

SUPPLY CHAIN MANAGEMENT HANDBOOK

# **Health Annex:**

## **Supporting National Supply Chain Health Systems**

## ABOUT CATHOLIC RELIEF SERVICES

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**PROMOTE HUMAN DEVELOPMENT** by responding to major emergencies, fighting disease and poverty, and nurturing peaceful and just societies; and,

**SERVE CATHOLICS IN THE UNITED STATES** as they live their faith in solidarity with their brothers and sisters around the world.

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# HEALTH ANNEX ACRONYMS

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<b>AIDS</b>	Acquired Immunodeficiency Syndrome
<b>API</b>	Active Pharmaceutical Ingredient
<b>CAT</b>	Capacity Assessment Tool
<b>CIPS</b>	Chartered Institute of Procurement and Supply
<b>CMM</b>	Capability Maturity Model
<b>CMS</b>	Centers for Medicare & Medicaid Services
<b>COVID-19, C19</b>	Coronavirus Disease 2019
<b>CTP</b>	Cash Transfer Programming
<b>CV</b>	Curriculum Vitae
<b>FBDI</b>	File-Based Data Import
<b>FFATA</b>	Federal Funding Accountability and Transparency Act
<b>GAVI</b>	Global Alliance for Vaccines and Immunization
<b>GDF</b>	Global Drug Facility
<b>GDP</b>	Good Distribution Practices
<b>GHTF</b>	Global Harmonization Task Force
<b>GHSC</b>	Global Health Supply Chain
<b>GMP</b>	Good Manufacturing Practice
<b>GSCM</b>	Global Supply Chain Management
<b>GSP</b>	Good Storage Practices
<b>HIV</b>	Human Immunodeficiency Virus
<b>HPM</b>	Health Product Management
<b>HPMT</b>	Health Product Management Template
<b>HR</b>	Human Resources
<b>HSS</b>	Health System Strengthening
<b>IDA</b>	International Dispensary Association (IDA Foundation)
<b>ICT4D</b>	Information and Communication Technologies for Development
<b>ITN</b>	Insecticide-treated Net
<b>ISO</b>	International Organization for Standardization

<b>JD</b>	Job Description
<b>JSI</b>	John Snow, Inc.
<b>KPI</b>	Key Performance Indicator
<b>LFA</b>	Local Fund Agent
<b>LLIN</b>	Long-lasting Insecticidal Net
<b>LOE</b>	Level of Effort
<b>M&amp;E</b>	Monitoring & Evaluation
<b>mg</b>	milligram
<b>MOH</b>	Ministry of Health
<b>NDRA</b>	National Drug Regulatory Authority
<b>NextGen</b>	Next Generation
<b>NMRA</b>	National Medicines Regulatory Authority
<b>NSCA</b>	National Supply Chain Assessment
<b>OOO</b>	Out of Office
<b>PEPFAR</b>	The United States President's Emergency Plan for AIDS Relief
<b>PMI</b>	President Malaria Initiative
<b>PO</b>	Purchase Order
<b>PQR</b>	Price Quality Reporting
<b>PSM</b>	Procurement and Supply Chain Management
<b>PUDR</b>	Progress Update Disbursement Request
<b>QA</b>	Quality Assurance
<b>QAT</b>	Quantification Analytics Tool
<b>QC</b>	Quality Control
<b>RACI</b>	Responsible, Accountable, Consulted, and Informed
<b>RDT</b>	Rapid Diagnostic Test
<b>RFP</b>	Request for Proposal
<b>RFQ</b>	Request for Quote
<b>RSSH</b>	Resilient and Sustainable Systems for Health
<b>SCM</b>	Supply Chain Management
<b>SOP</b>	Standard Operating Procedure

<b>SOW</b>	Scope of Work
<b>SRA</b>	Stringent Drug Regulatory Authority
<b>STGs</b>	Standard Treatment Guidelines
<b>TB</b>	Tuberculosis
<b>UNFP</b>	United Nations Population Funds
<b>UNICEF</b>	United Nations International Children’s Emergency Fund
<b>USAID</b>	U.S. Agency for International Development
<b>WHO</b>	World Health Organization

# HEALTH ANNEX GLOSSARY

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## A

**Active Pharmaceutical Ingredient (API):** Any substance or combination of substances used in a finished pharmaceutical product, intended to have a direct effect on the diagnosis, cure, mitigation, treatment, or prevention of disease.

**Adverse Drug Reaction:** A response to a drug that is noxious, unintended, and occurs at therapeutic doses for the prophylaxis, diagnosis, or therapy of disease, or the modification of physiological function.

## C

**Capacity Statement:** A document with information on CRS' expertise and ability to perform functions effectively, efficiently, and sustainably developed to attract potential donors.

**Capacity Assessment Tool (CAT):** Assessment tool used by the Global Fund to assess the principal recipient's readiness.

**Central Medical Stores:** National or parastatal entities in charge of the procurement, warehousing, and distribution of public health commodities. Some central medical stores have decentralized entities, while others are linked and used directly.

**Country Program Supply Chain Manager:** Country Program Supply Chain Manager playing the Supply Chain Manager persona for CRS' Enterprise Resource Planning system, known as Insight.

**COMPASS:** The COMPASS website supports CRS staff in attaining project management excellence across CRS emergency response and development projects. COMPASS provides step-by-step guidance and practical resources that support the [CRS project management standards](#).

## E

**Essential Medicines:** Satisfy the priority health care needs of a population. They are selected with due regard to disease prevalence and public health relevance, evidence of efficacy and safety, and comparative cost-effectiveness. Essential medicines are intended to be available in functioning health systems always, in appropriate dosage forms, of assured quality, and at prices individuals and health systems can afford. Every two years, WHO updates a [list of finished pharmaceutical products](#) used to treat HIV/AIDS, TB, malaria and other diseases, and reproductive health, assessed by WHO and found to be acceptable, in principle, for procurement by UN agencies.

## G

**Generic Medicine:** A pharmaceutical product usually intended to be interchangeable with the originator brand product, manufactured without a license from the originator manufacturer, and marketed after the expiry of the patent or other exclusivity rights.

**Global Fund Project Dedicated Supply Chain Manager:** Global Fund Project dedicated Supply Chain Manager, with a Logistics Manager persona in Insight.

**Good Storage Practices (GSP) and Good Distribution Practices (GDP):** WHO Guidance describing special measures considered appropriate for the storage and transportation of pharmaceuticals.

**Good Manufacturing Practices (GMP):** The part of QA that ensures that pharmaceutical products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the marketing authorization.

**Health Supply Chain Manager:** Terminology used to reflect the country focal point, supply

chain manager, or any other person supporting the health supply chain section.

## H

**Health Products:** At CRS, the terminology “health products” encompasses all pharmaceuticals, consumables, vaccines, and equipment acquired to cure, prevent, diagnose diseases, and protect health workers. Health supplies include pharmaceuticals and vaccines, other medical products (e.g., nutritional supplements, bed nets for malaria prevention, test kits, medical and laboratory equipment, and medical and laboratory supplies (e.g., gloves, syringes, gauze, and lab reagents). In most developing country contexts, the health supply chain is managed by the MOH or by parastatal organizations that receive funding and oversight from the government.

**Health Supply Chain Management:** A set of interlinked players and processes – including assessment, planning, procurement, shipping, goods clearance, warehouse and inventory management, in-country distribution, information management, and monitoring and evaluation – that ensure that the right quantities of the right supplies are delivered to the right locations at the right time, to meet the needs of the end-users in the most efficient manner possible (definition sourced from [the UNICEF Process Guide and Toolkit for Strengthening PUBLIC HEALTH SUPPLY CHAINS through Capacity Development](#)). It also encompasses the reverse flow of supplies upstream for waste management and the flow of finances and information upstream and downstream to support and improve supplies management.

## L

**Logistics Assessments:** Provide information related to infrastructure and service availability throughout the area of operation. These tactical assessments are designed to assist managers in identifying elements critical to logistics and the provision of operational support.

## P

**Pooled Procurement Mechanism:** A Global Fund strategic initiative that aggregates order volumes on behalf of grantees to negotiate prices and delivery conditions with manufacturers.

**Procurement and Supply Chain Management (PSM):** Terminology used in Global Fund grants that refers to procurement and supply chain activities.

**Pulled or Requisition system:** A system whereby products are supplied based on demand.

**Push or Allocation system:** A system whereby products are pushed through the supply chain. Distribution is based on forecasts.

## Q

**Quality Assurance (QA):** The totality of the arrangements to ensure that health products are of the quality required for their intended use, including quality monitoring.

**Quality Control (QC):** The part of quality monitoring that includes all measures taken, including the setting of specifications, sampling, testing, and analytical clearance, to ensure that health products conform to established specifications.

**Quality Medicines:** Must consistently and safely provide their intended benefit. All functions, from manufacturing, storing, transporting, and giving people access to medicines must meet quality standards to ensure doses are of the appropriate strength and free of contamination and defects.

**Quality Monitoring:** All activities are undertaken to ensure that health products continue to conform to the manufacturer’s established quality specifications during the storage, distribution, and use of such products, including QC in a laboratory.

## R

**Regulatory Authorities of the Founding Members of the Global Harmonization Task Force (GHTF):** The regulatory authorities of the United States, the European Union, Japan, Canada, and Australia.

## S

**Stringent Drug Regulatory Authority (SRA):** A regulatory authority that is (a) a member of the ICH (as specified on its website:); or (b) an ICH Observer, being the European Free Trade Association (EFTA) as represented by Swiss Medic, Health Canada and WHO (as may be updated from time to time); or (c) a regulatory authority associated with an ICH member

through a legally binding mutual recognition agreement including Australia, Norway, Iceland, and Liechtenstein (as may be updated from time to time).

## W

**World Health Organization (WHO):** The United Nations agency leading global efforts to expand universal health coverage and protect people from health emergencies. Universal health coverage includes improving access to essential medicines and health products as improving monitoring, data, and information. WHO establishes international standards that are integrated by countries, donors, and implementing partners.

# INTRODUCTION

As a Health Annex to the [CRS Supply Chain Management Handbook](#), this guide intends to describe CRS processes that govern the PSM of health products using national or third-party systems in public or private sectors. The goal is to ensure standardization, harmonization, and optimization of the health supply chain process across the agency and thus building sustainable health supply chain systems across the agency and in supported countries.

This Health Annex is intended to provide guidance and valuable resources to successfully implement HPM activities at each phase of the project lifecycle, per international standards and donor requirements. CRS also recommends using the public health system structure, where possible.

The intended audience of this Health Annex is CRS staff, primarily the CRS health supply chain workforce. CRS health supply chain staff are organized across the agency into three levels: country programs, regions, and GSCM.

CRS country programs execute and directly support supply chain activities that are led in the country. Regions provide direct oversight and technical guidance to country programs to achieve operational excellence. GSCM teams support regions and country programs for strategic and innovative interventions, best practices, and advice for quality implementation.

The guide follows the SCM cycle per the figures below and the CRS project management cycle. We have four main parts: 1) Design, 2) Start-up, 3) Implementation, and 4) Closeout (please refer to [COMPASS](#) for more details). For each specific health supply chain activity, we describe the health process and provide RACI tables and resources tables.





# PART I: DESIGN

CRS staff use Agency project management standards to design health supply chain projects. The [CRS Supply Chain Management Handbook](#) recommends and provides practical examples and guidance for successfully developing supply chain projects. This Health Annex includes complementary processes and tools to strengthen the design of health supply chain projects.

Part I focuses on health supply chain specificity during the design phase. It contains the required collaboration mechanisms with local partners, the MOH, private sector, and other key partners as well as the expected cross-discipline collaboration and the different assessments conducted by prominent donors in health.

## CHAPTER 1.1: PROPOSAL

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### POLICIES, PROCEDURES, REGULATIONS, AND GUIDELINES

#### CRS GUIDELINES

- [CRS COMPASS Standards - Design Phase](#)

#### DONOR POLICIES AND REGULATIONS

- [Global Fund The Challenging Operating Environments Policy](#) *Describes PSM capacities to be selected as a principal recipient for The Global Fund*

#### DONOR AND OTHER GUIDELINES

- [Chemonics SCM](#)
- [GAVI Immunisation Supply Chain](#)
- [JSI The Supply Chain Manager's Handbook](#)
- [The Global Fund Guide to Policies on PSM of Health Products](#)
- [USAID Logistics Handbook for Health Commodities](#)
- [USAID PMI Technical Guidance for FY 2023](#)
- [WHO QA](#)

# PROCESS

Preparing the capacity statement is one of the most important first steps of the proposal process. Capacity statements are tailored to each call for expression of interest depending on location and focus.

The GSCM Strategic Technical Assistance and Response Health team develops and regularly updates the organization's capacity statement to support new proposals. The capacity statement includes key information demonstrating CRS expertise in the health supply chain, including:

- A category of health commodities directly or indirectly procured, stored, transported, and distributed (e.g., antimalarial, RDTs), cold chain items, and medical equipment)
- Types of activities or services performed (e.g., warehouse and inventory management, technical assistance, ICT4D for SCM, and innovations)
- Types of partnerships - public and private - implemented
- Geographical areas covered
- Activity implementation type: Direct management or health systems strengthening
- Number of beneficiaries supported
- Success stories and evidence-based solutions

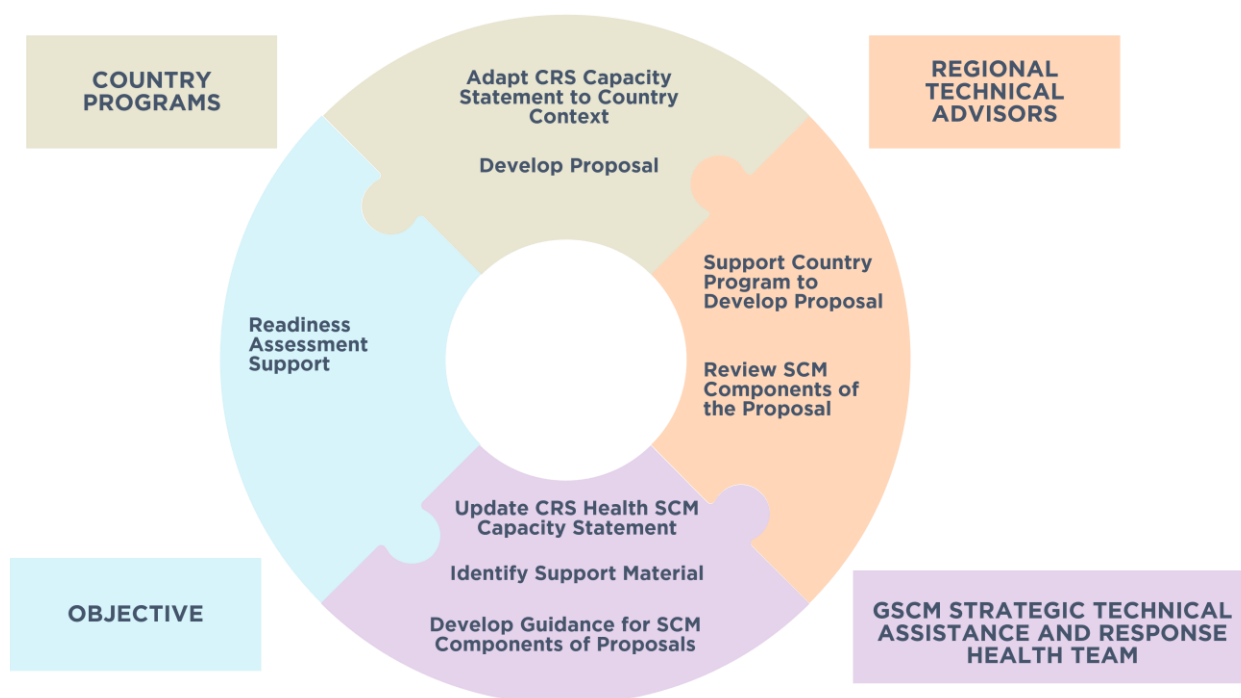
## What is a capacity statement?

A brief, written document showing the Agency's expertise, achievements, know-how, and differentiated approaches.



Capacity statements are used to support proposal development.

## CRS Health Supply Chain Management Process to Prepare Proposal Response



For new projects with no Health Supply Chain Manager position, the Supply Chain Manager of the country program is responsible for preparing and providing input to the response.

The design of a health supply proposal requires health supply chain expertise.

If the country program does not have health supply chain expertise, we recommend reaching the SCM Regional Technical Advisor for technical assistance support.



# CHECKLIST

## *Proposal Response Process*



In this process, the designation “**Health Supply Chain Manager**” refers to the **country focal point** identified to support the design process or the **Supply Chain Manager** of the country program. The present process underlines steps taken when country programs prepare the proposal response.

- ☐ The **Head of Programming** assembles a proposal team and assigns a coordinator per CRS project management standards. The coordinator profile can vary depending on the country program workforce and organization.
- ☐ The **Proposal Team Coordinator** informs and shares the RFP with the **Health Supply Chain Manager** and the **SCM Regional Technical Advisor**.
- ☐ The proposal team coordinator defines a timeline to prepare the RFP response, including quality checks and review from other departments.
- ☐ The **Health Supply Chain Manager** analyses the RFP and extracts the requirements for Health Products Management (HPM).
- ☐ The **Health Supply Chain Manager** analyzes HPM objectives and expected results considering the country program’s capacity. The **Health Supply Chain Manager** also identifies essential requirements to include in the capacity statement and resources required.
- ☐ The **Health Supply Chain Manager** prepares the proposal section related to health supply chain management based on the GHSC statement to tailor to RFP expectations and include the country context.
- ☐ The **Health Supply Chain Manager** coordinates review with the **SCM Regional Technical Advisor**. The **SCM Regional Technical Advisor** can request support from the **GSCM Strategic Technical Assistance and Response Health team** as necessary.
- ☐ The **SCM Regional Technical Advisor** reviews and provides feedback to the **Health Supply Chain Manager**.
- ☐ The **Health Supply Chain Manager** includes input and submits to the proposal team coordinator.
- ☐ The **Proposal Team Coordinator** combines all sections from other departments and prepares to finalize the proposal.
- ☐ The **Proposal Team Coordinator** informs the **SCM Regional Technical Advisor** and **Supply Chain Manager** of the final submission to the donor.

Please note the involvement of other stakeholders in proposals managed at the global level. For instance, internal stakeholders could be GKIM, The Global Fund Support Unit, and/or Regional Technical advisors. External stakeholders could be, national programs, Pharmacy Directorate, and/or international partners



## ROLES AND RESPONSIBILITIES

Function/Activity	Project Coordinator or Business Development Manager	Head of Programming	Supply Chain Manager	SCM Regional Technical Advisor	GSCM Strategic Technical Assistance and Response Health Team
Prepares and keeps Health PSM capacity statement updated	I	I	C	C	R
Informs and shares RFP	R	A	C	I	I
Prepares a submission timeline	R	A	C	I	I
Analyses RFP and extracts HPM activities	A	I	R	C	
Coordinates review with SCM RTA	A	I	R	C	
Reviews and provides feedback	I	I	A	R	C
Adjusts and submits to proposal team	A	I	R	C	
Informs on final version submitted	C	A	R	I	I

R=Responsible; A=Accountable; C=Consulted; I=Informed

# CHAPTER 1.2: HEALTH SUPPLY CHAIN ASSESSMENT

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## POLICIES, PROCEDURES, REGULATIONS, AND GUIDELINES

### CRS GUIDELINES

- [CRS Supply Chain Transformation for Excellence Project Assessment Guidance](#)

### DONOR AND OTHER GUIDELINES

- [The Global Fund Guidelines for LFAs for Capacity Assessment of Implementers](#) *Not addressed to implementers- but valuable to know how LFAs conduct capacity assessment meetings*
- [The Global Fund Guidelines on Implementers of Global Fund Grants](#) *Includes requirements for assessing Implementers of Global Fund grants*
- [The Global Fund Instructions on Implementation Arrangement Mapping](#) *Provides practical guidance on how to map relations and links between entities, provides the symbol list, how to record flows on roles and responsibilities, funds, commodities, and assets*
- [The Global Fund Technical Brief: Procurement and Supply Chain Management](#) *Helps countries and implementers define the SCM roadmap in planning, execution, and enablers*
- [USAID Organization Capacity Assessment Tools](#)
- [WHO Essential Medicines Prequalification List](#)
- [WHO Electronical Essential Medicines List](#) *Provides detailed information on medicines*
- [WHO Good Storage and Distribution Practices for Medical Products](#)
- [WHO Medicines Prequalification](#)

## PROCESS

Conducting initial health supply chain and logistics assessments for health projects is essential to guiding the design process and preparing to respond to donor requirements and reviews. Collecting baseline data on logistics systems capacity and performance can better inform the design, determine the resource requirements, and provide monitoring and evaluation data as shown in the figure below.



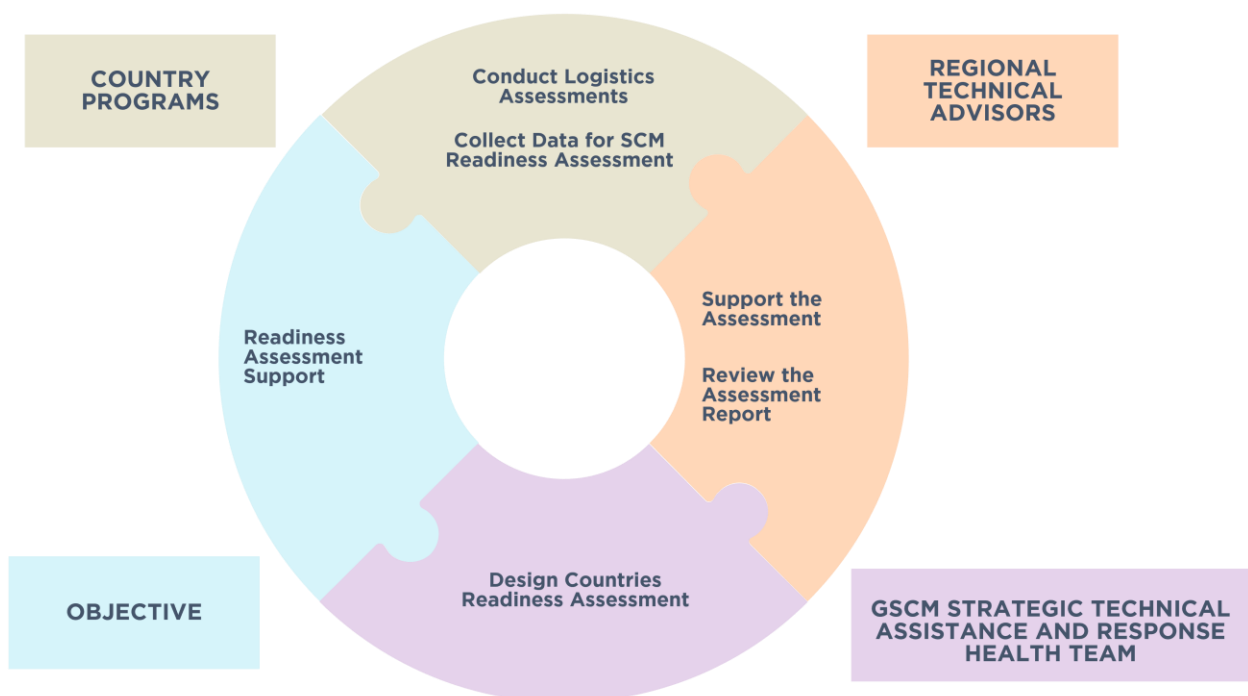
A health supply chain assessment is required to identify the strengths and weaknesses of health systems. However, considering the resources and time needed for that exercise, conducting a detailed assessment during the design phase may not be feasible. Thus, we recommend collecting information from previous reviews and requesting the donor perform a future thorough analysis.

The Health Supply Chain Manager needs to coordinate with implementers and stakeholders to conduct the healthy supply chain assessment. Various supply chain assessment tools exist that are already developed by well-known actors. Therefore, the available in-country information is leveraged.

Logistics Assessments: For more information, please refer to the Supply Chain Design chapter of the [CRS Supply Chain Management Handbook](#).



## CRS Health Supply Chain Management Process for Capacity Assessments





Health supply chain experts lead health supply chain assessments. Country programs without in-house expertise at the design phase need to request support from regions.

## CHECKLIST *Capacity Assessment Process*



In this process, “Health Supply Chain Manager” refers to the country focal point identified to lead the design process or the Supply Chain Manager of the country program.

- ☐ The Head of Programming/Chief of Party appoints the country program focal point to lead the health supply chain design, preferably with health supply chain expertise.
- ☐ The Head of Programming/Chief of Party, in collaboration with the Health Supply Chain Manager, defines a timeline for collecting, analyzing, and reviewing documents.
- ☐ The Health Supply Chain Manager conducts a logistics and supply chain assessment for a new country program or collects existing information. *Please refer to the [CRS Supply Chain Management Handbook](#) for detailed information on logistics assessments.*

### Sample of Main CATs

- **CRS Supply Chain Transformation for Excellence Project Assessment Guidance:** CRS’ internal assessment tool, The Supply Chain Transformation for Excellence Project, takes a comprehensive view of the supply chain opportunities ahead, including Project Insight, the release of the CRS Supply Chain Management Handbook, CTP, and the HR job standardization project. The goal of this tool is to transform CRS’ supply chain so that country programs can adapt to these changes. The Supply Chain Transformation for Excellence Project Assessment Guidance will ensure that country programs can 1) achieve program objectives, 2) meet global minimum standards, and 3) implement Project Insight.
- **USAID NSCA Toolkit:** Funded by USAID is a comprehensive toolkit that can assess the capability and performance at all levels of a health supply chain or focus on a specific level or site within the system. CMM and KPIs are the metrics used to assess capability and performance, respectively. The results of the assessment help supply chain stakeholders develop their strategic, operational, and/or investment plans and monitor whether activities are achieving desired outcomes.
- **UNICEF Supply Chain Maturity Model:** This model is a participatory, qualitative, and government-led supply chain assessment tool that governments and organizations can use to measure the performance of key supply chain functions across five levels. Level 1 brings evidence of minimum development, while level 5 reflects best SCM and practices. The maturity model complements other quantitative supply chain assessments such as the Effective Vaccine Management, NSCA, and Immunization Supply Chain Process scorecard. In addition, the tool allows for matching shifting country needs with external partner resources and helps partners with planning and coordination processes.

- **The Global Fund CAT (LFA template):** Before signing a grant agreement with a Principal Recipient, The Global Fund ensures that the proposed implementation arrangements are sound. To do so, The Global Fund, through the LFA, assesses whether the systems and capacities of grant implementers are adequate for effective management of the grant funds. Indeed, The Global Fund's CAT covers various aspects of a project from governance, finance, programmatic to procurement, and SCM. The assessment aims to:
  - Evaluate the capacity of CRS to implement the program.
  - Describe and assess the proposed implementation arrangements and systems in four functional areas: M&E, PSM, Finance, and Governance.
  - Determine if CRS has adequate capacity and systems in place to fulfill the role assigned in the program.
  - Identify critical capacity gaps and determine capacity-building measures to address these in the short and long term.

## CHECKLIST

*CAT Response Guidance*

- ☐ The **Health Supply Chain Manager** collects documents and information using the [CRS CAT Response Guidance](#).



# CHECKLIST

## Capacity Assessment Process



In this process, “**Health Supply Chain Manager**” refers to the **country focal point** identified to lead the design process or the **Supply Chain Manager** of the country program.

- ☐ The **Health Supply Chain Manager** will come up with the following information:
  - A first draft list of interventions, based on gaps identified. *Refer to the donor [The Global Fund Modular Framework Handbook](#) for appropriate interventions.*
  - Preliminary risk analysis.
  - Activities identification and mitigations as a response to the preliminary risk analysis.
- ☐ The **Health Supply Chain Manager** submits available documents and draft interventions for review by the **SCM Regional Technical Advisor**.
- ☐ The **SCM Regional Technical Advisor** provides input and comments to the list of interventions.
- ☐ The **Health Supply Chain Manager** integrates the **SCM Regional Technical Advisor’s** comments in the final documents and organizes working sessions with implementing partners to share outcomes of the review. Objectives of this working session should be to:
  - Confirm or adjust the weakness identified.
  - Confirm or change the risk analysis.
  - Confirm or modify the list of activities or mitigating actions.
- ☐ The **Health Supply Chain Manager** prepares for the capacity assessment conducted by the donor using the [CRS CAT Response Guidance](#). However, even if the donor performs the capacity assessment after the implementation arrangements, we recommended preparing earlier to begin addressing items that can be achieved before the evaluation.
- ☐ The **Health Supply Chain Manager** submits the information required during the capacity assessment conducted by the donor with the support of the **SCM Regional Technical Advisor**.

## ROLES AND RESPONSIBILITIES

Function/Activity	Heads of Programming /Chiefs of Party	Health Supply Chain Manager	SCM Regional Technical Advisor	GSCM Strategic Technical Assistance and Response Health Team
Appoints the country program focal point	R	C	I	I
Defines a timeline for collecting, analyzing, and reviewing documents	A	R	C	I
Conduct a logistics assessment and health supply chain assessment	A	R	C	I
Collects documents and information from stakeholders	A	R	C	I
Proposes key interventions to address weaknesses identified	A	R	C	I
Submits available documents and suggested interventions for review		R	C	
Provides input and comments to the list of interventions		C	R	C
Organizes a working session with implementing partners for feedback on analysis and activities identification	A	R	C	I
The Health Supply Chain Manager prepares for the capacity assessment conducted by the donor using the CAT assessment draft response	A	R	C	I
Submits the information required during the capacity assessment conducted by the donor with the support of the SCM Regional Technical Advisor	A	R	C	I

R=Responsible; A=Accountable; C=Consulted; I=Informed

# CHAPTER 1.3: HEALTH SUPPLY CHAIN DESIGN

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## POLICIES, PROCEDURES, REGULATIONS, AND GUIDELINES

### CRS GUIDELINES

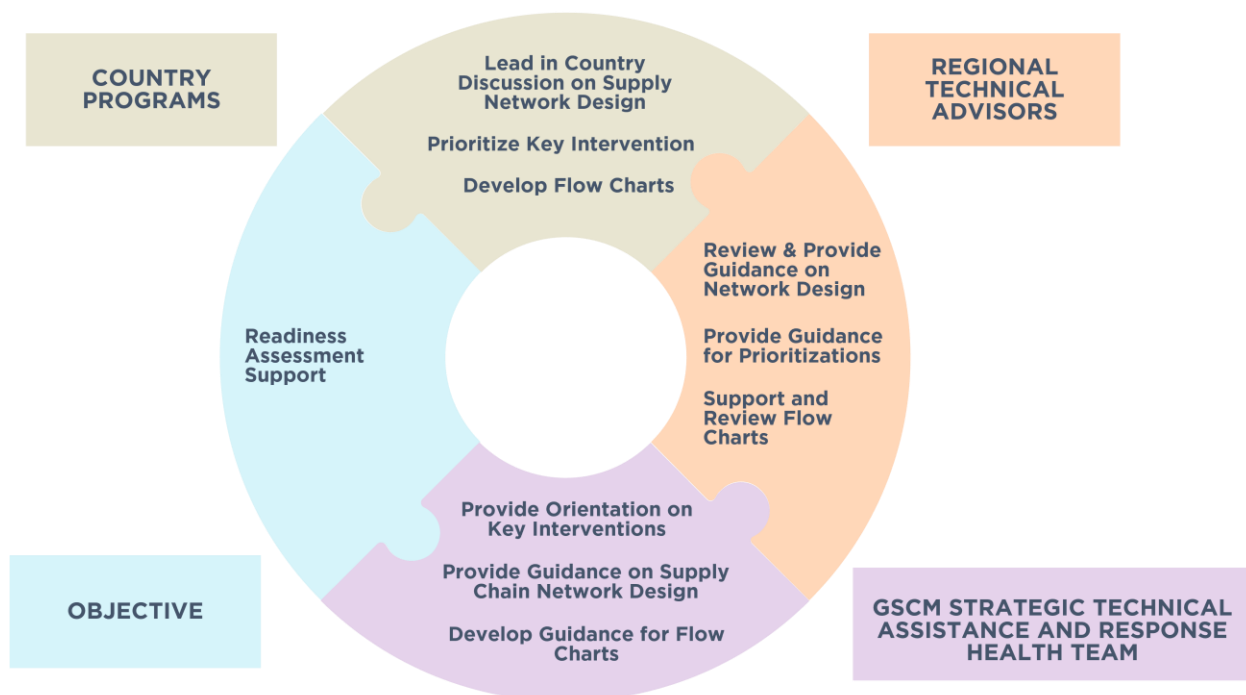
- [CRS Supply Chain Management Handbook](#). Chapter 4: Supply Chain Design

### DONOR AND OTHER GUIDELINES

- [JSI The Supply Chain Manager's Handbook, Chapter 2: System Design & Strategy](#) *Provides an understanding of the importance of dedicating resources to supply chain design and guidance*
- [JSI The Supply Chain Manager's Handbook, Chapter 3: Logistics Management Information Systems](#) *Provides further details about how data are used for routine operations, strategic decisions, and monitoring of the performance of the supply chain*
- [The Global Fund Instructions on Implementation Arrangements Mapping](#) *Provides practical guidance on how to outline the map, the relations, and links between entities; also provides the symbol list, how to record the roles, responsibilities, fund and commodity, and asset flows*
- [Village Reach Supply Chain Design: Options to Address Common Challenges](#) *Provides guidance on preparing supply chain design while using governmental systems*

# PROCESS

## CRS Health Supply Chain Management Process for Implementation Arrangement



Public health systems are often defined as all public, private, and voluntary entities that contribute to delivering essential public health services within a jurisdiction. A public health supply chain is a network of interconnected organizations or actors that ensures the availability of health commodities to the people who need them.

The purpose of designing the logistics system is to optimize the flow of commodities and information, as well as standardize the related business processes.

It is required to conduct optimization exercises based on the supply chain performance analysis and cost-effectiveness analysis outcomes to identify a more efficient warehousing and distribution mechanism. Coordination and discussion with stakeholders should be conducted to design a system that aligns with the national supply chain strategy. Propositions for redesigning the supply chain need to be aligned with existing national plans, if any (i.e., NSC transformation plans, conclusions of previous assessments, etc.). Any change in the supply chain design will likely have a cost impact (new contractors, required training, etc.) that will need to be accounted for in the budget.

The Health Supply Chain Manager should explore the identified [5 Promising Practices](#) to guide design discussions while using governmental supply chain systems. For example, the following five promising practices were successful, even for hard-to-reach communities: direct delivery, level jumping, outsourcing (engaging the private sector), resources sharing, and resupply frequency.



Country programs may not have the opportunity to conduct the detailed analysis and design recommended above due to various reasons. The implementation arrangements often align to the existing health supply chain network. **It is required to discuss arrangements with the donor to agree on the detailed analysis timeline later during the implementation.**

It is imperative to collaborate with the MOH and related departments to establish an implementation arrangement in the health supply chain. Understanding how the existing supply chain works helps country programs collaborate with implementing partners to define the best health supply chain network. The design of the health supply chain network can include:

- Leveraging on the existing health supply chain infrastructure.
- CRS directly distributing health products.
- Contracting third-party service.
- Combining various approaches above.

Procurement can be performed through a procurement service agent and/or directly by CRS. Warehousing and transportation of health products can be performed through Third-Party Logistics providers from the public sector, i.e., central medical stores, or the private sector. At last-mile delivery points, health products can be delivered to patients throughout various settings such as health facilities, directly through temporary distribution points, or via door-to-door advanced strategies.



## Health Supply Chain Arrangements

## CHECKLIST

*Health Supply Chain Arrangements*

- ☐ The **Health Supply Chain Manager**, based on audit findings, health supply chain past performance, assessment, and national documentation on health supply chain (i.e., supply chain operational plan, supply chain strategy) explores different supply chain arrangements to consider improving the efficiency of the current health supply chain.
- ☐ The **Health Supply Chain Manager** conducts visits in health infrastructures (i.e., central warehouse, regional, districts, health facilities, and health posts) to better understand the supply chain network.
- ☐ The **Health Supply Chain Manager** consults with partners (i.e., national entities such as CMS), national disease programmes, regulatory authority, other international technical partners, donor) on existing or upcoming SC initiatives.
- ☐ The **Health Supply Chain Manager**, in collaboration with the **SCM Regional Technical Advisor**, can leverage the in-country private sector to address gaps identified in the governmental supply chain systems.
- ☐ The **Health Supply Chain Manager** should explore the identified **5 Promising Practices** - direct delivery, level jumping, outsourcing (private sector), resource sharing, and resupply frequency - to guide the design discussion.
- ☐ The **Health Supply Chain Manager** proposes a different supply chain scenario collaborating with national stakeholders.
- ☐ The **Health Supply Chain Manager** initiates a discussion with **national stakeholders** and **donors** to agree on the best supply chain arrangements.
- ☐ The **Health Supply Chain Manager** works on the product and information flow to identify additional mitigation measures and the appropriate supply chain arrangements based on donor feedback.

# ROLES AND RESPONSIBILITIES

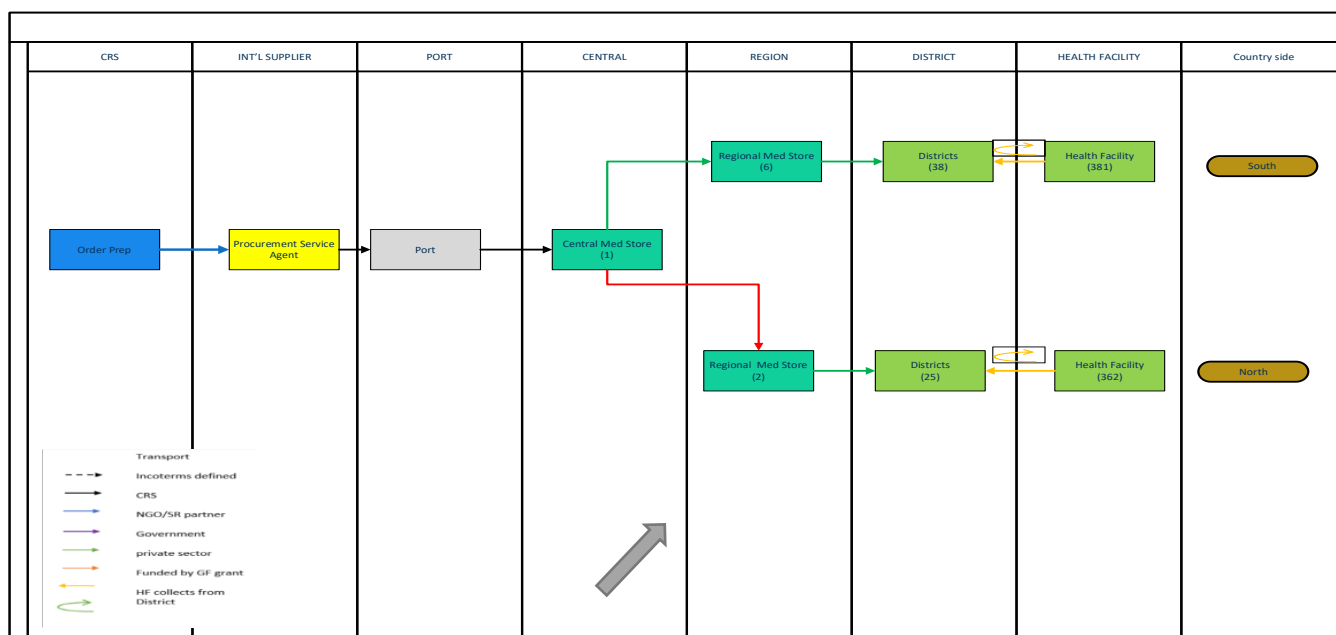
Function/ Activity	Heads of Programming/ Chiefs of Party	LMIS Officer	Logistics Manager	Country Program Supply Chain Manager	Health Supply Chain Manager	SCM Regional Technical Advisor	GSCM Strategic Technical Assistance and Response Health Team	Donors PSM	National Stakeholders
Explores different supply chain arrangements to consider improving the efficiency of the current health supply chain	A	C	C	C	R	C	C	I	I
Conducts visits to health infrastructures (central Warehouse, regional, districts, health facilities, and health posts) to better understand the supply chain network	A	C	C	R	C	C	I	I	C
Leverages the in-country private sector, or the best practices across CRS-supported countries to suggest supply chain arrangements	A	C	C	C	R	C	I	I	I
Proposes different scenarios of supply chain arrangements in collaboration with national stakeholders	A	C	C	C	R	C	I	I	C
Initiates discussion with national stakeholders and donors to agree on the best supply chain arrangements	R	C	C	C	C	C	I	C	C
Elaborates product flow and information flow to identify additional mitigation measures and the appropriate supply chain arrangements	A	C	C	C	R	C	I	C	C

R=Responsible; A=Accountable; C=Consulted; I=Informed

# CRS TOOLS TO SUPPORT THE DESIGN OF THE SUPPLY CHAIN

## PRODUCT FLOW CHART

Product flow charts intend to represent the physical path taken by the products from the port of entry to the patients or end-users. Having a clear picture of the distribution process from one point to another helps define how responsibilities and custody are managed and identify strengths and risks in terms of management as safety of the products and accountability. See the below figure that shows the seasonal malaria chemo prevention's product flow chart model.



The product flow chart sketches how products flow throughout the supply chain and defines which stakeholder has responsibility, custody, and accountability.

# CHECKLIST

## Product Flow Chart



- ☐ The **Health Supply Chain Manager** organizes a working session with the leading stakeholder (i.e., national program) to fill up the product flow chart questionnaire.
- ☐ The **Health Supply Chain Manager** prepares the product flow chart in collaboration with the **Country Program Supply Chain Manager** and **Finance Manager**. The product flow chart schematically reflects the results obtained from the questionnaire.
- ☐ The **SCM Regional Technical Advisor** reviews the product flow chart based on the product flow chart questionnaire and shares the review with the **Health Supply Chain Manager**.
- ☐ The **Health Supply Chain Manager** should organize a working session with the leading national stakeholder to adjust and validate the product flow chart.
- ☐ The **Health Supply Chain Manager** updates the risk analysis to integrate mitigation action identified after elaborating the product flowchart and then shares with the **SCM Regional Technical Advisor** for review.

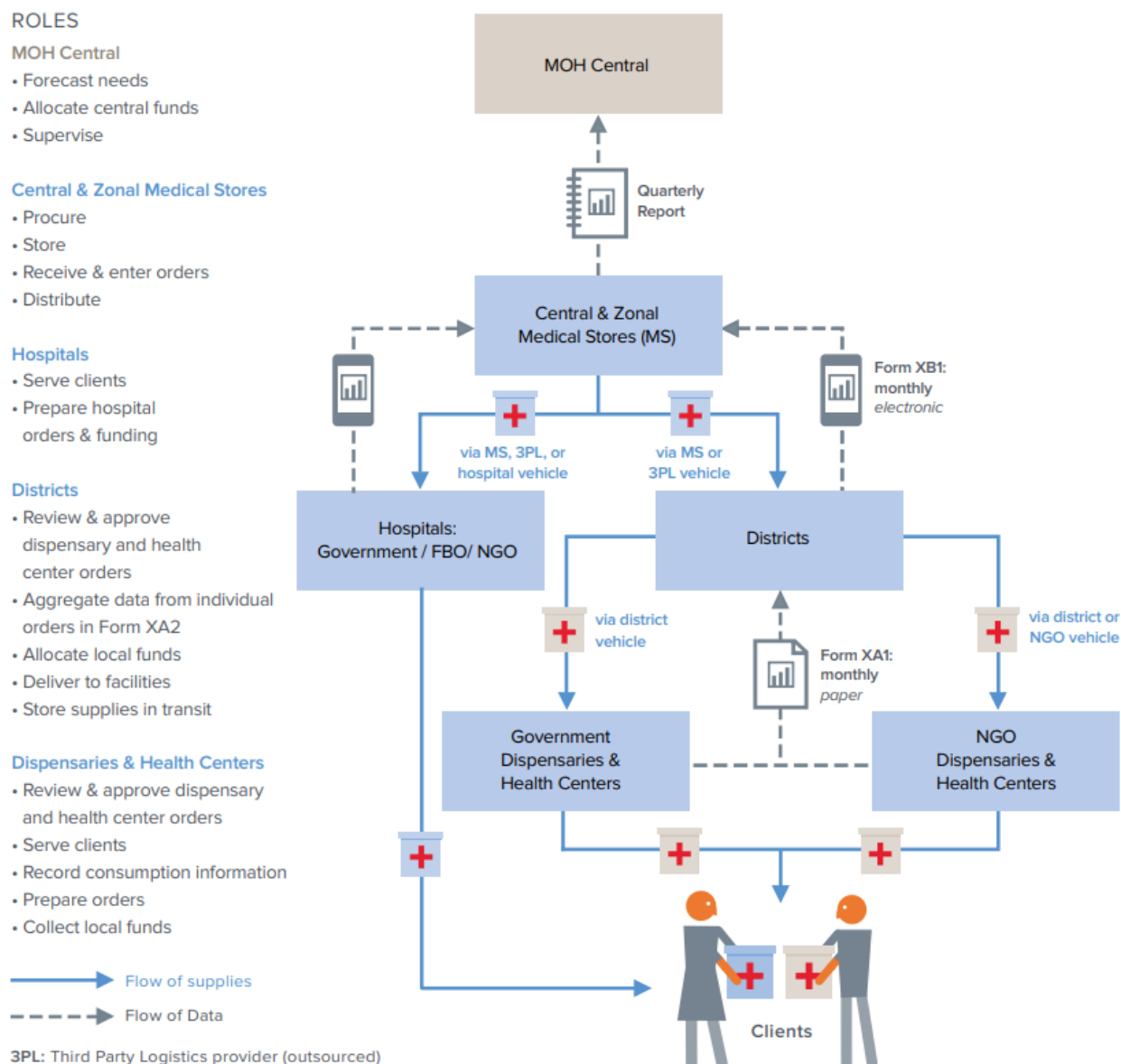
## ROLES AND RESPONSIBILITIES

Function/Activity	Heads of Programming/Chiefs of Party	Country Program Supply Chain Manager	Finance Manager	Health Supply Chain Manager	SCM Regional Technical Advisor	GSCM Strategic Technical Assistance and Response Health Team
Tailors the product flow chart questionnaire to the local context	I			C	R	C
Provides orientation on how to fill the product flow chart questionnaire	I			C	R	A
Organizes working sessions with the main stakeholder to collect responses on the product flow chart questionnaire	A	C	C	R	C	I
Prepares the product flow chart questionnaire	I	C	C	R	A	C
Organizes a working session with the leading national stakeholder to adjust and validate the product flow chart	A	C	C	R	C	C
Updates the risk analysis	A	C	C	R	I	I
Reviews and adjusts	A	I	I	C	R	C

R=Responsible; A=Accountable; C=Consulted; I=Informed

## INFORMATION FLOW CHART

Information flow charts represent the logistical information's physical (for paper-based supports) or virtual (for electronic support) stream. Having a clear picture of how the logistical information flows between the various points helps define reporting mechanism of key information (i.e., stock levels). The figure below from Chapter 3 of JSI's *The Supply Chain Manager's Handbook, A Practical Guide to the Management of Health Commodities* shows a sample of a logistic information and supply flow diagram.



Source: Sample LMIS Information and Supply Flow Diagram, *The Supply Chain Manager's Handbook, A Practical Guide to the Management of Health Commodities*, John Snow, Inc., 2020, p. 27.

# CHECKLIST

## *Information Flow Chart*



- ☐ The SCM Regional Technical Advisor adjusts the [information flow chart questionnaire](#) to the local context.
- ☐ The SCM Regional Technical Advisor provides an orientation to the Health Supply Chain Manager on how to complete the [information flow questionnaire](#).
- ☐ The Health Supply Chain Manager, in collaboration with the SCM Regional Technical Advisor, Country Program Supply Chain Manager, M&E, and LMIS Officer, prepares the first draft of the information flow chart. The information flow chart schematically reflects the information obtained from the questionnaire.
- ☐ The Health Supply Chain Manager organizes a working session with the leading national stakeholder to find the logistic information downstream and upstream flows. The supporting document to use for this exercise is the [information flow questionnaire](#).
- ☐ The SCM Regional Technical Advisor reviews and adjusts the information flow chart if necessary and submit it to the country program for final validation with the leading national stakeholder.
- ☐ The Health Supply Chain Manager updates the [risk analysis](#) and shares it with the Health Supply Chain Manager.
- ☐ The SCM Regional Technical Advisor reviews and adjusts the risk analysis.



## ROLES AND RESPONSIBILITIES

Function/Activity	Heads of Programming/Chiefs of Party	Country Program Supply Chain Manager	M&E	LMIS Officer	Health Supply Chain Manager	SCM Regional Technical Advisor	GSCM Strategic Technical Assistance and Response Health Team
Tailors the information flow chart questionnaire to the local context	I				C	R	C
Provides orientation on how to fill the information flow chart questionnaire	I	C	C	C	C	R	A
Prepares the first information flow chart draft	I	C	C	C	R	C	I
Organizes working sessions with the main stakeholder to collect responses on the information flow chart questionnaire	A	C	C	C	R	C	C
Finalize the information flow chart questionnaire	I	C	C	C	R	A	C
Updates the risk analysis	A	C	C	R	I	I	C
Reviews and adjusts	A	I	I	C	R	C	C

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# COLLABORATIVE PARTNERSHIPS

Health supply chain projects require partnering with various stakeholders. These stakeholders play key roles in the importation, transportation, warehouse and inventory management, data management, distribution, and dispensation. CRS can establish a partnership with the private sector (i.e., Third-party Logistics) and public sector (i.e., central medical store, national programs, and health facilities) entities.

To implement SCM activities, each party needs to have a common understanding of their roles and responsibilities. A detailed SOW will need to be developed to define the process, roles, and responsibilities in the collaboration.

The SOW, payment modalities, and donor guidance will constitute the agreements. More details on the contracting mechanism are provided later in the [contracting chapter](#). This section covers the establishment of the process.

## CHECKLIST *Collaborative Partnerships*



- ☐ The **Health Supply Chain Manager** lists key activities and deliverables that will need the development of solid collaborative processes to reach expected results.
- ☐ The **Health Supply Chain Manager** develops or adapts written processes for key activities such as organizing visits to warehouses, conducting joined supervisions, workshops, completing donor reporting requirements, training performance, etc.
- ☐ The **Health Supply Chain Manager**, in collaboration with the **Chief of Party, Country Program Supply Chain Manager, LMIS Officer, SCM Monitoring, and SCM Regional Technical Advisor**, organizes a working session with the partner to correct, adjust, and validate the process. These processes will inform the contracting mechanism with the partner.
- ☐ The **SCM Regional Technical Advisor** requests support from the **GSCM Health Strategic Technical Assistance and Response team** to prepare drafts of the collaborative processes or leverages on the previous existing partnership.

## ROLES AND RESPONSIBILITIES

Function/Activity	Heads of Programming/ Chiefs of Party	Country Program Supply Chain Manager	LMIS Officer	SCM Monitoring	M&E	Health Supply Chain Manager	SCM Regional Technical Advisor	GSCM Strategic Technical Assistance and Response Health Team
Lists key activities requiring solid collaborations	A	C	C	C	C	R	C	I
Prepares collaborative processes with main stakeholders	A	C	C	C	C	R	C	I
Organizes a working session with leading stakeholders to validate collaborative processes	A	C	C	C	C	R	C	I
Provides support to prepare the collaborative processes	C	C	C	C	C	C	R	C

R=Responsible; A=Accountable; C=Consulted; I=Informed

## CHAPTER 1.4: DEFINE PROCUREMENT AND SUPPLY CHAIN INTERVENTIONS

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### POLICIES, PROCEDURES, REGULATIONS, AND GUIDELINES

#### CRS POLICIES AND PROCEDURES

- [CRS COMPASS Standard 2](#)
- [CRS COMPASS Standard 3](#)

#### DONOR POLICIES AND REGULATIONS

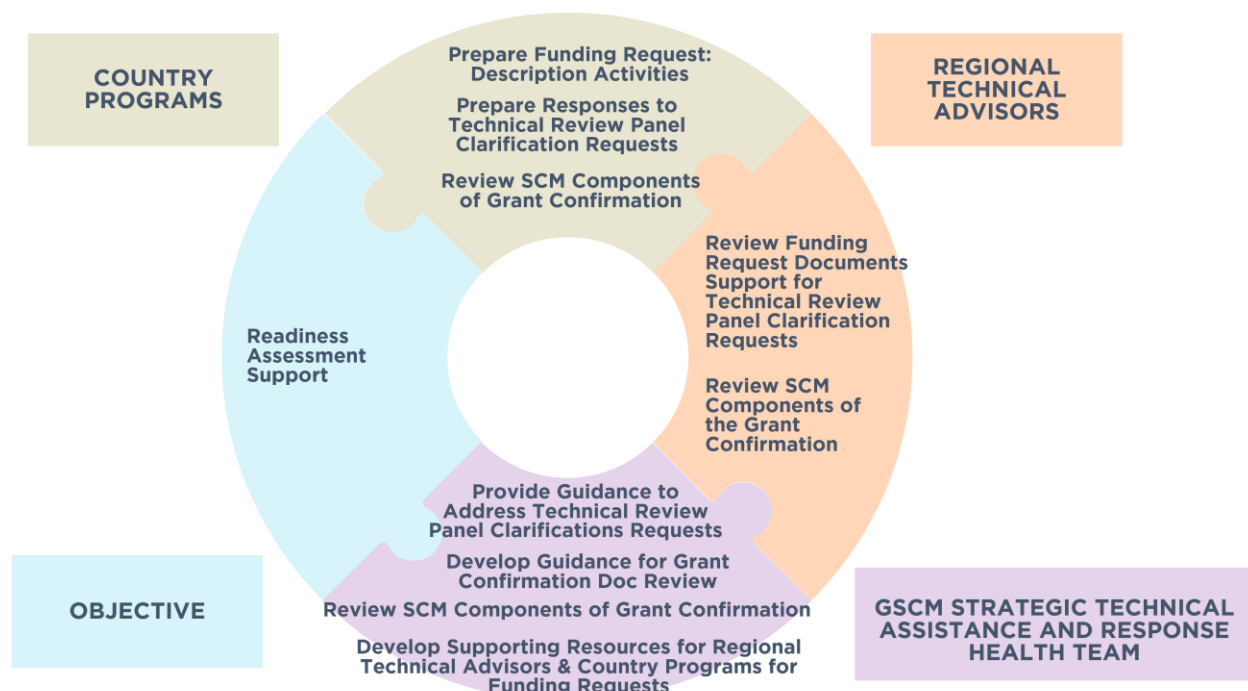
- [USAID Vision for HSS 2030](#)

#### DONOR AND OTHER GUIDELINES

- [The Global Fund Modular Framework Handbook](#)
- [The Global Fund Resilient and Sustainable Systems for Health](#)

# PROCESS

## CRS Health Supply Chain Management Process for Defining PSM Interventions



The procurement and supply chain interventions are defined based on the supply chain assessment outcomes and align with national supply chain strategies.

At CRS, we recommend including interventions justified by evidence-based needs or gaps and national stakeholders' early involvement in elaborating the strategy and interventions.

Supply chain interventions can be categorized into two categories:

- **Intervention related to the management of commodities for a project:** Includes the cost related to procurement, pre-shipment QC, international transport, warehousing, and in-country distribution.
- **Interventions related to strengthening the national procurement and supply chain system:** Includes capacity building for the SCM workforce, digitalization of the health system, system optimization, supply chain assessment, infrastructure improvement, strengthening the NMRA, and Pharmacovigilance.

Prominent donors are considerably investing in health supply chain system strengthening. PSM interventions should be elaborated in light of donors and country supply chain strategies.

- Global Fund refers to RSSH to design all the interventions for strengthening the health system. It includes improving procurement and supply chain, strengthening data systems and data use, building stronger community systems and responses, promoting integrated people-centered health services, and investing in HR. A detailed [Global Fund Supply Chain Road Map covering 2023-2025](#), developed with stakeholders, provides guidance relevant during the design phase.

- USAID also revised its strategies and implemented the [NextGen Global Health Supply Chain](#) with an emphasis on supply chain segmentation, improving private sector partnership, reinforcing government stewardship, increasing end-to-end visibility, using performance contracts, and improving risk management.

## HEALTH SUPPLY CHAIN GENERIC ACTIVITIES

The GSCM Strategic Technical Assistance and Response Health team developed a compendium of generic activities to support The Global Fund health supply chain team. Generic activities are intended to ensure alignment of in-country support provided by the CRS technical experts for implementing Global Fund grants and delineate the roles and responsibilities of the CRS supply chain supporting system: headquarters, regions, and country programs.

Per CRS' programmatic approach, the country program will implement activities; the SCM Regional Technical Advisor will provide direct support and technical oversight to the country program; and the headquarters team will develop strategic orientation, processes, procedures, and materials for capacity building.

The [CRS Detailed List of Health SCM Activities](#) will guide the supply chain manager in the country program and the SCM Regional Technical Advisor in implementing supply chain activities. The list describes the type of activities that the country program needs to implement to support the health supply chain grants.

This detailed list of activities intends to provide the country program and regional technical advisors with a systematic approach to use across the various grants and to better define the roles and responsibilities of stakeholders.

The activity list will also provide direction for the SCM Regional Technical Advisor to ensure required country program support is provided, as well as provide clarity on the GSCM Strategic Technical Assistance and Response health team activities.

## CHECKLIST

### *Health Supply Chain Generic Activities*

- ☐ The **Health Supply Chain Manager** reviews the list of activities at each phase of the grant implementation to identify interventions and support to request from the **SCM Regional Technical Advisor** and the **GSCM Strategic Technical Assistance and Response Health team**.



The [CRS Detailed List of Health SCM Activities](#) includes specific activities required during a Global Fund project's design, start-up, implementation, and close-out. The list has categorized the activities per intervention to facilitate the navigation per the list below:

1. Strengthening CRS internal health supply chain processes:
  - a) Readiness assessment support
  - b) Internal support & collaboration
  - c) Strategy, policies & procedures/compliance
  - d) Strong relationships with donor's supply chain division
  - e) Project implementation support
2. Elevate supply chain effectiveness through innovations:
  - f) Data management, analysis, and reporting
  - g) Risk mitigation
3. Reinforcing and institutionalizing the risk-based approach in health SC
4. Reinforce our workforce knowledge in health SC best practice
  - h) Reinforce and strengthen country program staff (Supply Chain Manager, Programming Staff) knowledge
  - i) Capacity building for partners
5. Reinforcing the use of metrics and performance
  - j) Metrics and performance

In addition to the above categories, we have included specific objectives expected to better guide end-users.

## CHECKLIST

### *Health Supply Chain Generic Activities*



- ☐ The **Health Supply Chain Manager** regularly evaluates activities with the generic list and raises challenges, bottlenecks, and questions to the **SCM Regional Technical Advisor**.
- ☐ The **Health Supply Chain Manager** updates the **SCM Regional Technical Advisor** via monthly calls on ongoing activities and raises any challenges.
- ☐ The **Health Supply Chain Manager** will reach out to the **SCM Regional Technical Advisor** for any technical issues or required guidance on SCM policy and procedures.
- ☐ The **SCM Regional Technical Advisor** regularly follows the evolution of health SCM activities and KPIs and submits a brief report of the regional implementation to the **GSCM Strategic Technical Assistance and Response Health team** on KPIs, success, challenges, and potential bottlenecks.

## SELECTION OF PSM INTERVENTION

After reviewing existing material from the donor, CRS, and outcomes of the supply chain assessment, the supply chain team will need to prioritize intervention.

### CHECKLIST

#### *Selection of PSM Intervention*



- ☐ The **Health Supply Chain Manager** collects all the suggested interventions during the health supply chain assessment, the design exercises, the preparation of the CAT, the risk analysis, the analysis of the product, and information flow to identify priorities activities.
- ☐ The **Health Supply Chain Manager** prioritizes activities in collaboration with the national stakeholders, using the following criteria:
  - Estimated budget of the interventions considering the available funds.
  - The impact of the selected activities on the success of the project.
  - National Health supply chain strategy priorities.
  - Support from other donors.
  - Alignment with donor priority.
- ☐ The **Health Supply Chain Manager** identifies the activities to include directly in the project or the HSS projects based on donor guidance.

## DEVELOPMENT OF PSM OPERATIONAL PLAN

The country program collaborates with national authorities and implementing partners to develop a clear description of PSM interventions and activities to gain donor approval. PSM interventions and activities that are new and/or require new technologies, and processes, or include some level of complexity require a detailed description or visualization to gain acceptance from stakeholders. The process below describes how to prepare the operational plan as additional resources detailing some of these activities.



## For New Projects with No Global Fund Supply Chain Manager Position Filled

### CHECKLIST

*New Projects w/ No Global Fund SCM Position*

- ☐ The **Health Supply Chain Manager** prepares the narrative, Terms of Reference, presentation, etc. Upon request, the **GSCM Strategic Technical Assistance and Response Health team** can provide a model.
- ☐ The **SCM Regional Technical Advisor** submits the document or presentation to the **GSCM Strategic Technical Assistance and Response Health team** for review.



Two types of descriptions are required: The PSM operational plan, detailing common PSM operations (warehousing, transport, procurement, etc.) and narratives or term of reference for more complex activities.

- For each suggested intervention, a concise description of the activity, with information on the issue to resolve, the reason for selecting that activity with evidence-based data, number of beneficiaries, participants, or facilities covered, the indicators to monitor, and the expected outcomes. See the [CRS Model of Budget Narrative](#).
- The operational plan provides information on the routine distribution and mass campaign distribution mechanism, logistics arrangements, and roles and responsibilities of the stakeholders. See the [CRS Model of Procurement and Supply Chain Management Plan](#).

## For Renewed and Ongoing Projects

### CHECKLIST

*Renewed & Ongoing Projects*

- ☐ The **Health Supply Chain Manager** prepares the narrative, Terms of Reference, presentation, etc.

For existing grants, similar types of narratives, budget narratives and operational plans, are required. The **Health Supply Chain Manager** leverages previous experience to improve the documents.

- ☐ The **Health Supply Chain Manager** submits the document or presentation to the **SCM Regional Technical Advisor** for review.
- ☐ The **SCM Regional Technical Advisor** submits the document or presentation to the **GSCM Strategic Technical Assistance and Response Health team** for review.



## PSM INTERVENTION BUDGETING

Providing an in-depth description of PSM activities allows to better plan for cost elements and budgeting. Each donor provides guidance on the elaboration of the budget and cost elements.

### CHECKLIST *PSM Intervention Budgeting*



- ☐ The **Health Supply Chain Manager**, in collaboration with the **Procurement Manager**, is required to collect the unit cost of key activities, such as:
  - Custom fees.
  - Freight and forward costs.
  - International and in-country insurance.
  - In-country transport cost.
  - Warehousing and storage costs.
  - Car rent.
  - Per diem rate.
  - Room rental.
  - Hotel rate.
- ☐ The **Health Supply Chain Manager** works in close collaboration with the **Finance Manager** to elaborate on a detailed budget for the PSM intervention.
- ☐ The **Health Supply Chain Manager** categorizes the activities in the appropriate modules and submits the draft budget for review by the **SCM Regional Technical Advisor**.
- ☐ The **SCM Regional Technical Advisor** reviews and provides input.

## ROLES AND RESPONSIBILITIES

Function/Activity	Heads of Programming /Chiefs of Party	Country Program Supply Chain Manager	Finance Manager	Procurement Manager	Health Supply Chain Manager	National Supply Chain Manager	SCM Regional Technical Advisor	GSCM Strategic Technical Assistance and Response Health Team
Reviews the list of generic activities at each phase of the grant implementation to identify interventions and support to request	C	A		C	R	C	C	C
Updates the SCM Regional Technical Advisor on ongoing activities and raise any challenges	A	C		C	R	C	C	C
Reaches out to the SCM Regional Technical Advisor for any technical issues or required guidance on SCM policy and procedures	A	C		C	R	C	C	C
Follows the evolution of the health SCM activities and KPIs and submits a brief report on the regional implementation of KPIs, success, challenges, and potential bottlenecks	A	C		C	C	C	R	C

Function/Activity	Heads of Programming /Chiefs of Party	Country Program Supply Chain Manager	Finance Manager	Procurement Manager	Health Supply Chain Manager	National Supply Chain Manager	SCM Regional Technical Advisor	GSCM Strategic Technical Assistance and Response Health Team
Prioritizes PSM intervention activities in collaboration with the national stakeholders	A	C		C	R	C	C	C
Prepares the PSM intervention narrative and operational plan	A	C		C	R	C	C	C
Collects the unit cost of key activities for the PSM interventions budget	A	C	C	C	R	C	C	C
Elaborates on a detailed budget for the PSM intervention	C	C	A	C	R	C	C	C

R=Responsible; A=Accountable; C=Consulted; I=Informed

# CHAPTER 1.5: QUANTIFICATION OF HEALTH PRODUCTS

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## POLICIES, PROCEDURES, REGULATIONS, AND GUIDELINES

### CRS POLICIES AND PROCEDURES

- [CRS COMPASS Standard 3](#)
- [CRS COMPASS Standard 5](#)
- [CRS COMPASS Standard 6](#)

### DONOR POLICIES AND REGULATIONS

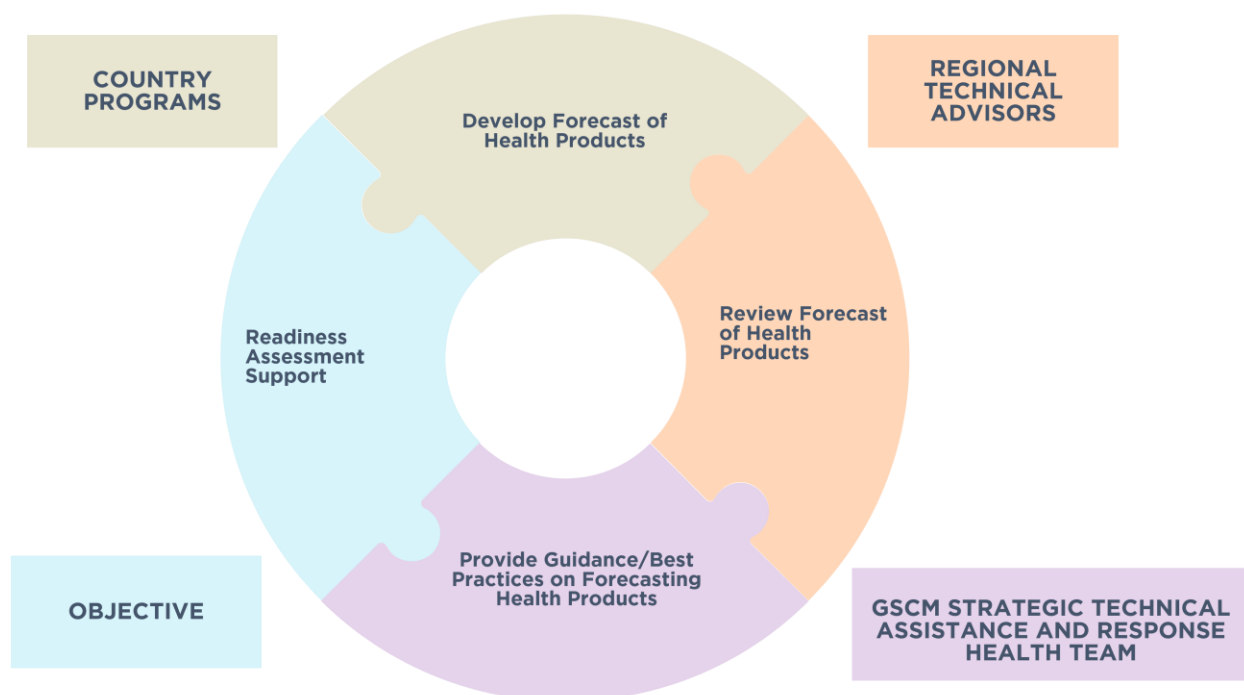
- [The Global Fund Procurement Policy](#)
- [The Global Fund QA Policy for Diagnostics Products](#)
- [The Global Fund QA Policy for Pharmaceutical Products](#)

### DONOR AND OTHER GUIDELINES

- [JSI The Supply Chain Manager's Handbook](#)
- [The Global Fund Guide to Policies on PSM of Health Products](#)
- [The Global Fund Interim QA Requirements for the Procurement of COVID-19 Diagnostic Products](#)

# PROCESS

## CRS Health Supply Chain Management Process for Quantification



Quantification is the process of estimating the quantities and costs of the products required for a specific health program (or service) and determining when to deliver the products to ensure an uninterrupted supply for the program.

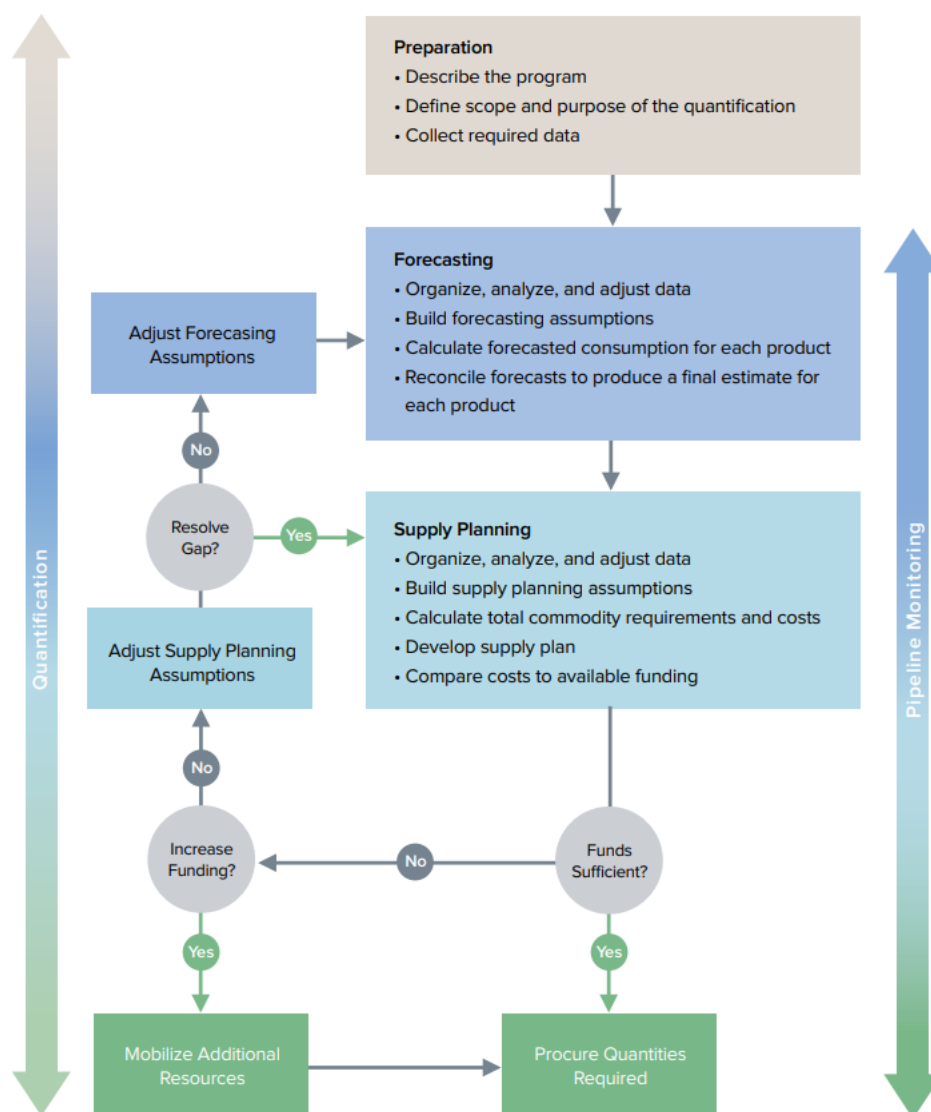
Quantification is a major and **iterative** exercise to ensure accessibility to essential medicines.

For new projects, the capacity assessment process (documentation review and interviews with leading stakeholders) as the gaps and risk analysis performed at the earlier stage (see [Part 1](#)) should provide the country program with an overview of strengths and improvements needed to support the quantification exercise.

For renewed grants, lessons learned are crucial to defining areas for improvement.



The guidance provided here describes how the three major steps of preparation, forecasting, and supply planning, sketched below, should be supported by country programs. The following figure sourced from Chapter 5 of JSI's *The Supply Chain Manager's Handbook, A Practical Guide to the Management of Health Commodities* shows key steps in quantification.



Source: Steps in Quantification, *The Supply Chain Manager's Handbook, A Practical Guide to the Management of Health Commodities*, John Snow, Inc., 2020, p. 55.

## PREPARATION

The preparation stage is critical to a successful forecast.

### CHECKLIST *Preparation Stage*

- ☐ The Health Supply Chain Manager checks the prerequisite to support the quantification exercise by addressing the questions in the below cheat sheet.



## Cheat Sheet for Quantification Prerequisite

### Quantification Logistics

- Who are the key actors needed for the quantification?
- Are the quantification stakeholders invited, and what are their profiles?
- Are quantification workshop dates, venue, and funding confirmed?

### Quantification Tools and Models

- Are the tools for forecasting and supply planning available and updated?
- Is the quantification team trained on tools, and can they access the tool?
- Are previous quantification reports available?
- Are members of the national quantification committee proficient in using Microsoft Excel spreadsheets or software programs to create and manage databases?

### Data

- What key data are needed for each category of product (i.e., consumption and/or distribution data, patient data, morbidity, stock levels, and pipeline)
- For each product, is there past consumption and service utilization data?
- Is data complete and accurate?

### Stock Status and PSM Arrangements

- Is there data on stock on hand? (stock levels, expiry dates)
- Is the pipeline data available (incoming stocks, not yet received)
- Are there several entities procuring the same commodities (i.e., apart from CRS, will the government or other technical partners also be procuring), and what is the split between these different entities?
- What is the required level of buffer stock for the different types of commodities?



## Preparation – Assemble a Quantification Team

# CHECKLIST

## *Assemble a Quantification Team*



- ☐ The **Health Supply Chain Manager**, in collaboration with the **SCM Regional Technical Advisor**, organizes a working session with the National Program to define:
  - Number of team members (most quantification teams have 6-15 members).
  - Profiles of the team members (program managers, procurement specialists, M&E officers or other information specialists, warehouse managers, service providers, donor agencies, implementing partners, and technical experts in quantification).
  - Identification of the team members (position and organization).
  - Tools and data to use.
  - Technical assistance needs.
  - Expected outcomes and deliverables.
  - Analysis of gaps in terms of skills and resources needs (i.e., training, software, IT equipment).
  - Number of days and location to conduct the quantification exercises.
  - Term of references for technical assistance recruitment.
  - Technical specifications to purchase IT equipment.
- ☐ The **Health Supply Chain Manager** initiates a requisition and secures approvals with the **Chief of Party** to identify the venue, catering, technical assistance recruitment, etc., for the Procurement Manager.
- ☐ The **Health Supply Chain Manager** supports the national program Supply Chain Manager in elaborating the [Concept Note](#) for the quantification exercises and the invitation letter and then submits for approval by the relevant authority in the MOH.
- ☐ The **Health Supply Chain Manager** supports the national program Supply Chain Manager in elaborating the [Terms of Reference](#) for technical assistance and identifying the technical support budgeted.
- ☐ The **Health Supply Chain Manager** requests technical support to the **SCM Regional Technical Advisor** if needed to organize training sessions of the quantification team members.
- ☐ The **Health Supply Chain Manager** coordinates the preparation phases and keeps implementing partners informed on the preparation evolution.
- ☐ During the quantification workshop, the team will first review the documents collected during the preparation phases, forecast the needs, and later elaborate a supply plan of product needs.

## Preparation – Describe the Program

CHECKLIST *Describe the Program*

- ☐ During the quantification workshop, the **Health Supply Chain Manager** ensures a consensus among participants on the program description and the inclusion of the following elements:
  - Geographical coverage (Full or partial, number of regions and districts, locations).
  - Population (whole or targeted groups, i.e., pregnant women and children under five years).
  - Health context and policies.
  - National treatment and testing guidelines.
  - Strategic objectives, i.e., % of population coverage.
  - Framework for reaching the population: routine distribution, mass campaigns, antenatal consultations, expanded program of immunization).

## Preparation – Define Scope and Purpose of the Quantification

CHECKLIST *Describe Scope & Purpose of Quantification*

- ☐ During the quantification workshop, the **Health Supply Chain Manager** ensures a consensus on the scope of the exercises:
  - Timing, i.e., MOH budgeting cycle and donor funding lifecycle, funding gaps.
  - Sources of funding, i.e., donors and government.
  - Products to be quantified.

## Preparation – Collecting Required Data

### CHECKLIST *Collecting Required Data*



- ☐ During the quantification workshop, the **Health Supply Chain Manager** supports the team to have a consensus on the documents to use (i.e., quarterly consumption reports), type of data to use (i.e., consumption, morbidity, mixed data), and sources of data ([DHIS2](#), active data collection, etc.).

For new projects, the national team may not involve CRS during the initial quantification workshop if the donors have not finalized the implementing partner's selection, in that case:

- ☐ The **SCM Regional Technical Advisor**, in collaboration with the **Health Supply Chain Manager**, gathers information on the quantification exercise organization at each step:
  - Collects profiles and skills of the quantification team members.
  - Collects data on the program description.
  - Collects data on the scope and purpose.
  - Collects information on the type of data and assumptions made, sources, and consensus reached.

## FORECASTING

Forecasting is the process of estimating the quantities of products that will be dispensed or used to meet the needs of a targeted population during a future period.

### Organize, Analyze, and Adjust Data

Forecasts are prepared based on historical consumption, services, morbidity, and/or demographic data. The table below defines types of data, sourced from definitions from JSI's *The Supply Chain Manager's Handbook, A Practical Guide to the Management of Health Commodities*.

Types of Data	
Historical Consumption Data	Consumption data are historical data on the actual quantities of health commodities that have been dispensed to patients or consumed at Service Delivery Points within a specific period. Consumption data are collected from a well-functioning LMIS that captures and aggregates data from Service Delivery Points. Consumption data are most useful in mature, stable programs that have a full supply of products and reliable data.

Types of Data	
Services Data	Services data are historical program-level or facility-level data on the number of patient visits to facilities, the number of services provided, the number of disease episodes or health conditions treated, or the number of patients who receive a specific service or treatment within a given period.
Morbidity and Demographic Data	Morbidity and demographic data include total population, population growth rates, incidence, and prevalence of specific disease/health conditions available by population group or through surveillance or research study group and extrapolated to estimate national-level incidence or prevalence rates of specific disease diseases/health conditions.
Difference between Morbidity and Demographic Data	Demographic data include data on the number and characteristics of the population targeted for services. In contrast, morbidity data are estimates of the number of episodes of a specific disease or health condition in a common denominator of the population. These data are extrapolated to define the total estimated need and then refined to determine specific targets, or percentage of total need, to be reached. Because forecasts using morbidity and demographic data tend to overestimate commodity needs, the forecast should be compared to the forecasts using consumption and service data.
Grant Targets	Often quantifications are based on grant's approved targets and these are essential when preparing the quantification

Source of Definitions in the above table: *The Supply Chain Manager's Handbook, A Practical Guide to the Management of Health Commodities*, John Snow, Inc., 2020.

## Build Forecasting Assumptions

The country's quantification guidance should define the type of data used. Then, the team needs to reach a consensus based on data reliability, availability, and informed or calculated extrapolations, if not available.

How to Determine When Data is Unreliable	
Types of Questionable Data	Practical examples.
Outdated Data	I.e., the population census is 10 years old.
Incomplete Data	I.e., for Malaria programs targeting pregnant women and children under five years, the number of children treated in the previous year is not available.
Questionable Source	Data is not validated.

Assumptions are made to adjust historical program data for poor quality (incomplete, outdated, unreliable, or unavailable) and for future program performance. Assumptions may include elements such as:

- Expected uptake in services (i.e., population migrations).
- Compliance with recommended treatment guidelines (i.e., adoption of WHO's Electronic Essential Medicines List).
- Future changes in STGs and introduction of new commodities.
- Impact of changing program policies and strategies on supply and demand.
- Service capacity (infrastructure, HR availability, and capacity).
- Client awareness of and access to services.
- Timing and amount of funding commitments for procurement.
- Seasonality (i.e., rainy periods).
- Geographic variations in disease incidence and prevalence.
- Other factors that may affect demand.

## CHECKLIST

### *Building Forecasting Assumptions*



- ☐ The **Health Supply Chain Manager** supports the quantification team when data are missing or are of questionable quality to:
  - Seek reliable alternative sources (i.e., World Malaria Report to define estimated malaria cases and deaths).
  - Formulate assumptions (i.e., "All treated cases were diagnosed with RDTs").
- ☐ The **Health Supply Chain Manager** supports the quantification team to list assumptions and keep documentation justifying the assumptions made. This is essential to address donors' and evaluators' requests for clarification.

## Calculate Forecasted Consumption

Forecasts completed using services, morbidity, demographic, or program target must be converted from several patients, visits, and episodes treated into estimates of quantities of products consumed. The conversion requires assumptions about applying and adherence to STGs, dispensing protocols, testing algorithms, or lab testing procedures.

## CHECKLIST

### *Calculate Forecasted Consumption*



- ☐ The **Health Supply Chain Manager** supports the quantification team to ensure that forecasts are accurate by adequately documenting the calculation method used for projection, the tools used, etc.

Type of Data	Conversion Factor			Forecasted Consumption	
Consumption	Estimated quantity of product to be dispensed/used			=	Quantities of products
Services HIV, Malaria, TB. Essential Medicines, Labs)	Estimated # of patients, #of episodes of disease or health condition, # of lab tests	X	STGs, testing algorithm, lab procedure	=	
Demographic, Morbidity					
Program Targets					

*Conversion of Data into Product Quantities – Source JSI*

CRS uses various tools and software to calculate forecasts:

Tools & Software	Description
Quantimed	This Microsoft Access-based tool facilitates forecasting pharmaceutical needs (medicines and health supplies) using three forecasting methods: historical consumption, morbidity (including scaling-up patterns), and proxy consumption. To obtain Quantimed, email <a href="mailto:quantimed@msh.org">quantimed@msh.org</a> or visit <a href="http://siapsprogram.org/tools-andguidance/quantimed/">http://siapsprogram.org/tools-andguidance/quantimed/</a> .
QAT	The QAT is a modernized solution for country-led supply planning. Funded by USAID, QAT leverages new technologies and enhances the existing supply planning tool, PipeLine. With an enhanced user interface and usability, greater analytical capabilities, and automated data exchange, this new tool enables program managers to optimize commodity procurement and delivery schedules, monitor products' stock status, and share data with external platforms and key stakeholders.
<a href="#">Roll Back Malaria Quantification Excel Tool</a>	Guidance note in the <a href="#">Malaria Programmatic Gap Analysis Guidance Note</a>
<a href="#">Quant TB Version 4.2</a> <a href="#">Quant TB e-course</a>	QuantTB is an electronic quantification and early warning system designed to improve procurement, ordering, and supply planning for TB treatment. When used regularly, QuantTB serves as an early warning system by providing information on actual versus planned consumption, impending expiries, and stock-outs of medicines.
Clinton Health Access Initiative ARV Forecasting Tools (Adult and Pediatric)	The Clinton Health Access Initiative Antiretroviral forecasting tools are well-known tools to facilitate the quantification of antiretroviral medicines (need to directly contact Clinton Health Access Initiative to get the latest versions).
ForLab	This multi-method forecasting tool measures laboratory service delivery and supply chain performance. The tool uses data from multiple sources (demographic, usage, and tests) to compare expected demographic/morbidity estimates with actual usage and service statistics to identify gaps between patient needs and existing service capacity.

## Validation of the Quantification Exercises

# CHECKLIST

*Validation of Quantification Exercises*



- ☐ The **Health Supply Chain Manager** prepares a presentation summarizing the outcomes of the forecast and submits it to the **SCM Regional Technical Advisor** for review.
- ☐ The **Health Supply Chain Manager** integrates **SCM Regional Technical Advisor** input and prepares the invitation letter for the validation meeting.
- ☐ The national program and the MOH authority overseeing the health SCM chair the validation meeting. However, there may be different approaches depending on the country. Thus, there is a need to develop national quantification guidance to clarify all the stakeholders' roles and responsibilities. For example:
  - In Nigeria, the quantification committee submits the exercises' outcomes to the Chair of the Procurement Supply Chain National Technical Working Group for validation. The committee is comprised of the national program, implementing partners, national integrated supply chain projects, donor representatives, etc.
  - In Guinea, the committee submits the report to the director of the national program, logistics management unit, implementing partners, and representatives of the prominent donors as USAID or UNFP.
- ☐ The **Health Supply Chain Manager**, in collaboration with the Supply Chain Manager from the national program and the MOH authority in charge of the supply chain of health commodities, presents a summary of the outcomes of the quantification exercises and secure the validation of the activities. The summary includes a PowerPoint presentation to share with all the stakeholders with key information.
- ☐ The **Health Supply Chain Manager** records the minutes of the validation meeting and the participant's list for submission to the donor.

## PREPARING THE QUANTIFICATION REPORT

Quantification exercises fall under the country's leadership or national program leadership. However, country programs must understand the assumption and process to champion the supply plan and PSM budget.



# CHECKLIST

## *Preparing the Quantification Report*



At the end of the quantification exercise:

- ☐ The **Health Supply Chain Manager** should be able to explain and justify each step of the quantification exercise, including:
- ☐ Scope, purpose, and timeframe of the quantification.
- ☐ Review of all data sources used and challenges in data collection and the data sources used to make those assumptions.
- ☐ Summary of supply planning assumptions (especially if assumptions about amounts and timing of funding commitments will affect procurement and delivery).
- ☐ Total quantities of each product required for each year of the quantification.
- ☐ Country stock status (stock on hand) for each product; highlight products that are about to expire, stocked out, or overstocked.
- ☐ Summary of pending orders and expected shipments delivery dates.
- ☐ HPM activities required (i.e., QC, insurance for violence and political risks, warehousing, and in-country distributions).

The quantification team should prepare and validate the quantification report. Finally, the quantification report summarizes all the information and supporting documents described above.

- ☐ The **SCM Regional Technical Advisor** should review the quantification report and provide recommendations if needed.
- ☐ The **Health Supply Chain Manager** should prepare the supply plan based on the information gathered in the quantification report.



# ROLES AND RESPONSIBILITIES

Function/Activity	Heads of Programming/Chiefs of Party	Country Program Supply Chain Manager	LMIS Officer	Procurement Manager	Health Supply Chain Manager	National Supply Chain Manager	SCM Regional Technical Advisor	GSCM Strategic Technical Assistance and Response Health Team
Checks prerequisite to support the quantification exercise	C	C	C	I	R	C	A	I
Supports implementing partners to prepare the Terms of Reference for quantification	A	C	C	I	R	C	C	I
Supports implementing partner to prepare the Terms of Reference for TA if needed	A	C	C	C	R	C	C	C
Supports implementing partners to organize training sessions for the quantification team members	A	C	C	C	R	C	C	C
Transfers requisition to procurement department to purchase services for workshop	C	C	C	C	R	C	I	
Keeps implementing partners updated on procurement status	A	A	C	R	C	C	I	
Supports the quantification team to ensure that the description of the program, scope, gaps, documents, and data used are accurate	C	C	C	C	R	C	A	
Supports the quantification team when data is questionable and lists assumptions	C	C	C	C	R	C	C	

Function/Activity	Heads of Programming/Chiefs of Party	Country Program Supply Chain Manager	LMIS Officer	Procurement Manager	Health Supply Chain Manager	National Supply Chain Manager	SCM Regional Technical Advisor	GSCM Strategic Technical Assistance and Response Health Team
Ensures accuracy of forecasts	A	C	C	C	R	C	C	
Validates the outcome of the quantification workshop with key stakeholders	A	C	C	C	R	C	C	
Collects information on quantification exercise and supply plans if the exercise was performed without CRS involvement	A	C	C	C	R	C	C	
Reviews the quantification report	A	C	C	C	R	C	R	I
Prepares the supply plan	A	C	C	C	R	C	C	

R=Responsible; A=Accountable; C=Consulted; I=Informed

## SUPPLY PLANNING

Supply planning is the final output of the quantification process that determines the quantities required to fill the health product pipeline, related costs, lead times, and shipment dates to ensure optimal procurement and delivery schedules.

There are various tools and software used to plan shipment:

The PipeLine Monitoring and Procurement Planning System

Designed to enable program managers to plan optimal procurement and shipment schedules for health commodities and to monitor the stock status of health products.

After health supply implementation arrangements are defined and distributed amongst main stakeholders and CRS, the supply planning will reflect product to procure and related procurement costs supported by CRS. For instance, if the QA/QC activity is included in the HSS grant funded by another recipient than CRS, the supply plan carried out by CRS must not have this activity.

## Supply Planning Tool

Donors have different supply planning tools to collect information on commodities – costs and delivery schedule information.

- PEPFAR-funded programs use the Commodities Supply Planning Tool. This Excel-based and interactive tool enables countries to perform projections within the next 18 months of all Antiretrovirals (adult, pediatric, infant prophylaxis, Prevention of Mother-to-Child Transmission, and Pre-exposure Prophylaxis) for Antiretroviral Therapy.
- US PMI projects use the Gap analysis table to collect information on required commodities to be funded by the donor.
- GAVI-funded programs use the vaccine portfolio template at the funding request stage.
- The Global Fund-funded program uses the [HPMT](#). The following paragraph will focus on how to complete this tool required by the donor at the CRS level.

## Completing Donor-Specific Templates (Global Fund Grants)

The HPMT and the detailed budget template are the final steps for completing The Global Fund’s funding request process. Both documents include PSM activities and related costs and should be prepared and completed by country programs.

Both templates are provided by The Global Fund’s country team to principal recipients with a timeline summarizing the due dates for the first submission, review, and final approval before grant signing.

# CHECKLIST

## Completing Donor-Specific Templates



- ☐ The Chief of Party/Head of Programming should share timelines for document submission with the **Health Supply Chain Manager** and **SCM Regional Technical Advisor**.
- ☐ The **SCM Regional Technical Advisor** informs the **GSCM Strategic Technical Assistance and Response Health team** of the support required, especially for new projects with no supply chain manager position.
- ☐ The **Chief of Party or Head of Programming** with the **SCM Regional Technical Advisor** and/or **Health Supply Chain Manager** should define a timeline for the first submission, CRS internal review, presentation to implementing partners, and factoring in the buffer time for quality checks and adjustments.

The HPMT provides detailed information on the health products, PSM costs, and delivery schedule for Global Fund grants.

The terminology PSM costs are often used in Global Fund grants and refer to all the costs encountered from sourcing, international transport, QA, in-country distribution, warehousing, and storage.

The table below describes the different types of PSM costs and where to find the reference prices.

Category of PSM Costs	Find Costing References
Pricing References and Delivery Schedule	<p>The Global Fund's website resources links:</p> <ul style="list-style-type: none"> <li><a href="#">Antimalarial Medicines</a></li> <li><a href="#">Antiretrovirals</a></li> <li><a href="#">HIV &amp; Malaria RDTs</a></li> <li><a href="#">LLINs</a></li> <li><a href="#">Other Essential Medicines</a></li> <li><a href="#">Procurement Services</a></li> <li><a href="#">Viral Load &amp; Early Infant Diagnosis</a></li> <li><a href="#">GDF Medicines Catalog</a></li> <li><a href="#">GDF Diagnostics, Medical Devices, &amp; Other Health Products Catalog</a></li> <li>USAID GHSC program – <a href="#">Product e-Catalog 2022</a> (pdf version)</li> </ul> <p>If prices are not available from the resources above, please use the most recent invoices and quotes.</p>
Procurement Agent and Handling Fees	<p>The Global Fund website's resources links:</p> <ul style="list-style-type: none"> <li><a href="#">Pooled Procurement Mechanism: Procurement Service Agent Fees and List of Allocated Activities</a></li> </ul>
Freight and Insurance Costs for Health Products	<p>The Global Fund's indicative reference costs for budgeting purposes: <a href="#">freight, insurance, and QA</a>. Please note that for high-risk countries, additional insurance should be required for high-value items.</p> <p>Historical freight costs per product category for a specific country should also be considered because each country has a unique profile (airlines connections, landlocked vs sea access).</p> <p>Global Procurement should be contacted as early as possible to support the gathering of insurance quotes to cover political and violence risks.</p>
Pre-shipment QA and QC Costs (QA/QC)	<p>The Global Fund's indicative reference costs for budgeting purposes: <a href="#">freight, insurance, and QA</a></p>
PSM Customs Clearance	<p>Please use the most recent invoices and quotes. New grants should use information from the former fund's recipient or main stakeholder (i.e., National Program).</p>
Warehouse and Storage Costs	<p>To be requested to the Central Medical store or Third-party Logistics service provider or former Global Fund recipient</p>
In-country Distribution Costs	<p>To be requested to the Central Medical store or Third-party Logistics service provider or former Global Fund recipient</p>

Category of PSM Costs	Find Costing References
In-country QA and QC Costs	Please use the most recent invoices and quotes if not included in HSS grants. New grants should use information from the former Global Fund recipient or main stakeholder (i.e., National Program).


The present paragraph focuses on the process to complete and validate the HPMT.

In the following paragraph, “**Health Supply Chain Manager**” designates any person supporting the roles; we understand that the position can be vacant during grant-making, and a selected country focal point can support or temporary technical assistance. The “**Health Supply Chain Manager**” reminds and highlights that the work requires expertise in health SCM.

### For New Projects with No Health Supply Chain Manager Position Filled

CHECKLIST

New Projects w/ No Health SCM Position Filled



- ☐ The SCM Regional Technical Advisor, with the Health Supply Chain Manager, carefully reads the instructions provided by [The Global Fund HPMT User Guidelines](#) and complied with the instructed steps.
- ☐ In collaboration with the Health Supply Chain Manager, the SCM Regional Technical Advisor ensures alignment of the quantification outcomes and the programmatic gaps table.
- ☐ The SCM Regional Technical Advisor with the Health Supply Chain Manager coordinate and plan for quote requests for those products and services that are not included in or might differ from The Global Fund pricing reference with appropriate departments (i.e., Global Procurement for political violence insurance coverage quotes).
- ☐ The SCM Regional Technical Advisor, with the Health Supply Chain Manager, refers to the quantification report, [Global Fund costing references as the delivery planning guide](#), and price quotation obtained to prepare the HPMT.
- ☐ The SCM Regional Technical Advisor, with the Health Supply Chain Manager, organizes a presentation of the HPMT to Implementing partners.
- ☐ The SCM Regional Technical Advisor should request a quality check review from the **GSCM Strategic Assistance and Response Health team**. It is essential to have this key template reviewed and validated globally to identify CRS health supply chain expectations and overcome any challenges raised.

## For Renewed and Ongoing Projects

# CHECKLIST

*For Renewed and Ongoing Projects*

- ☐ The **SCM Regional Technical Advisor** should provide an orientation to the **Health Supply Chain Manager** and Finance Officer on how to complete the HPMT and the resources to use as described in [The Global Fund HPMT User Guidelines](#).
- ☐ The **SCM Regional Technical Advisor** should define with the **Health Supply Chain Manager** a timeline for template completion and quality check review.
- ☐ The **Health Supply Chain Manager** refers to the quantification report, [Global Fund costing references as the delivery planning guide](#), and quotes obtained complete the HPMT.
- ☐ The **Health Supply Chain Manager** ensures alignment of the quantification outcomes and the programmatic gaps table.
- ☐ The **Health Supply Chain Manager** requests a quality check review from the **SCM Regional Technical Advisor**. Therefore, it is essential to have this crucial template reviewed and validated at the regional level to identify CRS health supply chain expectations.
- ☐ The **SCM Regional Technical Advisor** communicates with the **Strategic Technical Assistance and Response Health team** any challenges encountered.

## ROLES AND RESPONSIBILITIES

Function/Activity	Head of Programming/Chiefs of Party	Head of Operations	Procurement Manager	Country Program Supply Chain Manager	Finance Officer	Health Supply Chain Manager	SCM Regional Technical Advisor	GSCM Strategic Technical Assistance and Response Team
Shares timelines for document submission	R	I	I	I	I	I	I	
Defines due dates for internal submissions and reviews	A	C	C	C	C	R	I	I
Reads and orients on the donor's guidance to complete templates	C	I	C	C	C	R	A	
Plans and coordinates quote requests	I	A	R	C	C	R	C	
Prepares the HPMT	A	C	C	C	C	R	I	
Reviews the HPMT	A	I	C	C	C	R	C	C

R=Responsible; A=Accountable; C=Consulted; I=Informed

## DETAILED BUDGET (GLOBAL FUND GRANTS)

The Global Fund's funding allocation mechanism differentiates two types of interventions with specific interventions:

1. Direct supply chain interventions: Come in direct support to achieve program objectives and are disease specific. Interventions can include HPM functions such as procurement, quality monitoring, warehousing, transportation, and reporting.
2. RSSH interventions: Aim to build a stronger health system and capacities (including laboratory), thus, integrating the interventions for the three diseases (Malaria, TB, and HIV) to resolve systematic issues.

The [Global Fund Modular Framework Handbook](#) provides clear guidance on describing and categorizing the PSM activities, interventions, and modules.

# CHECKLIST

*Detailed Budget (Global Fund Grants)*



- ☐ The **SCM Regional Technical Advisor** provides an orientation to the new **Health Supply Chain Manager** and new **Finance Officer** on how to complete the PSM part of the detailed budget and the resources to use (see PSM and costing references table).
- ☐ The **Health Supply Chain Manager** carefully reads the instructions provided by [The Global Fund Modular Framework Handbook](#) and the budget guidance.
- ☐ The **Health Supply Chain Manager** coordinates and plans quote requests for the activities (except for HPM). Most activities are training, IT, and vehicle procurements, building renovations, technical assistance, and workshops. The procurement and finance departments support this step.
- ☐ The **Finance Officer** prepares the detailed budget and submits it to the **Chief of Party** or **Head of Programming** (for new projects).
- ☐ The **Chief of Party** shares the detailed budget with the **SCM Regional Technical Advisor** for review.

For New Projects with No Global Fund Supply Chain Manager Position Filled

# CHECKLIST

*New Projects w/ No Global Fund SCM Position*



- ☐ The **SCM Regional Technical Advisor** requests a quality check review from **GSCM Strategic Technical Assistance and Response Health team**. It is essential to have this crucial template reviewed and validated globally to identify CRS health supply chain expectations.



## For Renewed and Ongoing Projects

# CHECKLIST

*Renewed & Ongoing Projects*

- ☐ The **Health Supply Chain Manager** requests a quality check review from the **SCM Regional Technical Advisor**. It is essential to have this crucial template reviewed and validated at the regional level to identify CRS health supply chain expectations.
- ☐ The **SCM Regional Technical Advisor** communicates any challenges encountered with the **GSCM Strategic Regional Assistance and Response Health team**.



## Validating the HPMT and Detailed Budget with Implementing Partners

# CHECKLIST

*Validating HPMT & Budget w/ Partners*

- ☐ The **Health Supply Chain Manager** organizes a working session with implementing partners to present and validate the HPMT and detailed budget.
- ☐ The **Health Supply Chain Manager** adjusts if necessary and submits the HPMT detailed with all the supporting documents (please see HPMT user guidelines checklist) to the **Chief of Party**.



## Aligning the HPMT with the Detailed Budget

# CHECKLIST

*Aligning the HPMT w/ the Budget*

- ☐ The **SCM Regional Technical Advisor** reviews the PSM's budget lines and ensures alignment between the HPMT and the budget.
- ☐ The **SCM Regional Technical Advisor**, with the **Health Supply Chain Manager**, tracks any changes that may occur within the HPMT or the PSM lines of the detailed budget and constantly adjusts to keep both documents aligned.
- ☐ The **Chief of Party** submits HPMT and supporting documents to The Global Fund as per the defined timeline for review.



## Advocacy and Negotiations - Planning and Organizing GSCM Strategic Technical Assistance and Response Health Team Support

# CHECKLIST

## Advocacy & Negotiations



- ☐ The Chief of Party and Head of Programming inform the **Health Supply Chain Manager** and the **SCM Regional Technical Advisor** about the negotiation date and agenda.
- ☐ The **Health Supply Chain Manager**, in collaboration with the **SCM Regional Technical Advisor**, identifies the support required during the negotiation process.
- ☐ The **SCM Regional Technical Advisor** informs the **Strategic Technical Assistance and Response Health team** at least two weeks before the negotiation and specifies the support required.

Preparing for negotiations sessions with the donor and the main stakeholder includes listing and communicating what will be needed from the country program perspective in terms of support provided by regions and global departments.

Planning ahead will allow other departments to plan, organize, prepare, and coordinate for support during negotiations with donors.



Supporting evidence-based elements for grant negotiations can be:

- Narratives of activity description.
- Business case presentations for innovative activities.
- LOE analysis for PSM and data analyst staffing.
- JDs.
- Organizational charts and definition of PSM roles and responsibilities support to justify overheads costs.
- Cost elements justifications (contracts, prices, and invoices).
- Presentation from subject matter experts.
- Studies.

## Before Negotiating with the LFA

### CHECKLIST

*Before Negotiating with the LFA*

- ☐ The **Health Supply Chain Manager** prepares evidence-based elements for negotiations and submits them for review to the **SCM Regional Technical Advisor** and **GSCM Strategic Technical Assistance and Response Health team**. The support provided by the **GSCM Strategic Technical Assistance and Response Health team** should be defined and organized based on agreed timelines.



## Negotiating with the LFA

### CHECKLIST

*Negotiations with the LFA*

- ☐ The **Chief of Party** and **Head of Programming** informs and associates the **SCM Regional Technical Advisor** or **GSCM Strategic Technical Assistance and Response Health** (for new projects) with the negotiation sessions.
- ☐ The **Health Supply Chain Manager** adjusts the budget and HPMT following the request changes during negotiations and submits to the **Chief of Party**.
- ☐ The **Chief of Party** informs implementing partner (i.e., the National Program) of adjustments negotiated.
- ☐ The **Chief of Party** submits all grant documents to the **Global Fund Portfolio Manager** for final approval.



## ROLES AND RESPONSIBILITIES

Function/Activity	Heads of Programming /Chiefs of Party	Head of Operations	Finance Officer	Procurement Manager	Country Program Supply Chain Manager	Health Supply Chain Manager	SCM Regional Technical Advisor	GSCM Strategic Technical Assistance and Response Health Team
Orients on the completion of the PSM part of the budget	A	I	C		C	C	R	
Reads the donor guidance on the budget	A	I	C		C	R	C	
Coordinates and plans for quote requests	I	C		R	A	C		
Prepares the detailed budget	A	C	R	C	C	R	C	
Shares the detailed budget for review	R	C	I	C	C	C	C	C
Reviews to ensure alignment between HPMT and detailed budget	A	C	R	C	C	R	R	I
Presents HPMT to implementing partners	A	I			C	R	I	I
Prepares evidence-based justification for new PSM interventions	A	I			C	R	C	C
Reviews evidence-based justification for new PSM interventions	A				C	C	R	R

Function/Activity	Heads of Programming /Chiefs of Party	Head of Operations	Finance Officer	Procurement Manager	Country Program Supply Chain Manager	Health Supply Chain Manager	SCM Regional Technical Advisor	GSCM Strategic Technical Assistance and Response Health Team
Associates regions or GSCM to negotiations	R	I	I	I	C	C	C	C
Prepares adjustments	A	I	I	I	C	R	I	I
Informs implementing partners of adjustments	A	C			C	R		
Submits final documentation to donor	R	C			C	C	C	I

R=Responsible; A=Accountable; C=Consulted; I=Informed

## CHAPTER 1.6: RISK ASSESSMENT

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### POLICIES, PROCEDURES, REGULATIONS, AND GUIDELINES

#### CRS POLICIES AND PROCEDURES

- [CRS GSCM Operational Risk Register](#)

#### DONOR POLICIES AND REGULATIONS

- [The Global Fund Risk Management Policy](#)

#### DONOR AND OTHER GUIDELINES

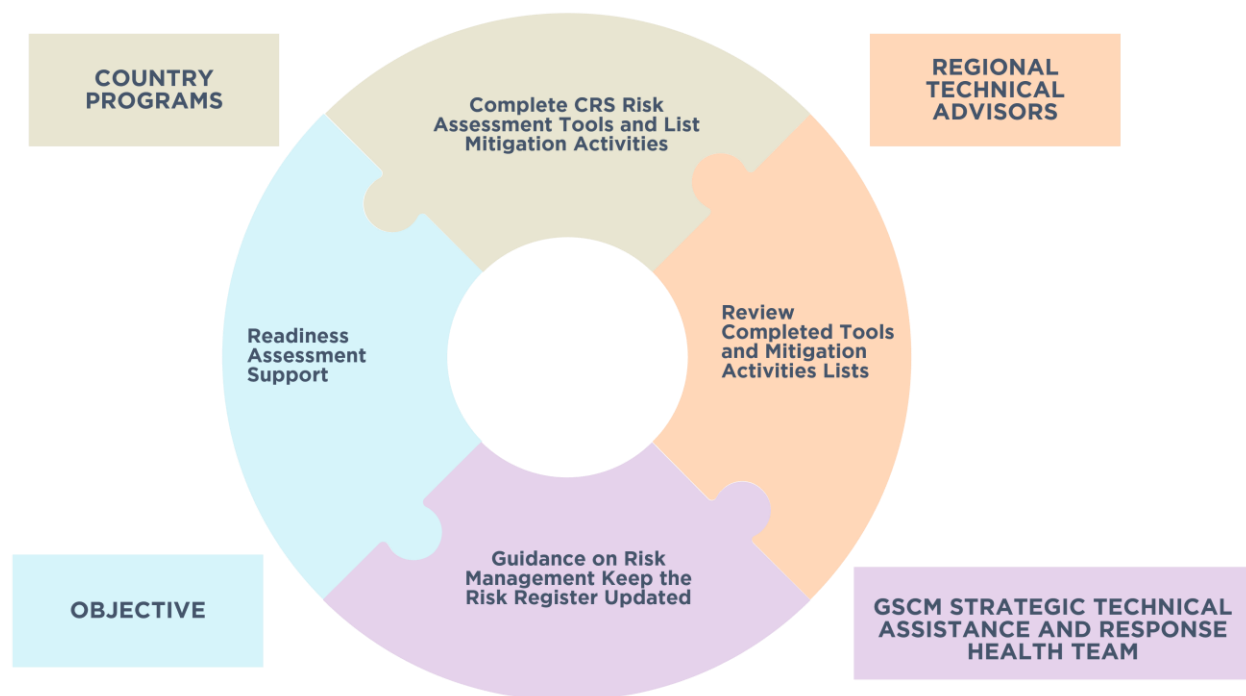
- [The Global Fund Risk & Assurance Toolbox](#)
- [USAID Risk Management for Public Health Supply Chains](#)

Risk management is a formal approach used to identify and mitigate the sources of disruption and dysfunction within the public health supply chain.

Risk management is an iterative process throughout the grant implementation.

# PROCESS

## CRS Health Supply Chain Management Process for Assessing Risks



## ASSESSING AND MONITORING RISKS

The health supply chain assessment, supply chain design, and the quantification of health products provide the country program with a good understanding of the activities to implement, and the risks attached.

Before signing the grant documents, the Agency must re-evaluate the grant risks and establish mitigation measures.

## Risk Assessment

CHECKLIST *Risk Assessment*

- ☐ The **Health Supply Chain Manager** updates the latest risk analysis information collected during the health supply chain assessment and the Global Fund Support Unit risk assessment tool (relevant only for Global Fund grants).
- ☐ The **Health Supply Chain Manager** consolidates identified risks and prepares a narrative including the description of the different risks and their mitigation actions. See [CRS Model of Narrative for Risk Analysis](#).
- ☐ The **Health Supply Chain Manager** submits the narratives for the **SCM Regional Technical Advisor** review.
- ☐ The **Health Supply Chain Manager** integrates the input and finalizes the risk management plan, which includes the description and the [CRS Model of Action Plan Following Risk Analysis](#).
- ☐ The **SCM Regional Technical Advisor** shares the completed supply chain risk analysis with the **GSCM Strategic Technical Assistance and Response Health Team** to review and provide input.

Donors might request country programs to complete the donor risk register.

- ☐ The **Health Supply Chain Manager** completes the donor risk assessment template.

## Performance and Monitoring

CHECKLIST *Performance & Monitoring*

- ☐ The **Health Supply Chain Manager** monitors the implementation of the required immediate actions such as early procurements to avoid stock-out risks.
- ☐ The **Health Supply Chain Manager** conducts continuous monitoring using the risk assessment.
- ☐ The **SCM Regional Technical Advisor** monitors and tracks the implementation of the mitigation actions.
- ☐ The **SCM Regional Technical Advisor** raises any concerns to the **GSCM Strategic Technical Assistance and Response Health team** if the activities implemented are not successful or if the country program faces challenges in their implementation



## ROLES AND RESPONSIBILITIES

Function/Activity	Heads of Programming/ Chiefs of Party	Head of Operations	Procurement Manager	Country Program Supply Chain Manager	Health Supply Chain Manager	SCM Regional Technical Advisor	GSCM Strategic Technical Assistance and Response Health Team	Global Fund Support Unit
Updates the latest risk analysis information using the risk register and Global Fund Support Unit risk assessment tool	A	C	C	C	R	C	I	I
Collects identified risks and prepare a narrative including the description of the different risk and their mitigation actions	A	C	R	C	R	C	C	C
Submits the narratives for the review	A	C	C	C	R	C	C	I
Integrates the input and finalize the risk management plan	A	C	C	C	R	C	C	C
Monitors the implementation of the required immediate actions	A	C	C	C	R	C	C	I
Shares the supply chain risk analysis	A	I	C	I	C	R	C	C

Function/Activity	Heads of Programming/ Chiefs of Party	Head of Operations	Procurement Manager	Country Program Supply Chain Manager	Health Supply Chain Manager	SCM Regional Technical Advisor	GSCM Strategic Technical Assistance and Response Health Team	Global Fund Support Unit
Completes the donor risk assessment template	A	C	R	C	R	C	C	C
Reviews the donor's risk assessment template	A	C	I	C	C	R	R	C
Monitors and tracks the implementation of mitigation actions	A	I	I	I	R	C	C	C
Raises any concern in the management of risks	A	I	I	C	R	C	C	C

R=Responsible; A=Accountable; C=Consulted; I=Informed

## PART II: START UP

Start-up is the phase between planning and execution. [COMPASS](#) provides further information and guidance on [navigating the project start-up journey](#).

In line with other projects, the health supply chain project requires human and financial resources for successful implementation.

Pharmaceutical and other health commodities are critical products and sometimes lifesaving, and therefore, particular attention must be paid to their management to maintain their quality and uninterrupted supply. Managing the peculiarities of health products requires:

- Recruiting a supply chain manager with an HPM background.
- Have a pharmacist on the team.
- Preparing agreements/contracts with third parties able to comply with good storage and distribution practices.
- Preparing for procurement activities.

# CHAPTER 2.1: RECRUITMENT OF THE HEALTH SUPPLY CHAIN MANAGER

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## POLICIES, PROCEDURES, REGULATIONS, AND GUIDELINES

### CRS POLICIES AND PROCEDURES

- [CRS COMPASS – Standard 9](#)
- [CRS Policy on Recruiting and Selection](#)

### DONOR AND OTHER GUIDELINES

- [JSI The Supply Chain Manager's Handbook](#) Chapter 10 outlines organizational capacity and workforce
- [The Global Fund Guide to Policies on PSM of Health Products](#) Section 2.4 related to QA Systems describes requirements to manage health products per WHO standards, including recruiting staff to oversee QA aspects

## PROCESS

### RECRUITING THE HEALTH SUPPLY CHAIN MANAGER

The processes outlined below describes the recruitment of health supply chain managers with HPM experience and/or pharmacist backgrounds.

The Supply Chain Manager supporting health grants should demonstrate special abilities in understanding national health supply chain management, identifying risks, developing technical arguments, and gathering information that adequately feeds decision-making processes.

Health supply chain management requires a pharmacist or experienced staff in product health management via national systems to fulfill donor requirements as per [The Global Fund Guide to Policies on PSM of Health Products](#) and [WHO Model QA for Procurement Agencies](#). The pharmacist or experienced staff in product health management must have the appropriate training to manage QA, drug use, and pharmaceuticals procurements.

# CHECKLIST

## *Risk Assessment*



The **Hiring Manager** initiates the recruitment process per CRS policy and procedures.

- ☐ The supply chain structure in a country program should align to the recommended SCM structure (Please refer to the SCM organization in the CRS Supply Chain Management Handbook).
- ☐ Any deviation should require HR and **Deputy Regional Director of Management Quality** approval for operations position per policy and procedure.
- ☐ Due to workload, context, or project-specific requirements, there are project-specific supply chain positions like the Global Funds grants. Those specific project positions are supervised by the **Chief of Party** or **Program Manager**.
- ☐ The **Head of Operations/Chief of Party** identifies the appropriate JD among the SCM JDs. JDs are standardized across the agency and developed at the global level. The country programs are just required to include the country's specificities.
- ☐ The **SCM Regional Technical Advisor** reviews and provides input, including those related to QA management. The **GSCM Strategic Technical Assistance and Response Health team** can also provide input when requested by the **SCM Regional Technical Advisor**.

HR departments from country programs manage selection processes based on the criteria or qualifications of the position advertised. HR selects five to 10 CVs to pass a written exam and interview.



The **SCM Regional Technical Advisor** supports the preparation of questions for interviews and written exams.

- ☐ The **SCM Regional Technical Advisor** corrects the written exam and provides a report scoring and ranking the results.
- ☐ The **SCM Regional Technical Advisor** participates in the interview panel.

The finalization of the recruitment process is handled by the country program. However, for international ones, the **HR Regional Technical Advisor** supports the recruitment process.

- ☐ **SCM Regional Technical Advisor** provides orientation. The onboarding process enables the **Health Supply Chain Manager** to understand the project component and expected results.

## ROLES AND RESPONSIBILITIES

Function/Activity	Supply Chain Manager	LMIS Officer	Head of Operations	Program Manager/Chief of Party	HR	Country Representative	SCM Regional Technical Advisor	HR Regional Technical Advisor
Initiates requisition for the Health Supply Chain Manager recruitment process				R		A	C	C
Adapts standard JDs			R	R		A	C	
Selects CV			A	A	R		C	R
Prepares interview questions and written exams			R	R	I	I	C	I
Finalizes the recruitment process			R	R	R	A	C	R
Supports the onboarding process			R	R		A	R	

R=Responsible; A=Accountable; C=Consulted; I=Informed

## CHAPTER 2.2: SUPPLY CHAIN STRATEGY AND COORDINATION

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### POLICIES, PROCEDURES, REGULATIONS, AND GUIDELINES

#### DONOR AND OTHER GUIDELINES

- [CIPS Strategic Supply Chain Management](#)
- [JSI The Supply Chain Manager's Handbook- Supply Chain Strategy Page 17](#)

### PROCESS

The supply chain strategy is the roadmap developed to guide the health supply chain management optimization. Supply chain strategy in the private sector considers the value that can be derived. This value is also valid in the public health sector; a cost-efficient supply chain in delivering products to patients allows better use of the scarce resources in the health system. Moreover, clear objectives and long-term goals defined in the supply chain strategy contribute to attaining less waste and addressing recurrent challenges.

Prominent donors recommend establishing a national strategy to facilitate resource mobilization and coordination among stakeholders.

The development of supply chain strategy can occur at the design, start-up, or implementation phases.

#### SUPPLY CHAIN STRATEGY

The supply chain strategy is developed in coordination with all stakeholders and led by the entity in the MOH in charge of health products. In most countries, this entity in charge is the National Pharmaceutical regulatory authority.

# CHECKLIST

## *Supply Chain Strategy*



For Global Fund grants, the strategic development falls under HSS.

- ☐ The **Health Supply Chain Manager** reaches out to the MOH and other implementers to verify an existing national supply chain strategy.
- ☐ If there is no national supply chain strategy, the **Health Supply Chain Manager** evaluates and discusses including the activity in the grants with the donor.
- ☐ Once the funds for the activity are secured, the **Health Supply Chain Manager**, in collaboration with the **SCM Regional Technical Advisor**, identifies the required technical assistance support.
- ☐ The **Health Supply Chain Manager** in collaboration with main national stakeholder, develops the Terms of Reference for the consultancy request and initiates the recruitment process per the Procure-to-pay process.
- ☐ The **Health Supply Chain Manager**, in collaboration with the national stakeholders, organizes the supply chain assessment using the different tools mentioned in the Health Annex [Assessment chapter](#).
  - The purpose of the assessment is to identify challenges in people, processes, and systems.
- ☐ The **Health Supply Chain Manager** collects former National Health Strategies and other key strategic documents as previous assessments to guide the strategic discussion.
- ☐ The **Health Supply Chain Manager**, in collaboration with the consultant, organizes interviews with key stakeholders to collect their vision and advocate for their support in the process.
- ☐ The **Health Supply Chain Manager**, in close collaboration with the national entities in charge of health products, organizes a workshop with key stakeholders and develops a SWOT to identify the short-term, middle, and long-term objectives that will serve the realization of the national health plan.
- ☐ The consultant finalizes the documents' redaction and submits to national stakeholders for input.
- ☐ The document includes three main components:
  - The strategy narrative: Clearly describing the vision, detailed objectives, and their alignment to the national health plan.
  - An action plan including the implementation timeline, the detailed and responsible entities, and the performance monitoring framework including key indicators.
  - The budget, including the cost of activities, information on the resources available, and the mobilization required.
- ☐ The **Health Supply Chain Manager** submits the documents for review and input to the **SCM Regional Technical Advisor** and **GSCM Strategic Technical Assistance and Response Health team**.
- ☐ The **Health Supply Chain Manager** integrates the comments in collaboration with the consultant.
- ☐ The **Health Supply Chain Manager** submits the documents for an official endorsement by the MOH.
- ☐ The **Health Supply Chain Manager** will regularly monitor the implementation of the strategic plan and report on the KPIs.
- ☐ The **Health Supply Chain Manager**, in collaboration with the national stakeholders, plans and conducts a two-year review.



## ROLES AND RESPONSIBILITIES

Function/Activity	Chief of Party	Country Program Supply Chain Manager	Health Supply Chain Manager	SCM Regional Technical Advisor	GSCM Strategic Technical Assistance and Response Health Team
Secures the inclusion of the activity in the grants with the donor	A	C	R	C	
Identifies the required technical assistance support	A		R	C	C
Develops the Terms of Reference for the consultancy request and initiates the recruitment process	A	C	R	C	C
Organizes the supply chain assessment	A	C	R	C	C
Organizes interviews with Key stakeholders	A	C	R	C	I
Organizes a workshop with key stakeholders and develops SWOT and identifies short-term, middle, and long-term objectives	A	C	R	C	I
Finalizes the documents' redaction and submits for national stakeholders' input	A	C	R	C	I
Submits the documents for internal review			C	R	C
Integrates the comments	A	C	R	I	I
Submits the documents for an official endorsement by the MOH	R	C	C	I	I
Monitors the implementation and conduct a two-year review	A	C	R	C	I

R=Responsible; A=Accountable; C=Consulted; I=Informed

## COORDINATION AND TECHNICAL WORKING GROUP

In health supply chain management, coordination is critical for efficient implementation and good use of the resources available in countries.

In most of the country program, the main stakeholders are:

- Implementing partners: Central Medical store, international NGOs, national entities, private service providers, etc.
- National stakeholders: MOH and their subdivision
- Donors: US PMI, USAID
- Suppliers: International and national suppliers

The supply chain technical working group includes representatives of the mentioned entities. However, variations from countries exist with disease-specific, sub-technical groups, or even decentralized coordination. Functional decentralized coordination aims to improve reporting rate, promptness, and data quality.

# CHECKLIST

*Coordination & Technical Working Group*



- ☐ The **Health Supply Chain Manager**, in collaboration with the national stakeholders, develops or reviews the term of reference of the technical working group, the executive committee (President and Secretary), and the list of members.
- ☐ The **Health Supply Chain Manager**, in collaboration with the national stakeholders, secures the MOH approval for the technical working group.
- ☐ The **Health Supply Chain Manager**, in collaboration with the national stakeholders, organizes the supply chain technical working group. They met at least once per month to:
  - Monitor the availability of commodities.
  - Organize redeployment if required.
  - Discuss the distribution plan.
  - Analyze the collected logistics information in the previous reporting period.
  - Monitor the performance of the supply chain and report to the relevant authorities.
  - Identify and propose a solution to address identified issues or bottlenecks.
  - Report challenges to the authority.
  - Approve the supply planning.
  - Conduct quantification exercises.
- ☐ The **Health Supply Chain Manager** prepares the meeting agenda and presentation to share with stakeholders.
- ☐ The **Health Supply Chain Manager**, in collaboration with the national stakeholders, documents the recommended actions and responsibilities in the minutes of the meeting.
- ☐ The **Health Supply Chain Manager** with the President of the technical working group's support monitors the implementation of the recommended actions and shares the outcomes in the following meeting.
- ☐ The **Health Supply Chain Manager** regularly submits the minutes of the technical working group with the quarterly report to the donor.

## ROLES AND RESPONSIBILITIES

Function/Activity	Chief of Party	Country Program Supply Chain Manager	Health Supply Chain Manager	SCM Regional Technical Advisor	GSCM Strategic Technical Assistance and Response Health Team
Develops or reviews the term of reference of the technical working group and the list of members	A	C	R	C	C
Secures the MOH approval for the technical working group	A		R	C	
Organizes the supply chain, the technical working group	A	C	R	C	
Prepares the meeting agenda and the presentation to share	A	C	R	C	
Documents the recommended actions and responsibilities in the minutes of the meeting	A	C	R	C	I
Submits the minutes of the technical working group with the quarterly report to the donor	A	C	R	C	I
Monitors the implementation of the recommended actions and shares the outcomes in the following meeting	A	C	R	C	I

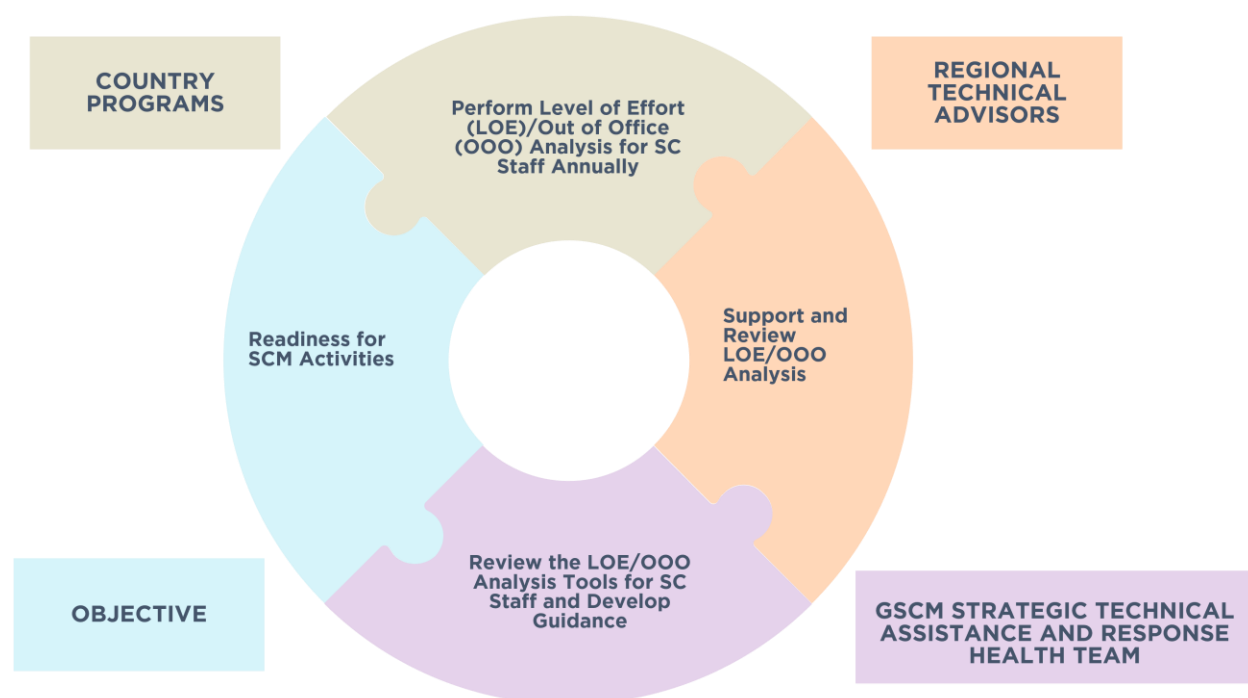
R=Responsible; A=Accountable; C=Consulted; I=Informed

## CHAPTER 2.3: HR ANALYSIS

### PROCESS

#### DEFINING HR NEEDS IN HEALTH SUPPLY CHAIN PROJECTS

CRS Health Supply Chain Management Process for Defining HR Needs



Successful health supply chain management requires adequate staffing to run and/or oversight HPM activities. Two types of approaches can be combined to evaluate SCM's staffing needs:

- Assessment of the volume of transactions (procurement or inventory): The information might only be available once country programs have the Insight SCM module deployed.
- Analysis of the expected workload per staff includes a three-step methodology:
  1. Modeling staff workload includes reviewing LOE and time OOO for each staff position.
  2. Analyzing the results by adjusting the allocated work as JDs and calculating appropriate staffing levels.
  3. Advocating for additional staff.

Staffing analysis should be conducted at the early stages of the start-up phase, annually during the implementation phase, and during the reprogramming stages. Evidence-based results of the analysis facilitate discussions and negotiations with donors and CRS leadership on staffing needs.



## LOE ANALYSIS

CHECKLIST *LOE Analysis*

- ☐ The Health Supply Chain Manager or SCM Regional Technical Advisor (for new projects) lists supply chain management tasks and duties required by the project.
- ☐ The Health Supply Chain Manager or SCM Regional Technical Advisor (for new projects) evaluates the time required per week to perform health SCM tasks and duties. The HR SCM analysis template can be used to perform this task (to be developed).
- ☐ The Health Supply Chain Manager provides an orientation to the SCM team members (LMIS, Data Specialist, and SCM Monitoring Officer) to quarterly perform the HR SCM analysis to evaluate workloads and to use it as an evidence-based analysis to request more support or duties shifts.
- ☐ The SCM Regional Technical Advisor reviews the analysis and provides input.

Title	Responsibilities	Detailed activities	LOE required per week	Change requested
Senior SCM Manager	Stakeholder engagement and coordination	1. Build and maintain productive relationships with national authorities, including the National Malaria Elimination Program (NMEP) within the Federal Ministry of Health (MoH), National Products Supply Chain Management Program (NPSCMP)/National Supply Chain Integration Project (NSCIP), National Agency for Food and Drugs Administration and Control (NAFDAC), Central Medical Stores, as well as technical and financial partners involved in the supply chain management of malaria commodities 2. Represent CRS at all relevant technical meetings and coordination forums. 3. In collaboration with the MoH and its technical and financial partners, ensure all procurement and supply chain management strengthening activities are well coordinated and implemented systematically, with a focus on specific needs for the Global Fund program	8	
	Forecast and supply planning	1. Maintain an updated demand forecast and supply plan for Health commodities 2. Serve as a technical resource to the national quantification committee, and support the annual national medical supplies needs planning process, with the objective of ensuring year round product availability and rational use on a national scale 3. Serve as a technical resource for the macro and micro planning for malaria resources and activities; review and analyze quarterly consumption and quantification reports and provide consumption and quantification updates as needed 4. Liaise with the relevant entities in the MoH to maintain an up-to-date planning vs implementation status for all pharmaceutical and health products, as well as an inventory of all health equipment purchased with the Global Fund resources	4	
	Procurement	1. Review and validate technical specifications for all the pharmaceutical and other health products and equipment to be procured with Global Fund resources, paying special attention to WHO, Global Fund and national regulations, guidelines, industry standards, competitiveness, transparency and value for money 2. Liaise with the Global Fund's PPM to place orders for health products, coordinating with relevant entities in the MoH to provide information on quantities, requested delivery date, and product description 3. Coordinate with the PPM in the processing of M-forms and obtaining of necessary procurement documents such as NAFDAC's import permit, and 'no objection' letters 4. Track health commodity orders, coordinating with the PPM and relevant national authorities to plan the delivery of products to the Central Medical Store and ensure necessary waivers (import visa, tax exemption) and port clearance are obtained 5. For non-PPM procurements, provide technical guidance in the procurement process for health products and equipment, through pro-active involvement in the bidding process, development and management of contracts/purchase orders, and monitoring supplier performance 6. Coordinate with the Central Medical Store and third party service provider contracted by the Global Fund to ensure goods are inspected, verify that the correct quantities of goods received and that they are intact and meet specifications, reporting any damage or errors	4	

The CRS Model for SCM HR Analysis can include justifications for change management as shown in the below table.

SCM Data specialist	Data base Management	Update and manage the program's malaria commodities and logistics data system/ database	16	
	Supply plan monitoring			Remove the amount of time dedicated to the supply plan monitoring to allow him to have
	Data validation and analysis	1. Review and analysis of SCM data from the States and submitted by MSH in line with the Malaria Commodity Logistics System (MCLS) 2. Reconciliation of proofs of delivery data from Chemonics and the PPM agents received at the central level or distributed from central level through long haul distribution 3. Generation of monthly/Quarterly consolidated stock status/reconciliation report of all health products received and distributed within the malaria program in close collaboration with the PSM lead of MSH, for dissemination to key stakeholders, including CRS HQ 4. Monitor supply chain pipeline to ensure access to high-quality, reliable and timely data to monitor program's commodities (shelf-life status, location, quantity etc.) and evaluate progress towards achievement of program objectives	32	
	Support the data managers at state level	1. Provide technical support to PSM/ logistics unit of SRs, as may be required, for strengthening their MCLS data management 2. Actively participate in the SCM Community of Practice with other CRS, SR and government staff	8	
	Provide support on Campaign activities			The data specialist shouldn't be involved in campaigning support an additional support will be required
	Distribution of commodities			Distribution of commodities should fall under the SCM officer to respect the 40 LOE required per individual
	Procurement	Placing of orders on Wambo for routine health products and campaign LLNs. -Processing of import documents (NAFDAC import permit, NAFDAC letter of No Objection, IDEC waivers, M Forms, PAAR etc.). -Monitoring and tracking delivery of routine health products and campaign LLNs. -Supporting the procurement of insurance for LLNs and ICT4D mobile devices.	4	

## OOO ANALYSIS

### CHECKLIST *OOO Analysis*



- ☐ The **Health Supply Chain Manager** identifies major activities that happen in each grant year that take the SCM team staff out of the office on field visits. It includes (but is not limited to):
  - ITN campaigns (both planning and implementation).
  - Seasonal Malaria Chemoprophylaxis campaign.
  - Quarterly data quality field visits.
  - Annual LMIS/HMIS data collection.
  - Stakeholder meetings (in Abuja/Lagos, States).
  - Warehouse assessment.
  - Annual and quarterly warehouse inspection.
  - Reception of commodities.
  - Staff vacation.
- ☐ The **Health Supply Chain Manager** estimates the number of days for the field visit for each SCM team and populates the Excel spreadsheet with the information on number of OOO days.

## Managing Outcomes

CHECKLIST *Managing Outcomes*

- ☐ The **Health Supply Chain Manager** sends the draft documents to the **SCM Regional Technical Advisor** for review and input.
- ☐ The **SCM Regional Technical Advisor** evaluates the analysis checking the following elements:
  - The LOE and OOO information reflect all health SCM projects: SMC, mass campaign, Integrate Community Case Management, Subrecipient supervision, PSM technical working group, training, etc.
  - All the SCM positions were considered in the analysis.
  - The support from the Country Program Supply Chain Manager was considered.
  - The calculations and assumptions are accurate.
- ☐ After reviewing the analysis, the **SCM Regional Technical Advisor** provides recommendations on the next steps. Recommendations can include:
  - Reassignment of some workload to another team member.
  - Review of the JD.
  - Request for a new staff: if the results of exceeding hours is above 40 hours.
- ☐ The **Health Supply Chain Manager** finalizes the review and work on actioning the recommendations suggested by the **SCM Regional Technical Advisor**.

## Study Case of Nigeria Analysis

## LOE Analysis

In the case of Nigeria, the five staff work 40-hour weeks. The total time required to complete all tasks was 280 hours, but the five staff members only have 200 hours. Therefore, the analysis suggests that the program needs at least two more staff members at 40 hours each to cover the remaining work. However, note that the LOE calculation does not consider staff OOO time.

## OOO Analysis

A totaled number of days each staff member would be out of the office running activities outside of the office. The calculation did not include travel time to the field. The Nigerian PSM staff JDs include the



amount of expected travel (ranging from 40-75%), and the OOO was compared to the amount of expected travel. The totals differed by 137%. This indicates the need for two or three additional staff.

The LOE nor the OOO calculations cover planned activities. Unplanned activities, such as a flood (e.g., Taraba, 2019) will increase the workload and the OOO requirement. If the donor adds additional deliverables to the grant (e.g., adding service to IDPs in Taraba), both the LOE and the OOO calculations should be reviewed.

Whenever the analysis results show discrepancies between existing JDs, workload, exceeding level of efforts, then the Health Supply Chain Manager or for new grants, the SCM Regional Technical Advisor, or the country program Supply Chain Manager should advocate for additional staffing.

## CHECKLIST *OOO Analysis*

- ☐ The **Health Supply Chain Manager** develops a presentation on the outcome of the exercises to share with the Chief of Party and Country Representative to request for additional staff.
- ☐ The **SCM Regional Technical Advisor** supports the presentation development and raises the issue to the **Deputy Regional Director** to support the **Supply Chain Manager** advocacy.



## ROLES AND RESPONSIBILITIES

Function /Activity	Supply Chain Manager	Supply Chain Monitoring Officer	LMIS Officer	Head of Operations	Program Manager for New Grants/Chief of Party	HR	Country Representative	SCM Regional Technical Advisor	Deputy Regional Director	Global Fund Support Unit
Conducts the LOE analysis	R	C	C	I	C			C		
Conducts the OOO analysis	R	C	C	I	C			C		
Reviews the analysis		C	C	I	I			R		I
Conducts the JD revision	R			A	R	C	A	C	I	I
Advocates for more staff	R			R	R	R	A	C	C	A

R=Responsible; A=Accountable; C=Consulted; I=Informed

## CHAPTER 2.4: CONTRACTING WAREHOUSE AND DISTRIBUTION SERVICES

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### POLICIES, PROCEDURES, REGULATIONS, AND GUIDELINES

#### CRS GUIDELINES

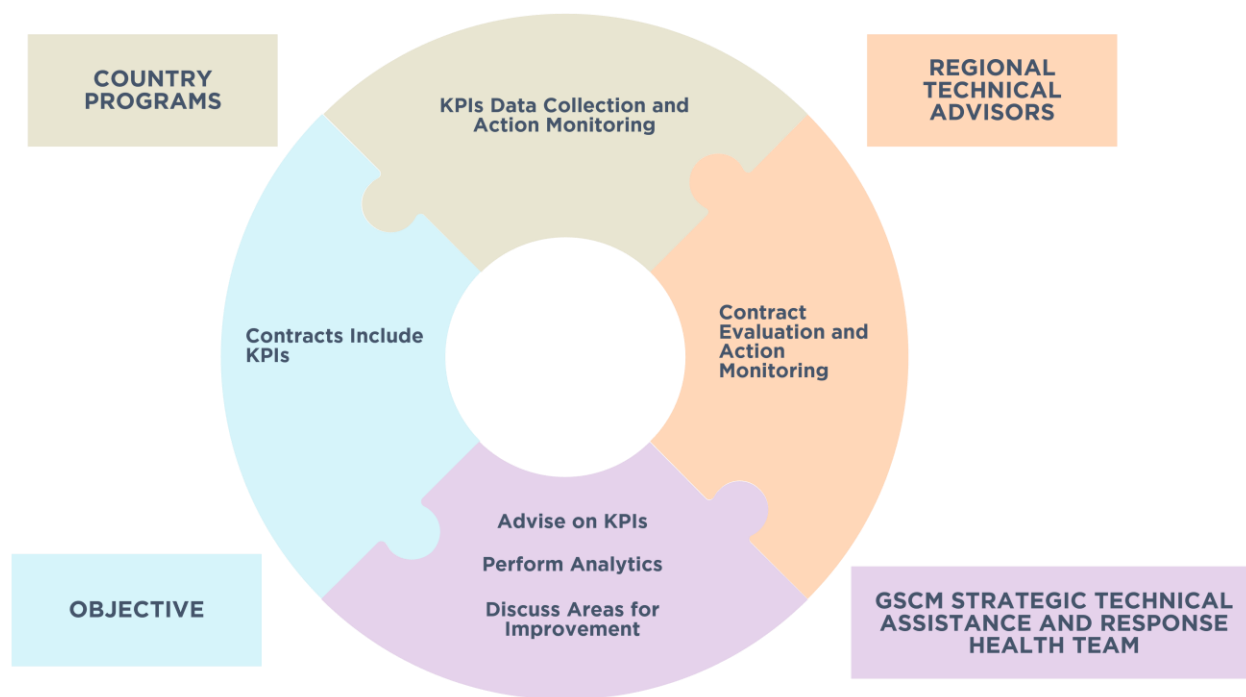
- [CRS COMPASS Standard 9](#)

#### DONOR AND OTHER GUIDELINES

- [JSI The Supply Chain Manager's Handbook](#) *Chapter 8 provides useful information related to warehousing and distribution*
- [The Global Fund Guide to Policies on PSM of Health Products](#)

# PROCESS

## CRS Health Supply Chain Management Process for Contracting Warehousing and Distribution Services



Health grants often build on existing national health supply chain networks. Global Fund, USAID, and GAVI-funded projects encourage that approach to ensure sustainability and strengthening of national health systems. In alignment with this view, CRS should establish agreements with national entities and/or service providers from the public and private sectors to manage SCM services, including performance-based contracts with KPIs. Agreements can cover warehousing, transportation, clearance, or other services related to SCM and logistics management information. Agreements can reflect various dynamics between donors, service providers, Principal Recipients from other grants, and CRS.

It is fundamental to plan provisions for reviewing agreement terms and include lessons learned after annual reviews.

The SOW should be aligned with in-country partners using the services of the CMS or third-party, using the in-country coordination mechanism. It is also recommended to conduct an annual review of the contracts for existing programs or new country programs include lessons learned.

# CHECKLIST

*Contracting Warehouse & Distribution Services*



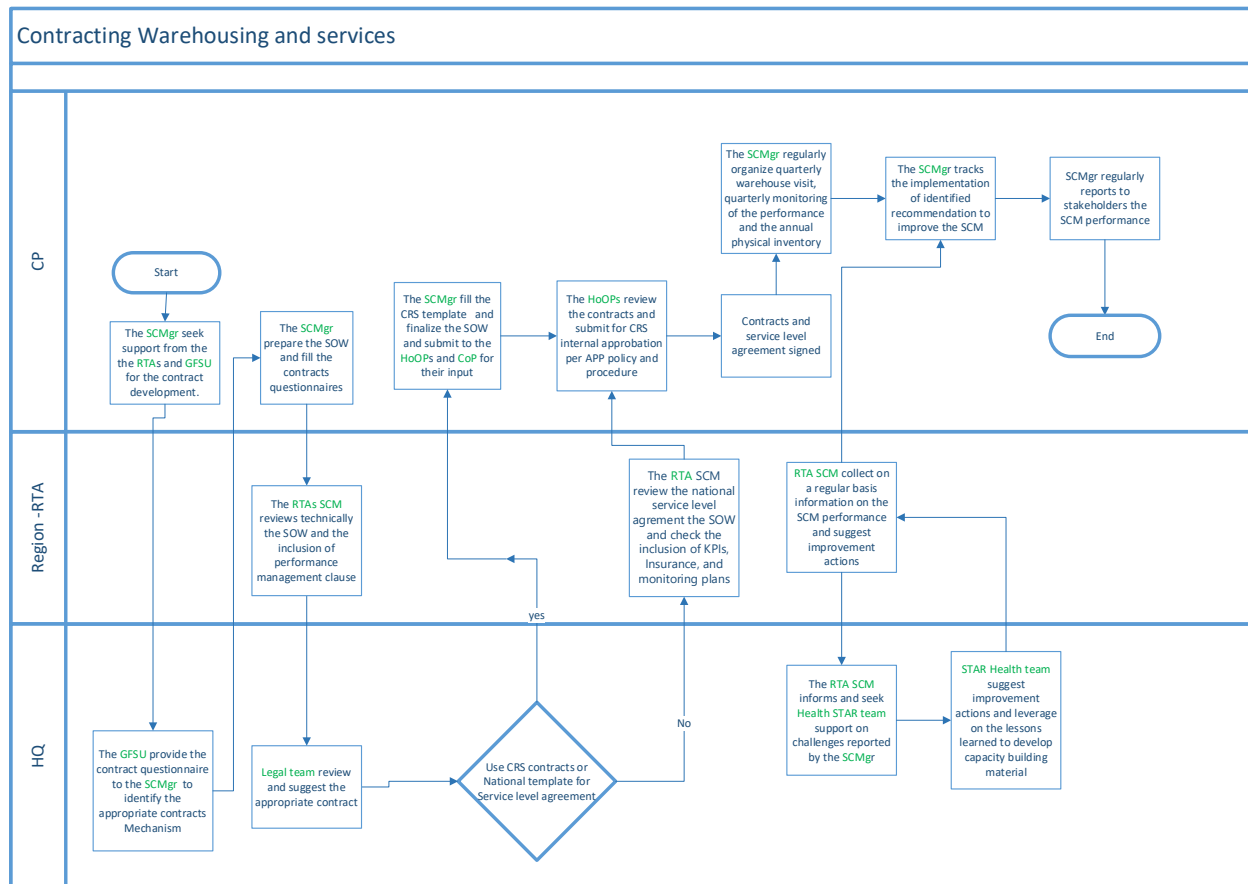
- ☐ The **Health Supply Chain Manager** prepares the SOW for the warehousing and services expected using a template provided by the **SCM Regional Technical Advisor**.
- ☐ The **Health Supply Chain Manager** fills the Global Fund Support Unit/legal questionnaire for new Global Fund grants.
- ☐ The **Health Supply Chain Manager** shares the draft SOW, the suggested payment mechanism and the questionnaire to the Chief of Party and Head of Operations for their input.
- ☐ The **Health Supply Chain Manager** requests a meeting with the Global Fund Support Unit focal point and the legal department to finalize the contract discussion.
- ☐ The **Health Supply Chain Manager** updates the SOW, if necessary, as per the discussion.
- ☐ The **Health Supply Chain Manager** selects and includes KPIs and descriptions of collecting data and checking the quality. See the Monitoring section in the [CRS Supply Chain Management Handbook](#) for more information on Supply Chain KPIs. Examples of Health SCM Key indicators: Supply chain key indicators are described in the SCM MEAL chapter; these are samples to consider for contracting CMS:
  - Stock according to plan.
  - Inventory accuracy.
  - Availability of tracer commodities.
  - Product loss.
  - On-time and in full delivery.
- ☐ The **SCM Regional Technical Advisor** reviews and provides input.
- ☐ The **Health Supply Chain Manager** integrates the performance reporting mechanism in the contracts/service level agreement and establishes the roles and responsibilities of the stakeholders.
- ☐ The **Health Supply Chain Manager** integrates in the contracts/service level agreements the requirement the annual physical requirements per CRS policy.
- ☐ The approval of the service level agreement per the Country Representative follows the [APP approval policy](#).
- ☐ The **Health Supply Chain Manager** organizes quarterly warehouse visits with the stakeholders.
- ☐ The **Health Supply Chain Manager** organizes quarterly performance meetings and documents the outcomes with a clear action plan to address identified weakness.
- ☐ The **Health Supply Chain Manager** shares the quarterly performance meeting documents with the **Regional Technical Advisors** for input and guidance.
- ☐ The **Regional Technical Advisors** provides comments and recommendations and identifies success, bottlenecks, or challenges to elevate to the **GSCM Strategic Technical Assistance and Response Health team** and Global Fund Support Unit.
- ☐ The **Health Supply Chain Manager** integrates the **Regional Technical Advisors** comments and shares the report to all stakeholders. The **Health Supply Chain Manager** should keep a copy for submission as supporting documents to the PUDR.
- ☐ The **Supply Chain Manager** regularly reviews the implementation of the performance improvement action plan and follows up with stakeholders.

## ROLES AND RESPONSIBILITIES

Function/Activity	Supply Chain Manager	SCM Monitor	LMIS Officer	Head of Operations	PM/Chief of Party	HR	Country Representative	SCM Regional Technical Advisor	Deputy Regional Director	Global Fund Support Unit
Develops and reviews – Negotiates agreement SOW and KPIs inclusion	R	C	C	R	C			C		
Reviews for final approbation	R	C	C	A	C			C		
Quarterly reviews of the performance	R	C	C	I	I			C		I
Organizes annual PIC	R			A	R	C	A	C	I	I

R=Responsible; A=Accountable; C=Consulted; I=Informed

## PROCESS MAP



## CHAPTER 2.5: SUPPLY PLANNING

Supply planning determines the required quantities per period from the annual forecast of health products after considering stock in countries and projected consumption to ensure inventory stock levels remain between minimum and maximum range levels.

### POLICIES, PROCEDURES, REGULATIONS, AND GUIDELINES

#### DONOR AND OTHER GUIDELINES

- [GDF Category and Product-level Procurement and Delivery Planning Guide \(TB\)](#)
- [GDF Resources](#)
- [The Global Fund Category and Product-level Procurement and Delivery Planning Guide – Health and Non-health Products](#)

### PROCESS

The **Health Supply Chain Manager** develops the supply plan based on forecasted quantities (refer to the [HPMT](#) for Global Fund grants). The supply plan must include the list of items procured via Pooled Procurement Mechanism and/or direct procurements. The supply plan can be prepared using software such as the [PipeLine](#), or using an Excel spreadsheet including the following information:

- The type of commodities and detailed specifications.
- The quantities of health products expected per shipment.
- Delivery dates (estimated time of arrival).
- Status of the shipment expected and if the orders were confirmed or not.
- The stock on hand at all levels at a specific period. For example, information collected during the last reporting period.
- The national established maximum and minimum levels of inventory.
- The estimate of the Months of Stocks.
- The expiration date of the health products.
- The consumption data (if not available, use the forecasted quantities).

At the end of the supply planning exercise, [the supply plan report](#) should be issued.

When CRS implements a new Global Fund grant as the primary recipient (PR), the stocks of previous PR must be formally transferred to CRS. This stock transfer should be considered during supply planning.





# CHECKLIST

## *Supply Planning*



- ☐ The **Health Supply Chain Manager** prepares a quarterly supply plan review regularly to monitor the availability of commodities closely and identify the orders required to maintain the products stocked according to plan. The review includes:
  - Assessing the stock levels with the recently reported consumption and the planned shipment will remain stocked according to plan.
  - Identifying if there is a need to change the delivery date of planned shipment either delay shipment or request for early delivery.
  - Identifying potential expiries requiring an adjustment of stock on hand and planned shipment.
  - Reviewing the stock of each health product and highlighting data discrepancies per product, which may be due to loss or poor reporting.
  - Forecasting accuracy analysis.
- ☐ The **Health Supply Chain Manager** submits the quarterly supply plan to the **SCM Regional Technical Advisor** for reviews and approval.
- ☐ The **SCM Regional Technical Advisor** reviews if all required information is integrated into the supply plan and provides feedback to the **Supply Chain Manager** on the shared documents.
- ☐ The **Health Supply Chain Manager** integrates **SCM Regional Technical Advisor** comments and coordinates with national stakeholders and the donor PSM for the validation of the supply plan.
- ☐ The **SCM Regional Technical Advisor** liaises with Global Procurement about the upcoming direct procurements by CRS (see the RACI below for more clarification on roles and responsibilities).
- ☐ The **Health Supply Chain Manager** initiates the requisition per Procure-to-pay and submits to the **Procurement Manager**.
- ☐ The **SCM Regional Technical Advisor** checks that **Health Supply Chain Manager** complies with donor requirements such as The Global Fund's administrative procedures to initiate procurement processes (Wambo.org, GDF platform, PQR).
- ☐ The **Health Supply Chain Manager** coordinates with national stakeholders to ensure that tax exemption is fully processed.
- ☐ The **Health Supply Chain Manager** updates the supply plan as per information provided by vendors (delivery dates and lead times).
- ☐ The **Health Supply Chain Manager** shares the updated supply plan with national stakeholders.
- ☐ The **SCM Regional Technical Advisor** records the updated supply plan in SharePoint.

## ROLES AND RESPONSIBILITIES

Function/Activity	Supply Chain Manager	Procurement Manager	Head of Operations	PM/Chief of Party	Country Representative	SCM Regional Technical Advisor	Global Procurement	Deputy Regional Director	Global Fund Support Unit
Develops the supply plan	R	C		C		C			
Segregates of direct procurement and Pooled Procurement Mechanism	R	C	A	C		C	C		
Coordinates with national stakeholders and donor PSM for validation	R	C	I	C		C	C		I
Shares supply plan with national stakeholders	R			A		C	I		I
Organizes and coordinates direct procurements	C	R	A	C	A	C	R		
Complies with The Global Fund's procurement requirements & Procure-to-pay	C	R	A	C		C	R		
Processes tax exemptions	R	C	I	I		C			I
Approves POs	R		A	R	A	C		I	I
Adequately records the supply plan in Share Point	A			R		I		I	I

R=Responsible; A=Accountable; C=Consulted; I=Informed

## CHAPTER 2.6: PROCUREMENT

Procurement of health products can be performed directly by CRS or using donors' procurement mechanism, systems, or solutions.

For example, Global Fund grants recommend the use of the Pooled Procurement Mechanism for Malaria and HIV products and GDF for Tuberculosis products. GAVI will recommend the use of UNICEF and WHO OPS. USAID identifies procurement solutions for each product.

## POLICIES, PROCEDURES, REGULATIONS, AND GUIDELINES

### CRS POLICIES AND PROCEDURES

- [CRS Policy on Consultants](#)
- [CRS Procurement Approvals Policy](#)
- [CRS Procurement Contracts Policy](#)
- [CRS Procurement Policy](#)
- [CRS Purchase of Program Property Policy](#)
- [CRS SCM Offline Transactions and Approvals Policy](#)
- [CRS Selection and Purchase of CRS Vehicles Policy](#)
- [CRS Supplier Master Policy and Procedure](#)
- [CRS Supply Chain Records Management Policy](#)

### DONOR AND OTHER GUIDELINES

- [The Global Fund Guidelines for Grant Budgeting](#) *Section 7 related to specific budgeting and costing guidance*
- [The Global Fund Guide to Policies on PSM of Health Products](#)
- [WHO Model QA System for Procurement Agencies](#)

## PROCESS

Please refer to the Procurement chapter of the [CRS Supply Chain Management Handbook](#) for the best guidance related to the procurement of health products.

## PART III. IMPLEMENTATION

With the approval of the grants, the implementation of supply chain activities can start as per the established detailed implementation plan.

In this part, we will discuss the critical process required in the supply chain of health products.

### CHAPTER 3.1: STOCK MONITORING

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## POLICIES, PROCEDURES, REGULATIONS, AND GUIDELINES

### CRS GUIDELINES

- [CRS eLMIS Implementation Guidelines and Checklist](#)
- [CRS COMPASS – Standard 12](#)

### DONOR AND OTHER GUIDELINES

- [JSI The Supply Chain Manager's Handbook Chapter 7 provides further information on Inventory Planning](#)
- [The Global Fund Principal Recipient Progress Update and Disbursement Request Section 3 of the procurement and supply management reporting chapter describes minimum requirements to conduct stock and expiry dates analysis](#)
- [USAID Pipeline Software Database Administrator's Guide](#)
- [WHO Harmonized Monitoring and Evaluation Indicators for Procurement and Supply Management Systems](#)

Health supply chain practitioners thrive on reducing the amount of stock held while endeavoring not to run out of stock or end up with expired products. This is achieved by monitoring the stock levels.

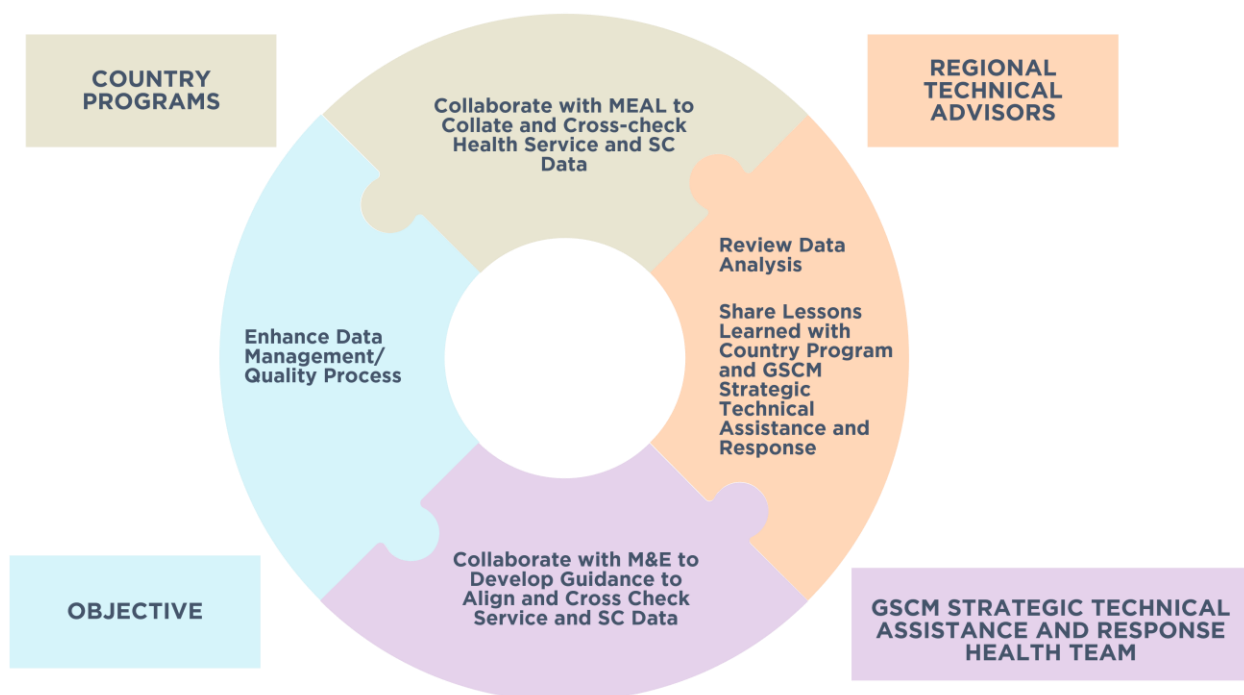
Stock monitoring in health grants involves collaboration with national health information systems, specifically the LMIS. Some countries have well-established LMIS systems with paper and electronic-based systems, while others are still building the system.

In some countries, logistics coordinating entities named the Logistic Management unit, oversee and coordinate logistics activities hosted by the MOH.

Thus, the LMIS reports are collected from decentralized teams and aggregated at the district/states and later at the central level. Therefore, the Supply Chain Manager, in collaboration with the program, should liaise with that unit to access the LMIS data.

# PROCESS

## CRS Health Supply Chain Management Process for Stock Monitoring



## STOCK MONITORING: STOCK STATUS AND EXPIRY DATES ANALYSIS

### CHECKLIST *Stock Monitoring*



It is critical to track stock levels and expirations to evaluate ordering needs and avoid stock-out risks.

- ☐ The **Health Supply Chain Manager** collects national stock status data quarterly (Inventory reports peripheral and central levels) from central medical stores and decentralized entities.
- ☐ For countries with an existing and functional LMIS, stock on hand is aggregated for health facilities, regional/district warehouses.
- ☐ The **Health Supply Chain Manager** adjusts the data based on the reporting and stockout rates. Please refer to [JSI's Quantification of Health Commodities](#) pages 19-20 for adjustment technics. For countries with weaker LMIS systems, the **Health Supply Chain Manager** estimates the stock on hand from the CMS distribution data. The **Health Supply Chain Manager** prepares stock analysis including monthly average consumption, stock adjustments, Months of stocks, stock levels (minimum and maximum).
- ☐ The **Supply Chain Manager** will use the recent consumption data or forecast to evaluate the actual stock on hand.
- ☐ The **Supply Chain Manager** will leverage on the national established Inventory level to estimate if the country is stocked according to plan or not based on the Months of stocks available in country.
- ☐ The **Health Supply Chain Manager** prepares a stock analysis report showing actions needed to ensure interrupted supply and avoid expiries, including need to place additional orders, modification of delivery dates for already placed orders and overstocks at risk of expiry. The analysis should produce some key data, for each product, such as Average Monthly Consumption and Months of Stocks. Quantity and cost of expired products should also be recorded as part of the analysis.
- ☐ The **SCM Regional Technical Advisor** reviews the stock analysis and the technical report and provides an action plan for improvements.
- ☐ The **Health Supply Chain Manager** shares with national stakeholders the stock analysis during the *PSM or logistics coordination monthly meeting* with stakeholders for discussion and approval.
- ☐ The **Health Supply Chain Manager** documents the meeting minutes, agreed action plan, and participants to the logistics coordination meeting.

# ROLES AND RESPONSIBILITIES

Function/Activity	Supply Chain Manager	LMIS Officer	Head of Operations	PM/Chief of Party	SCM Regional Technical Advisor	Global Procurement	Global Fund Support Unit
Quarterly collects national stock status data	A	R		I	C		
Coordinates review with national stakeholders	R	C	C	A	C	C	
Issues stock analysis and technical report	R			A	C	I	I
Reviews stock analysis and technical report	A	C		C	R		

R=Responsible; A=Accountable; C=Consulted; I=Informed

## QUARTERLY SUPPLY PLAN REVIEW

A quarterly supply planning review is required to allow an on-time replenishment of health commodities.

Different tools and software are used. For example, [The PipeLine Monitoring and Procurement Planning System \(PipeLine\)](#) was designed to enable program managers to plan optimal procurement and shipment schedules for health commodities and monitor the stock status of health products.

Under GHSC-PSM, the tool is being upgraded to [the new online QAT](#). This tool will have a comprehensive forecasting and supply planning solution with an enhanced user interface, automated and integrative analytics, and interoperability opportunities with external systems. The introduction and use of QAT will be conducted in a phased approach with countries.

# CHECKLIST

## Quarterly Supply Plan Review



After analyzing stock status, the quarterly supply plan should be prepared and reviewed:

- ☐ The Health Supply Chain Manager establishes the quarterly supply plan.
- ☐ The SCM Regional Technical Advisor reviews the supply plan quarterly.
- ☐ The Health Supply Chain Manager update the report template quarterly and submit to The Global Fund PSM expert for approval.
- ☐ The Health Supply Chain Manager adjusts per The Global Funds' PSM recommendations and sends the request of approval for placing orders to the Regional Technical Advisor.
- ☐ The Health Supply Chain Manager drafts PO forms in the Procurement Pooled Mechanism system and informs the Project Manager as Pooled Procurement Mechanism's system approves.
- ☐ The Health Supply Chain Manager performs a stock status analysis report quarterly and submits the report to the Project Manager and Regional Technical Advisors.
- ☐ The SCM Regional Technical Advisor analyzes the stock status report and provide guidance to address identified weakness.

## ROLES AND RESPONSIBILITIES

Function/Activity	Supply Chain Manager	LMIS Officer	Head of Operations	PM/Chief of Party	Country Representative	SCM Regional Technical Advisor	Global Procurement	Deputy Regional Director	Global Fund Support Unit
Reviews stock status report	R	C	C	A		C	C		
Quarterly reviews the supply plan	R			A		C	I		I
Quarterly updates the report template	R			A		C	I		I
Prepares PO forms	R			A					
Approves PO forms	A	C		R		C		I	

R=Responsible; A=Accountable; C=Consulted; I=Informed



## CHAPTER 3.2: FINANCIAL REPORTING OF HEALTH COMMODITIES

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### POLICIES, PROCEDURES, REGULATIONS, AND GUIDELINES

#### CRS POLICIES AND PROCEDURES

- [CRS COMPASS – Standard 13](#)
- [CRS COMPASS – Standard 15](#)
- [CRS FFATA Reporting Procedure](#)

#### CRS GUIDELINES

- [CRS Insight Inventory Management Reference Guide](#)

#### DONOR AND OTHER GUIDELINES

- [The Global Fund Guidelines Principal Recipient Progress Update and Disbursement Request](#). *Section 6 describes donor requirements*

### PROCESS

The ability to demonstrate that funding spent aligns with agreements in a transparent manner showing accountability is fundamental.

# CHECKLIST

## Reporting Health Commodities



To track and report on expenses related to health products:

- ☐ The **Health Supply Chain Manager** and **SCM Regional Technical Advisor** engage discussion with **Regional Implementation Advisors** to align the product flow charts with the Insight configuration.
- ☐ The **Health Supply Chain Manager**, **CRS program Supply Chain Manager**, and **Finance Manager** develop the in-country guidance for Global Fund inventory management in Insight. The guidelines include the reporting requirements with clear roles and responsibilities
- ☐ The **Health Supply Chain Manager** submits the guidance to the region for approval.
- ☐ The **Health Supply Chain Manager** collects/analyzes reports from third-party contractors.
- ☐ The **Health Supply Chain Manager** compares the reports with previous reports to identify errors and provide feedback to third-party contractors.
- ☐ Once the reports are finalized, the **Health Supply Chain Manager** compiles the data from the reports into the Insight FBDI templates.
- ☐ The **CRS program Supply Chain Manager** reviews and approves the FBDI.
- ☐ The **LMIS Officer** uploads information in Insight.
- ☐ The **Health Supply Chain Manager** regularly reviews the accuracy using the transaction errors records as described in reference guidance for Insight inventory management.

## ROLES AND RESPONSIBILITIES

Function/Activity	Supply Chain Manager	LMIS Officer	Head of Operations	PM/Chief of Party	Country Representative	SCM Regional Technical Advisor	Global Procurement	Deputy Regional Director	Global Fund Support Unit
Aligns the product flow chart with Insight configuration	R	R		I		C			
Develops in-country guidance for Global Fund inventory management in Insight	R	C	C	A		C			
Analyzes reports from 3 <sup>rd</sup> party contractor	A	R				C			I
Compiles into FBDI	C	R				I			
Uploads information on Insight	C	R				I			

R=Responsible; A=Accountable; C=Consulted; I=Informed

## CHAPTER 3.3: TRACKING PSM COSTS FOR GLOBAL FUND GRANTS

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### POLICIES, PROCEDURES, REGULATIONS, AND GUIDELINES

#### DONOR POLICIES AND REGULATIONS

- [The Global Fund Operational Policy Manual](#) *Section 2 includes operational procedures on annual funding decisions and disbursements and Pooled Procurement Mechanism*

#### DONOR AND OTHER GUIDELINES

- [The Global Fund Guidelines Principal Recipient Progress Update and Disbursement Request](#) *Section 6 describes donor requirements related to price and quality reporting*

PSM costs disbursed directly by The Global Fund country team to the procurement agencies need to be tracked for the inclusion in CRS financial reporting mechanism. The Global Fund country team shares disbursement notification to the Chief of Party, Country Representative, and the PR. Therefore, the Supply Chain Manager must collect that information to support reporting. In addition to the disbursement notification, the information is available on the Wambo.org platform. The Pooled Procurement Mechanism agencies also provide the quarterly financial report with the detailed cost incurred by the project.

# PROCESS

## CHECKLIST *Tracking PSM Costs*



To track and align PSM costs with disbursements:

- ☐ The **Health Supply Chain Manager** collects disbursement notifications submitted by The Global Fund.
- ☐ The **Health Supply Chain Manager** issues an Excel spreadsheet aligning disbursement notification with the PO number.
- ☐ The **Health Supply Chain Manager** cross checks information available on Wambo.org or any other Pooled Procurement Mechanism system and includes the summary in the Excel spreadsheet.
- ☐ The **Health Supply Chain Manager** meets with the SC accountant monthly to align PSM information with the finance account.
- ☐ The **Health Supply Chain Manager** identifies products received during the month and provides supporting documents to inform the finance team for accounting.
- ☐ The **Health Supply Chain Manager and Finance Officer** identify disbursement notifications from procurement agencies for products that are not yet delivered.
- ☐ The Finance Team provides feedback to the Global Fund and seeks guidance with HQ Finance for the treatment of those disbursement.

## ROLES AND RESPONSIBILITIES

Function/Activity	Supply Chain Manager	LMIS Officer	Finance Manager	PM/Chief of Party	SCM Regional Technical Advisor	Global Procurement	Global Fund Support Unit
Collects Global Fund disbursement notifications	R		I	I	C		
Issues Excel spreadsheet with disbursement notification and PO number	R		C	A	C		
Cross checks information from Wambo.org systems and Excel summary spreadsheet	R				C		I
Aligns with Finance	C		R		I		I
Updates on receptions	A	R	C		I		I

R=Responsible; A=Accountable; C=Consulted; I=Informed

## CHAPTER 3.4: QA

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# POLICIES, PROCEDURES, REGULATIONS, AND GUIDELINES

## CRS POLICIES AND PROCEDURES

- [CRS COMPASS – Standard 11](#)
- [CRS COMPASS – Standard 12](#)
- [CRS COMPASS – Standard 15](#)
- [CRS Inventory Counts Policy](#)

## DONOR POLICIES AND REGULATIONS

- [The Global Fund Operational Manual Policy](#)
- [The Global Fund QA Policy for Diagnostic Products](#)
- [The Global Fund QA Policy for Pharmaceutical Products](#)

## DONOR AND OTHER GUIDELINES

- [JSI Guidelines for Warehousing Health Commodities](#) *Appendix 1 includes a list of relevant questions to ask during the assessment.*
- [The Global Fund Guide to Policies on PSM of Health](#)
- [The Global Fund In-country Monitoring of Pharmaceutical Products in Global Fund-supported Programs](#)
- [WHO Assessment Tool Based on the Model QA System for Procurement Agencies: Aide-Memoire for Inspection](#)
- [WHO Good Storage and Distribution Practices for Medical Products](#)
- [WHO Guidelines for Sampling of Pharmaceutical Products](#)
- [WHO List of Prequalified In Vitro Diagnostic Products](#)
- [WHO QA Policy for the Procurements of Essential Medicines and Other Health Products](#)

# PROCESS

QA is a wide-ranging concept covering all matters that individually or collectively influence the quality of a product. It is the totality of the arrangements made to ensure that pharmaceutical products are of the quality required for their intended use.

NMRAs are legally responsible for overseeing the quality of pharmaceutical products in countries.

All parties involved in the distribution of pharmaceutical products are responsible for the quality and integrity of pharmaceutical products. The responsibility remains throughout the distribution process from the manufacturer's site to the entity dispensing or providing the product to the patient.

## QUALITY REQUIREMENTS FOR SOURCING AND PROCURING HEALTH PRODUCTS

The table below shows the minimum required quality standards to source and procure health products.

Products	Quality standards
Antiretroviral, Anti-TB, and Anti-malarial Medicines	Prequalified by the WHO Prequalification Program or authorized for use by an SRA or recommended for use by an Expert Review Panel.
Other Medicines	Need only to comply with the relevant quality standards that are established by the NDRA in the country of use. That usually includes authorization for use by the NMRA.
In-vitro Diagnostic Products and Imaging Equipment	<p>All products must be from manufacturers whose manufacturing sites are compliant with the requirements of the ISO 13485: 2003.</p> <p>Additionally, the products must meet one of the following four options:</p> <ul style="list-style-type: none"> <li>• Prequalification by the WHO Prequalification Program for in vitro diagnostics.</li> <li>• For TB products, recommendation by the relevant WHO program.</li> <li>• Authorization for use by one of the regulatory authorities of the founding members of the GHTF, when stringently assessed (with a high-risk classification): This option does not apply to RDTs for HIV self-testing.</li> <li>• Acceptability for procurement using grant funds, as determined by the Global Fund, based on the advice of the Expert Review Panel.</li> </ul>
Microscopes	Shall be manufactured at a site compliant with the requirements of the ISO 9000 series.
Vector Control Products including Long Lasting Impregnated Nets and Indoor Residual Sprays	<a href="#">WHO Vector Control Products Prequalification.</a>



For additional verification of compliance with The Global Fund QA policy, it is recommended to use the [Global Fund eligible products lists](#) (available on The Global Fund website, QA section) to ensure that the products to procure are listed.

Please refer to the Procurement chapter in the [CRS Supply Chain Management Handbook](#) for more guidance on sourcing and procuring health products including medicines, Rapid Diagnostic Products, and bed nets.

## CHECKLIST

*Complying with Quality Standards*



To source and select health products that comply with quality standards:

- ☐ The **Health Supply Chain Manager** should set specifications meeting quality standards as per in the table below and ensure that suppliers provide appropriate certifications.
- ☐ The **Health Supply Chain Manager** should ensure that products to be purchased either through Pooled Procurement Mechanism or direct procurement are authorized for use in the destination country at the time of delivery.

To perform the last check on the strict application of quality standards requirements:

- ☐ The **SCM Regional Technical Advisor** reviews and provides input.

## QUALITY MONITORING OF PRODUCTS IN STORAGE AND TRANSPORTATION

### Good Storage and Distribution Assessment

**GDP and GSP for Pharmaceuticals** apply to manufacturers, pharmaceutical importers, contractors, wholesalers, communities, and hospital pharmacies. Each guidance gathers the minimum and standard requirements to maintain pharmaceuticals of good quality for human use and should be incorporated into national regulations.

Donors funding projects, including the distribution of health products, require that patients or end users have access to good quality products. Therefore, as Principal Recipient, CRS needs to ensure that the quality of products is kept along the supply chain even while warehousing and transportation services are externalized to Third-party Logistics.

The main elements of QA in grant-supported programs are:

- Sourcing of products per Procure-to-pay and in compliance with donor's QA policies.
- Appropriate temperature conditions during international freight.
- Appropriate storage conditions at all levels of the in-country supply chain.
- Secured distribution systems.

- Batch traceability system throughout the supply chain.

## CHECKLIST *Quality Monitoring*



To constantly monitor the alignment to the best practices, the health supply chain practitioners perform regular assessments of the GDP and GSP following the process below:

- ☐ The **SCM Regional Technical Advisor** organizes or provides orientations on GDP and GSP to the Health Supply Chain Manager.
- ☐ The **Health Supply Chain Manager** provides orientation on GDP and GSP to **LMIS Officers, Warehouse Manager, Storekeepers**, and any other staff directly managing health products or participating in SCM field supervisions conducted at decentralized medical stores in regions or districts hospital and health facilities pharmacies.
- ☐ Orientation should be based on the following material:
  - [WHO Good Storage and Distribution Practices for Medical Products](#)

For joint collaborative supervisions (with national implementing entities) performed in hospitals and health facilities, the Health Supply Chain Manager, in coordination with the MEAL team, must support the revision of national supervision tools to integrate GDP and GSP.

- ☐ The **Health Supply Chain Manager** or **SCM Regional Technical Advisor** (for new projects) ensures that detailed budgets include sufficient provision to support quarterly field supervisions at hospitals and health facilities pharmacies.
- ☐ The **Health Supply Chain Manager** ensures that results from quarterly field supervisions are analyzed in collaboration with stakeholders to:
  - Identify risk areas.
  - Develop an action plan allowing hospitals and health facilities pharmacies to comply with GDP and GSP.
  - Estimate costs.
  - Share results with the national PSM technical working group and develop plans for donors' advocacy.
  - Review and provides input.

## To Ensure Quality Checks:

The **SCM Regional Technical Advisor** and **Health Supply Chain Manager** review the table below to guide the regular assessment:

Cheat Sheet to Conduct GDP Assessments	
Items	Aspects to check.
Record keeping	Adequacy.
Traceability	Products are traceable from manufacturing to end user.
Receiving at the Port of Entry	Storage conditions are met: •Temperature-sensitive products handled appropriately •Security measures in place (e.g., prevent theft, fraud, and bribery).
Receiving and Dispatch Bays	Activities below are performed: • Incoming containers cleaned, quarantined • Review of Certificates of Analysis • Released for use or distribution (responsible person involved).
Checks on Receipt	Checks below are performed: Alignment of documents and packages •Appropriate labels •Transport conditions were met •Integrity of packages and seals • Uniformity of containers.
Visual Inspection	Inspection for: •Contamination, tampering and damage, expiry date, and compliance with labeling and packaging instructions •Suspect containers and damaged containers are recorded and investigated • Products are released by a responsible employee.
Storage Areas	The conditions below are respected: No unauthorized access •Sufficient space •Adequate ventilation, temperature, and relative humidity •Conditions checked, monitored, and recorded •Segregation of rejected, expired, recalled, or returned stock •Toilet and washing facilities separated from storage areas •Narcotics/psychotropic medicines as per national legislation •SOP for fire control •No smoking or eating •SOP and records for cleaning •Waste management •Pest control •SOP for handling spillages •Access controlled.
Storage Conditions	The conditions below are respected: •Storage conditions are compliant with the ones established by the manufacturer •Orderly, batch segregation, stock rotation, First Expired, First Out •Stored off the floor •Space to permit cleaning and inspection •Pallets in a good state of cleanliness and repair •Stacking of products without damage •Freeze-sensitive products – use monitoring devices •Cold rooms (qualification, temperature mapping, alarm, monitoring, records, back-up system in case of failure).
Storage Conditions Monitoring	Activities below are performed: •Temperature mapping protocol and report •Calibrated sensors/devices •Ongoing monitoring with records.
Miscellaneous and Hazardous Materials	Activities below are performed: •Use of Rodenticides, insecticides, fumigating agents, and sanitizing materials •Toxic substances and flammable materials are segregated.

### Cheat Sheet to Conduct GDP Assessments

Stock Control	<p>Activities below are performed:</p> <ul style="list-style-type: none"> <li>•Validated stock control system</li> <li>•Batch number control and expiry dating</li> <li>•Periodic stock reconciliation</li> <li>•Significant stock discrepancies investigated</li> <li>•Records maintained</li> <li>•Damaged containers handled</li> <li>•Control and regular checks of obsolete and outdated materials and products.</li> </ul>
Recalled Materials and Products	<p>Activities below are performed:</p> <ul style="list-style-type: none"> <li>•SOP</li> <li>•Written records of actions with signatures</li> <li>•Products identified, recorded, reconciled, and stored separately</li> <li>•Decision by appropriately qualified and experienced member of staff.</li> </ul>
Returned goods	<p>Activities below are performed:</p> <ul style="list-style-type: none"> <li>•SOP</li> <li>•Quarantined and assessed</li> <li>•Redistribution conditions</li> <li>•Destruction in compliance with national requirements</li> <li>•Records are kept.</li> </ul>
Vehicles and Equipment	<p>Activities below are performed:</p> <ul style="list-style-type: none"> <li>•Temperature control and monitoring</li> <li>•Redistribution conditions</li> <li>•Safeguarding measures are in place</li> <li>•Suitable vehicles and equipment</li> <li>•Proper cleaning and Maintenance of vehicles</li> <li>•Proper training of drivers for health product handling and management to avoid products mix-up.</li> </ul>

To Ensure that Third-party Contractors Apply GDP and GSP:

## CHECKLIST *Applying GDP & GSP*



- ☐ The **Health Supply Chain Manager** ensures that agreements (contracts or memorandum of understanding) signed with providers of warehousing services include the minimum below obligations:
  - License from national regulatory authorities to store and transport pharmaceutical products. For storage service providers, these activities should be performed under the control of trained pharmacist staff.
  - Obligation for them to have a robust QA system applying GDP and GSP standards.
  - The ability for the country program to perform yearly or whenever necessary GDP and GSP compliance spot checks based on the checklist provided above.
  - Obligation for service providers to issue corrective action plans, including recommendations resulting from the spot check.
  - Ability to closely monitor corrective actions plans.
  - Key supply chain performance indicators.
  - Insurance covering losses, damages, fire, diversions, and risks of political violence, if necessary.
  - Physical Inventory counts.
- ☐ The **Health Supply Chain Manager**, in collaboration with stakeholder representatives (National regulatory authority, National disease programs, implementing partners), plans every year, a visit to third-party contractors' premises to monitor GDP and GSP 's application.
- ☐ The **Health Supply Chain Manager** issues a visit report including significant and critical findings with recommended actions.
- ☐ The **Health Supply Chain Manager**, with a third-party contractor, prepare a corrective action plan including recommendations and timelines.
- ☐ The **Health Supply Chain Manager** monitors the corrective action plan and reports on progress to the donor.

To Ensure that Agreements Signed with Third-party Contractors Include Minimum Obligations as Shown Above:

## CHECKLIST

*Ensure Minimum Obligations Are Included*



- ☐ The SCM Regional Technical Advisor reviews and provides input on agreements.
- ☐ The SCM Regional Technical Advisor ensures that the Health Supply Chain Manager conducts yearly visits to third-party contractors' premises.
- ☐ The SCM Regional Technical Advisor requests an update on progress made with the corrective action plan and address challenges met or seeks support for appropriate response.

## ROLES AND RESPONSIBILITIES

Function/Activity	Chief of Party	Head of Operations	Supply Chain Manager or Health SCM Focal Point	SCM Regional Technical Advisor	GSCM Strategic Technical Assistance and Response Health Team
Sets specifications meeting quality standards	A	I	R	C	
Ensures that suppliers provide appropriate certifications	A	I	R	C	
Reviews and provides input	I	I	C	R	
Organizes or provides orientations on GDP and GSP	I	I	C	R	A
Supports the revision of national assessment tools to integrate GDP and GSP	A		R	C	
Ensures that detailed budgets integrate quarterly PSM supervisions	A	I	R	C	

Function/Activity	Chief of Party	Head of Operations	Supply Chain Manager or Health SCM Focal Point	SCM Regional Technical Advisor	GSCM Strategic Technical Assistance and Response Health Team
Ensures that results from quarterly field supervisions are analyzed and action plans with costs elements are developed	A	I	R	C	
Reviews and provides input	I		C	R	
Signs assurance with third-party providers includes minimum obligations	A	I	R	C	
Reviews and provides input	I		C	R	

R=Responsible; A=Accountable; C=Consulted; I=Informed

## QC TESTING

QC testing will enable country programs to:

- Monitor the quality of the medicines procured and distributed by CRS and partners along the supply chain.
- Provide evidence that medicines reaching patients meet specifications.
- Identify products or batches not meeting specifications and remove them from the supply chain.
- Obtain information to support gap analysis and risk management in the supply chain.

For Contracting QC Testing Laboratories:

## CHECKLIST

*Contracting QC Testing Laboratories*



- ☐ The **Health Supply Chain Manager** or **RTA Supply Chain Manager** (for new projects) ensures that detailed budgets include activity lines for quality monitoring of pharmaceutical. Costing can be estimated with:
  - Quotes requests from QC laboratory and/or previous quotes.
  - The Global Fund suggests budgeting 2-3% of the total value (Ex-Works) of the medicines procured for quality-related activities – 2% in case of high procurement value and 3% in case of low procurement value.
- ☐ The **Health Supply Chain Manager** liaises with the NMRA to coordinate quality monitoring activities (such as inspection of consignments, sampling, and interpretation of out of specification results etc.) and accordingly prepares a quality monitoring plan.
- ☐ The **Health Supply Chain Manager** checks and confirm on [WHO list of Prequalified QC Laboratories](#) and [List of ISO 17025-Accredited QC Laboratories](#)
- ☐ The **Health Supply Chain Manager** in collaboration with NMRA prepares technical specifications for selecting QC laboratory. [The questionnaire for obtaining technical information](#) provided by The Global Fund can be used. Laboratories should specify the routines cost per batch required for complete testing of the product as the cost of method transfer for products that require testing as per the manufacturer's method (as opposed of tests specified in the monography of B.P, U.S.P and International Pharmacopeia)
- ☐ The **Health Supply Chain Manager** liaises with the Head of Operations to prepare bidding documents.
- ☐ The **Health Supply Chain Manager** as NRMA and implementing partners are associated to the awarding process.

To Ensure that Donors' Requirements Are Met:

## CHECKLIST

*To Ensure Donor Requirements Are Met*



- ☐ The **SCM Regional Technical Advisor** reviews and provides input on technical specifications.



## QC Testing/Sampling Plan

Sampling plans include lists of products that will be tested, collection date, and the testing method as the criteria to define acceptance. In addition, sampling plans should consider supply chain-related risks as well as product-related risks.

Example of Supply Chain Related Risks Triggering QC Testing		
	Quality Risks May Arise in Case of:	QC Strategies
Procurement	<ul style="list-style-type: none"> <li>✓ Poorly defined specifications and quality requirements.</li> <li>✓ Local pharmaceutical procurement.</li> </ul>	Sample products on receipt.
Port Clearance	<ul style="list-style-type: none"> <li>✓ Long shipping routes and several stops.</li> <li>✓ Frequent delays at the port.</li> <li>✓ Doubtful port storage conditions.</li> </ul>	Sample products on receipt.
Storage – Central Level	<ul style="list-style-type: none"> <li>✓ Large buffer stocks.</li> <li>✓ Seasonal peaks or campaigns.</li> <li>✓ Repackaging or relabeling.</li> </ul>	Sample products with long storage history and sensitive stability.
Storage – Peripheral Level	<ul style="list-style-type: none"> <li>✓ Poorly controlled storage conditions.</li> <li>✓ Poor stock management.</li> </ul>	Sample strategically number of patients treated and sensitive stability.
Distribution	<ul style="list-style-type: none"> <li>✓ Complex distribution chains.</li> <li>✓ Third-party Logistics.</li> <li>✓ Frequent emergency orders.</li> </ul>	Sample close to patient level.
Pharmacovigilance	<ul style="list-style-type: none"> <li>✓ No adverse reaction reporting system.</li> </ul>	Sample close to patient level.
Example of Product-Related Risks Triggering QC Testing		
<b>Stability</b>		
<ul style="list-style-type: none"> <li>✓ Products requiring storage below 8 °C.</li> <li>✓ Products containing an unstable API.</li> <li>✓ Products with a total shelf life of &lt; 2 years.</li> <li>✓ Liquids.</li> </ul>		
<b>Complex formulation</b>		
<ul style="list-style-type: none"> <li>✓ Fixed-dose combinations.</li> <li>✓ Tablets with less than 5 mg dose.</li> <li>✓ Products requiring sterile production (i.e., injectables).</li> </ul>		
<b>Unknown or unstable manufacturing quality</b>		
<ul style="list-style-type: none"> <li>✓ Products with quality problems reported during the past year or WHO alert.</li> <li>✓ Recently licensed, not previously procured.</li> <li>✓ Another product of the same manufacturer had a documented quality issue in the past year.</li> <li>✓ Products containing an API that is in global short supply.</li> </ul>		
<b>Exposure and harm-related risks</b>		
<ul style="list-style-type: none"> <li>✓ Large numbers of patients treated.</li> <li>✓ High product value.</li> <li>✓ Lifesaving and emergency medicines.</li> </ul>		

To Prepare for Product Sampling and Collection:

## CHECKLIST *Sampling & Collection Preparation*



- ☐ The **Health Supply Chain Manager** with the NMRA and National Program should discuss and prepare an annual sampling and testing plan: which products should be sampled at which locations under the QC testing plan based on the supply chain and product related risks.
- ☐ Additionally, the **Health Supply Chain Manager** ensures that “unplanned” or “on purpose” testing is done when specific adverse events happen (i.e., products knowingly exposed to extended bad storage conditions, reported adverse reactions with patients, visible quality defects). These are not included in the initial annual sampling plan but must be carried out.

For each product to be sampled, it is important to know in advance how many units (i.e., number of tablets, number of bottles) need to be collected. This information comes from the selected QC Laboratory.



- ☐ The **Health Supply Chain Manager** with the NMRA, National Program, and any other main stakeholder should discuss the organization for collecting the samples. Samples could be collected using the central medical store transportation and might require an amendment to the initial contract or by using Third-party Logistics services.
- ☐ The **Health Supply Chain Manager** supports the NMRA and National Program to communicate with entities from which samples will be collected and provide them with the product list, batch number, expected packaging, and collection date.
- ☐ The **staff designated to perform the sample collection** at the health facility should record the sample collection using a sample collection form, for each sample collected.
- ☐ The **Health Supply Chain Manager** coordinates with the Head of Operations for the recruitment of an express courier carrier and if necessary, the selection of a Third-party Logistics for sampling collection.
- ☐ The **Health Supply Chain Manager** coordinates with the express courier carrier and the QC laboratory the expedition of the samples. There may be a need for CRS to prepare an “invoice” for samples customs clearance purpose.
- ☐ The **Health Supply Chain Manager** monitors with the QC laboratory the status on tests. Results should be communicated to CRS no later than 30 days after reception of the samples by the laboratory.

To Communicate Results to Main Stakeholders and Prepare for An Action Plan:

## CHECKLIST

*Communicating Results to Stakeholders*



- ☐ Once results are received, the **Health Supply Chain Manager** communicates the results with the NMRA and national program.
- ☐ If the results are Out-Of-Specifications (non-conformity), the **Health Supply Chain Manager** seeks guidance from the **Regional Technical Advisor**.
- ☐ The **Health Supply Chain Manager** communicates results to the donor
- ☐ The **Health Supply Chain Manager**, with the NMRA and national program, prepares an action plan if results do not meet acceptance criteria. The action plan can include quarantining the batch numbers with defects, organizing collection and destruction, and placing emergency orders to replace stocks.
- ☐ All QC results should be recorded by the **Health Supply Chain Manager** in a QC database.

## ROLES AND RESPONSIBILITIES

Function/Activity	Chief of Party	Head of Operations	Supply Chain Manager or Health SCM Focal Point	SCM Regional Technical Advisor	GSCM Strategic Technical Assistance and Response Health Team
Ensures that detailed budgets include activity lines for quality monitoring of pharmaceutical	A	I	R	C	
Liaises with the NMRA to coordinate quality monitoring activities and accordingly prepares a quality monitoring plan	A	I	R	C	
Checks WHO list of Prequalified QC Laboratories and List of ISO 17025-accredited QC laboratories	A	I	R	C	

Function/Activity	Chief of Party	Head of Operations	Supply Chain Manager or Health SCM Focal Point	SCM Regional Technical Advisor	GSCM Strategic Technical Assistance and Response Health Team
Prepares technical specifications for selecting QC laboratory	A	I	R	C	
Reviews and provides input on technical specifications	I		C	R	
Liaises internally to prepare bidding documents	A	C	R	I	
Associates NRMA and implementing partners with the awarding process	A	C	R		
Discusses and prepares with QC laboratory QC testing plan	A	I	R	C	
Discusses the organization for collecting the samples	A	C	R	C	
Coordinates internally for the recruitment of an express courier carrier and if necessary, the selection of a Third-party Logistics for sampling collection	A	C	R	I	
Supports NMRA and National Program to communicate with entities from which samples will be collected and provide them with the product list, batch number, expected packaging, and collection date	A		R	C	
Coordinates with the express courier carrier and the QC laboratory the expedition of the samples	A	C	R	I	

Function/Activity	Chief of Party	Head of Operations	Supply Chain Manager or Health SCM Focal Point	SCM Regional Technical Advisor	GSCM Strategic Technical Assistance and Response Health Team
Monitors with the QC laboratory the status of tests	A	I	R	C	
Communicates results with main stakeholders including donor	A		R	C	
Prepares an action plan if results do not meet acceptance criteria and support its implementation	A	I	R	C	

R=Responsible; A=Accountable; C=Consulted; I=Informed

## CHAPTER 3.5: DISTRIBUTION

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# POLICIES, PROCEDURES, REGULATIONS, AND GUIDELINES

## CRS POLICIES AND PROCEDURES

- [CRS COMPASS – Standard 12](#)
- [CRS Digitizing Health Campaigns Improves Outcomes](#)
- [CRS In-Country Management and Distribution of Long Lasting Insecticide-Treated Nets](#)
- [CRS Inventory Counts Policy](#)

## DONOR POLICIES AND REGULATIONS

- [WHO Model QA System for Procurement Agencies](#)

## DONOR AND OTHER GUIDELINES

- [WHO Good Storage and Distribution Practices for Medical Products](#)
- [The Alliance for Malaria Prevention Toolkit 2.0](#)
- [The Task Force for Global Health Decision Toolkit on Health Campaign Integration](#) *Designed to assist officials and stakeholders at the country and global levels to identify and collect information on potential opportunities for health campaign integration*

## PROCESS

Distribution consists of moving products down the pipeline from the national central warehouse until they are dispensed to patients or made available to end users.

The most common in-country distribution system is a system where products flow from central medical stores to regions and or districts and ultimately to Service Delivery Points. Distribution networks need to consider what is the ideal distribution network that will provide a satisfactory level without stock outs at dispensing facilities.

## ROUTINE DISTRIBUTION FROM CENTRAL LEVEL TO SERVICE DELIVERY POINTS

Routine distribution, as opposed to mass campaign distribution, aims to maintain a constant supply of products as per cycles defined by national guidance. For instance, national schemes can have established that Service Delivery Points are supplied monthly, district pharmacies every quarter, regional warehouses every semester, and central medical stores annually. Distribution can be based on a pull system (requisition), push system (allocation), or hybrid approach combining pulling and pushing systems.

### Collaborative Partnerships

Implementing successful distributions depends on establishing a solid collaborative partnership with main stakeholders to ensure that the right products are delivered at the right locations, right time, and in the right quantities. Modeling, organizing transportation, and planning to deliver the right quantities before needed is key.

# CHECKLIST

## *Collaborative Partnerships*



- ☐ The **Health Supply Chain Manager** evaluates distances between locations as well as roads accessibility and prepares a map.
- ☐ The **Health Supply Chain Manager** prepares an estimative analysis on quantities and values to be distributed to each region and districts. National programs should validate this analysis.
- ☐ The **Health Supply Chain Manager** assesses central medical, regional, and district stores' fleet capacities to define if fleet capacities at different levels of the supply chain can respond to distribution cycles and comply with GDP. Results of this assessment will define the transportation model.
  - If transportation capacities are adequate from all storage points, the **Health Supply Chain Manager** prepares an agreement with the central medical store and MOH organizing transportation of products.
  - If no transportation capacities are available, the **Health Supply Chain Manager** needs to coordinate internally for the recruitment of Third-party Logistics accordingly to open and competitive processes.
  - If transportation capacities are limited to certain points of the supply chain, the **Health Supply Chain Manager** needs to support implementing partners in defining the appropriate transportation model that will help maintain scheduled deliveries as per the national scheme. In this case, the transportation model will consider costs, security risks, ease in operationalization, country program's capacities to manage multiple Third-party Logistics.
- ☐ The **Health Supply Chain Manager** prepares technical specifications and requirements including locations and distance mapping, quantities, and values to be distributed to negotiate with central medical stores.
- ☐ The **Health Supply Chain Manager** liaises internally with the **Head of Operations** to procure Third-party Logistics services and provides the technical specifications and requirements.
- ☐ The **Health Supply Chain Manager** negotiates with contractors the integration of relevant points such as:
  - Metrics in Contracts or Service Level Agreements signed with public or private sector Third-party Logistics. Indeed, KPIs will allow CRS to monitor service provider performances, alert on issues, and feed activity reports to donors. For more information on CRS supply chain KPIs, refer to the Monitoring chapter of the [CRS Supply Chain Management Handbook](#).
  - Insurance obligations.
  - Submission of documentation such as packing lists, good distribution notes, and good reception notes.
- ☐ The **SCM Regional Technical Advisor** reviews and provides input.



# CHECKLIST

## *Scheduling Deliveries*



- ☐ The **Health Supply Chain Manager** reviews the product flow chart and confirms the national distribution cycle with implementing partners as the distribution system (push, pull, or hybrid).
- ☐ The **Health Supply Chain Manager**, with implementing partners, defines processes to prepare, validate, and communicate the distribution plan to entities in charge for transportation. Processes should be written.
- ☐ The **Health Supply Chain Manager** reviews the distribution plan based on the distribution system (push, pull, or hybrid). The review will cover data and analysis performed to elaborate the distribution plan, such as POs, stock on hands from Service Delivery Points, and hospital attendance rates.
- ☐ The **Health Supply Chain Manager** follows up on the execution of the distribution plan.
- ☐ The **Health Supply Chain Manager** gathers proof of deliveries and reception and keeps appropriate recording.
- ☐ The **Health Supply Chain Manager** performs a comparison between distribution plans and deliveries.
- ☐ The **Health Supply Chain Manager** discusses and questions with warehousing and transportation providers discrepancies between distribution plans and deliveries.
- ☐ The **Health Supply Chain Manager**, with implementing partners, prepares distribution reports.
- ☐ The **Health Supply Chain Manager** reviews and provides input.

## ROLES AND RESPONSIBILITIES

Function/Activity	Chief of Party	Head of Operations	Supply Chain Manager or Health SCM Focal Point	SCM Regional Technical Advisor
Evaluates distances between locations as roads accessibility and prepares maps	A	I	R	C
Prepares an estimative analysis on quantities and values to be distributed to each region and if possible, districts	A	I	R	C
Assesses central medical, regional, and district stores fleet capacities	A	I	R	C
Prepares technical specifications and requirements including locations and distance mapping, quantities, and values to be distributed to negotiate with central medical stores	A	I	R	C
Liaises internally with the Head of Operations to procure Third-party Logistics services and provides the technical specifications and requirements	A	I	R	C
Negotiates with contractors the integration of relevant points	A	I	R	C
Follows up on the execution of the distribution plan	A	I	R	C
Gathers proof of deliveries and/or reception and keeps appropriate recording	A	I	R	C
Performs a comparison between distribution plans and deliveries	A	I	R	C

Function/Activity	Chief of Party	Head of Operations	Supply Chain Manager or Health SCM Focal Point	SCM Regional Technical Advisor
Discusses and questions with warehousing and transportation providers discrepancies between distribution plans and deliveries	A	I	R	C
Prepares distribution reports	A	I	R	C
Reviews and provides input	I		C	R

R=Responsible; A=Accountable; C=Consulted; I=Informed

## MASS CAMPAIGN DISTRIBUTION

Mass distribution campaigns aim to reach an important number of beneficiaries to prevent diseases. Distribution for mass campaigns can be organized through door-to-door or fixed-point deliveries.

Health mass campaign distribution activities are organized to reach many beneficiaries for a given period. Mass campaign distribution is used for various health interventions to reach higher coverage. The types of products used varies from vaccines, ITNs, Nutrition (Vitamin A), drugs for Seasonal Malaria Chemoprophylaxis, and Neglected Tropical Diseases.

For a successful mass campaign, many complex and disparate activities are performed, such as:

- **Macroplanning:** Include the planning process with the development of an action plan, timeline, and the elaboration of the Macro budget managed at the central level.
- **Procurement:** Health products and services providers for transport, storage, printing tools, and vouchers.
- **Coordination:** A coordination mechanism with clear roles and responsibilities at all national system levels.
- **Microplanning:** Engaging the operational level to gather bottom-up critical information for logistics and detailed budget.
- **Behavioral change activities:** To sensitize the community at all levels on the benefits of the health interventions.
- **Household mobilization:** To enumerate the number of beneficiaries in each household either using technologies or a paper-based system.
- **Training the practitioners** on the distribution activities, household mobilization, and supervision.
- **Supervision and monitoring** of activities.
- **Distribution** activities.

- **Payment of services providers.**
- **Reverse logistics and waste management.**

For more details on the above, see the [AMP Tool Kits Chapter 7](#) on implementation.

The following explanations of full integration and partial integration are sourced from The Task Force for Global Health, [Technical Brief on the Integration Between Health Campaigns: Intervention Co-delivery and Collaboration](#).

### Full Integration: Co-delivery of Campaign-based Products/Health Interventions

Full integration involves coordinating most or all typical campaign components (microplanning, registration, logistics, implementation, and evaluation) to allow co-delivery or simultaneous delivery of two or more health interventions at the point of service delivery.

### Partial Integration: Collaboration and Sharing of Campaign Components

Partial integration involves collaboration or sharing of specific campaign components between vertical health programs to improve efficiency and effectiveness of multiple campaigns but without co-delivery of interventions.

## INITIATION OF THE PROCUREMENT PROCESS

### CHECKLIST

#### *Procurement Process Initiation*

- ☐ The **Health Supply Chain Manager** requests the national programs to confirm the specification of the required health products and placed the orders per Procure-to-pay process.
- ☐ The **Health Supply Chain Manager** initiates recruitment process of required staff.
- ☐ The **Health Supply Chain Manager** initiates the RFQ for tools, storage location, transport, security services, Financial Service Providers, etc.
- ☐ **Regional Technical Advisors** support the review of the RFQ for those procurement processes.
- ☐ The **Chief of Party**, in collaboration with the national program, establishes a detailed implementation timeline.
- ☐ The **Chief of Party** and national program establish the national coordination entity of the mass campaign.
- ☐ The **Health Supply Chain Manager** and the program PSM chair organize regular national logistics coordination entity meetings.



## Macroplan

CHECKLIST *Macroplan*

- ☐ The **Health Supply Chain Manager** and national stakeholders prepare the operational plan (Macroplan).
- ☐ The **Health Supply Chain Manager** and national stakeholders identify needs, risks (warehousing, transportation, data management), and mitigation plan.
- ☐ The **Regional Technical Advisor** reviews the macro plan and the mitigation plan and provides input.
- ☐ The **Health Supply Chain Manager**, in collaboration with the national stakeholders, assesses the feasibility of partial or integrated deliveries using the "Decision Guidance tool kits for campaign integration".
- ☐ The **Health Supply Chain Manager** follows to ensure the finalization of transport contracts, warehouse renting, and recruitment of logistics consultants.
- ☐ The **Health Supply Chain Manager** organizes warehouse assessment.

## Microplan and Census

CHECKLIST *Macroplan & Census*

- ☐ For a non-digitalized campaign, the **Supply Chain Manager**, in collaboration with the M&E team, organizes the Microplan training using AMP guidance.
- ☐ The **Health Supply Chain Manager**, M&E with the support of the ICT4D team, establishes aggregation tools for Microplanning.
- ☐ The **Regional Technical Advisor** provides technical support and guidance to the Supply Chain Manager for the Microplanning process.
- ☐ For the digitalized campaign, the **Supply Chain Manager** collaborates closely with ICT4D to include the track of commodities at all levels throughout the SC.
- ☐ During COVID-19 restrictions, door-to-door mechanisms are preferred. Microplanning is organized remotely, and the census/household registration is combined with the distribution.
- ☐ The **Health Supply Chain Manager** coordinates the health commodities deliveries and ensures proper documentation is in place at all levels.
- ☐ The **SCM Regional Technical Advisor** performs a spot check to assess the inventory management and proper documentation of the health products at all levels.

## Distribution

# CHECKLIST *Distribution*



- ☐ The **Supply Chain Manager** guides the review and finalization of the Micro planning budget.
- ☐ The **Supply Chain Manager** organizes the redeployment per the microplanning plan.
- ☐ The **Supply Chain Manager** coordinates the selected transport entities for the distribution in collaboration with the Logistics Managers.
- ☐ The **Supply Chain Manager** performs regular supervision to ensure proper tracking of health products and documentation of the process.
- ☐ The **Supply Chain Manager** organizes and guides the inventory of the remaining LLINs and the reverse logistics in collaboration with the Subrecipients.
- ☐ **Regional Technical Advisors** reviews the tracking system in place to ensure proper reporting and review the logistics report of the campaign.

## ROLES AND RESPONSIBILITIES

Function/Activity	Health Supply Chain Manager	Procurement Manager	Head of Operations	PM/Chief of Party	SCM Regional Technical Advisor
Requests National programs to confirm specifications of the required Health products and places the orders per Procure-to-pay process	R	C	I	A	
Initiates recruitment process of required staff	R			A	C
Initiates RFQ for Tools, storage location, transport, security services, Financial Service Providers	R	C	C	A	I
Supports the review of the RFQ for those procurement process	C	C	I	I	R
Establishes a detailed implementation timeline with national programs	C		I	R	C
Establishes the national coordination entity of the mass campaign with national programs	C			R	C
Organizes regular meetings of the national logistics coordination entity	R			A	C
Prepares the operational plan (Macroplan) with national stakeholders	R		I	A	C
Reviews the Macroplan and the mitigation plan and provide input	C			I	R
Assesses the feasibility of partial or integrated deliveries using " Decision Guidance tool	R			A	C

Function/Activity	Health Supply Chain Manager	Procurement Manager	Head of Operations	PM/Chief of Party	SCM Regional Technical Advisor
kits for campaign integration"					
Follows up on finalization of transport contracts, warehouse renting, and recruitment of logistics consultants	R	C	C	A	I
Organizes warehouse assessment	R	I	I	A	C
Organizes the Microplan training using AMP guidance	R			A	C
Establishes an aggregation tool for Microplanning tools.	R			A	C
Provides technical support and guidance to the Supply Chain Manager for the Microplanning process	C			I	R
Works closely with the ICT4D to include the track of commodities at all levels throughout the SC.	R			A	C
Coordinates deliveries of health commodities and ensures proper documentation are in place at all levels	R			A	C
Provides spot check to assess the inventory management and proper documentation of the health products at all levels	R			A	C
Provides guidance for the review and finalization of the Microplanning budget	R			A	C
Organizes the redeployment per the microplanning plan	R			A	C



Function/Activity	Health Supply Chain Manager	Procurement Manager	Head of Operations	PM/Chief of Party	SCM Regional Technical Advisor
Coordinates the selected transport entities for the distribution in collaboration with the logistics Managers	R		C	A	C
Performs regular supervision to ensure proper tracking of Health products and documentation of the process	R			A	C
Organizes and provides guidance for the inventory of the remaining LLINs and the reverse logistics in collaboration with the Subrecipients	R			A	C
Reviews the tracking system in place to ensure proper reporting and review the logistics report of the campaign	C			I	R

R=Responsible; A=Accountable; C=Consulted; I=Informed

## CHAPTER 3.6: COLD CHAIN PROGRAM

### POLICIES, PROCEDURES, REGULATIONS, AND GUIDELINES

#### DONOR AND OTHER GUIDELINES

- [WHO-UNICEF Temperature-sensitive Health Products in the Expanded Program on Immunization Cold Chain](#)

### PROCESS

The “cold chain” is a system for storing and transporting temperature-sensitive products at recommended temperatures from the point of manufacture to the point of use. Effective management of the cold chain is key to maintaining the safety and potency of vaccines and temperature-sensitive pharmaceuticals during storage, transport, and service delivery.

To ensure efficacy and quality of care, health systems must find ways to ensure all cold chain medical products are properly managed from the manufacturer, through the entire supply chain, to the point of use.

#### PLACING ORDER FOR COLD CHAIN COMMODITIES

### CHECKLIST *Cold Chain Commodities*

- ☐ The **Health Supply Chain Manager** assesses the Cold chain option available in the country (some information may be available from the initial SC assessment).
- ☐ The **Regional Technical Advisor** supports the review of the forecast needs to ensure that the quantities ordered will be consumed within the required time frame. At the same time, the **Regional Technical Advisor** should ensure that the cold chain space at reception is sufficient to absorb the quantities expected.
- ☐ The **Health Supply Chain Manager**, in collaboration with the national program, establish collaboration mechanism with the national entities for storing the commodities.



## RECEPTION

### CHECKLIST *Reception*



- ☐ The **Health Supply Chain Manager** identifies the appropriate port of entry with cold chain requirements and ensures that there is a specific mechanism in place with the customs clearance agent for fast clearance of cold chain items. The customs clearance agent should also have a specific process in place to expedite clearance of cold chain items.
- ☐ The **Health Supply Chain Manager** informs the freight forward and transporters.
- ☐ The **Health Supply Chain Manager** informs the warehouse staff in advance of any incoming cold chain goods for cold chain space preparation at reception.

## STORAGE AND DISTRIBUTION

### CHECKLIST *Distribution*



- ☐ The **Health Supply Chain Manager** inspects the storage location to verify the calibration of the cold chain equipment as well as the temperature monitoring system and records.
- ☐ The alarm system should be in place to alert staff in case of temperature excursions. A contingency plan is required in case of serious issue with the cold chain system: alternative storage location, alternative energy source (solar, gas) in case of power failure etc.
- ☐ Cold chain products exposed to temperature excursions need to be segregated and unavailable to distribution, while a verification on the usability of these products is conducted and completed.
- ☐ The **Health Supply Chain Manager** identifies the required cold chain equipment for transport throughout the supply chain, which includes items such as cool boxes, ice packs, and dataloggers. Warehouse staff in charge of packing cold chain goods for distribution should be adequately trained for the task. For larger volumes, the use of refrigerated trucks needs to be considered.
- ☐ The **Health Supply Chain Manager** ensures that transportation duration of goods packed in cool boxes does not exceed the capacity of the cool packing to maintain adequate temperatures.

## ROLES AND RESPONSIBILITIES

Function/Activity	Health Supply Chain Manager	Procurement Manager	Head of Operations	PM/Chief of Party	SCM Regional Technical Advisor
Assesses the Cold chain option available in country	R	I	I	A	C
Supports the review of the forecast needs to ensure that the quantities ordered will be consumed within the required time frame	C	I	I	C	R
Establishes collaboration mechanism with the national entities for storing the commodities	R	I	I	A	C
Identifies the appropriate port of entry with Cold chain requirements	R	I	I	A	C
Informs the freight forward and transporters	R	I	I	A	C
Inspects the storage location to verify the calibration of the cold chain equipment	R	I	I	A	C
Identifies the required cold chain equipment for transport throughout the supply chain	R	I	I	A	C

R=Responsible; A=Accountable; C=Consulted; I=Informed

## CHAPTER 3.7: WASTE MANAGEMENT

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### POLICIES, PROCEDURES, REGULATIONS, AND GUIDELINES

#### CRS POLICIES AND PROCEDURES

- [CRS COMPASS – Standard 12](#)

#### DONOR POLICIES AND REGULATIONS

- [The Global Fund Guide to Policies on PSM of Health Products](#) *Section 10 describes donor requirements*

#### DONOR AND OTHER GUIDELINES

- [WHO Guidelines for Safe Disposal of Unwanted Pharmaceuticals in and After Emergencies](#)
- [WHO Safe Management of Wastes from Health-care Activities](#)

### PROCESS

In this section, health waste products are those pharmaceuticals and RDTs expired, with quality issues, damaged, etc.

Waste management requires increased attention and diligence to avoid adverse health outcomes associated with poor practice, including exposure to infectious agents and toxic substances. WHO considers waste management as part of the supply chain.

The following are considered pharmaceutical waste (“unusable” products): expired products, unsealed syrups and eyedrops, breakage (i.e., vials), products with confirmed quality issues. They must be disposed of safely and with minimal environmental impact, per the national regulations.

There are two aspects to waste management:

- Health systems strengthening: The strengthening of the national waste management systems (policies, operations, funding, HR, infrastructure, and equipment).
- Operational: When CRS manages a health project, unusable products must be collected, inventoried, and safely disposed of regularly.

#### HSS – Waste Management

Waste management traditionally falls under HSS grants.

### Type of Waste Management Activities Provided by Global Fund's Modular Framework

Assessments and interventions for responsible green procurement of health products and sustainable 'Deliver' and 'Return' supply chains compliant with international and national regulations.

Assessment and development of policy frameworks, guidance, and operational plans for management of health care and/or supply chain waste.

Risk assessment and development of sustainable, safe, and environmentally friendly interventions for the management and/or disposal of specific health products (such as Antiretrovirals, ACTs, RDT, LLINs, viral load testing) and non-health products (e-waste, solar panel, batteries) as part of the national waste management system.

Setting up and strengthening the national waste management systems including the safe collection, classification and segregation, handling, return transportation, recycling, and/or treatment and disposal of waste.

Training of HR across all tiers in the public and private sector to increase awareness and improve competency in waste management practices including the return supply chain.

Infrastructure and equipment for the collection, transport, treatment, and disposal of health care waste that are compliant with environmental and occupational health standards.

Public-private partnerships for sustainable and environmentally friendly health care waste management.

Engagement with communities and civil society to implement environmentally friendly health care waste management practices.

Introduction of sustainable innovative methods that seek to comply with the waste management hierarchy to prevent, minimize, reuse, and recycle health care waste.

Evaluation of carbon footprint of 'end-to-end' supply chain, especially waste management and disposal options and promotion of climate-smart waste management systems and practices.

# CHECKLIST

## Waste Management



To define waste management related activities that will be included in the grant:

- ☐ The **Health Supply Chain Manager** or **SCM Regional Technical Advisor** (for new projects) liaises with appropriate national authorities to define waste management activities to be included in the detailed budget.
- ☐ The **Health Supply Chain Manager** supports the preparation of Terms of Reference. Terms of Reference for conducting the activity must include clear and actionable deliverables as milestones and provision for mid-term reviews.

To check on comprehensiveness and added value of activities selected:

- ☐ The **SCM Regional Technical Advisor** reviews and provides input.

To hire technical assistance supporting waste management selected activities:

- ☐ The **Health Supply Chain Manager** elaborates Terms of Reference (to be reviewed by the **Regional Technical Advisor**).
- ☐ The **Health Supply Chain Manager** coordinates internally with the **Head of Operations** and Global Procurement to proceed with the recruitment of consultancy for technical assistance.
- ☐ The **Health Supply Chain Manager** closely monitors progress made by the technical assistance and communicates them to the donor.
- ☐ The **Health Supply Chain Manager** and **Regional Technical Advisor** review reports from the technical assistance.

## Operational Waste Management (I.e., Waste Management Responsibilities in Global Fund Grants)

# CHECKLIST *Operational Waste Management*



Collection, transport, record, treatment, and disposal of health products waste:

- ☐ The **Health Supply Chain Manager** supports the inventory of damaged products or expired at all levels to issue packaging lists and locations.
- ☐ The **Health Supply Chain Manager** supports the preparation of a report identifying the type, quantity, and locations of products.
- ☐ The **Health Supply Chain Manager** prepares technical specifications to organize the collection of products.
- ☐ The **SCM Regional Technical Advisor** reviews and provides input.
- ☐ The **Health Supply Chain Manager** liaises internally with the Head of Operations to organize procurement of transportation services to collect wastes and deliver them at the agreed point.
- ☐ Health product waste should be disposed of at regular intervals (6 months), adhering to the national waste management protocols. Disposal of products needs to be recorded and documented (with details on products, quantities, and date/location/method of disposal).
- ☐ The **Health Supply Chain Manager** compares the disposal report to the packing list and communicates it to the donor.
- ☐ For health product waste that cannot be disposed of (for any reason, such as lack of funds, lack of agreement with national counterparts, etc.), these products must be kept in an identified and secure location, with updated inventory records.



## ROLES AND RESPONSIBILITIES

Function/Activity	Health Supply Chain Manager	Procurement Manager	Head of Operations	PM/Chief of Party	SCM Regional Technical Advisor
<b>HSS - Waste Management (Technical Assistance)</b>					
Liaises with appropriate national authorities to define waste management activities to be included in the detailed budget	R			A	C
Supports the preparation of Terms of Reference	R			A	C
Reviews and provides input	C			I	R
Liaises internally to organize the procurement of transportation services to collect wastes and deliver them at the agreed point	R	C	C	A	I
Monitors progress made by the technical assistance and communicates them to the donor	R			A	C
Reviews reports from the technical assistance	A			I	R
<b>Collection, Transport, Treatment, and Disposal of Healthcare Waste</b>					
Supports the inventory of damaged products or expired at all levels to issue packaging lists and locations	R		I	A	C
Prepares technical specifications to organize the collection of products	R	I	I	A	C
Reviews and provides input	C	I	I	I	R
Liaises internally with the head of operations to organize the	R	C	C	A	I

Function/Activity	Health Supply Chain Manager	Procurement Manager	Head of Operations	PM/Chief of Party	SCM Regional Technical Advisor
procurement of transportation services to collect wastes and deliver them at the agreed point					
Compares the disposal report to the packing list and communicates it to the donor	R			A	C

R=Responsible; A=Accountable; C=Consulted; I=Informed

## CHAPTER 3.8: PHARMACOVIGILANCE

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### POLICIES, PROCEDURES, REGULATIONS, AND GUIDELINES

#### DONOR POLICIES AND REGULATIONS

- [The Global Fund Guide to Policies on PSM of Health Products](#) Section 4.6 describes donor requirements for managing adherence to treatment protocols, drug resistance, and adverse effects

#### DONOR AND OTHER GUIDELINES

- [WHO Pharmacovigilance Indicators: A Practical Manual for the Assessment of Pharmacovigilance Systems](#)

Pharmacovigilance is the science and activities relating to detecting, assessing, understanding, and preventing adverse effects or any other medicine/vaccine-related problem. An adverse drug reaction is a harmful response caused by the medicine after it was given to the patient in the recommended manner (dose, frequency, route, and administration technique). All medicines and vaccines undergo rigorous testing for safety and efficacy through clinical trials before they are authorized for use.

The objective of pharmacovigilance is to identify adverse drug reactions or effects, misuse of medicines and drug interactions, detect substandard and falsified medicines, medication errors, lack of efficacy of medicines, the interaction between medicines, safety, and tolerability of medicines.

Pharmacovigilance will thus improve patient care and safety, promote the rational and safe use of medicines, and educate patients on matters related to medicine safety.

### PROCESS

Pharmacovigilance falls under the NMRA's functions. Therefore, pharmacovigilance should be part of an integrated approach and reflected in HSS grants. However, in some contexts, donors may accept the inclusion of pharmacovigilance activities in disease-specific related grants.

As part of CRS' efforts to strengthen national systems, pharmacovigilance can be an area of support, if identified as a priority by the NMRA.

Pharmacovigilance-related activities can be directly undertaken by the Health Supply Chain Manager whenever capacity and availability allow, or these activities can be managed through technical assistance contracts. In the latter, the Health Supply Chain Manager, supported by the SCM Regional Technical Advisor, will need to provide oversight and validate deliverables.

The activities that CRS can support in pharmacovigilance include:

- Assessment of the national PV system.
- Technical training for the PV unit staff.
- Support the adhesion of WHO Uppsala Monitoring Centre (UMC) and its global reporting system.
- Support to the design, distribution of national Adverse Reactions Forms, as well as related trainings for use of the forms.
- Support to the NMRA Pharmacovigilance IT system or database (for collection, transmission, and analysis of PV reports).

## Assessing Pharmacovigilance Systems

Spontaneous reporting systems form the basis of global pharmacovigilance. Other mechanisms and tools can be used as drug registries and electronic health records. The functionality of the pharmacovigilance system involves systematic collection and analysis of reports of suspected ADR to enable the detection of signals, their communication, and risk management.

### CHECKLIST

#### *Assessing Pharmacovigilance Systems*



- ☐ The **Health Supply Chain Manager**, in collaboration with appropriate national entities, supports the evaluation of the pharmacovigilance system. The evaluation should include:
  - Reviewing tools and mechanism (quality of the tools, flow, compilation, validation, and completeness).
  - Assessing the performance over the past two years: Event occurrences, reporting and analysis lengths and steps (national, regional, and health facility levels).
  - Assessing recommendations, actions taken, and improvements.
  - Health workforce awareness, capacity, and diligence to conduct the activity and trainings.
  - Mapping out other donor initiatives, such as WHO.
- ☐ The **Health Supply Chain Manager** supports appropriate national entities to identify gaps and propose budgeted activities as timelines addressing gaps.
- ☐ The **SCM Regional Technical Advisor** reviews and provides input.

## ROLES AND RESPONSIBILITIES

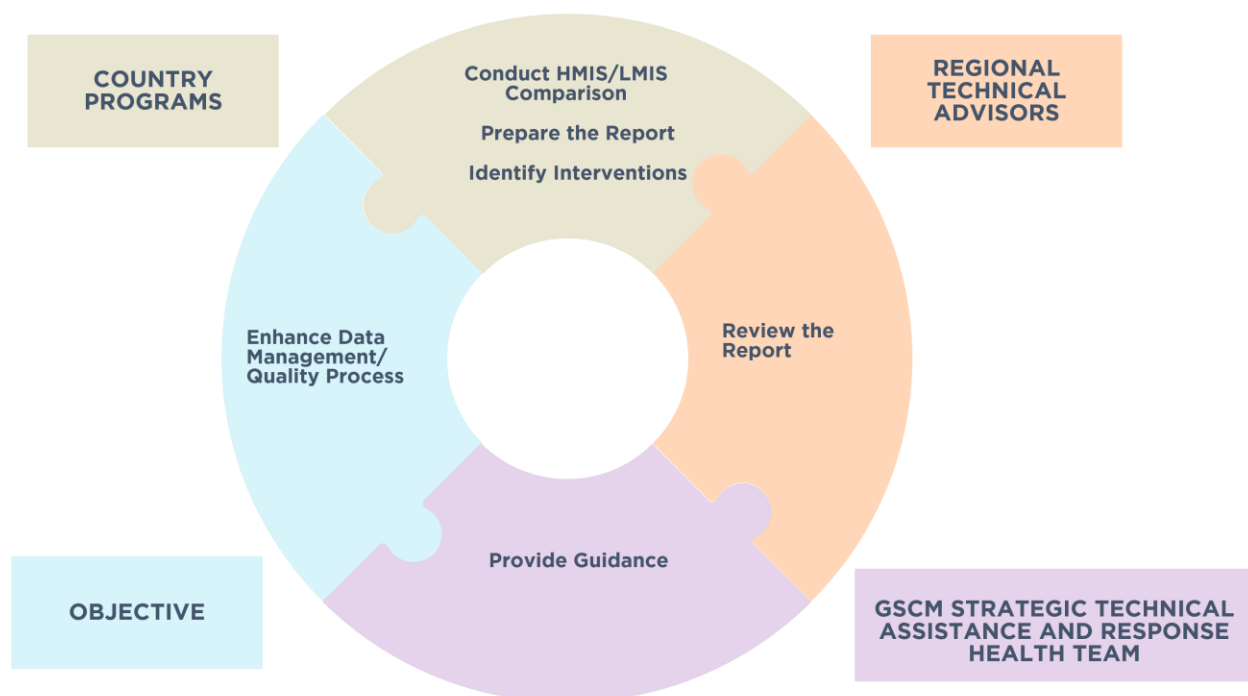
Function/Activity	Chief of Party	Head of Operations	Supply Chain Manager or Health SCM Focal Point	SCM Regional Technical Advisor
Supports the evaluation of the pharmacovigilance system	A		R	C
Supports appropriate national entities to identify gaps and propose budgeted activities as timelines addressing gaps	A		R	C
Reviews and provides input	I		C	R

R=Responsible; A=Accountable; C=Consulted; I=Informed

## CHAPTER 3.9: HMIS/LMIS DATA COMPARISON

### PROCESS

CRS Health Supply Chain Management Process for HMIS/LMIS Data Comparison



The data collected in HMIS tools mainly focus on service delivery, but usually includes indicators related to drug or vaccine supply such as duration of stock outs.

LMIS data are collected and used for primarily operational supply chain decisions but are also used to generate performance indicators. Comparing HMIS/LMIS data has various benefits including improved monitoring and evaluation, reduced data duplication, availability of additional data sets for quantifications, etc. It also provides coherence and justifies consumption.

The overall objectives are to:

- Ensure that health/service data tally with commodity consumption data.
- Promote data use culture at the facility level and build the capacity of health staff.
- Ensure data registers are completed.

Specific forms are needed to conduct this exercise. See the [Health Facility Monthly Data Triangulation Form](#) and the [User Guide on the Health Facility Monthly Data Triangulation Form](#).

## Active Data Collection Preparation

### CHECKLIST

#### *Active Data Collection Preparation*

- ☐ The **Health Supply Chain Manager**, in collaboration with M&E manager, prepares the SOW to organize field HMIS/LMIS data collection (which facilities, which products).
- ☐ The **Health Supply Chain Manager**, in collaboration with M&E manager, prepares or revises the questionnaire/form.
- ☐ The **SCM Regional Technical Advisor** reviews and provides input.
- ☐ The **Health Supply Chain Manager**, in collaboration with M&E Manager, identifies support needed to prepare the report and coordinates support.



## Data Collection

### CHECKLIST

#### *Data Collection*

- ☐ Data are collected by CRS staff and/or health facilities' staff using the validated forms and as per the agreed schedule and SOW.
- ☐ Data to be collected includes:
  - Health data, collected from Out and In Patients Departments, laboratory, maternity, Immunization Programme etc. (i.e., number of malaria cases, number of complicated malaria cases, number of Antenatal Care visits etc.).
  - Commodities data, collected from pharmacy and other services dispensing medicines (Artemisinin-based Combination Treatment, artesunate, Sulfadoxine Pyrimethamine, LLIN etc. dispensed to patients).
- ☐ At the end of the exercise, signed forms are collected by CRS staff.



## Analysis

# CHECKLIST *Analysis*



- ☐ The **Health Supply Chain Manager**, in collaboration with M&E Manager, compares data at health facilities, district, and regional levels, with the overall objective to ensure that there coherence with service data (i.e., number of malaria cases) and commodity data (i.e., ACTs dispensed). Comparison can be performed on:
  - Proof of delivery as per reported by the central storage to proof of delivery at each level of the health care system (primary, secondary, and tertiary).
  - Data collected by the LMIS system to health facilities data.
  - District Health Information System 2 data to health facility HMIS data.
  - Health facility LMIS to HMIS data.
  - Consumption data to number of patients treated and positive tests.
- ☐ The **Health Supply Chain Manager** issues the list of facilities/regions/districts with a high percentage of discrepancies for proper feedback and for the organization of targeted supervision.



## ROLES AND RESPONSIBILITIES

Function/Activity	Chief of Party	LMIS Officer	M&E Manager	Supply Chain Manager or Health SCM Focal Point	SCM Regional Technical Advisor
Reviews quantities of ACT procured and distributed for the full year	A	C	I	R	C
Conducts quarterly or bimonthly comparison of the LMIS and HMIS data	A	C	I	R	C
Issues the list of facilities/Region/District with a high percentage of discrepancies for proper feedback and the organization of targeted supervision	A	C	C	R	I
Prepares the SOW to organize field HMIS/LMIS data collection	A	C	C	R	I
Prepares or revises the questionnaire	A	C	C	R	I
Reviews and provides input	I	C	I	C	R
Identifies support needed to prepare the report and coordinates support	A	C	I	R	C
Compares data at health facilities, district, and regional levels	A	C	I	R	C

R=Responsible; A=Accountable; C=Consulted; I=Informed

## CHAPTER 3.10: PUDR DONOR REPORTING REQUIREMENTS (GLOBAL FUND)

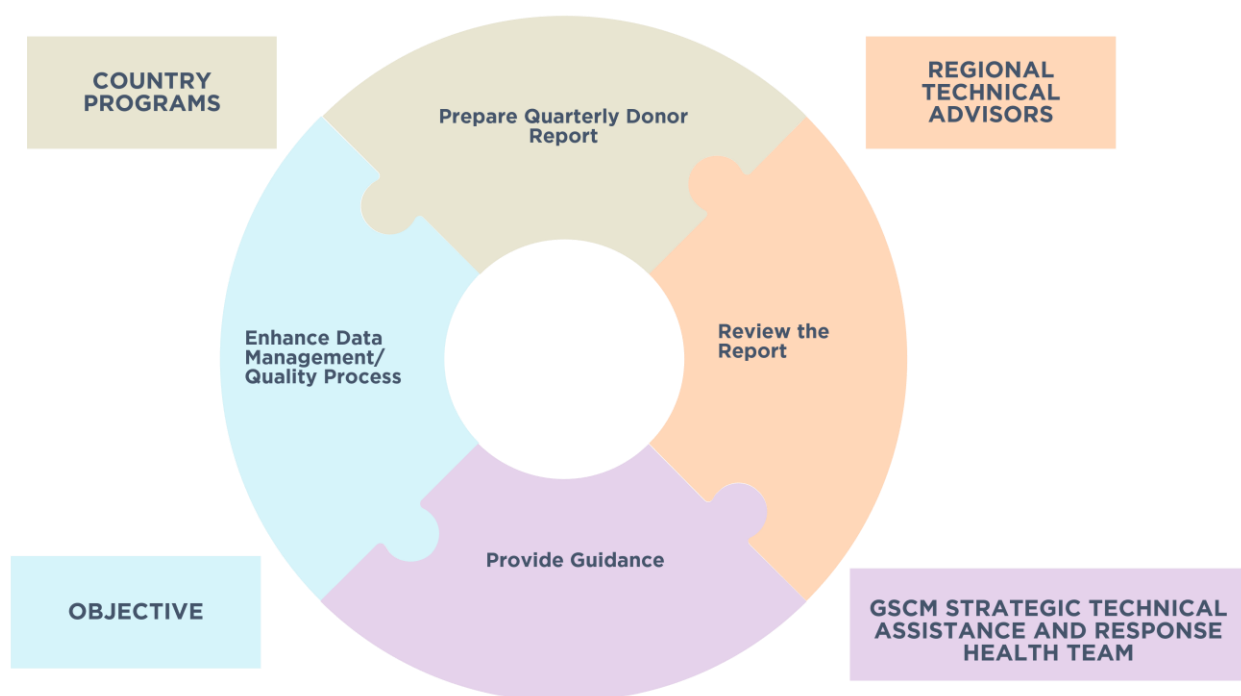
### POLICIES, PROCEDURES, REGULATIONS, AND GUIDELINES

#### DONOR AND OTHER GUIDELINES

- [The Global Fund Principal Recipient Progress Update and Disbursement Request](#)

### PROCESS

#### CRS Health Supply Chain Management Process for PUDR



The PUDR is both a progress update on the latest completed period of program implementation and a request for funds for the following execution and buffer period. The PUDR Tool includes a PSM part (worksheet “Health Products – PSCM 8”) that must be completed and reviewed twice a year.

There are three main sections to be completed in the health products worksheet: PQR reporting, risk of stockout and expiry, and additional information.

- **PQR Reporting:** Indicate whether the PQR is up to date. It is important to record all the receptions of products during the semester covered by the PU in the PQR.
- **Risk of Stockout and Expiry:** For the key categories of products listed in the table, indicate whether there is any risk of stockout or expiry during the next reporting period. It is essential to perform a stock analysis at the end of the reported period to determine whether there are such risks (key date needed to perform the analysis: stock-on-hand with expiry dates central only? national?), average monthly consumptions (or distribution if AMC not available), quantities in the pipeline.
- **Additional information:** Indicate important additional information relevant to health products management (any challenges, progresses made with HSS activities, training conducted, etc.).

The PUDR must be properly filled with relevant, sufficient, and quality information including a clear level of writing (coherent and complete sentences, without typos).

## CHECKLIST *PUDR*



- ☐ The **Health Supply Chain Manager** and **SCM Regional Technical Advisor** agree on a timeline to prepare, review, and internally submit the PUDR. This timeline needs to be approved by the program manager.
- ☐ The **Health Supply Chain Manager** collects inventory reports and data from national stakeholders and third-party contractors, as well as CRS' procurement tracking table.
- ☐ The **Health Supply Chain Manager** verifies that all received consignments of health products have been entered in the PQR. If that's not the case, the missing consignments must be entered.
- ☐ The **Health Supply Chain Manager** performs a stock situation analysis including (stock on hand at central and peripheral levels, expiry dates, stocks in the pipeline, average monthly consumption, remaining Month of stocks, re supply levels) to anticipate stock out and expiry risks.
- ☐ The **Health Supply Chain Manager** completes PSM sections of the PUDR: Section 3 "Procurement tab"; section 8 "Health products - PSCM; section 9 Grant Management; section 10:" Assessment and Sign off".
- ☐ The **Health Supply Chain Manager** shares all supportive documents as analysis to **RTA Supply Chain Manager** as per the date agreed on the timeline.
- ☐ The **Regional Technical Advisor** performs the quality check of all the PSM PUDR section and provides input.
- ☐ The **Health Supply Chain Manager** clarifies, adjusts, or addresses the input.
- ☐ The **Health Supply Chain Manager** shares the stock situation and analysis with national stakeholders.
- ☐ The **SCM Regional Technical Advisor** updates Global Fund Support Unit-PUDR checklist and shares it with The Global Fund Support Unit and GSCM.

## ROLES AND RESPONSIBILITIES

Function/Activity	Chief of Party	LMIS Officer	Supply Chain Manager or Health SCM Focal Point	SCM Regional Technical Advisor
Agrees on a timeline to prepare, review, and internally submit the PUDR	A	C	R	C
Collects inventory reports and data from National stakeholders as 3rd party contractor	A	R	C	I
Performs a stock situation analysis	A	R	C	I
Completes PSM sections of the PUDR	A	C	R	I
Shares all supportive documents as analysis to RTA SCM as per the date agreed on the timeline	A	I	R	C
Performs the quality check of all the PSM PUDR sections and provides input	I	C	C	R
Clarifies, adjust, or address the input	A	C	R	C
Shares the stock situation and analysis with national stakeholders	A	C	R	I
Updates Global Fund Support Unit-PUDR checklist and shares it with The Global Fund Support Unit and GSCM	I	I	C	R

R=Responsible; A=Accountable; C=Consulted; I=Informed

## CHAPTER 3.11: PQR DONOR REPORTING REQUIREMENTS (GLOBAL FUND)

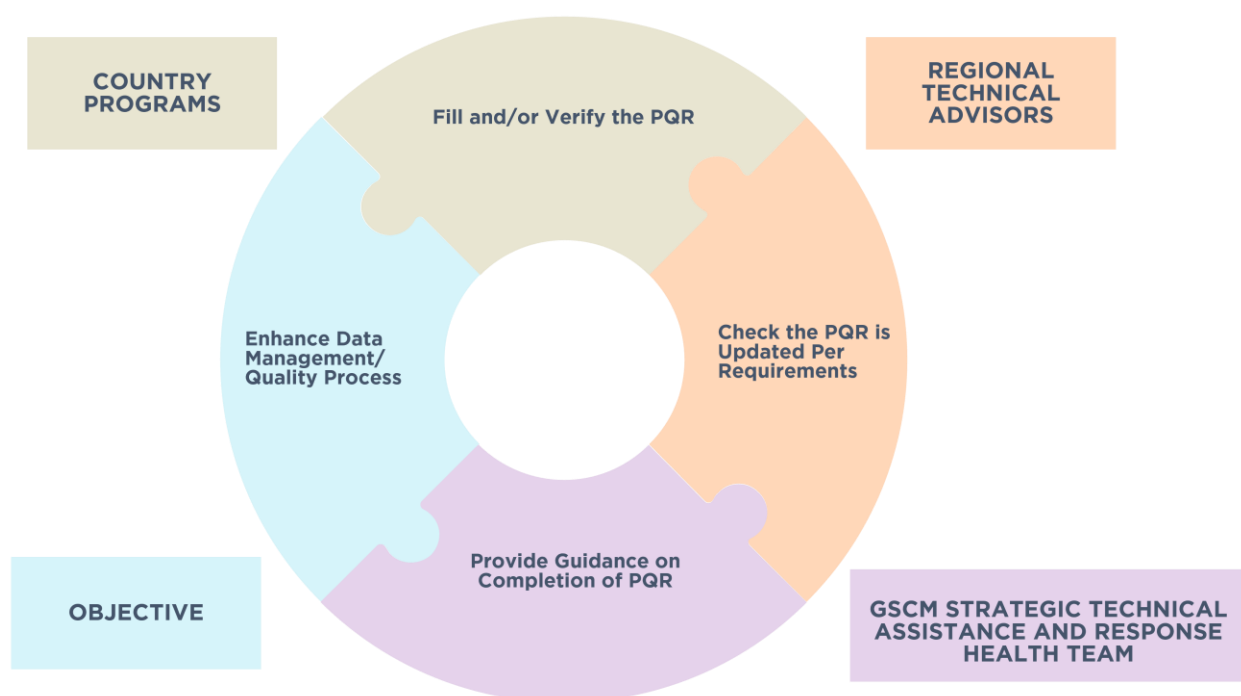
### POLICIES, PROCEDURES, REGULATIONS, AND GUIDELINES

#### DONOR AND OTHER GUIDELINES

- [A Quick Guide to The Global Fund's PQR](#)

### PROCESS

#### CRS Health Supply Chain Management Process for PQR



The PQR is the Global Fund online database to record prices and PSM costs of some key categories of health products procured by their Principal Recipients. When CRS is PR of a Global Fund grant, it is the responsibility of CRS to update regularly the PQR database. Only the following categories of products must be entered in the PQR:

- Antiretrovirals, anti-malarial, anti-TB, and anti-hepatitis pharmaceutical products.

- LLIN and insecticides for indoor residual spraying activities.
- Diagnostic tests for HIV, TB, malaria, and co-infections such as syphilis, hepatitis B, and hepatitis C.
- COVID-related products (surgical and non-surgical masks, respirators, class C and class D medical devices such as lung ventilators, pulse oximeters, etc.).

Regularly updating the PQR database provides The Global Fund with updated and accurate information on consignments of health products received in the country (products, quantities, prices, and PSM costs, manufacturer, supplier, etc.).

## Steps to Update the PQR

### PQR Profile Creation

## CHECKLIST *PQR Profile Creation*

- ☐ The **Health Supply Chain Manager** creates their own profile in the PQR system. The creation will then be approved by The Global Fund PQR team.
- ☐ The **SCM Regional Technical Advisor** ensures that the **Health Supply Chain Manager's** profile created in the PQR system is active.



## Recording Information in PQR and Monitoring

## CHECKLIST

*Recording Info in PQR & Monitoring*

- ☐ When procurement is not done through Wambo.org (i.e., procurement via GDF or direct procurement), the **Health Supply Chain Manager** ensures that when the products are received, the corresponding entry is made into the PQR.
- ☐ When procurement is done through Wambo.org, the **Health Supply Chain Manager** verifies on a regular basis (monthly) that the products that have been received have been recorded into the PQR by the Procurement Service Agent (that includes verifying all the entered information: products, quantities, prices, manufacturer, supplier, order date and reference, reception date, as well as verifying that invoices have been uploaded).

At the end of each calendar semester, the Health Supply Chain Manager compares the procurement tracking table (containing information on PO numbers, invoice references, products, and corresponding EXW amount, and delivery dates) with the PQR entries to confirm there are no missing entries.

For this purpose, the Health Supply Chain Manager can request the financial reconciliation of expenses from the Finance Department and needs to maintain records of invoices and delivery notes from the Procurement Service Agent or other suppliers. This verification is very important as the LFA, and The Global Fund do verify completeness and accuracy of PQR during each PU/DR review.



## Monitoring PQR updates made by Procurement Service Agents

## CHECKLIST

*PQR Updates by Procurement Service Agents*

- ☐ The **SCM Regional Technical Advisor** performs the quality check of the entire process as supportive documentation included analysis.
- ☐ When the PQR is not properly completed or includes mistakes from the Procurement Service Agent, the **Health Supply Chain Manager** prepares a summary report listing identified gaps and sends it to the Procurement Service Agent with The Global Fund PSM and LFA PSM experts in copy.
- ☐ The **Regional Technical Advisor** follows up on the requests sent to PSA until satisfactory and ensures complete PQR entries are made.

## ROLES AND RESPONSIBILITIES

Function/Activity	Chief of Party	Finance Manager	Supply Chain Manager or Health SCM Focal Point	SCM Regional Technical Advisor
Creates own profile in the PQR system	A		R	C
Ensures that the Health Supply Chain Manager's profile is created in the PQR system is active	I		C	R
Requests from finance department the financial reconciliation of expenses	A	C	R	I
Keeps proper records of invoices and delivery notes from Procurement Service Agent or another supplier	A	C	R	I
Lists on Excel the PO numbers, Invoices references, and corresponding Ex-Works amount, delivery dates	A	C	R	I
Checks that the PSA has adequately uploaded invoices and entered the correct information in the PQR system	A	I	R	C
Performs the quality check of the entire process as supportive documentation including analysis	I	I	C	R
Prepares a summary report listing identified gaps and sends it to the PSA with Global Fund PSM and LFA PSM experts in copy	A	I	R	C
Follows up on the requests sent to PSA on a regular basis until appropriate actions are taken	I	I	C	R

R=Responsible; A=Accountable; C=Consulted; I=Informed



## CHAPTER 3.12: QUALITY PULSE CHECK DONOR REPORTING REQUIREMENTS (GLOBAL FUND)

### POLICIES, PROCEDURES, REGULATIONS, AND GUIDELINES

#### DONOR AND OTHER GUIDELINES

- [Completing and Submitting Pulse Checks – Guide to Principal Recipients](#)

### PROCESS

The Pulse Check is a quarterly tool that provides visibility into HIV, TB, malaria, RSSH, and COVID-19 Response Mechanism investments to report to the Global Fund Board and support timely identification of emerging risks and issues to enable more agile course correction.

The purpose of the pulse check is to update The Global Fund on ongoing activities and identification or anticipation of any potential bottlenecks.

#### CHECKLIST *Quality Pulse Check*

- ☐ The Health Supply Chain Manager and SCM Regional Technical Advisor agree on a timeline to prepare, review, and internally submit the pulse check.
- ☐ The Health Supply Chain Manager prepares the pulse check report.
- ☐ The SCM Regional Technical Advisor reviews and provides input.
- ☐ The Health Supply Chain Manager discusses and/or integrates adjustments.
- ☐ The Health Supply Chain Manager internally submits the pulse check PSM part to Chief of Party.
- ☐ The SCM Regional Technical Advisor completes [The Global Fund Support Unit's pulse check's checklist](#).



## ROLES AND RESPONSIBILITIES

Function/Activity	Chief of Party	Procurement Manager	Supply Chain Manager or Health SCM Focal Point	SCM Regional Technical Advisor
Agrees on a timeline to prepare, review, and internally submit the PUDR	A	I	R	C
Prepares the pulse check report	A	C	R	I
Reviews and provides input	I	C	C	R
Discusses and/or integrates adjustments	I	I	R	C
Submits the pulse check PSM part to the Chief of Party	I	I	R	C
Completes The Global Fund Support Unit's pulse check checklist	I		C	R

R=Responsible; A=Accountable; C=Consulted; I=Informed

## CHAPTER 3.13: PROCUREMENT REPORTING REQUIREMENTS FOR COVID-19 (GLOBAL FUND)

### POLICIES, PROCEDURES, REGULATIONS, AND GUIDELINES

#### DONOR AND OTHER GUIDELINES

- [The Global Fund COVID-19 Response Mechanism Guidelines](#)
- [The Global Fund C19 RM Procurement Progress Reporting Template](#)

### PROCESS

The purpose of the template is to capture information on the award of contracts by implementers and fulfillment of deliveries by suppliers under these purchased orders.

#### CHECKLIST

*Procurement Requirements for COVID-19*

- ☐ The **Health Supply Chain Manager** prepares the list of direct procurement and Pooled Procurement Mechanism.
- ☐ The **Health Supply Chain Manager** fills the C19 procurement reporting template with processed orders for the corresponding period and continuously updates it as new orders for COVID-19 Response Mechanism products are placed.
- ☐ Before sharing the report with The Global Fund, the **SCM Regional Technical Advisor** reviews and provide input.
- ☐ The **Health Supply Chain Manager** shares the report with the Program Manager as per the agreed timeline.



## ROLES AND RESPONSIBILITIES

Function/Activity	Chief of Party	Procurement Manager	Supply Chain Manager or Health SCM Focal Point	SCM Regional Technical Advisor
Prepares the list of direct procurement and Pooled Procurement Mechanisms	A	C	R	I
Fills the C19 procurement reporting template with processed orders for the corresponding period	A	C	R	I
Reviews and provide input	I	I	C	R
Keeps the C19 procurement reporting template updated with information received from PSA or suppliers	A	C	R	I

R=Responsible; A=Accountable; C=Consulted; I=Informed

## PART V. CLOSE OUT/TRANSITION

### PROCESS

Close out of a health project is not significantly different from closing out other types of projects. Refer to the Close Out chapter in the [CRS Supply Chain Management Handbook](#).

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