Track & Trace

A global context and UNICEF Activities
Some of the traceability related challenges in the end to end immunization supply chain
Countries with track and trace legislation in place
Developments in Public Health Supply Chains

• Global development partners are on a drive to improve supply chain security & efficiency for health commodities distributed in developing countries

• Harmonized global data standards for product and location identification, data capture and exchange have been identified as the foundation to bring about supply chain security and efficiency.

• Global partners have now developed harmonized guidance to act as a reference document for suppliers and partners on data standards for track and trace.

• The harmonized global guidance will be reviewed annually and UNICEF will make its contributions after completion of the GS1 impact evaluation study.

Track & Trace as a solution

- Track and Trace systems enable the traceability/visibility of products from origin through various distribution processes down to patient
- Regulatory Authorities have identified traceability systems as key tools to fight against falsification and illicit distribution of medical products
- Countries have the responsibility to issue traceability regulations and many are at different stages of implementation or consideration
- Countries may implement national track and trace systems for their own purposes that may not be inter-operable
- GS1 and other global standards provide opportunities for inter-operability and the global sharing of data
Developments in Public Health Supply Chains

The broad objectives of global development partners are to;

i. Enable end-to-end data visibility through globally unique item and location identification;

ii. Facilitate increasingly mature master data management practices, which create opportunities for improved systems interoperability;

iii. Identify and implement supply chain efficiencies through use of automatic identification and data capture (AIDC) (e.g., barcode) technology across donors, procurement agencies, and donor-supported country supply chains;

iv. Ensure supply chain security through chain-of-ownership or chain-of-custody product management that identifies risk and incident of product loss, expiry, and diversion; and

v. Increase patient safety through use of serialization to enable improved controls against substandard, spurious, falsified labelling and counterfeit medicines.
Timeline on traceability initiatives and way forward

- **2013**
  - VPPAG recommended introduction of barcodes on vaccines
  - VVPAG barcoding survey with 15 vaccine manufacturer

- **2014**
  - WHO revised guideline* incl:
    - GS1 compliant barcodes on secondary & tertiary levels as preferred characteristics
    - GS1 barcoding possibly mandatory for new product submissions to PQT.

- **2015**
  - UNICEF SD includes GS1 barcoding as preferred product characteristics on secondary & tertiary packaging, while it is not applied as evaluation criteria.

- **Q2 2019**
  - UNICEF SD conducts Supply base Survey on status of GS1 barcoding/standards adoption

- **Q3 2019**
  - UNICEF SD issues RFP to conduct a comprehensive impact evaluation of GS1 adoption on global operations, supply chains and markets

- **Q4 2019**
  - UNICEF SD will commission GS1 Impact Evaluation Study
  - WHO expected to issue a policy position on track and trace
  - GAVI Alliance issues statement outlining new requirements for GS1 standards compliance for vaccines it funds.

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Q3 2019
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- WHO establishes Expert Review Committee for track and trace
- Global Standards Technical Implementation Guidelines Issued

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National governments determine the scope of a traceability system.

SCOPE OF TRACK AND TRACE SYSTEMS

- **Primary Level**
  - (Box of primary containers)
  - Low Cost & Complexity

- **Secondary Level**
  - (Box of primary containers)
  - Moderate Cost & Complexity

- **Tertiary Level**
  - (Pallet and or shipping unit)
  - High Cost & Complexity

UNICEF Requirements
Gavi Alliance announcement on GS1

https://www.unicef.org/supply/index_103734.html
UNICEF Impact Evaluation Study

1. Impact on Vaccines

- Is there a potential change in the cost of vaccines UNICEF procures as a result of mandatory GS1 barcode requirements?
- Are the potential market access risks for vaccines procured by UNICEF (manufacturing and delivery lead-times etc.)?
- Impact on freight data exchange via existing links and technologies?

2. Cost Benefit Analysis

- High level determination of initial affordability and long-term cost of ownership by national governments in LIC/MIC

3. Review of internal ERP system, processes and catalogues

- UNICEF VISION ERP system, material master data, processes and transactions.
- Explore potential use cases for GS1 standards/technologies across UNICEF’s product categories
Role of Manufacturers in the UNICEF Impact Evaluation Study

• Facilitating interviews requested by UNICEF appointed consulting firm
• Completing questionnaires
• Providing related information
Thank You!