National Pharmaceutical Traceability Vision and Strategy Development Reference Note

USAID GLOBAL HEALTH SUPPLY CHAIN PROGRAM

Procurement and Supply Management

Version, 1.0, February 2021
Introduction
How To Use This Resource

This resource provides guidance and tools that may be used in developing a traceability vision and strategy, including:

• Vision and strategy development workshop materials and exercises
• Traceability results framework
• High-level roadmap for implementing traceability
• Guidance and framework for drafting a national pharmaceutical traceability strategy document

We provide guidance on which stakeholders to engage, key focus areas to consider in strategy development, and exercises and templates that can be used to create a traceability results framework and high-level implementation roadmap. You can adopt and adapt these materials to conduct a vision and strategy development workshop with stakeholders.
Background
National Pharmaceutical Traceability Strategy Development Stakeholders

INTERNATIONAL
- Manufacturers
- Importers/Distributors/Wholesalers
- Logistics Providers
- GS1 Member Organizations Regional Harmonization Initiatives

NATIONAL
- Ministries of Health
- Regulatory Authorities
- Customs and Revenue Authorities
- Law Enforcement/Inspector General
- National Standards Bureaus
- Central Medical Stores
- Private Sector Federations

DEVELOPMENT PARTNERS
- Donors
- Procurement Agents
- Financing Institutions
- Public Health Implementing Partners

SUBNATIONAL
- Regional/District Medical Stores
- Service Delivery Points (e.g., Hospitals, Clinics)
- Health Workers
- Patients/ Clients
GHSC-PSM Traceability Planning Framework

Vision and Strategy development is phase two of the GHSC-PSM’s Pharmaceutical Traceability Framework

The “Why”

Vision and Strategy
Identifying the problem statement to develop a declaration of the reason for implementing traceability, its short-term and long-term objectives and goals.

Education & Awareness
Investing in key stakeholders to provide a baseline understanding of global standards, traceability, and what it takes to implement it.

The “What”

Architecture
Data and systems models to enable implementation of the stated vision.

Policy
Supporting policies that enable implementation of the stated vision.

The “How”

Implementation Plan
A management tool that details the critical strategic steps, milestones, and resources required to execute on the vision.

Strategy development is informed by the GHSC-PSM Traceability Implementation Roadmap to enable implementation within national supply chains.
What does it take? A holistic approach that includes...

- Enabling Environment & Governance
- Regulation & Policy
- Supply Chain Operations
- Systems & Technology
- Service Delivery
<table>
<thead>
<tr>
<th>Standards Implementation Focus Areas</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Enabling Environment &amp; Governance</strong></td>
</tr>
<tr>
<td><strong>Regulation &amp; Policy</strong></td>
</tr>
<tr>
<td><strong>Supply Chain Operations</strong></td>
</tr>
<tr>
<td><strong>Systems &amp; Technology</strong></td>
</tr>
<tr>
<td><strong>Service Delivery</strong></td>
</tr>
</tbody>
</table>
Steps to Traceability Strategy Development

1. **Identify Country Priorities**
   Identification of the priorities that you would like global standards to address in the country

2. **Define Strategic Objectives**
   Longer-term, higher-order changes expected from the traceability program

3. **Define Intermediate Results**
   Medium-term, discrete results of traceability strategy that are measurable

4. **Define Outputs and Activities**
   Tangible deliverables and activities to drive the traceability program

5. **Develop a Results Framework and Roadmap**
   Graphical representation of strategic objectives, Intermediate Results (IRs), outputs, and activities against realistic timeframes

The traceability program should be tied to national health strategies and objectives.
Identifying Country Priorities
Traceability Strategic Objectives

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The traceability program should be tied to national health strategies and objectives.
Activity: Stakeholder Priorities

Identify the priorities that you would like global standards to address in the country. The goal is to have an initial understanding of each stakeholder’s priority areas so that we can narrow the focus to what is important to achieve with global standards. Results will help guide vision and strategy development.

- Allow each person three votes.
- Review list of global standards objectives.
- Evaluate each area on your own.
- Vote for which outcomes would be important focus areas based on the reality today.
- Try not to be influenced by others’ votes!
Activity: Traceability Country Priorities

[ ] Visibility of where the product is within the supply chain
[ ] Efficiency of inventory management and distribution
[ ] Pharmacovigilance and control of outcome of treatments
[ ] Counterfeit or stolen product that is obtained by the patient/end user
[ ] Counterfeit or stolen product detected in the legitimate supply chain
[ ] Visibility to decrease or eliminate reimbursement fraud
[ ] Visibility of product “status” (e.g., expired, recalled)
[ ] Accuracy and efficiency of procurement operations
[ ] Efficiency of payment and payment monitoring processes
[ ] Theft or diversion of products from the legitimate supply chain
[ ] Efficiency of “reverse” logistics processes (e.g., returns, recalls)
[ ] Harmonized trade/customs clearance procedures

Activity
Rank in order of priority the country’s supply chain challenges that can be solved through global standards adoption.
Activity: Vision Statements

The traceability vision statement reflects a country’s aspiration of the end state desired after adopting global standards for traceability.

✓ A vision statement must reflect the national health plans and traceability priorities.

Example 1
A supply chain that enables every citizen to access safe and secure medicines

Example 2
Patient safety through enhanced data visibility in the supply chain

Example 3
Every citizen has access to quality and affordable health products.
Vision Statement Work Instructions

1. Review example assigned to your group.
2. Brainstorm key elements of your vision statement reflective of traceability and national priorities.
3. Discuss with your group; challenge one another!
4. As a group, agree on the best traceability vision statement for the country.
5. Document your vision statement.
Developing Strategic Objectives
Traceability Strategic Objectives

1. Identify Country Priorities
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   Graphical representation of strategic objectives, IRs, outputs, and activities against realistic timeframes

The traceability program should be tied to national health strategies and objectives.
**What is a strategic objective (SO)?**
An objective that defines **higher-order changes** in systems, communities, or organizations that are developed by understanding the problem and defining what success looks like.

**Tips for developing SOs:**
- Reflect the best assessment of what can be achieved realistically and resourced in a 5- to 10-year timeframe
- State SOs clearly and precisely to lend themselves easily to objective measurement
- Emphasize the results of actions, not the actions themselves

<table>
<thead>
<tr>
<th>PROBLEM</th>
<th>✓ What problem are we trying to solve?</th>
<th>✓ High levels of inefficiencies in inventory management at the central medical warehouse</th>
</tr>
</thead>
<tbody>
<tr>
<td>SUCCESS</td>
<td>✓ How will you know when the program has been successful in solving the problem?</td>
<td>✓ Automatic identification and data capture of pharmaceutical products</td>
</tr>
</tbody>
</table>
Illustrative Strategic Objectives

SO1 Governance

Example: Sustained governance structure that is accountable for implementing the traceability strategy

SO2 Regulation & Policy

Example: Expanded regulatory framework for verification and traceability of quality pharmaceutical products through legitimate supply channels

SO3 Supply Chain Operations

Example: Efficient public and private supply chain through standardized identification, capture, and reporting of high-quality supply chain data

SO4 Systems & Technology

Example: Integrated information and communication technologies that support end-to-end data visibility and pharmaceutical traceability

SO5 Service Delivery

Example: Health care providers enabled to provide safe and good-quality pharmaceutical products to the client
Strategic Objectives Group Work Instructions

1. Review example assigned to your group.
2. Write down your individual thoughts and recommendations.
3. Discuss with your group; challenge one another!
4. As a group, agree to a strategic objective.
5. Document your consensus-recommended strategic objective.
Developing Intermediate Results
Traceability Intermediate Results

1. Identify Country Priorities
   Identification of the priorities that you would like global standards to address in the country.

2. Define Strategic Objectives
   Longer-term, higher-order changes expected from the traceability program.

3. Define Intermediate Results
   Medium-term, discrete results of traceability strategy that are measurable.

4. Define Outputs and Activities
   Tangible deliverables and activities to drive the traceability program.

5. Develop a Results Framework and Roadmap
   Graphical representation of strategic objectives, IRs, outputs, and activities against realistic timeframes.

The traceability program should be tied to national health strategies and objectives.
What is an Intermediate Result?
A set of discrete results that create causal links in the results chain and bridge the gap between the current state and the desired SO.

Tips for developing IRs:
- Establish a clear link between your proposed IRs and your SO
- Develop multiple IRs to achieve each SO
- Ensure IRs are SMART
- Emphasize the results of activities and outputs, but not the activities and outputs themselves

<table>
<thead>
<tr>
<th>PROBLEM</th>
<th>What problem are we trying to solve?</th>
<th>Poor visibility into where the product is within the supply chain, limiting efficiency of reverse logistics</th>
</tr>
</thead>
<tbody>
<tr>
<td>SUCCESS</td>
<td>How will you know when the program has been successful in solving the problem?</td>
<td>End-to-end visibility of product information within the supply chain</td>
</tr>
<tr>
<td>DISCRETE RESULT</td>
<td>How will you measure that success?</td>
<td>Harmonized product master data enabled through interoperable National Product Catalogue</td>
</tr>
</tbody>
</table>
Intermediate Results Group Work Instructions

1. Review example assigned to your group.

2. Write down your individual thoughts and recommendations.

3. Discuss with your group; challenge one another!

4. As a group, agree on three to five well-defined IRs for your SO.

5. Document your consensus-recommended IRs.
Developing Outputs and Activities
Traceability Outputs and Activities

1. Identify Country Priorities
   Identification of the priorities that you would like global standards to address in the country

2. Define Strategic Objectives
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The traceability program should be tied to national health strategies and objectives.
<table>
<thead>
<tr>
<th>Output</th>
<th>Activity</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>What is an output?</strong></td>
<td><strong>What is an activity?</strong></td>
</tr>
<tr>
<td>Completed and delivered product of a specific activity. Outputs should be specific and tangible products or services.</td>
<td>An individual task to be executed by an organization; typically, the smallest unit of work that needs to be completed to develop a specific output.</td>
</tr>
<tr>
<td><strong>Tips for developing outputs:</strong></td>
<td><strong>Tips for developing activities:</strong></td>
</tr>
<tr>
<td>• Each output should be discrete and contained</td>
<td>• Each activity should be discrete</td>
</tr>
<tr>
<td>• Output information does not tell you anything about the actual results achieved or the consequences of the products and services delivered</td>
<td>• Each activity should directly influence the output</td>
</tr>
<tr>
<td>• Outputs are important to show the scope or size of what the inputs and activities produce</td>
<td>• Activities should be scoped so that resource inputs can be defined</td>
</tr>
</tbody>
</table>

**Example:** Establish a Steering Committee for traceability

**Example:** Develop training materials for global standards and traceability; train trainers in curriculum delivery
Output Group Work Instructions

1. Review example assigned to your group.

2. Brainstorm one to two outputs and corresponding activities for each IR.

3. Discuss with your group; challenge one another!

4. As a group, agree on outputs and at least one activity per output.

5. Document your objectives and activities.
Developing a Results Framework & Roadmap
Traceability Results Framework and Roadmap

1. Identify Country Priorities
   Identification of the priorities that you would like global standards to address in the country.

2. Define Strategic Objectives
   Longer-term, higher-order changes expected from traceability program.

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   Medium-term, discrete results of traceability strategy that are measurable.

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   Tangible deliverables and activities to drive the traceability program.

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Traceability Strategy Development
The traceability program should be tied to national health strategies and objectives.
Results Framework

What is a Results Framework?
A graphical representation of the cause-and-effect linkages between the different levels of changes expected to be achieved from a traceability program.

A Results Framework includes:
- Vision Statement
- Goal Statement
- Strategic Objective
- Intermediate Results
- Outputs
- Activities
Illustrative Traceability Results Framework

Goal: Improved health and quality of life for all citizens

Vision: A supply chain that enables safe and equal access to safe and secure medicines

SO1: Sustained governance

IR 1.1: Strengthened coordination implementation of traceability strategy

OUTPUT 1.1.1: Established Technical Working Group

ACTIVITY 1.1.1.1: Host stakeholder coordination and engagement meetings

SO2: Expanded regulatory and policy framework for traceability

IR 2.1: Availability of regulation for standardized labelling of pharmaceutical products

OUTPUT 2.1.1: Approved guideline for standardize labelling of pharmaceutical products

ACTIVITY 2.1.1.1 Assess existing regulations on pharmaceutical labelling

SO3: Integrated information and communications technology for end-to-end supply chain data visibility

IR 3.1: Harmonized product and location master data available o supply chain trading partners

OUTPUT 3.1.1: Harmonized product master data list

ACTIVITY 3.1.1.1: Align product data across the supply chain

OUTPUT 3.1.2: National Product Catalogue (NPC) deployed

ACTIVITY 3.1.2.1: Define requirements for National Product Catalogue

SO4: Efficient standardized identification, capture, and reporting of supply chain data

IR 4.1: Increased efficiency in inventory management through automatic identification and data capture (AIDC)

OUTPUT 4.1.1: Trained personnel to implement AIDC

ACTIVITY 4.1.1.1: Develop training plan

OUTPUT 4.1.2: Barcoding enabled at the Central Medical Stores

ACTIVITY 4.1.1.2: Procure hardware for barcoding
Traceability Roadmap

What is a Traceability Roadmap?
A management tool that details a high-level overview of critical steps mapped against strategic objectives with timelines and activity owners required to execute the traceability strategy.

Tips for developing IRs:
✓ Ensure the Traceability Roadmap is developed and managed by the championing body of the traceability initiative (e.g., health ministry, regulatory body, or cross-sector steering committee).
✓ Consider reasonable timelines and resources required by various sector stakeholders and trading partners to meet implementation requirements.
Traceability Roadmap Development Group
Work Instructions

1. Review example assigned to your group.

2. Write down your individual thoughts and recommendations.

3. Discuss with your group; challenge one another!

4. As a group, agree on reasonable timelines and initiative owners at the output level for each SO.

5. Document your consensus-recommended timelines and initiative owners.

Focus Area
# Roadmap Example

<table>
<thead>
<tr>
<th>Level and Description</th>
<th>Owner (Output) &amp; Timeline (Activity)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>STRATEGIC OBJECTIVE 1</strong>: Sustained governance structure that is accountable for implementing the traceability strategy</td>
<td></td>
</tr>
</tbody>
</table>

**INTERMEDIATE RESULT 1.1**: Strengthened coordination, resource mobilization, and oversight of implementation of traceability strategy

<table>
<thead>
<tr>
<th>OUTPUT 1.1.1: Approved national traceability strategy for implementation</th>
<th>Ministry of Health</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACTIVITY 1.1.1.1: Finalize national traceability strategy, inclusive of participant feedback, and submit to Minister for approval or endorsement</td>
<td>X</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>OUTPUT 1.1.2: Established Global Standards &amp; Traceability Steering Committee Group</th>
<th>Ministry of Health</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACTIVITY 1.1.2.1: Develop Terms of Reference for Steering Committee and seek approval from the Ministry of Health</td>
<td>X</td>
</tr>
</tbody>
</table>

| OUTPUT 1.1.3: Costed implementation plan | Global Standards & Traceability TWG |
| ACTIVITY 1.1.3.1: Identify implementation requirements by stakeholder and document roles and responsibilities | X |

**STRATEGIC OBJECTIVE 2**: Expanded regulatory framework for verification, traceability, and pharmacovigilance of quality pharmaceutical products through legitimate supply channels

**INTERMEDIATE RESULT 2.1**: Expanded existing regulatory framework to encompass medicines, verification, and traceability under the mandate

| OUTPUT 2.1.1: Regulation updated to encompass SF medicines, verification, and traceability | Food and Drug Administration |
| ACTIVITY 2.1.1.1: Develop a draft statutory instrument to include SFs, verification, and traceability | X |
National Pharmaceutical Traceability Strategy Document
Traceability Strategy Document Assumptions

Market Context

Accounts for local market dynamics, including local legal requirements, technological sophistication, trade practices and other similar dynamics.

Standards Adoption

National authorities will leverage the GS1 system of standards to advance traceability objectives.

Traceability Model Section

Traceability model (track & trace, verification or both) that will be implemented is not defined when the document is initially developed, but will be through the strategy implementation process.
<table>
<thead>
<tr>
<th>Strategy Outline</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>01 Executive Summary</td>
<td>High level summary of the strategy including vision statement, key priorities, strategic objectives and expected outcomes that are anchored on existing national health policy.</td>
</tr>
<tr>
<td>02 Introduction</td>
<td>Highlights the national health priorities as defined in the national health strategy, current initiatives undertaken for the adoption of global standards for traceability, and overview of traceability objectives.</td>
</tr>
<tr>
<td>03 Approach</td>
<td>Summary of the scope of the document and what is out of scope that must be informed by market assessments, additional stakeholder consultation, and reference implementations. For example, selection of traceability model and the specific products and locations subject to traceability efforts.</td>
</tr>
<tr>
<td>05 Global Standards Adoption</td>
<td>Summary of how global standards will contribute to achieving the strategic objectives for traceability. It is recommended for countries to reference GS1 identify, capture, share and use standards as defined by GS1 (<a href="https://www.gs1.org/sites/default/files/docs/architecture/AG_Flyer_final.pdf">https://www.gs1.org/sites/default/files/docs/architecture/AG_Flyer_final.pdf</a>).</td>
</tr>
<tr>
<td>06 National Traceability Results Framework</td>
<td>A graphical representation of the strategy document depicting expected change from traceability implementation at each level of implementation including Mission, Vision, Strategic Objectives, Intermediate Results and Outputs.</td>
</tr>
<tr>
<td>07 Strategic Objectives, Intermediate Results and Outputs</td>
<td>Description of the strategic objectives, intermediate results, and outputs described in the results framework and the approach for implementing each of these. It is recommended for a country to take a holistic approach to the development of its strategy to advance traceability across the entire health system, phasing implementation and scaling based on lessons learned.</td>
</tr>
<tr>
<td>08 Traceability Roadmap</td>
<td>A time-phased roadmap focused on initiatives that should be accomplished to achieve the set vision as aligned with national fiscal year and plans and detailing illustrative activities to initiate implementation of the strategy.</td>
</tr>
<tr>
<td>09 Glossary of Terms</td>
<td>Definition of terms used in the strategy. It is recommended that interested parties consult the GS1 General Specification and use references and terms therein whenever available.</td>
</tr>
</tbody>
</table>
The USAID Global Health Supply Chain Program-Procurement and Supply Management (GHSC-PSM) project is funded under USAID Contract No. AID-OAA-I-15-0004. GHSC-PSM connects technical solutions and proven commercial processes to promote efficient and cost-effective health supply chains worldwide. Our goal is to ensure uninterrupted supplies of health commodities to save lives and create a healthier future for all. The project purchases and delivers health commodities, offers comprehensive technical assistance to strengthen national supply chain systems, and provides global supply chain leadership. For more information, visit ghsupplychain.org.

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