Capacity Assessment Tool

PSM Arrangements

Upload implementation map: File Attachment

Current User: rconstant Current Role: Admin Current Domain: gf

Section 1: KEY STAKEHOLDERS IN SUPPLY CHAIN AND COORDINATION

IMPLEMENTER INFORMATION

1.1 Institutional capacity

Please list the main national and international stakeholders, including national programs, public or private associations, academic institutions and technical partners, that play a role in the pharmaceutical system related to HIV, TB or Malaria.

1.2 PR's management capacity for the management of health products

Please explain in broad lines the composition of the staff/team that will manage the supply of relevant health products

Upload the ToRs and organisational chart

File Attachment

1.3 Coordination of national and international stakeholders

Is there a coordination mechanism established where institutions discuss issues related to quantification, forecasting, procurement, distribution and use of health products at national level? (Please select the answer or answers that better fit the country situation)

- ☐ Yes, with national and international stakeholders.
- ☐ Meetings are called when needed, but there is no official committee.
- ☐ Yes, but only participate national stakeholders.
- ☐ Yes, but only for disease-specific medicines.

Is it a national or Global Fund grant-specific mechanism? Select...

Explain below in broad lines the membership and how the committee/mechanism works and frequency of meetings

Please upload the TORs

File Attachment

Are the minutes of the last 2 meetings available? Select...

Add any additional clarification you consider relevant to this section

Please identify key challenges, if any, related to the above section which are or need to be addressed.

LFA INFORMATION *Select...*

Based on your knowledge of the country, systems, and PR, is the information provided by the PR complete and accurate?

Based on your assessment, does the information provided reflect the reality / true situation and would you consider the system/entity/mechanism to be functional and effective?

In conducting your analysis, please take into consideration the following:

- are the ToRs for each PSM position appropriate for the function, is the PR adequately staffed to manage health products?
- are the people employed against the ToR meeting the requirements of the ToR?
- are the minutes/records of coordination meetings available, shared with participants and relevant stakeholders, and are actions followed-up?

Please provide an overall conclusion of your assessment for this Section; highlighting key issues/risks and, where appropriate, provide recommendations to the Secretariat on how to manage the risks together with indicative timelines.

COUNTRY TEAM INFORMATION Select...

Based on your knowledge of the country, systems, and the implementer and considering any other relevant information (e.g. partner reports, in-country missions), please provide an overall conclusion of the section.

File Attachment

Section 2: PRODUCT SELECTION

IMPLEMENTER INFORMATION

Please select the product categories that will be procured under this grant and the institution(s) in charge of product selection for each category:

- ☐ Health Products
- ☐ Pharmaceutical products
- ☐ Diagnostic products

Add any additional clarification you consider relevant to this section

Please identify key challenges, if any, related to the above section which are or need to be addressed.

LFA INFORMATION

Select...

Based on your assessment, does the information provided reflect the reality / true situation and would you consider the system/entity/mechanism to be functional and effective?

In conducting your analysis, please take into consideration the following:
- Verify that the selection of products is consistent with available guidelines and comply with the Global Fund QA Policies

Please provide an overall conclusion of your assessment for this Section; highlighting key issues/risks and, where appropriate, provide recommendations to the Secretariat on how to manage the risks together with indicative timelines.

COUNTRY TEAM INFORMATION

Select...

Based on your knowledge of the country, systems, and the implementer and considering any other relevant information (e.g. partner reports, in-country missions), please answer the questions below and provide an overall conclusion of the section.

QUART Questions

3.3.1 National guidelines and protocols related to prevention, diagnosis and treatment are inadequate or non compliant with international standards — Select...

3.3.2 Evidence or indications of non adherence to approved national or WHO guidelines when selecting medicines formulations, diagnostic tools or other health products for procurement — Select...

File Attachment

Section 3: FORECASTING/QUANTIFICATION AND SUPPLY PLANNING

IMPLEMENTER INFORMATION

3.1: Forecasting/quantification

How is the forecasting/quantification process for each product category managed?

- ○ An appointed expert/specialist from the institution
- ○ A standing mutidisciplinary committee of experts from the institution
- ○ A standing multidisciplinary committee of experts from various institution
- ○ Other (specify)

What are the profile of the participants (tick box)

- ☐ Pharmacists and/or pharmacy assistants or technicians
- ☐ Clinical and/or lab and/or nursing staff
- ☐ Procurement experts
- ☐ Logistics/warehouse experts
- ☐ Other (specify)

Is the forecasting/quantification supported by technical assistance ? Select...

Is there a system in place to validate the forecasting/quantification exercice? Select...

Is there a mechanism to review and update forecasting and quantification during implementation? Select...

Is there a system in place to validate the forecasting/quantification ? Select...

LFA INFORMATION

Select...

Based on your knowledge of the country, systems, and PR, is the information provided by the PR complete and accurate?

Based on your assessment, does the information provided reflect the reality / true situation and would you consider the system/entity/mechanism to be functional and effective?

In conducting your analysis, please take into consideration the following:
- Are relevant institutions (including disease programs) involved in forecasting and quantification of health products needs?
- Are the forecast methods adequate to the type of products and context to ensure continued supply?
- Are the data and information required for a timely forecasting available and reliable?
- If any emergency procurement ocurred, was it a result of poor planning, poor quantification or other?

Please take into consideration the submitted quantification for health products included in the grant when commenting on the PR capacity for forecasting/Quantification and issues with Stock outs related to Quantification and Forecasting.

Based on your assessment, does the information provided reflect the reality / true situation and would you consider the system/entity/mechanism to be functional and effective?

COUNTRY TEAM INFORMATION

Select...

Based on your knowledge of the country, systems, and the implementer and considering any other relevant information (e.g. partner reports, in-country missions), please answer the question below and provide an overall conclusion of the section.

QUART Questions

3.1.1 History of stock-outs, treatment disruptions, or emergency procurements — **Select...**

File Attachment

3.2 - Supply planning

Do you have a disease program supply plan? Select...

Add any additional clarification you consider relevant to this section

Please identify key challenges, if any, related to the above section which are or need to be addressed.

Section 4: MANAGEMENT INFORMATION AND REPORTING SYSTEMS

IMPLEMENTER INFORMATION

Is there an LMIS manual of procedures? Select...

Product information and reporting system

Product Name	Product Type	Name of the system and institution in-charge	Is the system integrated in a national system or is it parallel?
			Select...
			Select...
			Select...

Patients information and reporting system

Product Name	Product Type	Name of the system and institution in-charge	Is the system integrated in a national system or is it parallel?
			Select...
			Select...
			Select...

Section 4.1: Health product information and reporting system

Name of the system:

For each type of information, indicate the lowest level at which the information is generated

Consumption data Select...

Delivery data Select...

Stock outs Select...

Inventory levels per batch & expiration date Select...

Expired products Select...

How is the information captured?

Central level Select...

Peripheral stores Select...

Health care facilities Select...

Community level Select...

How is the information reported?

LFA INFORMATION Select...

Based on your knowledge of the country, systems, and PR, is the information provided by the PR complete and accurate?+ does it generate any risk

Based on your assessment, does the information provided reflect the reality / true situation and would you consider the system/entity/mechanism to be functional and effective?

In conducting your analysis, please take into consideration the following:

- Is there an Information system(s) that generates the required information?
- Verify availability of LMIS manuals and SOPs as well adherence to those guides for elements such as reporting frequencies, information/ data transmission, completeness and accuracy of reporting . Review the various forms that are used to collect and aggregate data as well as LMIS sample reports. Comment on whether the information is used for decision making in the supply chain.
- Based on the guidance of the CT, please visit a sample of health facilities, warehouses, stores, points of data aggregation, validation and analysis to get a broad picture of the functionality of the system.
  NB: For Patient Management System, concentrate on key data elements that would be useful in forecasting quantification only
- Please, see if the forecasting and the assumptions behind submitted for the next implementation period reflect the description of the systems and type of data generated

Please provide an overall conclusion of your assessment for this Section; highlighting key issues/risks and, where appropriate, provide recommendations to the Secretariat on how to manage the risks together with indicative timelines.

COUNTRY TEAM INFORMATION Select...

Based on your knowledge of the country, systems, and the implementer and considering any other relevant information (e.g. partner reports, in-country missions), please answer the questions below and provide an overall conclusion of the section.

QUART Questions

3.1.5 Lack of reliable consumption data, or effective processes and management information systems for reconciliation between inventory and patient information to support forecasting and quantification Select...

File Attachment

From the central level to other institutions Select...

From the peripheral stores to the upper level Select...

From the health care facilities to the upper level Select...

From the community level to the upper level Select...

List the institutions that have access to this information

What measures/strategies are in place to ensure data quality?

According to the records of the last 12 months, what is the % of reports sent on time?

How is the inventory management system at the stores ? Select...

If electronic system, Is inventory management system maintenance performed regularly at the stores? Select...

Are the following reports produced ?

Quarterly and Annual status reports to national level/ Select...

Feedback reports from National level to warehouse/facilities) Select...

Section 4.2: Patients information and reporting system

Name of the system:

Select from the lists below the type of information on patients management that is captured in the system.

HIV/AIDS

People on ART Select...

People (adults) on ART Select...

People (pediatrics) on ART Select...

People on ART by regimen Select...

Pregnant women receiving PMCT Select...

People receiving CPT Select...

Episodes of opportunistic infections Select...

Condoms distributed Select...

Number of people on OST Select...

People receiving VCT Select...

Malaria

number of antimalarial treatment by age/weight group Select...

Confirmed malaria cases (microscopy or RDT) Select...

Pregnant women receiving IPT Select...

Tuberculosis Co-infection

Patients on FLD TB medicines by treatment category Select...

HIV positive patients receiving IPT Select...

Patients on SLD TB medicines by regimen Select...

Patients of TB patients receiving VCT for HIV Select...

Please describe and include if available a flow diagram showing the flow of data/information between the various functionalities of the Management Information systems; Logistics Management Information Systems (LMIS) and Patient Management Information Systems (PMIS). If the LMIS is a part of the PMIS-Health Management Information System/District Health Information System, please elaborate if the PMIS has been configured to capture all the essential Logistics Data and transmits them to the personnel managing the supply chain. Please provide an overview of the current

challenges to reporting, data aggregation, validation, and analysis including system strengthening measures that are on-going or planned during the next implementation period.

Add any additional clarification you consider relevant to this section

Please identify key challenges, if any, related to the above section which are or need to be addressed.

Section 5: PROCUREMENT

IMPLEMENTER INFORMATION

5.1 Procurement specifications

Institution in charge of development of technical specifications for procurement

Who contributes to the development of technical specifications for procurement?

Products specifications (product info including QA requirements, etc.) Select...

Package specifications (labelling, unique identifier, etc.) Select...

5.2- Procurement entity

Name the entity(ies) that will conduct the procurement of health products during the next implementation period? (where it differs by category, please ensure you specify all relevant entities per product category)"

Entity Type

- National entity
- International Procurement Agent

Are key functions of procurement well segregated (specification development, tender evaluation, ordering) ? Select...

Who participates in the evaluation of the bids? Select...

Do members participating in the evaluation sign a conflict of interest statement? Select...

Does the procurement entity have a manual covering all relevant procurement activities ? Select...

Does the manual include procedures for emergency procurement? Select...

When was the last update of the manual?

LFA INFORMATION Select...

Based on your knowledge of the country, systems, and PR, is the information provided by the PR complete and accurate?

Based on your assessment, does the information provided reflect the reality / true situation and would you consider the system/entity/mechanism to be functional and effective?

In conducting your analysis, please take into consideration the following:

- As per Global Fund policies, do the procurement procedures allow competitive, transparent and open process to achieve value for money?
- Are product specifications adequately defined to meet the needs and ensure competitive and transparent procurement?
- Was there any challenge/bottleneck experienced with the registration of new products? If so, please describe actions taken
- Does the procurement entity have capacity to procure the relevant products? In considering the capacity, has this procurement entity in the last 2 years managed procurements of similar products , volume and value? If no, critically focus on capacity to manage procurement during the next period?
- Was procurement efficiently conducted?
- Has any issue of non compliance with the GFprocurement policies being identified during the previous implementation period. Are prices obtained in line with international reference prices?
- Have any challenges/bottlenecks been experienced during the procurement process?
- If a national entity other than the PR is procuring health products under the grant, please also assess the capacity of that entity to perform procurement activities
- If a private entity is doing the procurement, please review how the entity was selected, is the contract adequate, how frequently is retendered and is performance adequately monitored?

Please provide an overall conclusion of your assessment for this Section; highlighting key issues/risks and, where appropriate, provide recommendations to the Secretariat on how to manage the risks together with indicative timelines.

COUNTRY TEAM INFORMATION Select...

Based on your knowledge of the country, systems, and the implementer and considering any other relevant information (e.g. partner reports, in-country missions), please answer the questions below and provide an overall conclusion of the section.

QUART Questions

3.1.3 History of poor planning of procurement activities. History of delays in tendering Select...

3.1.4 Lack of adequate quality SOPs for procurement process or indications of poor adherence to these by procurement staff Select...

File Attachment

Is there a standard bidding document adapted to pharmaceuticals and health products ? Select...

Are procurement records available and easily accessible for the following items? (check all that apply)

- ☐ Tender documents
- ☐ Evaluation reports and procurement proceedings
- ☐ Contracts
- ☐ Supplier performance monitoring records
- ☐ Payments to suppliers

If this is an international procurement agent that will be managing procurement for the next implementation period, please specify the selection process of that agent. (competitive process, previous use, other please specify)

5.3- Regulatory Status

Do health products under the grant need to be registered? Select...

If there are products that are not registered, are there any fast track registration procedures or import licensing procedures (e.g. waivers, special authorizations) in place for relevant product categories?

5.4 - Intellectual Property Regulations

Does IP regulations impact on the products that will be procured? Select...

Please explain.

Add any additional clarification you consider relevant to this section

Please identify key challenges, if any, related to the above section which are or need to be addressed.

Section 6: RECEIPT, STORAGE AND INVENTORY MANAGEMENT

IMPLEMENTER INFORMATION

Section 6.1 Customs Clearance

Who is in charge of the customs clearance ?

For the last 12 months, what was the average length of time for customs clearance?

Is there a detailed written procedure for customs clearance? Select...

Is storage at the port of entry adequate? Select...

Section 6.2: Receipt, storage and inventory management at central level

Name of the warehouse:

Name of the institution responsible for managing the warehouse

What categories of health products (e.g. pharmaceuticals, RDTs,

LFA INFORMATION Select...

Based on your knowledge of the country, systems, and PR, is the information provided by the PR complete and accurate?

Based on your assessment, does the information provided reflect the reality / true situation and would you consider the system/entity/mechanism to be functional and effective?

In conducting your analysis, please take into consideration the following:

- Is there a systematic inventory control (stock taking, stock reconciliation, shelf life management, expired products management and reporting)?
- Are there specific and adequate security measures in place, including for narcotics, if relevant?
- Are inventory control records/reports available and current for stock

COUNTRY TEAM INFORMATION Select...

Based on your knowledge of the country, systems, and the implementer and considering any other relevant information (e.g. partner reports, in-country missions), please answer the questions below and provide an overall conclusion of the section.

QUART Questions

3.1.8 indications of poor storage and distribution planning or budgeting at central and peripheral levels Select...

3.1.10 Evidence of poor oversight of stock levels for key products at any level of the supply chain Select...

3.2.5 Lack of adequate SOPs for storage and distribution and product quality monitoring. Select...

condoms, laboratory consumables & reagents, etc.) are being stored here?

Are there standard operating procedures for receiving, storing and inventory management? Select...

When was the last update of the SOPs?

Is there a manual describing all relevant warehousing activities ? Select...

Are stores walls, floors and ceiling in good condition? Select...

If not, are renovations already planned? Select...

Are stores properly equipped with the following? (Check all that apply)

- ☐ Pallets / Shelving
- ☐ Forklifts / Equipment
- ☐ Generator / Power back-up
- ☐ Cold Room / Refrigerator
- ☐ Thermometers
- ☐ Fire Extinguisher
- ☐ Other (please specify)

If not, are there plans to procure the equipment? Select...

If yes, is there a maintenance plan? Select...

Are the stores temperature monitored and controlled? Select...

What are the minimum and maximum temperatures of the stores during the year?

Do stores have cool rooms (8 to 15 ºC)? Select...

What is the capacity of the stores (m3 or number of pallets)?

Is there enough storage space to manage the additional volumes of health products to be procured under the next implementation period ? Select...

Are the stores insured? Select...

Are the goods in the store insured? Select...

If yes, what is the maximum value of the goods insured?

Add any additional clarification you consider relevant to this section

Please identify key challenges, if any, related to the above section which are or need to be addressed.

Section 6.3: Receipt, storage, and inventory management at Regional Level (this section is to be filled in upon CT's request)

Name of the warehouse:

Name of the institution responsible for managing the warehouse

reconciliation, shelf life management, damaged products?

- Based on guidance from the Country Team, please visit a sample of peripheral health facilities and warehouses to get a broad picture of the functionality and compliance with good storage practices across the supply chain

Please provide an overall conclusion of your assessment for this Section; highlighting key issues/risks and, where appropriate, provide recommendations to the Secretariat on how to manage the risks together with indicative timelines.

File Attachment

What categories of health products (e.g. pharmaceuticals, RDTs, condoms, laboratory consumables & reagents, etc.) are being stored here?

Is sufficient storage space available at all levels of the distribution chain? Select...

Please provide the total number of storage facilities available at the peripheral level for the products that will be procured under the grant, distinguish between regional stores and treatment sites (e.g. hospitals and clinics)

Are stores walls, floors and ceiling in good condition? Select...

Are the stores temperature monitored and controlled? Select...

Add any additional clarification you consider relevant to this section

Please identify key challenges, if any, related to the above section which are or need to be addressed.

Section 7: DISTRIBUTION

IMPLEMENTER INFORMATION

Section 7.1: Distribution from central to peripheral stores

Distribution entity:

Health product distributed (list of categories)

Number of peripheral stores supplied from the central warehouse

Type of peripheral stores

- Regional stores (indicate number)
- District stores (indicate number)
- Other stores (indicate number)

Are requisition, delivery and reception forms used standardized? Select...

Is there a system in place to ensure that a copy of the delivery form signed by the recipient (proof of delivery) is available at the point of dispatch? Select...

What distribution system is being used?

- Push: Central store distribute the quantities according to its own estimations and planning
- Pull: Peripheral level requests the quantities they need

What supply mechanism is in place ?

- Central stores delivers the products with its own vehicles

LFA INFORMATION Select...

Based on your knowledge of the country, systems, and PR, is the information provided by the PR complete and accurate?

Based on your assessment, does the information provided reflect the reality / true situation and would you consider the system/entity/mechanism to be functional and effective?

In conducting your analysis, please take into consideration the following:

- Are the overall distribution settings efficient?
- Are there sufficient and trained staff?
- Are there adequate transportation means that ensure appropriate conditions according to product types, seasons and destination?
- Are copies of the delivery form signed by the recipient (proof of delivery) available at the point of dispatch?
- Are there sufificient security measures against theft, diversion and damages?
- If a private entity is providing distribution services please review how the entity was selected, is the contract adequate, how frequently is retendered and is performance adequatly monitored?

Please provide an overall conclusion of your assessment for this Section; highlighting key issues/risks and, where appropriate, provide recommendations to the Secretariat on how to manage the risks together with indicative timelines.

COUNTRY TEAM INFORMATION Select...

Based on your knowledge of the country, systems, and the implementer and considering any other relevant information (e.g. partner reports, in-country missions), please answer the questions below and provide an overall conclusion of the section.

QUART Questions

3.1.7 Inadequate facility capacity conditions, logistics or vehicles for storage and distribution at central and peripheral levels Select...

3.1.8 indications of poor storage and distribution planning or budgeting at central and peripheral levels Select...

File Attachment

Transport is outsourced

Peripheral stores or sites collect the products from central stores.

Are there standard operating procedures in place, assuring good distribution practices?	Select...
Are products distributed in accordance with the label requirements (e.g temperature, light, humidity)	Select...
Are products insured while in transit?	Select...
Is there a distribution schedule?	Select...
Does the actual distribution complies with the distribution schedule?	Select...
Does the distribution fleet provide adequate protection against the elements (e.g rain, temperature) and security during transport?	Select...
Are there special procedures for emergency requests?	Select...
What is the number of peripheral stores supplied from the central warehouse?	

Add any additional clarification you consider relevant to this section

Please identify key challenges, if any, related to the above section which are or need to be addressed.

Section 8: QUALITY ASSURANCE

IMPLEMENTER INFORMATION

Section 8.1: Quality monitoring for pharmaceuticals

Is there a document or SOPs that describe the quality assurance activities throughout the supply chain (including link with National Quality monitoring program)?	Select...
Name of the QC Lab will be used to perform Quality control testing?	
Is the laboratory WHO prequalified ? or ISO 17025 certified?	Select...
Have you sampled and tested procured in the last 12 months? Please make the testing results available to the LFA	Select...
Is there SOPs for managing QC activities for pharmaceutical products?	Select...
Is there a written procedure in place to manage QC testing failure?	Select...

Section 8.2: Quality monitoring for non-pharmaceuticals

Name of the QC Lab will be used to perform Quality control testing?	
Is the laboratory ISO 17025 certified?	Select...
Are LLINs and insecticides tested according to WHOPES specifications methods?	Select...
Are condoms tested according to ISO 4074 specifications?	Select...
Is there SOPs for managing QC activities for non pharmaceutical products?	Select...

LFA INFORMATION Select...

Based on your knowledge of the country, systems, and PR, is the information provided by the PR complete and accurate?

Based on your assessment, does the information provided reflect the reality / true situation and would you consider the system/entity/mechanism to be functional and effective?

Are the current PSM arrangements and QA systems in place will enable the PR to be compliant with the Global Fund QA policies?

Please provide an overall conclusion of your assessment for this Section; highlighting key issues/risks and, where appropriate, provide recommendations to the Secretariat on how to manage the risks together with indicative timelines.

COUNTRY TEAM INFORMATION Select...

Based on your knowledge of the country, systems, and the implementer and considering any other relevant information (e.g. partner reports, in-country missions), please answer the questions below and provide an overall conclusion of the section.

QUART Questions

3.2.1 History of Non compliance with Global Fund QA policies	Select...
3.2.2 Inadequate planning of budgeting of product quality monitoring activities	Select...
3.2.4 Past experience of expired, contaminated, counterfeit or poor quality products in the supply chain	Select...
3.2.6 Insufficient technical capacity, testing capability or resources at national regulatory authorities to implement and oversee quality monitoring activities	Select...

File Attachment

Section 8.3: Pharmacovigilance

Name of the institution in charge	
Is there an Adverse Drug Reaction ADR reporting program?	Select...
Are ARVs, antituberculosis and antimalarial medicines part of the ADR reporting system	Select...
In the last 12 months, what was the number of ADR reports received ?	
Is there a program that reports on the problems with the product quality?	Select...
Name of the institution and/or department responsible for the quality reporting program	
In the last 12 months, what was the number of quality reports received ?	

Section 8.4: Rational Use of Medicines & Health Products

	Adults	Children
How many first-line ARV regimens are currently in use? For adults and for children		
How many second-line ARV regimens are currently in use ? For adults and for children		
How many treatment regimens are currently in use for tuberculosis? For adults and for children		
How many treatment regimens are currently in use for Malaria? For adults and for children		
What systems are in place to monitor prescriber adherence to Standard Treatment Guidelines?		
What strategies will be used to encourage adherence to and compliance with treatment (e.g use of fixed dose combination medicines, once a day formulations, peer education and support etc)		

Add any additional clarification you consider relevant to this section

Please identify key challenges, if any, related to the above section which are or need to be addressed.

Overall Assessment of PSM Arrangements

LFA OVERALL RATING Select...

Executive summary of conclusions and recommendation

Based on your assessment of the implementer's capacities and systems against the relevant assessment requirements, please provide a rationale for the overall rating of the functional area and a summary of analysis/findings on the capacity of the implementer to implement an assigned role in the program.

COUNTRY TEAM OVERALL RATING Select...

Executive summary of conclusions and recommendation

Based on your assessment of the implementer's capacities and systems against the relevant assessment requirements, please provide a rationale for the overall rating of the functional area and a summary of analysis/findings on the capacity of the implementer to implement an assigned role in the program.

PSM LFA Recommended Action Plan

Action	Responsible	Start Date	End Date	Estimated Cost	Source of Funding

PSM Country Team Action Plan

Action	Responsible	Start Date	End Date	Estimated Cost	Source of Funding