Traceability – Global Status – Developments worldwide

2nd African Healthcare conference
Lagos, Wednesday 18 September 2019
USAID MTaPS: Strengthening Regulatory Systems in Low- and Middle- Income Countries

Comfort Ogar, Principal Technical Advisor, MTaPS
2nd African GS1 Healthcare Conference
18 September 2019, Lagos, Nigeria
Program Data

<table>
<thead>
<tr>
<th>Name:</th>
<th>Medicines, Technologies, and Pharmaceutical Services (MTaPS) Program</th>
</tr>
</thead>
<tbody>
<tr>
<td>Funding Level:</td>
<td>Ceiling: $169,706,489</td>
</tr>
<tr>
<td>Duration:</td>
<td>5 years</td>
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<td>September 20, 2018–September 19, 2023</td>
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<tr>
<td>Place of Performance:</td>
<td>Worldwide</td>
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<td>The contract will work at the global level but will largely direct its efforts to USAID focus countries</td>
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</tbody>
</table>
MTaPS Team

CORE
- Boston University
- FHI360
- Overseas Strategic Consulting
- Results for Development
- International Law Institute-Africa Centre for Legal Excellence
- NEPAD

CAPACITY RESOURCE
Ten regional organizations with range of PSS expertise
2. Ecumenical Pharmaceutical Network
3. U3 SystemsWork
4. University of Ibadan
5. University of Ghana’s WHO Pharmacovigilance Collaborating Center
6. Kilimanjaro School of Pharmacy
7. Muhimbili University
8. Pharmaceutical Systems Africa

GLOBAL EXPERT
- Brandeis University
- Deloitte USA
- Duke-National University of Singapore
- El Instituto de Evaluacion Tecnologica en Salud
- ePath
- IC Consultants
- Imperial Health Sciences
- IQVIA
- University of Washington

COLLABORATORS
1. International Pharmaceutical Federation
2. Howard University
3. University of Notre Dame
4. WHO
5. World Bank
Evolution to MTaPS

Strengthening Pharmaceutical Systems Program (2008–2011)
Systems for Improved Access to Pharmaceuticals & Services Program (2011–2018)
Medicines, Technologies, and Pharmaceutical Services Program (2018–2023)

USAID-funded pharmaceutical management projects implemented by MSH
Where We Currently Work

- Field Buy-ins
  - Afghanistan
  - Bangladesh
  - Jordan
  - Mozambique
  - Nepal
  - Philippines
  - Rwanda
  - Asia Regional Bureau

- GHSA Countries
  - Burkina Faso
  - Cameroon
  - Cote d’Ivoire
  - DRC
  - Ethiopia
  - Kenya
  - Mali
  - Senegal
  - Tanzania
  - Uganda
MTaPS Goal and Purpose

- **Goal:** enable low- and middle-income countries to strengthen their pharmaceutical systems to ensure sustainable access to and appropriate use of safe, effective, quality assured, and affordable essential medicines and pharmaceutical services.

- **Purpose** provide pharmaceutical system strengthening assistance for sustained improvements in health system performance and to advance USAID’s goals of preventing child and maternal deaths, controlling the HIV/AIDS epidemic, and combatting infectious disease threats, as well as expanding essential health coverage.
MTaPS Program Objectives

- Pharmaceutical sector governance strengthened
- Institutional and human resource capacity for pharmaceutical management and services increased, including regulation of medical products
- Availability and use of pharmaceutical information for decision making increased and global learning agenda advanced
- Pharmaceutical sector financing, including resource allocation and use, optimized
- Pharmaceutical services, including product availability and patient-centered care to achieve desired health outcomes, improved
MTaPS Guiding Principles

- Utilize a systems strengthening approach
- Optimize allocation and use of resources for medicines and related functions in health systems
- Build on and strengthen existing systems
- Support integration
- Build/strengthen the capacity of local nongovernmental organizations
- Support country-led coordination
- Provide global technical leadership
USAID’s Pharmaceutical Systems Strengthening Approach
MTaPS Regulatory System Strengthening (RSS) Approach
MTaPS Regulatory System Strengthening (RSS) Objectives

• Strengthening regulatory capacity and pharmaceutical-sector governance to protect the public from substandard and falsified products

• Promoting transparency and accountability through appropriate laws, regulations, policies, and standard operating procedures

• Improving human and institutional capacity to manage pharmaceutical regulatory systems and services, including protecting patient safety and slowing the emergence and spread of antimicrobial resistance
MTaPS Key Approaches for RSS (Governance)

• Assist countries to adopt model pharmaceutical legislation, policies, guidelines, and norms or update existing tools

• Help establish mechanisms to ensure oversight and enforcement of policies, laws, and regulations

• Support NMRAs’ strategic planning for regulatory system strengthening with a focus on product registration
MTaPS Key Approaches for RSS (Institutional capacity)

• Develop NMRAs’ institutional capacity through on-the-job training and knowledge sharing, and assist in establishing certification programs

• Strengthen/develop pharmaceutical regulatory professional and preservice programs in collaboration with MTaPS partners Regional Centres of Regulatory Excellence in Africa and the Centre of Regulatory Excellence in Asia

• Support coordination and advocacy efforts for regional harmonization through regional economic communities and platforms like the African Medicines Regulatory Harmonization initiative
MTaPS Key Approaches for RSS (Data for decision)

- Support interoperability of regulatory data among countries through creation of data exchange systems, and use of information solutions such as Pharmadex and PViMS
- Improve pharmacovigilance (PV) systems through increasing reporting of adverse reactions and enhancing use of safety data
- Design active surveillance systems for monitoring new medicines to support the use of high-risk and novel technologies
Building on MTaPS Predecessor Programs
Previous RSS Support to Countries

• Conducted regulatory systems assessments in Angola, Bangladesh, Mozambique, Namibia and Mali

• Provided technical assistance to improve product registration processes in 11 countries

• Assisted NMRAs in 6 countries (Bangladesh, Benin, DRC, Ethiopia, Mozambique, and Namibia) to implement electronic information systems for registration
Previous RSS Support to Regional Initiatives
NEPAD/AMRH

- Supported 3 regional regulatory harmonization initiatives to standardize regulatory practices across countries
  - African Medicines Regulatory Harmonization Initiative (AMRH)
  - East African Community (EAC)
  - Economic Community of West Africa States (ECOWAS)
- PV systems strengthening in the East Africa region

- Development of the African Union Model Law on Medical Products Regulation
- Selection and development of KPIs for Regional Centers of Regulatory Excellence (RCOREs) to increase Africa’s regulatory workforce capacity
- Development of M&E framework for RCORE activities
- Participated in critical NEPAD-led meeting in Midrand, South Africa, at which the major players contributed to the reforms and reached consensus on key elements of the new governance framework
How MTaPS can help implement GS1 standards
MTaPS RSS country support to implement GS1 standards

• Support the drafting of policies, regulations, and/or guidelines that stipulate requirements and timelines for implementation of global standards

• Perform assessments of the market to determine status and adherence to GS1 standards

• Analyze regulatory system readiness for GS1 adoption and selection of the relevant traceability model

• Support regulatory bodies in strategic planning for adoption, implementation, and use of GS1 standards
MTaPS RSS country support to implement GS1 standards

• Analyze current stakeholder capabilities to apply standards, for example, suppliers using GS1 standards, such as: Global Trade Item Number (GTIN), Serial Shipping Container Code (SSCC), and other standards

• Support implementation of strategies to improve stakeholder capacity, including use of GS1 standards software and hardware, guidelines, websites, and eLearning courses

• Support steering committees and working groups implementing GS1 standards, specifically as it pertains to the structure or terms of reference of the group(s)

• Support public health supply chains through deployment of technology for automated data capture and reporting to improve patient safety and traceability of medicines
MTaPS Regional support - NEPAD/AMRH (MTaPS Core Partner)

• Support efforts on regional regulatory collaboration for harmonized policies, guidelines, and procedures on the use of GS1 standards

• Strengthen networks of countries for the exchange of knowledge, expertise, and lessons learned on implementing GS1 standards

• Support regional knowledge dissemination and institutional capacity building/strengthening activities
Conclusion

- MTaPS’ history and demonstrated capacity in regulatory systems strengthening and its experience in pharmaceutical systems strengthening can be leveraged to advance implementation of global standards in LMICs.

- It will support countries and regional efforts to implement GS1 standards for pharmaceutical product traceability.

- We look forward to working with NMRAs in Africa to strengthen their regulatory systems to implement GS1 standards and ensure safety for patients.
Thank you
FOR MORE INFORMATION

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Regulatory developments around the world

Ulrike Kreysa, Senior Vice President Healthcare, GS1 Global Office
2nd African GS1 Healthcare Conference
18 September 2019, Lagos, Nigeria
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The globally harmonised approach: a serialised secondary pack
The road to medicinal products traceability

1. Analysis of the local healthcare market and definition of the regulatory objectives:
   - patient safety and/or
   - payment monitoring and/or
   - supply chain efficiency

2. Choice of the relevant traceability model
   Eg. Track and Trace; Point of Dispense verification system

3. Definition of the product scope

4. Definition of the timeframe

5. Definition of the implementation approach & collaboration between regulators and industry

6. Definition of the data carriers (barcodes), identification and data exchange using GS1 Global standards

www.gs1.org/docs/healthcare/Public-Policy/GS1_Healthcare-ROAD-MAP_FINAL.pdf
Traceability Standards for Long Lasting Insecticide-treated Nets (LLINs)

Clerisse Lemke, PMI
2nd African GS1 Healthcare Conference
18 September 2019, Lagos, Nigeria
TraceNet

Problem Statement:
LLINs are not directly addressed by existing GS1 standards for healthcare, as they are not a pharmaceutical or medical device. A GS1 global health procurement requirement will enable identification, data capture, and data exchange for LLINs. Lack of this procurement requirement has limited end-to-end LLIN traceability from manufacturer to household resulting in inefficient and less effective distribution and allocation.

Objective:
Establish a feasible and achievable recommendation for a GS1 compliant LLIN identification, labeling, and data exchange requirement(s) with the donor, country, and manufacturer communities to support identification and traceability of LLINs.
Use Cases

- Reduce Inventory Loss & Diversion
- Enable Reverse Logistics
- Support LLIN Research
TraceNet Process

- Biweekly Meetings: Collaborative forum focused on identify, capture and share components of GS1 to create the enabling environment in country for greater traceability of LLINs

<table>
<thead>
<tr>
<th>Chairs</th>
<th>TheGlobalFund</th>
<th>USAID</th>
<th>CDC</th>
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<tbody>
<tr>
<td>Coordinator</td>
<td><strong>USAID Global Health Supply Chain Program</strong></td>
<td>Procurement and Supply Management</td>
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<tr>
<td>Members</td>
<td>LLIN Manufacturers, USAID GHSC-PSM Country Directors, USAID GHSC Technical Staff, GS1, Innovative Vector Control Consortium</td>
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Outstanding Questions

• What is the demand for serialization?
• Are bales a trade item?
• What are the identifiers required on the individual net vs the bag?
• Additional use cases?

• And more we haven’t thought of...
We appreciate feedback!

Contacts:
• Clerisse Lemke, Malaria Technical Advisor
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• Chris Warren, Supply Chain Technical Advisor
  — jwarren@usaid.gov
• Collins Agoro, Traceability Technical Advisor
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• Kaitlyn Roche, Manager for Global Standards and Traceability
  — kroche@ghsc-psm.org
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Thanks to our sponsor

[Logos of co-hosts and sponsors]

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Be sure to complete each feedback form!

For every feedback form completed, we will donate 5USD to the chosen conference charity “The North East Children Trust”

https://healthcare-nigeria.gs1.org/
COFFEE BREAK
### Afternoon at a glance

**Wednesday 18 September 2019**

<table>
<thead>
<tr>
<th>Time</th>
<th>Event</th>
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<tbody>
<tr>
<td>13:10-14:15</td>
<td>General Networking lunch &amp; visit of marketplace</td>
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<tr>
<td>14:15-15:45</td>
<td><strong>Two parallel streams</strong></td>
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<td>Stream I – Government and regulatory body Think Tank – Discussing the possibility of</td>
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<td>regulatory alignment across Africa</td>
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<tr>
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<td>Stream II – Traceability – global status – developments worldwide</td>
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<tr>
<td>15:45-16:15</td>
<td><strong>Coffee break</strong></td>
</tr>
<tr>
<td>16:15-17:45</td>
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<td>Stream II – Data as the base for supply chain</td>
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</table>
Networking event at
The Civic Centre tonight at 19:00

The Civic Centre
Ozumba Mbadiwe Avenue
Opposite 1004, Victoria Island
Lagos, Nigeria

PLEASE WEAR YOUR EVENT BADGE 😊

Bus departure: meet in the main hotel lobby at 19:00 sharp!

Bus return: beginning at 21:30 shuttle buses will take you back to the EKO Hotel

Dress code: Business casual