality ,value for Money supply chain services

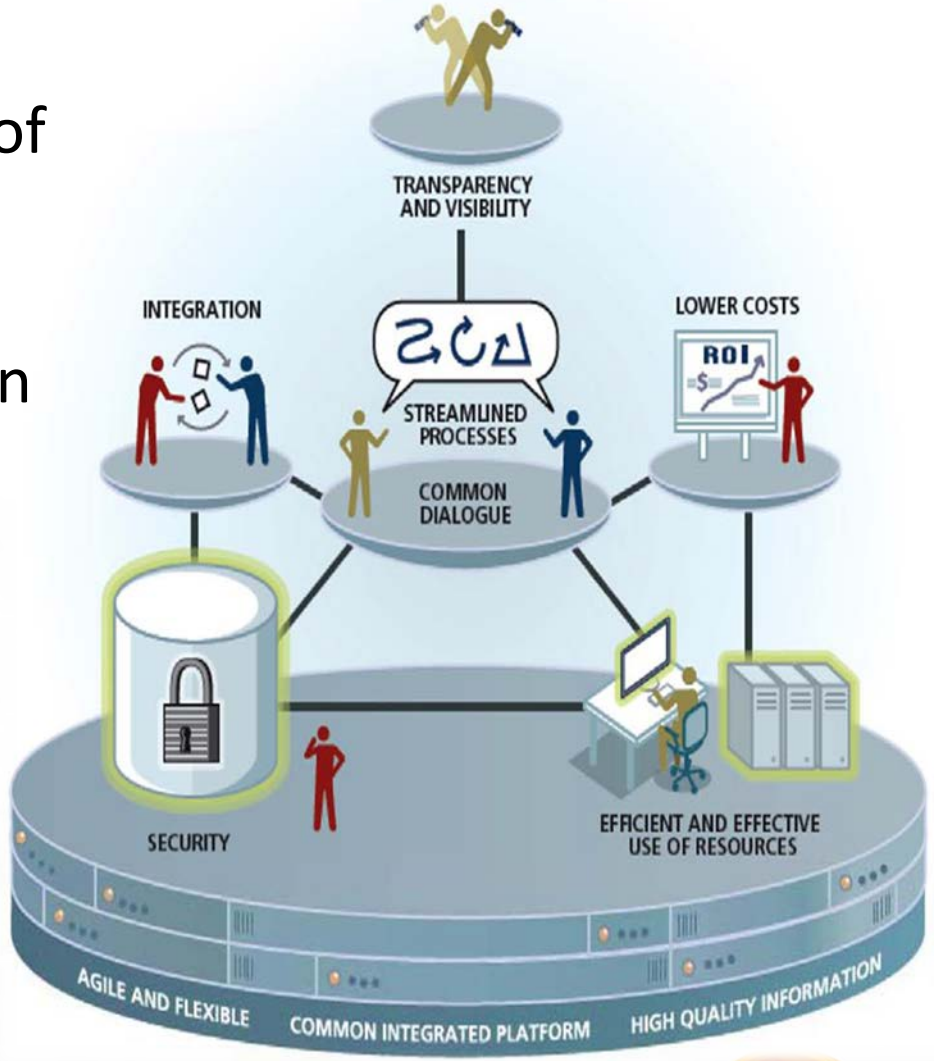
The Supply chain consists of flow of products, funds and information as shown below



LEVERAGE ON TECHNOLOGY

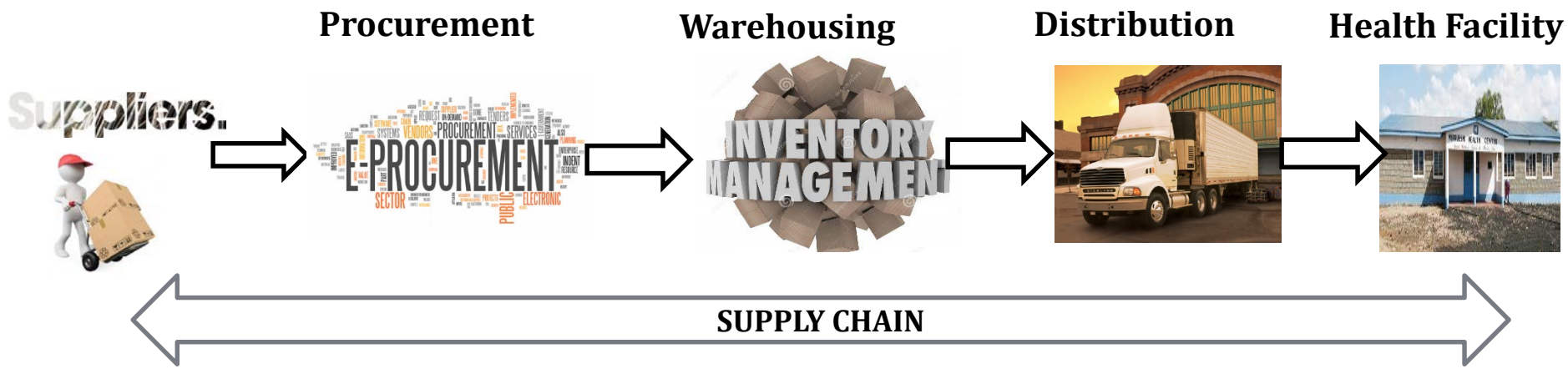
KEMSA has advanced innovations especially in the area of ICT. Some of the innovations include:

- All Business processes automated and integrated on an ERP platform to manage the whole supply chain
- Mobile applications
- E- tools: - self-service portal (LMIS)



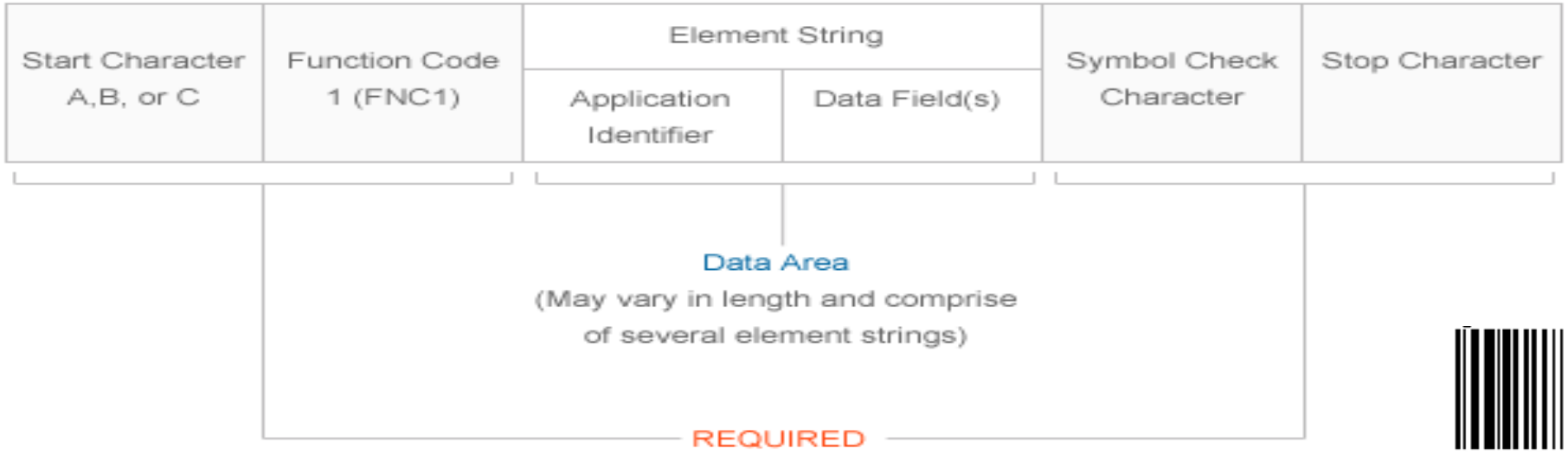
GS1 BARCODE IMPLEMENTATION

- Prior to adopting **G**lobal **S**tandards **1 (** GS1) barcode system, KEMSA was generating its own barcodes
- On 1st July 2014 KEMSA became a member of GS1 through GS1 Kenya
- KEMSA Signed contract with GS1 Kenya for training and implementation of GS1 barcode system
- KEMSA upgraded its ERP system and mobile application to align with the GS1 barcode requirements . All relevant staff were trained.
- GS1 is now a mandatory requirement in the tender documents.


Procurement
Warehousing
Distribution
Health Facility
Suppliers.
E-PROCUREMENT
INVENTORY MANAGEMENT
SUPPLY CHAIN

ENSURING EFFICIENCY AND TRACEABILITY THROUGH GS1 BARCODES

KEMSA has Adopted the GS1-128 Standard Structure



The GS1-128 barcode has the following:

Code 128 start character (START-A, START-B or START-C)

- Code 128 FNC1 character
- Application Identifier (AI)
- Encoded Data
- Symbol Check character
- Stop Character

Information in Barcode:-

- Product Code
- Expiry Date
- Batch

BENEFITS

The use of GS1 barcoding standards has provided KEMSA with the following benefits:

- Fast and accurate data capture at every point in the supply chain
- Traceability of medical commodities from supplier to the patient
- Less stock-holding and less waste
- Better control over distribution and storage
- Fewer errors in the recognition of goods
- Improved communications throughout the supply chain
- One standard for use with all trading partners, therefore no conflicting demands.

KEMSA
KENYA MEDICAL SUPPLIES AUTHORITY — YOUR PARTNER IN HEALTHCARE

STRATEGIC PARTNERS:

COUNTY GOVERNMENTS

REPUBLIC OF KENYA
MINISTRY OF HEALTH

USAID
FROM THE AMERICAN PEOPLE

The World Bank

HIRA

The Global Fund
To Fight AIDS, Tuberculosis and Malaria

DFID
Department for International Development

KENYANS AND AMERICANS IN PARTNERSHIP TO FIGHT HIV/AIDS

unicef

Danish International Development Agency
DANIDA

kfw

innovating to save lives
Jhpiego
an affiliate of Johns Hopkins University

AMREF
Better Health for Africa

CDC
CENTERS FOR DISEASE CONTROL AND PREVENTION

KOFIH

From the People of Japan

KENYA MEDICAL SUPPLIES AUTHORITY YOUR PARTNER IN HEALTHCARE

KENYA MEDICAL SUPPLIES AUTHORITY

YOUR PARTNER IN HEALTHCARE

Thank You

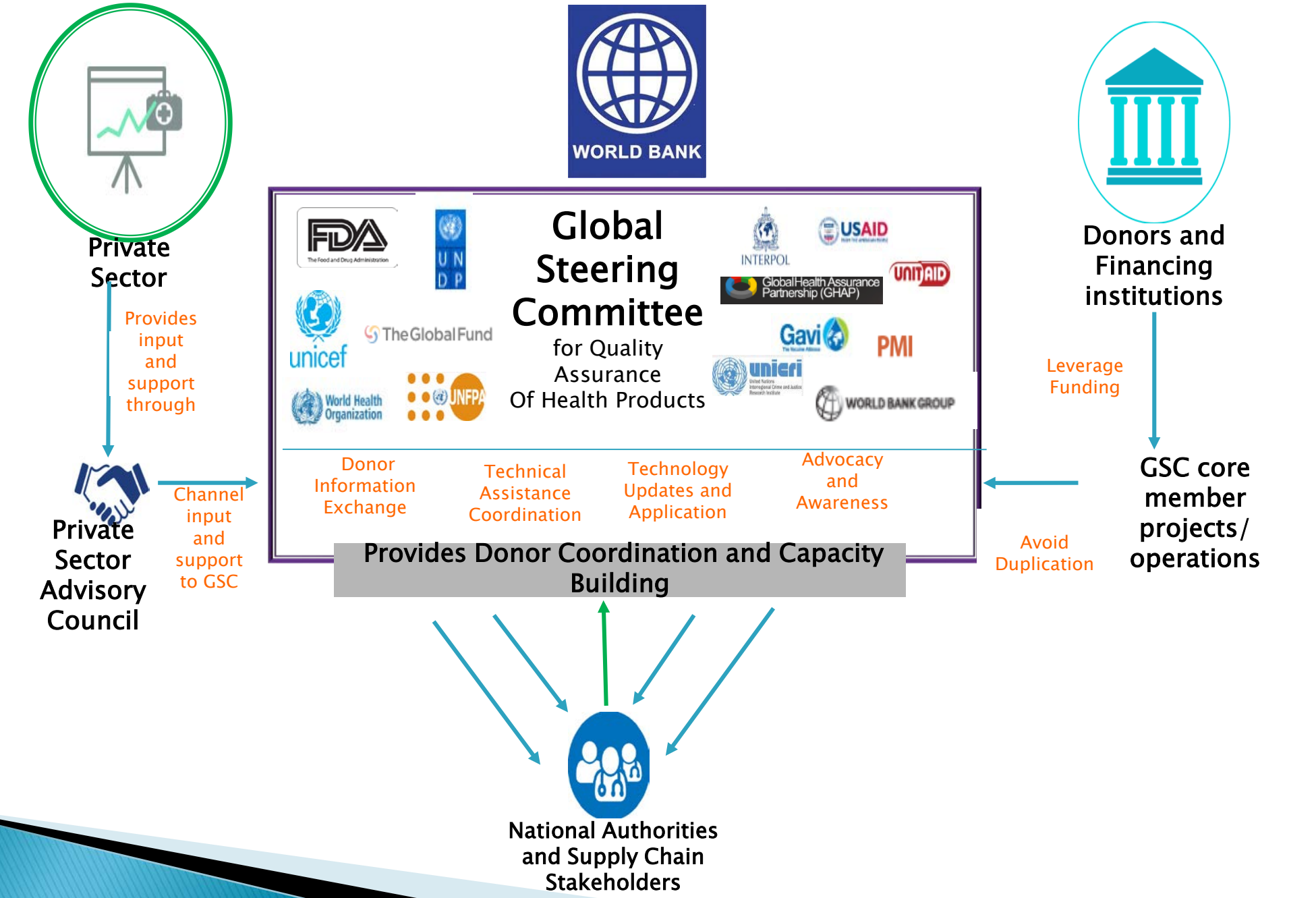
Your Partner in HealthCare

www.kemsa.co.ke

Email: info@kemsa.co.ke, sales@kemsa.co.ke kemsakenya @Kemsa_Kenya

Global Steering Committee for Quality Assurance of Health Products

A voluntary coalition of health development agencies working with the private sector to enhance supply chain integrity through health system strengthening


Private Sector
Provides input and support through
Private Sector Advisory Council
Channel input and support to GSC
WORLD BANK
Global Steering Committee
for Quality Assurance
Of Health Products
Donor Information Exchange
Technical Assistance Coordination
Technology Updates and Application
Advocacy and Awareness
Provides Donor Coordination and Capacity Building
National Authorities and Supply Chain Stakeholders
Donors and Financing institutions
Leverage Funding
GSC core member projects/ operations
Avoid Duplication

Creating Impact

- Awareness/Joint Learning – aid organizations share ideas and map solutions for internal use and in partnership with national authorities
- Coordination – GSC members exchange information with WHO, African Medicines Regulatory Harmonization (AMRH), leading regulatory agencies, Private Sector Initiatives, and high level political commitments
- Health Systems Strengthened – development institutions apply new information, technology, supply chain reform to achieve efficiency and integrity in their own programs and in coordination with national partners
- Communication – health procurement reforms engage manufacturers and help private sector providers tailor services to needs of development agencies
- Network Expansion – GSC and Privates Sector meet regularly and develop an ongoing collaborative network of supply chain, health development, and solution experts.

How Can the GSC Support You?

- Sustainable Regulatory Impact through health system strengthening

  - Track and Trace/Serialization – mapping a course for global standards
  - Market Surveillance – regular data collection for enforcement and measuring improvement
  - Field Detection and Forensics – technology application for rapid response, tailored needs, and laboratory strengthening
  - Policy, Regulatory, and Legal Frameworks – enforcement and prosecution to disrupt and shut down illicit behavior
  - Technical Capacity Building – national task force creation, investigative training, technology training and deployment, regulatory harmonization and cross border coordination

Connecting the Pieces…

- GSC members are health financing agencies dedicated to upstream and last mile supply chain integrity

- Health system strengthening is a core focus

- Strong regulatory systems are a global mandate and a shared responsibility

Thank You!

Tom Woods
Chairman
Global Steering Committee
twoods@worldbank.org

Contribution from the US FDA

Leigh Verbois, Associate Commissioner for International Programs, US FDA, U.S.A.

Next steps …

Many achievements and benefits – e.g. Turkey

- Safe medicines, prevents counterfeiting
- Prevents resale of medicine
- Expedites recalling of medicine
- Prevents sale of expired medicine
- Preventing drug shortages
- Quality data for insurances
- Provides statistics to develop policies on Rational Medicine Use
- Enables pharmacovigilance and strategic planning

Closing remarks

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Géraldine Lissalde-Bonnet
GS1 Global Office
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Take away

- Have a better understanding of traceability (e.g. drivers, approaches)
- Understand the benefits of working with stakeholders for regional/local harmonisation
- Understand good practices for traceability systems around the world
- Understand the need for a phased development of a national traceability project and its implementation
- Understand the benefits of using global data standards
- Align on what next steps could be