WHO guidance on traceability of medical products

World Health Organization

Global supply chain security of medical products

11 March 2021

Anita SANDS Substandard/Falsified Medical Products Team | Medicines and Health Products Division

Traceability systems

Opportunities

- Prevent entry of falsified medical products into regulated supply chains
- Detects falsified medical products
- Identifies risk of degradation leading to substandard products
- Better patient safety through increased capacity for market recalls/withdrawals, particularly for substandard products
- Improved supply chain efficiency by minimizing wastage and mitigating shortages

Challenges

- Requires resource investment (financial, human, technology)
- Inter-operability between countries and systems
- Data security
- Sustainability

Use cases

1. Prevent, detect and respond to substandard and falsified medical products
2. Corrective action through market recalls
3. Maintaining supply chain integrity

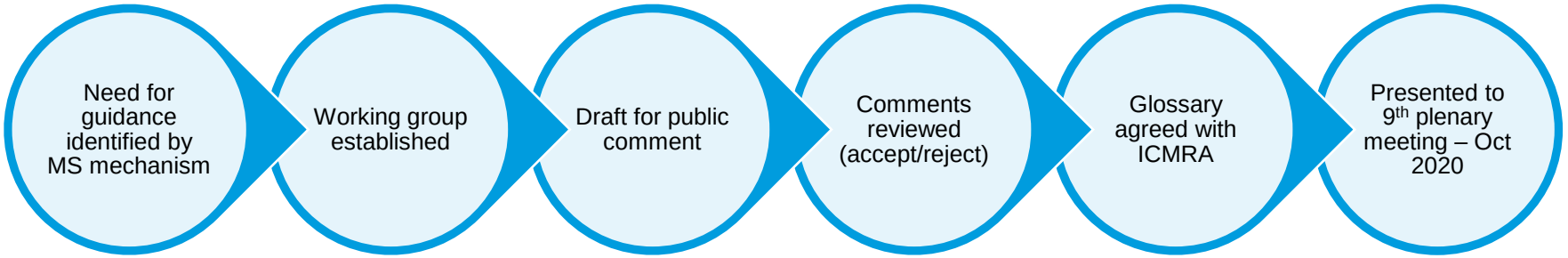
Pharmacovigilance and product reimbursement

Source: Policy paper on traceability of medical products. Geneva: World Health Organization; 2021. Licence: CC BY-NC-SA 3.0 IGO.

WHO guidance development process

WHO Member State mechanism on substandard and falsified medical products

The goal of the **WHO Member State mechanism on substandard and falsified medical products** is to **protect public health** and promote **access to affordable, safe, efficacious, and quality medical products**, and to promote through **effective collaboration among Member States** and the Secretariat, the prevention and control of substandard and falsified medical products and associated activities.



Designated NRA focal points must be informed of substandard/falsified medical products identified as a result of national traceability systems

Source: The WHO Member State Mechanism on Substandard and Falsified Medical Products How WHO Member States work together to safeguard access to safe and effective medicines, vaccines and other medical products WHO/MVP/EMP/SAV/2019.04 © World Health Organization 2019. Some rights reserved. This work is available under the CC BY-NC-SA 3.0 IGO licence

Regulatory collaboration

International Coalition of Medicines Regulatory Authorities (ICMRA)

- Joint ICMRA – Industry Working Group was established to ensure multi-stakeholder approach
- ICMRA developed a paper with recommendations on common technical denominators for track and trace systems
- Aims to facilitate the implementation of interoperable systems for medicines
- Collaboration between ICMRA and WHO Member State mechanism to ensure common understanding of terminology (i.e. shared glossary) and information sharing of country/regional experiences
- WHO and ICMRA documents are complementary

Key points of the guidance

- **Scope**
  - Pharmaceutical products, including medicines and vaccines, as finished products
  - In the supply chain from the point of manufacture to receipt by the dispenser (e.g. pharmacist) or administrator (e.g. hospital or clinic).

Suggests Member States should:

1. Establish **governance** for the traceability system
2. Include a **costing** analysis and **sustainability** mechanism
3. Use of **global standards** for product identification, production identification, automatic identification, and data capture and data exchange

Source: Policy paper on traceability of medical products. Geneva: World Health Organization; 2021. Licence: CC BY-NC-SA 3.0 IGO.

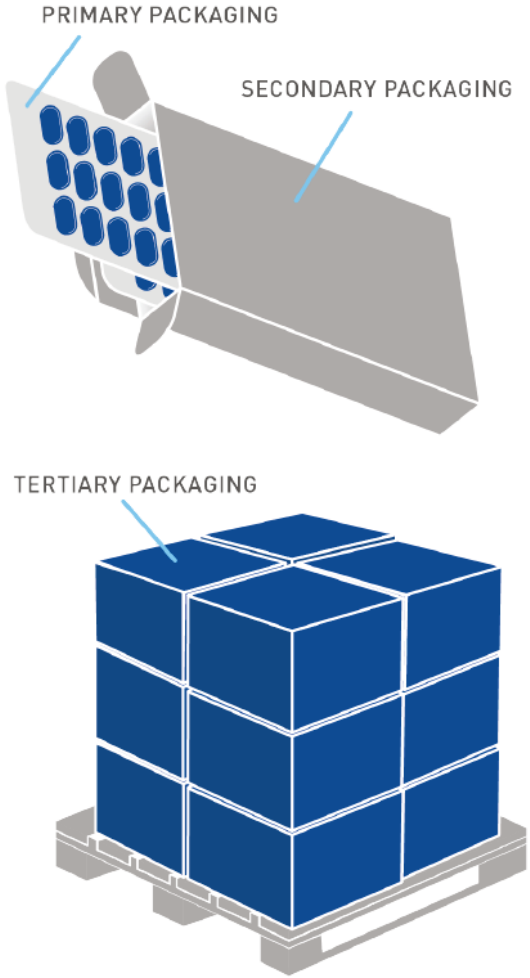
Features of a traceability system

1. Identification of product, stakeholder, production and location
2. Use of global standards
3. Batch/lot-level traceability
4. Unit-level serialization
5. Aggregation data
6. Verification
7. Full track and trace vs point of dispense verification
8. Patient verification
9. Detection and response, including reporting

Source: Policy paper on traceability of medical products. Geneva: World Health Organization; 2021. Licence: CC BY-NC-SA 3.0 IGO.

Unit-level serialization

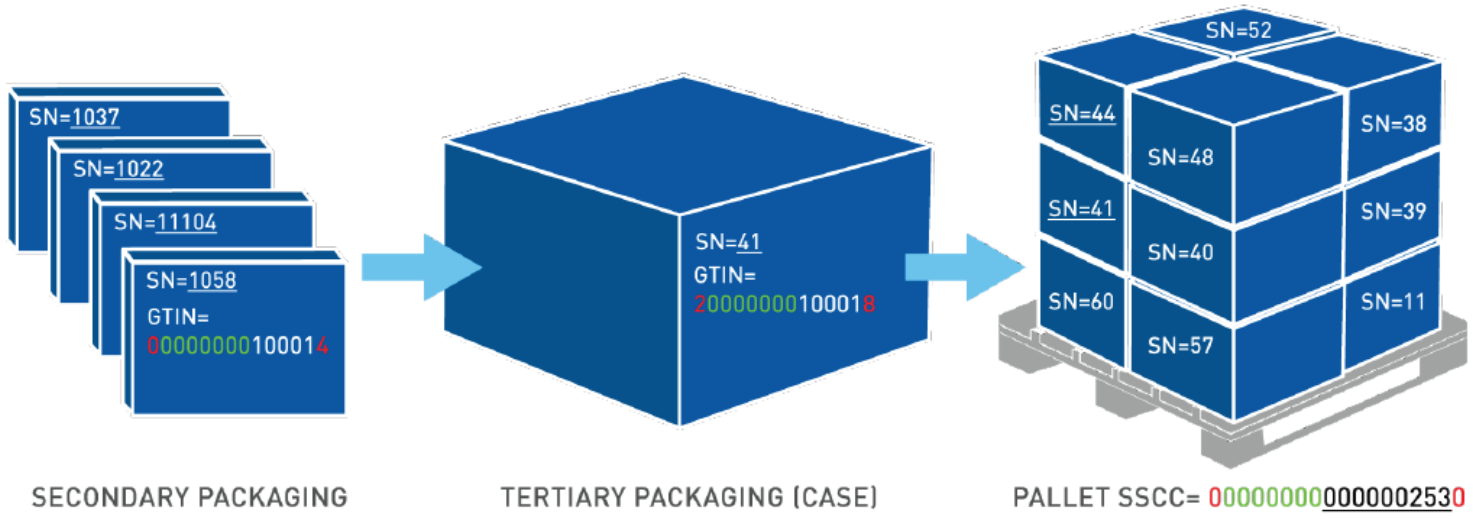
- Unique serial number in combination with a product code on every saleable unit
- Likely to be more costly
  - For manufacturers (changes to production processes)
  - For other economic operators (reading product identifiers, managing data)
- But benefits are great for consumers and regulators
- Automatic identification and data capture (AIDC)
  - Bar code, QR code, RFID
- Ensure measures to prevent falsification of unique identifiers



Source: Policy paper on traceability of medical products. Geneva: World Health Organization; 2021. Licence: CC BY-NC-SA 3.0 IGO.

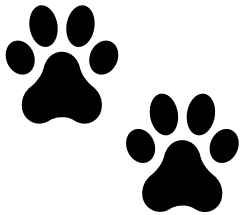
Aggregation data

- Aggregation data is valuable when multiple levels of packaging (secondary, tertiary, pallet) are serialized
- Summarizes the parent-child relationships between serialized containers (the “parents”) and the serialized units inside the containers (the “children”)
- Implementing unit-level serialization without aggregation data requirements can be counter-productive



Source: Policy paper on traceability of medical products. Geneva: World Health Organization; 2021. Licence: CC BY-NC-SA 3.0 IGO.

Full track and trace vs. verification



- **Track** – where is the product right now
- **Trace** – where has the product been with the supply chain prior to now

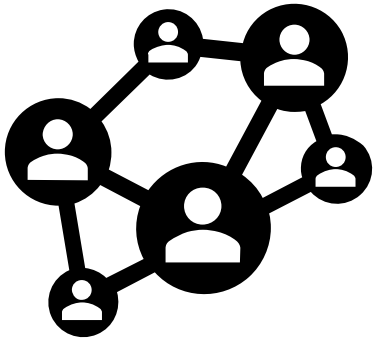
- **Full track and trace** where medical products are verified for each change of ownership in the supply chain
  - Aims to detect falsified medical product more quickly (as they enter the supply chain), can be more costly

- **Point of dispense verification** where medical products are verified only at the end point of dispense or use/administration
  - Aims to protect patients from harm while minimizing costs
- **Patient verification** where patient sends a SMS or photo of a unique identifier on the medical product for verification against data held in a central repository
  - Not to be implemented as stand-alone solution

Source: Policy paper on traceability of medical products. Geneva: World Health Organization; 2021. Licence: CC BY-NC-SA 3.0 IGO.

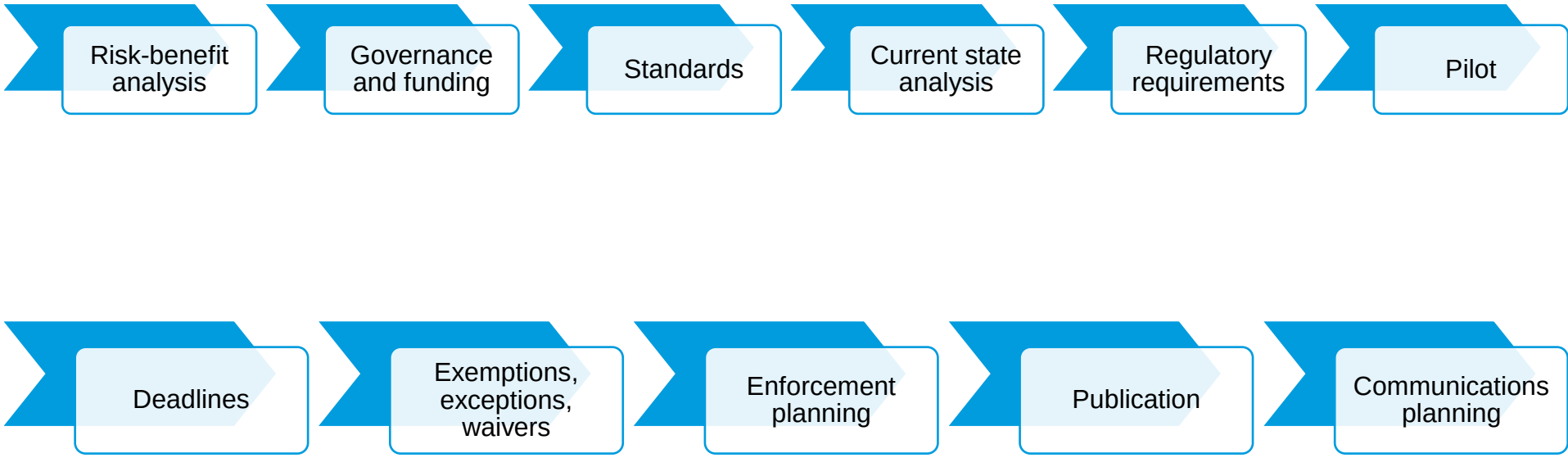
Detection and response

- Trained NRA focal points should carry out the following activities:
  - Respond to incidents of substandard/falsified medical products detected, and authentication or verification failures
  - Support users to quarantine/store suspected product
  - Issue rapid product alerts or notifications for increased surveillance
  - Ensure retrieval of evidence to be used for enforcement purposes
  - Report incidents to the WHO Global Surveillance and Monitoring System and ensure coordination with regional networks
  - Participate in the WHO Member State mechanism on substandard and falsified medical products



Source: Policy paper on traceability of medical products. Geneva: World Health Organization; 2021. Licence: CC BY-NC-SA 3.0 IGO.

Developing a traceability system



Source: Policy paper on traceability of medical products. Geneva: World Health Organization; 2021. Licence: CC BY-NC-SA 3.0 IGO.

Case studies – COVID-19 vaccines

Reporting to Global Surveillance & Monitoring System

With the deployment of COVID-19 vaccines, increased reports to WHO Global Surveillance and Monitoring System for falsified vaccines

- 20 reported incidents in 14 countries concerning COVID-19 medical products
- 59 reported suspect products - of which 11 SF COVID-19 vaccines

Emerging Risks: the following factors heighten the likelihood of SF COVID-19 Vaccines in the regulated supply chain

- Corruption and diversion of vaccines
- Fraudulent offers to supply COVID-19 vaccines targeting Ministries of Health/Immunization programs
- Improper disposal of empty vials resulting in refilling and use for falsified vaccines

Report any suspicious products to rapidalert@who.int

Source: WHO Global Surveillance and Monitoring System

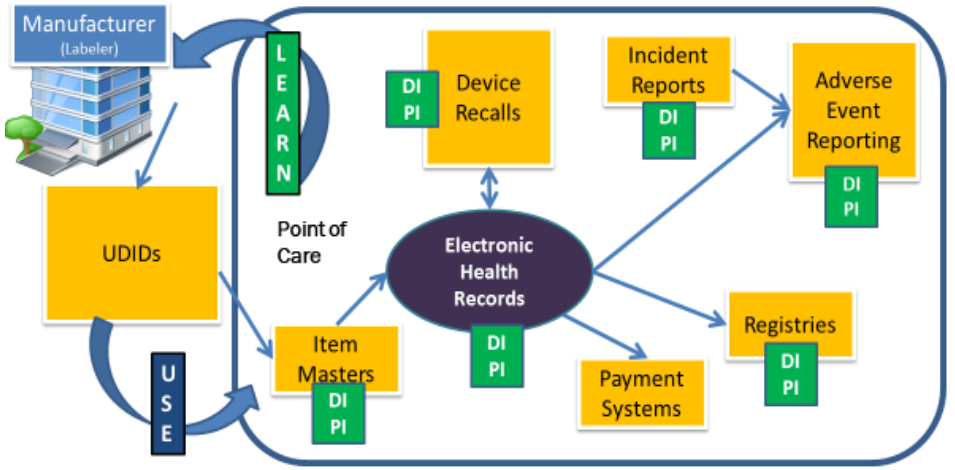
Leveraging innovative approaches

- Distributed ledger technologies
  - A type of database that is not owned by any one entity
  - Data is added as a block that is immutable and cannot be changed
  - Each block is linked to the previous block in a chain, by a cryptographic hash
  - Industry currently leads the DLT agenda

Traceability of medical devices

Unique Device Identification system

- Proposed by IMRDF, coming into force in EU and USA, others to follow
- UDI is composed
  - Device Identifier (UDI-DI)
    - Numeric or alphanumeric code that identifies the product
  - Production Identifier (UDI-PI)
    - Lot number, serial number, date of expiry, date of manufacture, software version number
- On the label or device itself in human readable form and AIDC carrier



- NRAs are responsible for developing their own UDI databases

Sources: Policy paper on traceability of medical products. Geneva: World Health Organization; 2021. Licence: CC BY-NC-SA 3.0 IGO.
International Medical Device Regulators Forum. Unique Device Identification system (UDI system) Application Guide IMDRF/UDI WG/N48 FINAL: 2019

Thank you.

WHO

20, Avenue Appia
1211 Geneva

Switzerland

E-mail: sandsa@who.int