

WHO Healthcare Track & Trace Policy Brief Development



2nd African GS1 Healthcare Conference – Lagos

September 2019

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“Together for a healthier world”

Dr Tedros Adhanom Ghebreyesus



Key Themes of WHO's 13th General Programme of Work 2019-2023

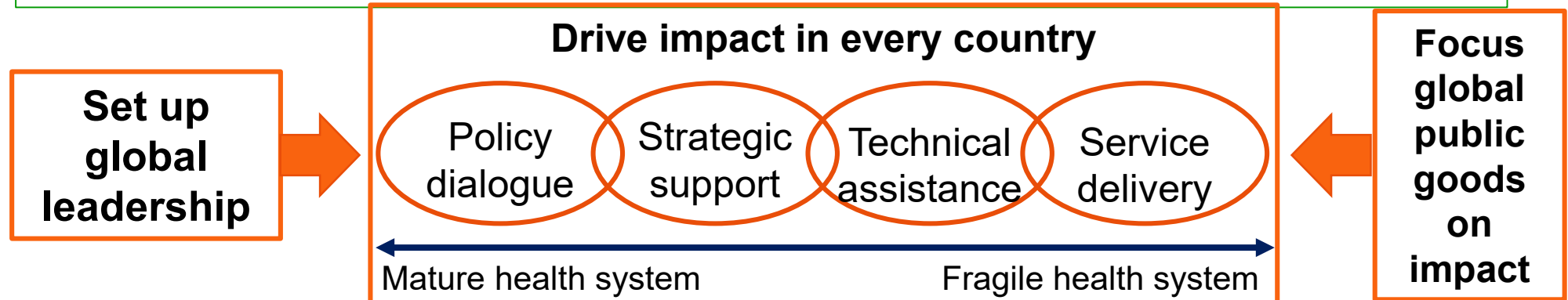
Mission

Promote Health - Keep the World Safe - Serve the Vulnerable

Strategic Priorities

Health Coverage: 1 billion more people with health coverage
Health Emergencies: 1 billion more people made safer
Health Priorities: 1 billion lives improved

Strategic Shifts



72nd World Health Assembly: Access Roadmap



Ensuring quality, safety and efficacy of health products

- **Regulatory systems strengthening**
- Assessment of the quality, safety and efficacy of health products through prequalification
- Market surveillance of quality, safety and performance

Improving equitable access

- R&D that meets public health needs and improves access to health products
- Application & management of IP to contribute to innovation & promote public health
- Evidence-based selection and fair and affordable pricing
- **Procurement and supply chain management**
- Appropriate prescribing, dispensing and rational use

- Aims to assist in achieving the Sustainable Development Goals by ensuring “availability, accessibility, acceptability and affordability” of health products of assured quality
- Based on existing WHO mandates in key Health Assembly resolutions of the last 10 years related to access to safe, effective and quality medicines, vaccines and health products
- outlines the programming of WHO’s work on access to medicines and vaccines for the period 2019–2023, including activities, actions and deliverable

http://apps.who.int/gb/ebwha/pdf_files/WHA72/A72_17-en.pdf

WHO DG Vision and its implementation



Engaging countries and strengthening partnerships

- effective engagement with all Member States across multiple sectors
 - maximizes inclusive partnerships, collective priority setting with all stakeholders
 - country ownership
- WHO science-led and innovation-based approach



How?

- Dr Soumya Swaminathan, Chief Scientist / John Grove, Director Quality Assurance Norms & Standards (QNS)
- WHO normative guidance to be more impactful with robust QA processes and norms and standards fit for purpose



Essential medicines and health products

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WHO to work on a policy position on the introduction of track and trace technologies and standards

Since 2014, the pharmaceutical international development community has promoted the use of global data standards to provide a wider and harmonized framework for supply chain visibility, strengthening anti-counterfeiting measures and sharing of data between parties. In the context of the 2030 target for UHC for all, the World Health Organization is welcoming the opportunities offered by Supply Chain technologies, such as Track&Trace or traceability, aiming at improving its efficiency and ultimately access to healthcare products. However, no proper global guidance has been provided so far to WHO Member States on how to address the numerous questions raised by the implementation of these technologies in the supply chain of healthcare products. WHO's opinion is that a policy position is needed to advice Member States about the governance of the traceability systems handling product data (master data e.g. product name and variable data, e.g. batch/Lot number, expiry data, serial numbers, price). Data management would fall

Meetings & events



- 69th INN Consultation on International Nonproprietary Names (INN) for Pharmaceutical Substances 22-25 October 2019
- 19th International Conference of Drug Regulatory Authorities (ICDRA)

The WHO Project Work Team



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Member States authorities represented

AFRO region

Benin
Ethiopia
Kenya
Liberia
Mozambique (2)
Nigeria
Tanzania

PAHO region

Argentina
Brazil
Chile
Mexico
United States (2)

EMRO region

Iraq

EURO region

EDQM
Russia (2)
Spain
Ukraine



SEARO region

India (2)
Indonesia

WPRO region

South Korea

Stakeholders

International Procurement Agencies

StopTB	Global Fund
UNFPA	UNDP
USAID	UNICEF
GAVI	

Standard setting

GS1
ISO
Others

Industry & Supply Chain stakeholders

- IFPMA International Federation of Pharmaceutical Manufacturers & Associations
- IGBA International Generic and Biosimilar Medicines Association
- International Federation of Pharmaceutical Wholesalers' (IFPW)
- International Pharmaceutical Federation (FIP)

Others

World Bank – Global Steering Committee

Purpose Of This Group

Develop a World Health Organization Policy Brief on healthcare supply chain traceability

- Offer guidance to regulators on the use of international harmonized standards for the development and strengthening of traceability systems, and an appropriate governance in terms of data (use and ownership), including:
 - **Opportunities** and **risks** of Track & Trace (T&T) technologies for product supply and patient safety depending on the various forms and goals of T&T systems;
 - **Data governance** between manufacturers, distributors, and regulators depending on the data type and depth, with consideration of information technology systems;
 - **Roles** and **responsibilities** of regulators versus supply chain stakeholders and roles of standard setting organizations;
 - Importance of **supply chain master data** as the foundation for T&T;
 - Importance of **international standards** in T&T;
 - Advice on **T&T features** that should be defined through international standards; and
 - Facilitation of local and global **pharmacovigilance**

WHO Policy Brief on Track & Trace Outline

Summary of Results of Questionnaire to Member States



- **Top Challenges:**

- Limited technology capability in SC
- funding (system development and/or for enforcement.
- technical knowledge in the government
- regulatory environment



- **Governance**

- Data ownership between government and stakeholder
- Funding between government and industry stakeholders

- **Stage of progress / implementation timing *phased***

Summary of Results of Questionnaire to Member States (2)



- **primary purpose of T&T systems**

- Prevention, detection and response to substandard and falsified medical products
- Supply chain efficiency
- Pharmacovigilance & Medicovigilance
- Product reimbursement



- **Standards** used mostly “global” rather than “domestic” - GS1 Standards most of the time - GS1 Datamatrix barcode most mentioned data carrier
- **Scope** = human medicines incl. vaccines (blood products and MDs mentioned)
- “**Costs** borne by...” ranged from “government” to “MAH” and “stakeholders”.
Concerns about access to medicines raised.

WHO Policy Brief on Track & Trace: Outline

Final Policy Brief

Target audience: National and/or regional regulatory authorities

Aim: Guide regulators on the use of international harmonized standards for the development and strengthening of traceability systems, and an appropriate governance in terms of data (use and ownership)

Companion document: Track & Trace technology and updated mapping document from the International Coalition of Medicines Regulatory Authorities (ICMRA), expected to be published sometime after the WHO Policy Brief (next year?).

Final Policy Brief Target messages:

- List the elements of track & trace **governance** and explain how each will impact interoperability, cost, security and regulatory control;
- Discuss implications of **track & trace costs** on the government, the industry, patients and access to medicine;
- Encourage the use of **global standards** for product identification, production identification, Automatic identification and data capture (AIDC) and data exchange to reduce creation and operating system costs and maximize interoperability;

Final Policy Brief Draft Outline

1. Introduction

- Globalization and complexity of product supply chains; need for supply chain integrity
- Global recognition of benefits of track & trace processes and technologies, including Member State Mechanism identifying this work as a prioritized activity
- Need for Member States to better understand use of international harmonized standards
- Focus on governance with companion work on technology by ICMRA

2. Scope of Policy Brief

- ## 3. Opportunities and risks of T and T technologies for product supply and patient safety depending on the various forms and goals of T and T systems

Final Policy Brief Draft Outline (continued)

4. Developing a workable healthcare track & trace regulation

- Problem definition and analysis
- High-level system design choices
 - Model
 - Funding
 - Standards
- Gap analysis
- Requirements
- Deadlines
- Enforcement plan
- Publication

Final Policy Brief Draft Outline (continued)



5. Elements of governance in healthcare product T&T

- Track and Trace Models (defined, with examples and implications to costs and regulatory control)
 - Centralized
 - Semi-Centralized
 - Distributed (aka, Decentralized)
- Identification (product, production, location)
 - Importance to Track & Trace
 - Value of global standards



Final Policy Brief Draft Outline (continued)



- Unit-level Serialization
 - Primary, Secondary, Tertiary Serialization
 - Aggregation
- Data
 - Master data
 - Data repositories
 - Data ownership and rights
 - Data access
 - Data exchange



Final Policy Brief Draft Outline (continued)

- Roles and responsibilities in a track and trace system
 - Regulatory body
 - Manufacturers
 - Importers
 - Repackagers
 - Wholesale distributors
 - Healthcare providers
- Funding

Final Policy Brief Draft Outline (continued)

6. Conclusion

- Resources

7. Annex

- Updated Member State Mechanism Document on “Experiences in Countries”
- https://www.who.int/medicines/regulation/ssffc/mechanism/country-experience-table_updated-nov2017.pdf?ua=1

EXISTING TECHNOLOGIES AND “TRACK AND TRACE” MODELS IN USE AND TO BE DEVELOPED BY MEMBER STATES

TABLE: EXPERIENCES IN COUNTRIES (updated November 2017)

Next Steps

- African GS1 HC Conference – Lagos
- October WHO SF Member State Mechanism technical meeting in Geneva
- WHO parallel information session with stakeholders 23 October
- Electronic consultation with stakeholders 4Q19
- WHO Policy Brief end 2019 / 1 2020

Thank you



World Health
Organization

WHO

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