



### **Nuran Idris**

### Manager, Healthcare Africa, GS1 Global Office





Nuran joined the GS1 global office in January 2020. Her primary responsibility within the Healthcare team is to promote the awareness of GS1 global standards and assist African countries in implementing pharmaceutical traceability using these standards.

With over 10 years of experience in healthcare digitalization and recently in global standards, Nuran is a dedicated collaborator and a strong advocate for harmonization across Africa. She firmly believes that the adoption of standards can lead to greater efficiencies and significantly improved patient care.

Nuran holds qualifications as a Political Scientist and a global eHealth specialist.



### **Nelson John Uyirwoth**

### Team Leader Industrial Engagement | GS1 Kenya





Nelson John Uyirwoth has been with GS1 Kenya for the past seven years and currently serves as the Team Leader for Industrial Engagement. In this role, he is responsible for promoting and supporting the adoption of GS1 Standards and solutions across key sectors of the Kenyan supply chain, including Healthcare, Construction, Academia, and Transport & Logistics.

He collaborates closely with major stakeholders through capacity-building programs and awareness initiatives aimed at enhancing supply chain efficiency, traceability, and interoperability. Nelson brings a wealth of experience in the technical implementation of GS1 Standards and has led or contributed to numerous projects supporting their integration across diverse industries.

Nelson is a scholar in Information Technology and Business Administration, with a strong foundation in applying supply chain traceability.



## Agenda



- What is track & trace, serialisation
- What is GS1
- A close look at the GS1 DataMatrix
- Building blocks of traceability
- How much entry point (Cost)
- Not a burden concern of vendors, vendor driven initiatives

The Global Language of Business

Map of regional developments



### Counterfeit medicines are everywhere:



2025	2024	2023	2022
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14 May 2025 | Medical product alert

Medical Product Alert N°3/2025: Falsified IMFINZI (durvalumab) injection 500mg/10ml

23 April 2025 | Medical product alert

Medical Product Alert N°2/2025: Falsified HEALMOXY (Amoxicillin) Capsules 500mg

31 March 2025 | Medical product alert

WHO information notice for users of malaria IVDs 2025/1

12 March 2025 | Medical product alert

Medical Product Alert N°1/2025: Falsified (contaminated) OXYCONTIN 80mg 23 December 2024 | Medical product alert

Medical Product Alert N°5/2024: Falsified IMFINZI (durvalumab) injection 500mg /10ml

10 October 2024 | Medical product alert

Medical Product Alert N°4/2024: Falsified USP/EP PROPYLENE GLYCOL

5 August 2024 | Medical product alert

Medical Product Alert N°3/2024: Falsified (contaminated) Oxymorphone Hydrochloride 40mg

19 June 2024 | Medical product alert

Medical Product Alert N°2/2024: Falsified OZEMPIC (semaglutide) 7 December 2023 | Medical product alert

Medical Product Alert N°8/2023: Substandard (contaminated) syrup and suspension medicines

4 September 2023 | Medical product alert

Medical Product Alert N°7/2023: Falsified DEFITELIO (defibrotide)

7 August 2023 | Medical product alert

Medical Product Alert N°6/2023: Substandard (contaminated) syrup medicines

19 July 2023 | Medical product alert

Medical Product Alert N°5/2023: Substandard (contaminated) syrup medicines 27 December 2022 | Medical product alert

Medical Product Alert N°8/2022: Substandard (contaminated) METHOTREX 50mg

2 November 2022 | Medical product alert

Medical Product Alert N°7/2022: Substandard (contaminated) paediatric liquid dosage medici...

5 October 2022 | Medical product alert

Medical Product Alert N°6/2022: Substandard (contaminated) paediatric medicines

25 August 2022 | Medical product alert

Medical Product Alert N°5/2022: DIPRIVAN



# How global standards strengthen supply chains





Data quality visibility and insights



Reduced time and costs to gather and verify data



Easy access to product data





Better brand and counterfeit protection

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Improved patient safety and care outcomes



### So, are there any benefits?



- Ensuring only authorized products, registered or approved, circulate in the legal supply chain
- Preventing the distribution and/or dispensing of falsified, expired, prohibited or recalled products
- 3. Facilitating efficient and fast product recalls
- 4. Improved visibility in the supply chain enabling multiple opportunities including facilitating real-time monitoring, enhancing quantification & forecasting capabilities
- 5. Identifying shortages and monitoring the reasons for shortages and stockouts.

**Source:** WHO Policy Paper on traceability <a href="https://www.who.int/publications/i/item/policy-paper-on-traceability-of-medical-products">https://www.who.int/publications/i/item/policy-paper-on-traceability-of-medical-products</a>



### GS1 – the global language of business



Global Organisation

- SDO , Standard Development Organisation
- NGO, Non-Governmental Organisation





NATIONS UNIES

DEPARTMENT OF ECONOMIC AND SOCIAL AFFAIRS

Office for ECOSOC Support and Coordination - NGO Branch

DC1-1480, 1 UN PLAZA, NEW YORK, N.Y. 10017

Tel: (212) 963-8652 • Fax: (212) 963-9248 www.un.org/ecosoc/ngo

1 August 2011

Dear NGO Representative,

I am pleased to inform you that the Economic and Social Council (ECOSOC) at its Substantive Session of July 2011 adopted the recommendation of the Committee on Non-Governmental Organizations (NGOs) to grant Special consultative status to your organization (SGS)". On behalf of all staff of the Non-Governmental Organizations Branch, please accept our heartfelt congratulations.

Consultative status for an organization enables it to actively engage with ECOSOC and its subsidiary bodies, as well as with the United Nations Secretariat, programmes, fitnds and agencies in a number of ways. In order to better understand this relationship, we take this opportunity to provide some critical information about the privileges that consultative status with ECOSOC confers on your organization, as well as the obligations that your organization will be required to meet under this relationship. We therefore urge you to take the time to carefully review the information we have provided below.



# GS1 is a global organisation



155 Neutral & Not for **Local Organisations** profit Countries User driven Billion barcodes scaned per Million compagnies day members of GS1 Global Local 2 500 Inclusive & Collaborative Staff worlwide



### GS1 is both global and local





#### **GS1 Global Office**

Identification, creation, development and maintenance of standards and our foundational architecture, coordination with other international bodies, development of training programmes...

### **GS1** Member Organisations

Local offices in 120 countries around the globe. Implementation of standards, local regulatory adjustments, community management and relationship management with government, local stakeholders, regulatory agencies...



### The GS1 Standards















### What is traceability?



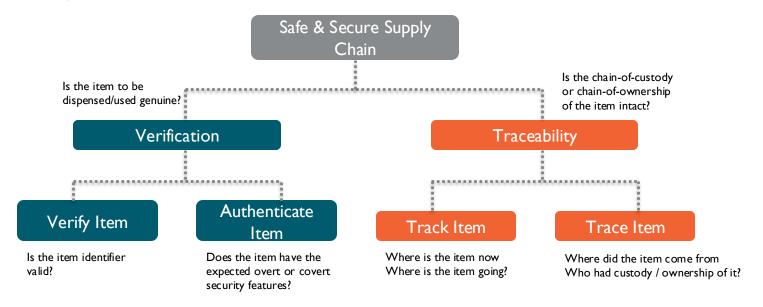
- "Traceability is the ability to track froward the movement through specified stage(s) of the extended supply chain and trace backward history, application or location of that which is under consideration".
- Fundamental to traceability: in parallel with the flow of product there has to be a flow of information about the product.



### Verification vs Track & Trace



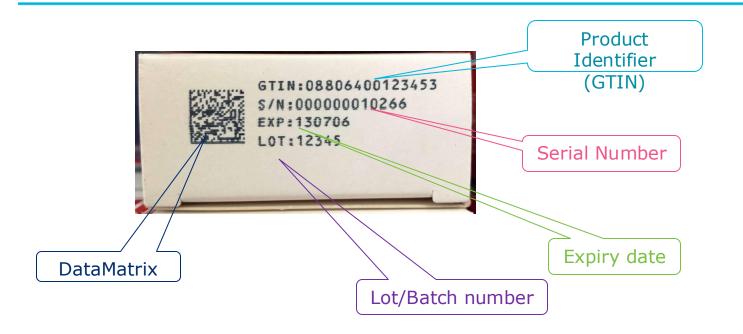
- Can the product identification features be verified?
- Can the product be tracked to where it is or traced from where it has been?





### Harmonising behind the GS1 DataMatrix





- 1. Referenced by WHO in 2021 policy paper: https://www.who.int/publications/i/item/policy-paper-on-traceability-of-medical-products
- 2. GS1 Position paper deep dive on GS1 DataMatrix: https://www.gs1.org/sites/default/files/gs1\_datamatrix-final\_approved.pdf



### Why use the GS1 DataMatrix?

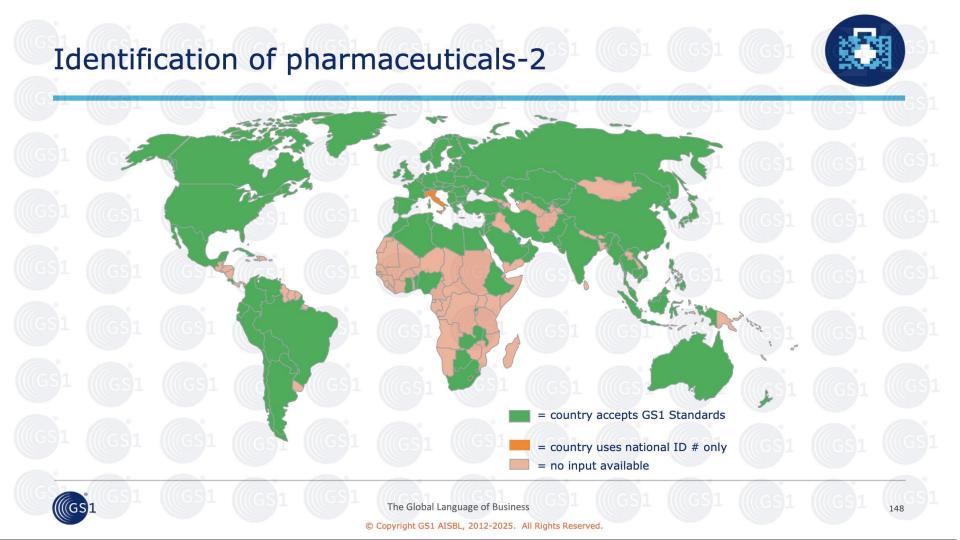


 Today, regulators from over 70 countries are systematically requesting for 4 data elements included in a standardised barcode type – GS1 DataMatrix

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- This enables harmonisation on the asks from the manufacturers/distributors.
- Actual implementation varies vastly from country to country









# **Regulation** as the primary building block

■ Regulation

Regulation DRAFT

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# Some cost Elements for Health Product Standardization Implementation\*



#### 1. Hardware & Software:

- System Upgrades, Integration & Development
- Master Data Management (MDM) Setup
- o Data Cleansing & Migration
- Scanners, printers, verifiers etc.

#### 2. Process enhancements

- Training & Capacity Building
- Change Management & Stakeholder Engagement
- Monitoring, Evaluation & Continuous Improvement

#### 3. Labelling & Packaging

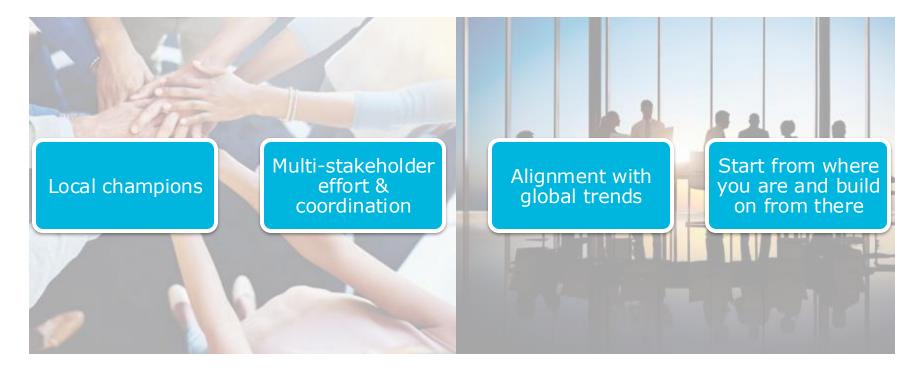
- Procurement and set up
- Definition of requirements & setting up compliance mechanisms

\*NB: A full set of cost items can be established after reviewing the existing capabilities and defining the vision



### What are some common learnings?







## GS1 Kenya | Supporting Stakeholders











**Training** 



**Collaborations** 



### What are these barcode types?



# Option 1



# Option 2





### Interested to learn more? Please reach out!





**Manager Healthcare Africa, GS1 Global Office** 

E <u>nuran.idris@gs1.org</u>

W gs1.org/healthcare

### **Nelson John Uyirwoth**

**Team Lead Industrial Engagement, GS1 Kenya** 

E nelson@gs1kenya.org / info@gs1kenya.org

W ww.gs1kenya.org



# Questions & answers!!







### Three key resources & 2 videos





https://www.who.int/public ations/i/item/policy-paperon-traceability-of-medicalproducts



https://iris.who.int/bitstrea m/handle/10665/380837/9 789240103535eng.pdf?sequence=1



https://www.gs1.org/docs/ healthcare/positionpapers/GS1-DataMatrix-Position-Paper-FINAL.pdf



https://youtu.be/6lSGMQEXoIg? si=4irpjl3whSEefe3Q



https://youtu.be/Rwre5x8a1nA? si=1eFqvmHBNSH4S9dS



#### Healthcare

# Turkish Pharmaceutical Track and Trace System (ITS)

ITS was the first successful application of a "Pharmaceutical Track and Trace System" in the world and is designed to track the location of every drug unit to ensure the reliable supply of drugs to patients.

#### Challenge

To ensure and guarantee the reliable supply of legitimate drugs to patients in Turkey. Like most countries, this supply was put at risk by illegal activities that could seriously impact public health and safety.

#### **Approach**

Turkey developed a Pharmaceutical Track and Trace System and built a centralised repository to monitor drug movement throughout the supply chain. With this central management system in place, the ITS can track and trace a drug from the point of manufacture to the point of dispense by leveraging GS1 identification keys, attributes and barcodes.

#### **Results**



Reliable and safe supply of drugs to patients Enhanced
ability to combat
illicit drug sales,
barcode scams
and theft



More than

45
million

through ITS

L

Response time is 0.02 seconds per transaction



Sophisticated and efficient recall management

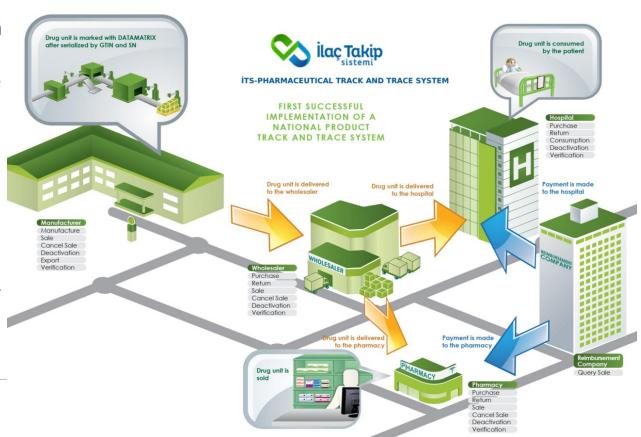


# Turkey: Track & Trace – actions connected to a central database



Communication with a central database is critical throughout the movement of the product

Watch an illustrative video: <a href="https://youtu.be/6ISG">https://youtu.be/6ISG</a>
MQEXoIg?si=iMsqoYQ



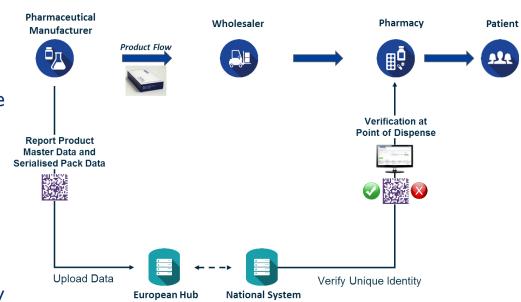


XkICQhid-

## EU: **Verify** before dispensing



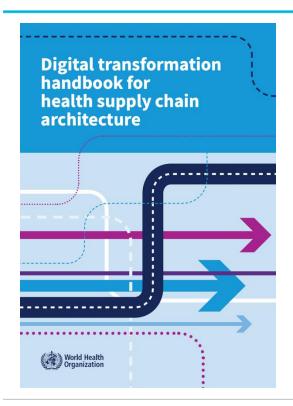
- The manufacturer has to register product data to the EU HUB.
- Each product has to be identified by the manufacturer using a unique identifier harmonized across the EU.
- The dispenser to verify the product registered in the HUB before dispensing
- Dispenser is obligated to report any suspicion of falsified medicines.





### Broad focus on digital transformation





 Implementation of tools and technologies to digitally transform the health supply chain cannot happen in isolation.

https://www.who.int/publications/i/item/978924010119

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