

# Traceability Governance Terms of Reference Guidance and Template

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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.

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# Introduction

This Governance Terms of Reference (TOR) template is intended for national authorities to use in defining the purpose, expectations, and structure of the governance body tasked with implementing a national traceability strategy enabled by global standards. The TOR template provides a framework for establishing a formal governance structure. This structure will guide the general decision-making process and representation required to facilitate the work needed to meet the stated traceability goals and objectives.

The document and template are a framework for establishing a governance structure that is responsive to a country's traceability vision and strategy.

The TOR template provides a working framework for a traceability governance group, referred to throughout this document as a “governance body.” However, entities may adopt alternative monikers for a governance body, including technical working group, steering committee, or technical committee. Or, entities may elect to divide the tasks described between two groups, for example, a steering committee and a technical working group.

The document, including the template, does not provide information or a structure for an implementation team that will be overseen and guided by the governance body. Guidance and resources for establishing an implementation team can be found in the resource *Human Resources for Traceability Implementation: Tools for Establishing Your Implementation Team*.

## How to Use this Document

The template provides a structure and illustrative text that you can adapt and adopt to support the selected governance structure for traceability implementation. The template assumes that a traceability strategy is in place and a lead champion or executive sponsor has been identified to guide TOR development. You will need to change the structure and content of the template to reflect more closely the governance and stakeholder needs in a specific context. If you adopt the language as is, you will need to complete the fields denoted in **blue** to reflect context-specific information. Also, where illustrative objectives and member organizations are included, you will need to adapt them to reflect context-specific objectives and organizations. In the template, these objectives and organizations are depicted in italics.

## Key Considerations

The template highlights the important elements you need to consider when establishing TOR for a governance body. To support application of the template in a specific context, consider the following factors. Key considerations are referenced against the sections of the TOR template.

Focus Area	Consideration	Template Reference Section
<b>BACKGROUND</b>	<p>The template assumes that a traceability strategy is in place. Use this section to provide a brief overview of how and when the strategy was developed and its objectives. We have provided illustrative text that you can adapt based on implementing context.</p> <p>In the absence of a traceability strategy, use this section to describe why a governance structure is being established.</p>	Section 1
<b>OBJECTIVE</b>	<p>Use this section to provide an overview of the objectives of the governance body. Specific objectives and functions align with the national traceability strategy. We have included illustrative objectives. Revise them to align with the primary objectives of the governance body.</p>	Section 2
<b>GOVERNANCE AND MEMBERSHIP</b>	<p>A country must decide on the form of governance structure, such as a steering committee or technical working group. The TOR referenced in the template can be applied broadly to any structure instituted.</p> <p>We recommend that the governance body be led by a chairperson who is supported by a secretariat. Members of the governance team should include representation from public- and private-sector stakeholders that will impact or be impacted by the traceability strategy. Annex A provides a list of illustrative stakeholders who should be represented.</p>	Section 3
<b>FREQUENCY AND FORMAT</b>	<p>We recommend that a country collectively determine the frequency and nature of meetings that will be convenient to ensure effective execution of their mandate to advance activities, discuss recommendations, provide an advocacy forum with industry, and share relevant technical and programmatic information. Use this section to outline these agreed-upon determinations.</p>	Section 5

**Template**

## **COVER PAGE**

# **Traceability Governance Terms of Reference (TOR)**

**Government of [Country]**

**Governing the Implementation of Global Standards and Traceability  
for Pharmaceutical Products**

**For Comments: [INSERT CONTACT INFORMATION]**

# REVISION HISTORY

Version	Author	Date	Comments

TEMPLATE

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TEMPLATE



# ACRONYMS

GHSC	Global Health Supply Chain
MOH	Ministry of Health
PSM	Procurement and Supply Management
TWG	Technical working group
TOR	Terms of Reference
GS1	Global Standards

TEMPLATE

# 1. BACKGROUND

In [INSERT DATE], the [NATIONAL AUTHORITY] conducted a series of stakeholder workshops. The workshops were intended to build awareness of the benefits of product traceability and how existing global standards used in the health care industry enable traceability and supply chain end-to-end data visibility. Through a collaborative process, the group established a traceability vision for health care products in [INSERT COUNTRY] by assessing the current state, identifying gaps, and defining a strategy for implementation. The strategy document, [INSERT NAME OF COUNTRY TRACEABILITY STRATEGY DOCUMENT NAME], is intended to be a starting point to drive implementation across the health sector. It will be a “living document” that is updated over time as the long-term objectives and requirements become more defined. With this strategy, [INSERT NAME OF COUNTRY] seeks to enable an environment that:

- *Decreases the presence of substandard and falsified medications*
- *Ensures the quality and desired efficacy of pharmaceuticals*
- *Promotes trust in the pharmaceutical sector and health care system*
- *Provides visibility of product status across the supply chain*
- *Creates supply chain efficiencies from manufacturers to patient receipt*

Achieving these goals requires proper processes, execution, and oversight across impacted stakeholders. This document serves as Terms of Reference for the governance body, namely, a [NAME OF THE TRACEABILITY GOVERNANCE BODY] as mandated by the [NAME OF COUNTRY TRACEABILITY STRATEGY DOCUMENT], to achieve its strategic objectives for traceability.

- Strategic Objective 1:
- Strategic Objective 2:
- Strategic Objective 3:

Successfully achieving these strategic objectives requires strong leadership, supporting resources, and accountability to execute supporting activities.

## 2. OBJECTIVE

The principle objective of these Terms of Reference is to define the purpose and structure of a [NAME OF THE TRACEABILITY GOVERNANCE BODY] that will oversee and guide implementation of the strategic objectives of the [NAME OF COUNTRY TRACEABILITY STRATEGY DOCUMENT]. The [NAME OF THE TRACEABILITY GOVERNANCE BODY] will serve as the governing forum to:

1. Engage relevant stakeholders in traceability implementation to:
  - a. Learn from stakeholder implementation experience in other environments
  - b. Determine readiness, opportunities, and constraints for implementation
  - c. Identify cost implications across stakeholder groups
  - d. Build consensus on approach, requirements, and timelines
2. Determine roles and responsibilities for strategy implementation
3. Discuss opportunities and limitations for adopting global standards for:
  - a. Product and location identification
  - b. Packaging, presentation, and data capture
  - c. Master, transaction, and event data exchange
4. Inform the design of the regional or national traceability model, system(s), and supporting policies
5. Support development of a detailed roadmap and costed implementation plan to fulfill the traceability mandate and mobilize required human and financial resources to support these
6. Provide opportunities for education and awareness of global standards and traceability within and outside of the stakeholder groups represented
7. Serve as an advocacy group for adopting global standards and traceability across the public and private health sectors

### 3. GOVERNANCE AND MEMBERSHIP

The [NAME OF THE TRACEABILITY GOVERNANCE BODY] is convened by [CONVENING ORGANIZATION], which is committed to ensuring the necessary administrative support and member representation are in place to support effective functioning of the group. The [GOVERNING BODY] is chaired by an appointed representative from [CHAIRING ORGANIZATION]. The chair is supported by a representative from [SECRETARIAT ORGANIZATION], who will serve as the secretariat and is responsible for supporting the group in coordinating and managing meetings, providing communications management, and maintaining a repository of documentation.

The [GOVERNING BODY] chair will be supported by members of the group representing a broad group of stakeholders whose role it will be to advise on planning, operationalizing, and overseeing strategy implementation. The convening organization will nominate member organizations. Each member organization will nominate a single individual to represent the organization, along with an alternate to ensure consistent representation. Member organizations must ensure that their representatives have expertise in area(s) that align with the objectives of the [GOVERNING BODY], including manufacturing, supply chain, data standards, information systems and technology, policy and regulation, and traceability. The [GOVERNING BODY] may engage additional subject matter experts on an ad hoc basis to support specific activities.

A complete list of member organizations and representatives is included in Annex A.

## 4. MEMBER RESPONSIBILITIES

[GOVERNING BODY] members are expected to work collectively to:

1. Provide strong leadership and accountability in executing supporting activities as contained in the traceability strategy.
2. Advocate among key health sector stakeholders for advancing the implementation and use of global standards for trade item and location identification, data capture, and data exchange.
3. Guide all activities and implementation team(s) that will support achieving the vision for pharmaceutical traceability implementation and the use of global standards.
4. Mobilize resources and coordinate with donor partners to develop and resource yearly work plans containing agreed-to funding and associated key performance indicators

## 5. FREQUENCY AND FORMAT

### 1.1. Schedule for meetings

The governance body will hold **monthly** meetings to advance activities, discuss recommendations, provide an advocacy forum with industry, and share relevant technical and programmatic information. Members are encouraged to submit proposed agenda items to the secretariat, who circulates the agenda, along with minutes of the previous meeting, to members before each meeting.

### 1.2 Planning for meetings

The chair, through the secretariat, will ensure that all matters on the agenda are ready for presentation at the meeting. This includes all documents related to the functions and activities listed above.

### 1.3 Conducting a meeting

The secretary will send by e-mail (or as hardcopy) the draft minutes of the previous meeting, an agenda specifying the matters that will be discussed at the meeting to the chairperson and members and, depending on the agenda items, to invited subject matter experts, and any supporting documents against any agenda items that are required at the meeting.

The agenda will include the following standard items:

- **Opening of the meeting**
- **Correction of the minutes**
- **Matters arising from the previous minutes**
- **Fixed agenda items, including, for example:**
  - (a) **Review of action items from the previous minutes**
  - (b) Any other business**

# ANNEX A: MEMBERSHIP

## CHAIR

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National Authority	<ul style="list-style-type: none"><li>• Name, Title</li><li>• Name, Title</li></ul>
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## SECRETARY

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	<ul style="list-style-type: none"><li>• Name, Title</li><li>• Name, Title</li></ul>
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## COMMITTEE MEMBERS

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National Authority	<ul style="list-style-type: none"><li>• Name, Title</li><li>• Name, Title</li></ul>
Ministry of Health	<ul style="list-style-type: none"><li>• Name, Title</li><li>• Name, Title</li></ul>
Distributors Association	<ul style="list-style-type: none"><li>• Name, Title</li><li>• Name, Title</li></ul>
Pharmacies Association	<ul style="list-style-type: none"><li>• Name, Title</li><li>• Name, Title</li></ul>
Private-sector Federation	<ul style="list-style-type: none"><li>• Name, Title</li><li>• Name, Title</li></ul>
Hospitals Association	<ul style="list-style-type: none"><li>• Name, Title</li><li>• Name, Title</li></ul>
Association of Manufacturers	<ul style="list-style-type: none"><li>• Name, Title</li><li>• Name, Title</li></ul>
Donor agencies representative	<ul style="list-style-type: none"><li>• Name, Title</li><li>• Name, Title</li></ul>
Bureau of Standards organization	<ul style="list-style-type: none"><li>• Name, Title</li><li>• Name, Title</li></ul>
Public procurement organization	<ul style="list-style-type: none"><li>• Name, Title</li><li>• Name, Title</li></ul>
Country information systems authority	<ul style="list-style-type: none"><li>• Name, Title</li><li>• Name, Title</li></ul>
Central medical stores	<ul style="list-style-type: none"><li>• Name, Title</li><li>• Name, Title</li></ul>
Public/private health authority	<ul style="list-style-type: none"><li>• Name, Title</li><li>• Name, Title</li></ul>

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