SECTION G – GLOBAL FUND ESSENTIALS

G.   GLOBAL FUND ESSENTIALS

This section provides a brief overview of essential information on some of the key subject areas concerning the work of the Global Fund.

G1   Country Coordinating Mechanism

Country Coordinating Mechanisms (CCMs) are country-level multi-stakeholder partnerships made up of representatives of all sectors involved in the fight against the diseases. This includes governments, multilateral or bilateral agencies, non-governmental organizations, academic institutions, private businesses and people living with the diseases.

Country Coordinating Mechanisms play an important role in the Global Fund architecture. They are responsible for:

- Coordinating the development and submission of funding requests;
- Nominating the Principal Recipient(s) that will implement the grant;
- Overseeing implementation of the approved grant;
- Approving any reprogramming;
- Ensuring linkages and consistency between Global Fund grants and other national health and development programs.

G1.1   Eligibility Requirements and Minimum Standards

The Global Fund has defined six Eligibility Requirements with which Country Coordinating Mechanisms must comply in order to be eligible for funding. The CCM Eligibility Requirements are detailed in the *CCM Guidelines and Requirements*, but can be summarized as follows:

- Eligibility Requirement 1: Transparent and inclusive concept note development process
- Eligibility Requirement 2: Open and transparent PR selection process
- Eligibility Requirement 3: Oversight planning and implementation
- Eligibility Requirement 4: Country Coordinating Mechanism membership by affected communities, including and representing people living with diseases and people from and representing Key Affected Populations
- Eligibility Requirement 5: Processes for electing non-government Country Coordinating Mechanism members
- Eligibility Requirement 6: Management of conflict of interest on Country Coordinating Mechanisms

The six requirements for Country Coordinating Mechanism eligibility apply equally to sub-national Country Coordinating Mechanisms and to Regional Coordinating Mechanisms (RCMs).

The Eligibility Requirements do not apply to Non-Country Coordinating Mechanism applicants and Regional Organization applicants.

The Global Fund will accept non-Country Coordinating Mechanism applications under the following exceptional conditions:

- Countries without a legitimate government; or
- Countries in conflict, facing natural disasters, or in complex emergency situations; or
- Countries that suppress or have not established partnerships with civil society and non-governmental organizations.

Country Coordinating Mechanism Minimum Standards that measure core functions of a Country Coordinating Mechanism represent *additional* criteria that are enforceable and compulsory for grant signing as of January 2015.

The Global Fund monitors compliance with CCM Requirements on a yearly basis and with every new Country Coordinating Mechanism's application for funding. Continued compliance with all Eligibility Requirements (and Minimum Standards as of 1 January 2015) throughout program implementation is a condition for access to Global Fund financing.

In the new funding model, the process for reviewing the CCM Eligibility Requirements is as follows:
- Requirements 1 and 2 are assessed at the time of Concept Note submission.
- Requirements 3 to 6 are assessed annually through the Country Coordinating Mechanism Performance Assessment tool, with the support of a Technical Assistance (TA) provider. This involves a self-assessment and an evaluation of compliance with Eligibility Requirements and Minimum Standards to determine the level of functionality of the Country Coordinating Mechanism.

For non-compliant Country Coordinating Mechanisms, technical assistance providers will assist the Country Coordinating Mechanism to develop a milestone-driven improvement plan. The Global Fund will determine if the proposed plan is reasonable and agree on whether or not it is acceptable. Non-adherence to the improvement plan will impact current and future funding.

Country Coordinating Mechanisms may also undergo appraisal by the Global Fund in the form of:
- Performance reporting relating to CCM Funding (see below);
- Assessments by the OIG, particularly for Country Coordinating Mechanisms in more challenging environments.

For further information on Country Coordinating Mechanism eligibility please refer to the *Guidelines and Requirements for Country Coordinating Mechanisms*.

G1.2   Country Coordinating Mechanism Funding

In order to fulfill their responsibilities, Country Coordinating Mechanisms inevitably incur administrative costs and may not have the independent resources to cover these costs.

The Global Fund offers financial support to Country Coordinating Mechanisms through two-year CCM Funding Agreements. These allow Country Coordinating Mechanisms to access funding linked to measurable performance directly linked to the CCM Eligibility and Minimum Standards. The purpose of the CCM Funding Policy is to enable Country Coordinating Mechanisms to meet their intended purpose and role.

Country Coordinating Mechanisms may not draw directly from approved grant funds to support Country Coordinating Mechanism costs.

The Global Fund has established a separate pool of funds to finance Country Coordinating Mechanism costs. CCM Funding is available to Country Coordinating Mechanisms or other national bodies that meet the minimum CCM Requirements and have taken on the role and function of the Country Coordinating Mechanism. A Country Coordinating Mechanism or other body may receive funding as long as there is at least one active grant under implementation in that country. A grant is considered active from approval of a funding application through to the end of Grant Closure.

CCM Funding requests should cover eligible costs[1] for a two-year period. For amounts exceeding US$ 200,000 per two-year period, the Country Coordinating Mechanism must demonstrate that it has mobilized 20% of the amount exceeding US$ 200,000 from sources other than the Global Fund for the same CCM budget period.

There is no limit to the number of times that a Country Coordinating Mechanism may apply for funding, and a request for CCM Funding may be submitted at any time. The CCM Funding Policy sets out the requirements and formalities to be completed by Country Coordinating Mechanisms seeking access to CCM Funding. These include a detailed two-year budget, a Performance Framework consistent with the budget and supporting documentation for the funding request (including but not limited to proof of endorsement of the funding request application by all Country Coordinating Mechanism members).

During implementation, the Country Coordinating Mechanism is required to submit:
i. A progress update describing results achieved against intended targets and expenditures incurred;
ii. Where applicable, a report on co-payment(s) showing evidence that the pledged amount has been made available to the Country Coordinating Mechanism. This will determine the funding level by the Global Fund.

The Secretariat may request the Country Coordinating Mechanism to complete the CCM Eligibility and Performance Self-Assessment as necessary.

For more information on Country Coordinating Mechanism Funding, please refer to the *CCM Funding Policy*, *Guidelines CCM Funding* and the *Step-by-Step Guide CCM Funding*.

G1.3   Oversight provided by the Country Coordinating Mechanism

The Country Coordinating Mechanism is responsible for oversight of the funding request development, grant implementation and grant closure. In terms of Eligibility Requirement 3, Country Coordinating Mechanisms are required to have an oversight plan in place in order to be eligible for funding.

The core principle of oversight is to ensure that resources—financial and human—are being used efficiently and effectively for the benefit of the country. The Country Coordinating Mechanism is responsible for understanding grant implementation at the macro level, but does not need to immerse itself in the details, which is the responsibility of the Principal Recipient.

The Global Fund has developed a grant oversight tool ("dashboard") to support Country Coordinating Mechanisms in carrying out their oversight function, should they choose to use it. The grant oversight tool supports:
- Country Coordinating Mechanism oversight of grant implementation and Principal Recipients; and
- Country Coordinating Mechanism governance and communication with constituencies.

For more information on the Country Coordinating Mechanism's oversight role, please refer to the *Guidance Paper on CCM oversight*.

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[1] Eligible costs are defined in the available guidance documents and may include salaries of Country Coordinating Mechanism secretariat staff, consultancy fees, office expenses, meeting expenses, communication and information dissemination, organization and facilitation of meetings and workshops.

G2 Financial Management

The Global Fund's purpose is to attract, manage and disburse resources to fight AIDS, Tuberculosis and Malaria. Principal Recipients play a major role in the Global Fund's programs by receiving funds and converting this money into tangible results by implementing programs or contracting and managing other sub-recipients to do so.

LFAs are regularly requested to conduct assessments or verifications and provide recommendations concerning the financial management and reporting of a grant. As described in other sections of this Manual, these services may, amongst others, include the assessment of implementers' financial management systems and capacities, reviewing budgets and reported expenditures, and providing recommendations concerning the disbursement of Global Fund funds. For a detailed description of services the LFA may be asked to perform during the grant life cycle, please refer to section C, D and E of this Manual.

G2.1 Before Grant Signing

The Global Fund needs to ensure adequate fiduciary controls for the financial management of donor funds at the implementer level. The evaluation of the Financial Management capabilities of a Principal Recipient to effectively implement programs while meeting Global Fund's standards is of major importance and is performed by addressing the following topics[2]:

- Organization and Personnel: organizational structure, experience and human resource management to support financial management,
- Budgeting: budgeting processes (multiyear planning, periodical reforecast etc.) and budget monitoring (control, performance reports etc.),
- Accounting and Recordkeeping: accounting systems, chart of accounts structure, modalities for journal entries, financial reporting capabilities (trial balance, management reports, financial statements),
- Purchasing and Procurement: procurement policies, processes for purchase requisitions / orders and for receipting of goods or services,
- Invoicing and Payment: monitoring of payables and receivables, payment terms, travel expenses procedures,
- Payroll: policies and procedures, management of payroll information, payroll control,
- Cash Management: management of bank accounts, use of checks and receipts, bank reconciliation, petty cash management,
- Fixed Assets Management: management of inventories and assets movements,
- Audit: external audit assignment, organization and activities of internal audit structure,
- Implementing Partners Management Capacity: framework to select, support and monitor sub-recipients.

The outcome of this assessment provides the basis for the assurance plan that is monitored during grant implementation.

G2.2 During Grant Implementation

During grant implementation, Principal Recipients are required to report financial information at least annually from the grant start date. The financial information reported should include budgets, expenditures

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[2] The capacity assessment of Principal Recipients/Key Implementers and possible LFA involvement is further described in section C of this Manual. The Capacity Assessment Tools is available on the Global Fund website (http://www.theglobalfund.org/en/lfa/documents/).

and variance analysis (a) by cost input; (b) by intervention; and (c) by implementing entity.[3]

As part of the assurance framework, Principal Recipients are also required to present an annual audit report. The audits are primarily intended to provide the Global Fund with assurance that disbursed funds were used for the intended purposes in accordance with the grant agreement, including the approved budget and the Performance Framework and that the financial statements fairly represent the financial transactions and balances of the grant.[4]

Reliable financial information regarding the implementation of grants is important for the Global Fund to:

- Apply performance based funding and assist in grant management: by providing suitable financial information to link Global Fund resources to programmatic results and by providing financial information which can be used to improve grant management and performance.
- Identify areas of financial risks: tracking expenditures against budgets to enable an analysis of financial risks across the portfolio of programs funded by the Global Fund (weak control systems and risks of fraud/mismanagement).
- Respond to requests from the Global Fund Board, donors and stakeholders: they want to know "where the money is going" and "how it is being spent". It is critically important for the Global Fund to be able to respond to these requests both in respect to the principles of transparency and accountability as well as to maintain the organizational credibility of the Global Fund as a financing institution.
- Improve the ability of the Global Fund to assess value for money in its investments: it is essential for the Global Fund to have information available concerning actual expenditures by grant objectives and interventions in order to analyze the cost of providing certain key interventions.
- Leverage additional financial resources.
- Improve forecast and optimize treasury management

When conducting any related service, it is important for the LFA to refer to relevant Global Fund guidelines and tools.

G3   Monitoring & Evaluation

Monitoring and evaluation (M&E) is one of the cornerstones of a country's response to fighting HIV/AIDS, TB and malaria and strengthening health and community systems; it provides the information needed to make evidence-based decisions for program management and improvement, policy formulation, and advocacy. It also generates good-quality data to satisfy accountability requirements.

M&E is intrinsic to the Global Fund's system of performance-based funding[5], which ensures that funding decisions are based on a transparent assessment of results against time-bound targets.

More information on each of the below mentioned areas can be found in the Monitoring and Evaluation section of the Global Fund website. The website also contains e-learning modules which provide a good overview of M&E at the Global Fund.

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[3] Please refer to the Global Fund Global Fund Guidelines for Grant Budgeting and Annual Financial Reporting, as well as the Progress Update and Disbursement Request Guidelines, available on the Global Fund website (http://www.theglobalfund.org/en/lfa/documents/).

[4] Please refer to the Guidelines for Annual Audits of Global Fund Grant Program Financial Statements.

[5] For a description of the Global Fund's performance-based funding model, please refer to section A4 in this Manual.

G3.1   Fundamental Principals

Among the key principles of the Global Fund are the focus on measuring and maximizing impact and the alignment to national systems. This subsequently leads to an emphasis on data quality, as well as the quality of services, as further expanded below.

The Global Fund is committed to aid effectiveness and has focused on alignment to country systems and processes. By aligning to and strengthening national M&E systems, the Global Fund contributes to long-term investments in these systems and a reduction in transaction costs of collecting and reporting data.

The Global Fund for example requires the provision of national, rather than grant-specific M&E plans and encourages investments in national M&E systems as part of its grant funding. Likewise, the Global Fund's core list of indicators has been developed and agreed with partners, including WHO, UNAIDS and PEPFAR; there are no Global Fund specific indicators.

The Global Fund strategy and the new funding model emphasize the imperative to deliver maximum impact against the three diseases.

The Global Fund Secretariat prepares *Impact Profiles* of recipient countries to capture information on the disease epidemiology, summarizing the latest publicly-available national-level data on disease burden and program coverage and outcome indicators measuring key interventions. Impact Profiles serve to help all parties involved (including Country Teams, the CCM, Technical Review Panel and the Grant Approvals Committee) to obtain an overview and build a common understanding of the disease trends and key gaps in program coverage, to inform strategic discussions during the Country Dialogue and Concept Note development and the monitoring of progress towards impact, including the need for adjustments during grant implementation, as applicable. LFAs do not participate in the development of the Impact Profile, but should be aware of its content.

Accurately measuring impact against the three diseases is crucial and accounts for the Global Fund focus on data quality. The Risk Management Framework notes that "risk management can only be as good as the quality of data and accuracy of information on which risk assessments and decisions are based." This applies to the quality of data management within the Global Fund and at country level. The dimensions of data quality can be defined as follows:

- Accuracy: how correct is the data?
- Timeliness: how current (up to date and available on time) is the data?
- Completeness: how much of all expected data is present?
- Integrity: how protected is the data from manipulation?

The Global Fund's funding process and performance-based funding system are both data-driven. Performance-based funding relies heavily on the quality of data reported by countries. Poor data quality can lead to inadequate program management and an inability to demonstrate accurate results.

The push to maximize impact against the three diseases has also led the Global Fund to focus on the quality of service provision. The assessment of the quality of services is integrated into the Global Fund performance-based funding model and is aimed at ensuring that the Global Fund-supported programs are implemented according to internationally recognized policies and guidelines.

G3.2   M&E and the Grant Set-up

M&E aspects are crucial elements in all grant negotiations and signing processes.[6] It is important to ensure that grants not only feature activities most likely to result in impact, but also that indicators and results will allow the measurement of the grants' performance. The following elements of the Global Fund's grant set-up, on which more information is provided in Section C, relate most directly to M&E aspects:

o   **M&E plan**

The Global Fund requires the submission of a national M&E plan as part of the funding request. Where a national M&E plan does not exist or in cases in which the national M&E plan does not contain the information required for grant management, the Global Fund will accept a grant-specific M&E plan but will encourage the country to develop the national M&E plan.

The Global Fund may request the LFA to review and analyse the M&E plan to ensure that the main components of the M&E system are described.[7] More information on the M&E plan, including M&E plan guidelines, is available on the Global Fund website.

o   **M&E systems assessment**

An assessment of M&E systems is fundamental to identifying gaps in M&E systems and to developing an action plan and mitigation measures to address these gaps. The Global Fund will assess M&E systems through the Capacity Assessment Tool (CAT), usually before grant signing. The Capacity Assessment Tool (CAT) assesses the M&E capacities of key implementers in key, targeted areas of M&E. The Principal Recipient and the LFA may be asked to input into the sections of the CAT specified by the Country Team with the aim of identifying gaps and building mitigation measures into the Global Fund grant.

o   **M&E investment**

Sufficient funds should be dedicated to strengthen M&E systems in the country. The Global Fund generally recommends grants to allocate 5-10% to M&E, including to strengthen national data systems of reporting (analytical capacity and reviews; strengthening HMIS; population based and risk group surveys; civil registration). The activities must be included in the concept note and the funds to support each of these interventions included in the funding request and budget.

o   **Modular template & performance framework**

As part of the new funding model, the Global Fund introduced the *modular approach*. The modular approach derives its name from the modules that constitute the building blocks of applications under the new funding model. The comprehensive list of modules and interventions has been drawn from the investment guidance of major agencies including WHO and UNAIDS.

These modules are detailed in the *modular template*. The purpose of the modular template is to describe the relationship between what is planned, what results are expected and how much it will cost. It includes modules, interventions, related indicators and budgets at intervention level. This information is initially provided as part of the funding request, with the details further developed during grant making, and serves during grant implementation to track progress of the supported programs.

The *performance framework* depicts the key components of a program supported by the Global Fund and the resulting impact using a set of standardized indicators.[8] The performance framework captures the modules, interventions and indicators for a selected grant and is part of the grant agreement.

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[6] For more information on access to Global Fund funding and the grant making process please refer to section C.

[7] This is usually requested as part of the capacity assessment / M&E systems assessment before a grant is signed.
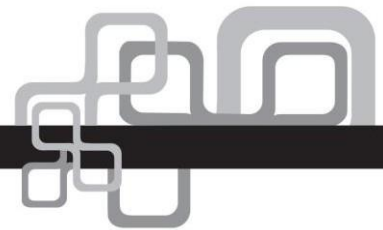
Impact and outcome and coverage indicators are reported at the national program level and should demonstrate progress of the overall national program. The use of internationally-recognised indicators aims to reduce the reporting burden for countries as existing M&E systems are used and strengthened where required. In case where funding is requested for projects aimed at specific populations or a defined sub-national target area, some of these indicators may be reported at project or sub-national level.

G4   Procurement and Supply Management of Health Products

Procurement and supply management activities are fundamental to program performance. Global Fund policies on procurement and supply management aim to ensure the timely procurement, distribution and appropriate use of quality-assured products at the best possible price, in accordance with the national and international laws, and in a transparent manner.

In order to ensure access to effective and quality-assured health products, the Global Fund has developed a set of policies and principles on procurement and supply management. The Global Fund website contains a wealth of useful information and links to relevant documents relating to procurement and supply management issues.[11]

Please note that this section does not cover procurement and supply management related services provided by the LFA during the grant life cycle. These services are described in sections C to E. Section D also provides information on the Private Sector Co-Payment Mechanism for ACTs.

G4.1   Quality Assurance Policies and Requirements

Quality assurance refers to the management activities required to ensure that the medicines and other health products that reach patients or end users are safe, effective and acceptable to the patients/end users.

The Global Fund has quality assurance policies for the procurement of pharmaceuticals and diagnostic products. The two Board policies are available on the Global Fund website's Procurement and Supply Management page, along with requirements for other health products.

Requirements and processes are further elaborated in the Operational Policy Note on the implementation of the quality assurance policy for pharmaceutical products.

In addition to the Global Fund's procurement policies, Principal Recipients must comply with the principles set out in the interagency guidelines *A Model Quality Assurance System for Procurement Agencies*.

Pharmaceuticals and other health products procured with Global Fund resources must also comply with national regulations and, where applicable, be authorized by the national drug regulatory authority (NDRA) in the country concerned.

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[10] Please refer to section D3.8 on Implementation Spot Checks.
[11] http://www.theglobalfund.org/en/procurement/

Quality Assurance Policy for Pharmaceutical Products

Global Fund grant funds may only be used to procure finished pharmaceutical products meeting the standards set out in the Quality Assurance Policy for Pharmaceutical Products. The policy defines quality requirements for finished pharmaceutical products, specifically antiretrovirals, antimalarials and anti- tuberculosis, and for all other finished pharmaceutical products.

Antiretrovirals, antimalarials, anti- tuberculosis finished pharmaceutical products must be
- Pre-qualified by the WHO Prequalification Programme or authorized for use by a Stringent Drug Regulatory Authority (SRA); or
- Recommended for use by an Expert Review Panel. The eligibility criteria for review by the Expert Review Panel are set out in the policy[12].

Other finished pharmaceutical products only need to comply with the relevant quality standards established by the national drug regulatory authority (NDRA) in the country of use. Finished pharmaceutical products must be selected in accordance with national drug regulatory authority requirements.

The policy requires the Principal Recipient to monitor performance of suppliers with respect to product and supply chain management and details provisions for monitoring product quality. [13] Where a Principal Recipient procures a finished pharmaceutical product that is recommended by the Expert Review Panel, the Global Fund will make the necessary arrangements for quality control sampling prior to delivery. The cost of sampling in these cases will be borne by the Global Fund.

The Operational Policy Note sets out the principals and processes linked to non-compliance with the Quality Assurance Policy for Pharmaceutical Products, e.g. failure to provide required notifications.

### Quality Assurance Policy for Diagnostic Products

Diagnostic products are defined as all durable and non-durable in vitro diagnostic products, imaging equipment and microscopes used in the Global Fund financed programs for diagnosis, screening, surveillance or monitoring purposes.

Each Principal Recipient must ensure that procurement of diagnostic products with Global Fund money is done in compliance with applicable laws, regulations, rules and decrees. In addition, grant funds may be used only to procure diagnostic products that are consistent with World Health Organization guidance or comply with applicable national guidelines. The policy stipulates standards for specific diagnostic products and also makes provision for an Expert Review Panel, which will advise the Global Fund on potential risks and benefits of using a diagnostic product that does not meet the criteria as set out in the policy.

The policy also stipulates measures to ensure quality of use including compliance with World Health Organization guidelines for good purchasing, storage, inventory management and distribution practices, use by appropriately trained and suitably qualified persons in the intended settings and lot testing. Lot testing involves quality control testing of a lot or batch of a diagnostic product after manufacture and release from the manufacturing site.

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[12] See section 13 of the Quality Assurance Policy for Pharmaceutical Products
[13] The costs for quality control activities may be budgeted for in Global Fund grants.
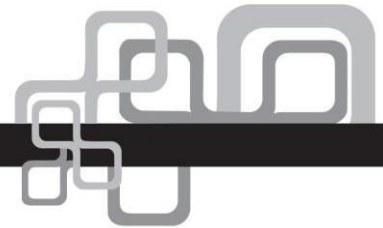
In addition to this policy, Principal Recipients are expected to comply with all other Global Fund procurement policies and practices that may apply to diagnostic products; and the conditions set out in the Global Fund grant agreement.

Quality Requirements for Other Health Products

These requirements stipulate requirements for the procurement of specific health products with grant funds, for example:

- **Long-lasting insecticidal mosquito nets** must be recommended for use by the World Health Organization Pesticide Evaluation Scheme (WHOPES).
- **Other pesticides** (e.g. for indoor residual spraying and treatment of mosquito nets) must comply with specifications indicated by WHOPES. The webpage provides links to further guidance on pesticides.
- **Male and female condoms** must also be compliant with specifications determined by the World Health Organization. Links to these specifications are provided on the Global Fund webpage.

Health Products other than pharmaceutical products, diagnostic products, long-lasting insecticidal mosquito nets, other pesticides, and condoms should be selected from the applicable list of prequalified products, if any, and must comply with the quality standards applicable in the country where such products will be used.

G4.2   Pharmaceutical Systems Strengthening and Pharmacovigilance

The significant scale-up of service delivery in low- and middle-income countries has highlighted the need for increased investment in national health systems. The Global Fund supports Health Systems Strengthening within the framework of its mandate by linking Health Systems Strengthening investments to health outcomes. Health Systems Strengthening investments contribute to addressing health system constraints that hinder the effective and efficient delivery of disease programs. Global Fund contributions in this area must be well coordinated with the countries' own investments in their health systems and other partners' resources. Under the new funding model the Global Fund encourages countries to allocate a portion of their funding envelope for cross-cutting Health Systems Strengthening interventions. Cross-cutting health systems strengthening contributes to strengthening performance of a priority health system component; has a direct linkage to improving HIV, TB and/or malaria outcomes; benefits more than one disease program (including HIV, tuberculosis, malaria and beyond), and benefits the health outcomes of women and children.

Pharmaceutical systems strengthening falls within the framework of Health Systems Strengthening. A well-functioning health system ensures equitable and continued access to products and technologies of assured quality, safety, efficacy and cost-effectiveness, as well as their scientifically sound and cost-effective use. The Global Fund pays considerable attention to supporting countries in strengthening their Procurement and Supply Management Systems in order to effectively forecast, procure, store, distribute and assure the quality of these products.

Interventions aiming at pharmaceutical systems strengthening fall into two categories:

First, those that assure appropriate, uninterrupted, efficient and transparent planning, purchase and distribution of quality medicines and other health products and technologies all along the supply chain, to benefit HIV/AIDS, TB and malaria programs. They include:

- Supporting authorities in developing or reviewing the national pharmaceutical policy and operational plan;
- Strengthening the capacity of the national regulatory authority that regulates marketing authorization and rational use of health products. National regulatory authorities define the standards and guidelines and monitor the movement of pharmaceuticals and health products in a country (e.g. through medicine/health products registration, inspection of pharmaceutical facilities, quality monitoring and pharmacovigilance);
- Building the procurement and supply management workforce capacity;
- Developing quality assurance and performance monitoring activities throughout the supply chain, to ensure availability of quality health products; etc.

Secondly, those that ensure the appropriate storage and distribution of medicines and other health products. These include:
- Refurbishment or scale-up of storage facilities;
- Improving transportation for distribution; etc.

Pharmacovigilance is defined by the World Health Organization as "the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other possible drug- related problems". It is a key means to enhance program effectiveness and the safety and quality of medicines and is critical for assessing risks and benefits of deploying new medicines for large-scale use. Investment in pharmacovigilance promotes the monitoring of quality, usage and efficacy of the drugs procured and tracks adverse events among patients and other post-marketing product defects.

G4.3   Price and Quality Reporting

The Price and Quality Reporting (PQR) Tool is a web-based system used by the Global Fund to gather and track information about product prices and quality for key pharmaceutical and health products.

The system's objectives include:
- To communicate market information to recipients;
- To enable the Global Fund to benchmark prices achieved against international reference sources and relevant comparators;
- To monitor compliance with the Global Fund's Quality Assurance policies; and
- To build market intelligence and inform policymaking.

As a condition to disbursement, the Global Fund requires Principal Recipients to report into the Price and Quality Reporting tool all purchases from the following eleven categories of health products:
1. Antiretrovirals
2. Antimalarial medicines
3. Antituberculosis medicines
4. Insecticide treated nets
5. Condoms
6. HIV and malaria rapid diagnostic tests
7. Insecticide products for Indoor Residual Spraying (IRS)
8. HIV viral load instruments and consumables
9. Early Infant Diagnostics (EID) instruments and consumables
10. CD4 machines and consumables
11. TB testing products, including GeneXpert instruments and cartridges

Purchases of products that do not fall within these eleven categories do not need to be entered into the Price and Quality Reporting system.

The Principal Recipient should enter data in the Price and Quality Reporting tool upon receipt of a consignment using the best information available at the time, including uploading essential documents such as invoices, packing lists, insurance certificates etc. Information in the Price and Quality Reporting tool should be updated by the Principal Recipient.

The Global Fund may request the LFA to review and validate information provided in the Price and Quality Reporting tool. This validation by the LFA is usually required at the time of each PU/DR, as further described in Section D2.1 of this Manual. It is however recommended that LFAs undertake verifications of the Price and Quality Reporting by reviewing the documents provided and validating the accuracy of the reporting on a monthly basis in order to maintain ongoing data quality.

Purchases made using the Pooled Procurement Mechanism [14] will be reported into the system by the procurement agent, and need not be entered by the Principal Recipient; however the LFA will usually be required to verify the information entered by the procurement agent.

Special provisions apply for UN organizations serving as Principal Recipient.[15]

> The document *An LFA's Guide to the Price and Quality Reporting* provides useful guidance on the tool, as well as common data entry errors and common verification errors within the Price and Quality Reporting.

G4.4   Pooled Procurement Mechanism

The Global Fund facilitates the procurement of health products by Principal Recipients through a Pooled Procurement Mechanism established by the Global Fund in which order volumes from participating Principal Recipients are aggregated to leverage market spend. The mechanism may also prove helpful in situations where Principal Recipients/national systems encounter challenges in procuring health products for Global Fund grants.

The Pooled Procurement Mechanism is discussed in more detail in section F on Special Implementation Arrangements.

G4.5   Operational Partnership with the Green Light Committee

The Green Light Committee (GLC) Initiative is a partnership aimed to accelerate scale up to achieve universal access to prevention, early diagnosis and effective patient-centered treatment for drug resistant tuberculosis.

Global Fund Board policies require that all Global Fund grant recipients implementing treatment of drug-resistant tuberculosis conduct the procurement of drug-resistant-tuberculosis treatments through the Green Light Committee. The related procurement is factually being managed by the Global Drug Facility (GDF).

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[14] Please refer to section F for more information on the Pooled Procurement Mechanism.
[15] Please refer to the document *An LFAs Guide to the Price and Quality Reporting*.

The Board policies also recognize that the Green Light Committee provides a package of services that cannot be disaggregated, and the Global Fund agreed that for each Global Fund program that is used to finance drug-resistant- tuberculosis activities, an annual contribution, called a "cost sharing element" will be made to the Green Light Committee from grant funds. The cost sharing element is a flat-rate fee which must be captured in the grant budget. These funds must be included in the Principal Recipients' disbursement requests and subsequent expenditure reports, but the payment will be done as a direct disbursement from the Global Fund to the Green Light Committee. The disbursement of the cost-sharing element to the Green Light Committee is not subject to the performance of the grant.

> The Operational Policy Note on the Implementation of the Memorandum of Understanding between the Green Light Committee and the Global Fund[16] specifies how the collaboration is operationalized.

LFAs may be asked to review grant documentation and disbursement requests with a view of ensuring adherence to the Memorandum of Understanding and Operational Policy Note.

G5 Health Systems Strengthening

Health Systems Strengthening to Maximize Impact of HIV, TB and Malaria Programs and Improve Health of Women and Children

Over the last decade, the Global Fund mobilized substantial resources for health programs in low-and middle-income countries, which has helped reducing the burden of HIV/AIDS, TB and malaria. However, significant scale-up of service provision has placed new demands on national health systems and revealed weaknesses in the performance and sustainability of their key components. As a major financial partner, the Global Fund supports countries' health systems strengthening (HSS) efforts with the objective to maximize the impact, efficiency, sustainability, equity and quality of the three disease programs. By contributing to improved performance of key health system components, the Global Fund's investments also help generating system-wide effects and thus benefit a broader range of health outcomes, primarily in the reproductive, maternal, newborn and child health domain.

Under the new funding model the Global Fund prioritizes specific components of the health system for investments. These priority areas have been identified based on an analysis of the Global Fund's grant portfolio, which revealed a number of health-system-related risks that directly affect successful implementation of HIV/AIDS, TB and malaria programs. These risks are mostly associated with the following five areas:

1. Procurement and supply chain management
2. Health information systems
3. Health and community workforce
4. Service delivery
5. Financial management

Eligible countries have the flexibility to request cross-cutting health systems strengthening support either by including health systems strengthening modules under disease Concept Notes, or by developing a separate Health Systems Strengthening Concept Note for a stand-alone Health Systems Strengthening grant.[17]

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[16] The Operational Policy Note is part of the Operational Policy Manual.
[17] Please refer to section C for more information on Access to Global Fund Funding and Concept Notes.

Under the new funding model the Global Fund prioritizes two explicit objectives of the 2012-2016 Strategy: to maximize the impact of its investments on strengthening health systems and to maximize impact on improving the health of mothers and children. As such, the new funding model encourages and represents an opportunity for countries to invest more strategically for a greater impact on the broader Millennium Development Goals (MDGs), beyond HIV, TB and malaria, with objective view to improve the health of women and children. This can be achieved by coordinated investments in diseases programs and cross- cutting health systems strengthening aimed at leveraging and strengthening existing reproductive, maternal, newborn and child health service delivery platforms to deliver HIV/AIDS, TB and/or malaria services, or vice-versa - by integrating these health services into the three national disease programs, in order to maximize their overall effectiveness and broaden the scope of their impact. For more information on health systems strengthening and reproductive, maternal, newborn and child health investments, please refer to the respective guidance documents available on the Global Fund website.[18]

G6   Community, Rights and Gender

In any public health crisis – such as the spread of AIDS, TB and malaria – it is critically important that the interventions to prevent and treat the diseases reach all those affected. In reality, however, there are many people who are not reached because they are discriminated against, stigmatized, criminalized, or otherwise denied access to health care, driving these populations underground and away from Global Fund-supported health services.

Reaching these people is of critical importance in the response to the diseases, and is central to the work of the Global Fund. Efforts to reach out to and meet the needs of everyone without discrimination can be grouped together under the framework of "Community, Rights, Gender". While it is relevant for all programs, this framework is particularly important in the context of efforts to reach key populations[19].

Community, rights and gender are often grouped together. Human rights issues and gender barriers affect many aspects of public health, from vulnerability to health risks, to quality, availability, and access to services. Community responses – working with and through community systems both to deliver services and to advocate for change – are key tools for addressing these issues.

During the concept note development process, countries are required to outline the human rights barriers and assess gender issues within their country, and propose how to address these barriers to health care. The Global Fund Secretariat has developed guidance for countries on how programs can best address human

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[18] http://www.theglobalfund.org/en/fundingmodel/support/infonotes/

[19] The Global Fund uses the following definitions: Key populations are groups that face an increased burden and/or vulnerability to at least one of the three diseases due to a combination of biological, socioeconomic, and structural factors combined with lower access to services due to human rights violations, systematic disenfranchisement and criminalization. In addition, all people living with HIV and those who currently have, or have survived, TB fall within this definition. The following groups are considered to be key populations: HIV: gay, bisexual and other men who have sex with men / transgender people (with a special focus on transgender women) / people who inject drugs /sex workers. TB: prisoners and incarcerated people / people living with HIV / migrants, refugees and indigenous populations. Malaria: refugees / internally displaced people / indigenous populations in malaria-endemic areas.
Vulnerable populations are those groups that do not meet the criteria above but who experience a greater vulnerability and greater impact of the three diseases. These may include those whose situations or contexts make them especially vulnerable, or who experience inequality, prejudice, marginalization and limits on social, cultural and other rights. Examples include: orphans / street children / people living in extreme poverty / people with disabilities / mobile workers / girls / pregnant women

In the context of this report, the term "key populations" is understood to mean all of the groups mentioned above. The Global Fund recognizes that key populations are central to the fight against HIV, TB and malaria.

rights and gender barriers and integrate the needs of key populations, as well as how to make use of community systems in order to develop effective programs.

G6.1   Community

Involving communities and developing community responses helps to ensure that everyone who needs to be reached, including key populations, are reached and supported. While many interventions are delivered directly at the community level, making services available is often not enough. The impact of programs, and their sustainability, is increased considerably when communities themselves become involved in delivering programs, overseeing services, and advocating for their needs. Community systems strengthening refers to a set of interventions designed to ensure that community systems – informed, capable and coordinated groups, organizations, networks and structures – are an effective part of the response to AIDS, TB and malaria.

The Global Fund supports programs where community-led organizations are directly involved in implementation and delivery of services. During the concept note development stage of the funding process, therefore, countries are required to map out implementation arrangements for the grants, and to indicate where and how community organizations will be involved in service delivery.

The Global Fund Measurement Framework also contains a specific module for community systems strengthening, which applicants can and should include in their programs in order to make sure that all community-led elements of the program receive the support they require to be effective. Community systems strengthening is framed by the Global Fund using four key interventions.

1. **Community-based monitoring**: community-based organizations and other community groups are strengthened to monitor, document and analyze the performance of health services as a basis for accountability, advocacy and policy activities.

2. **Advocacy for social accountability**: communities and affected populations conduct consensus, dialogue and advocacy at the local and national levels aimed at holding to account service providers, national programs, policy-makers, and local and national leaders for the effective delivery of services, activities and other interventions, as well as for the protection and promotion of human rights and gender equality.

3. **Social mobilization**: involving communities and affected populations in activities to improve their health and their own environment through community action, the creation of community organizations and also networking with other actors and broader movements such as human rights and women's movements.

4. **Building institutional capacity**: providing communities, organizations and networks with skills in planning, institutional and organizational development, systems development, human resources, leadership, and community sector organizing. This can also involve the provision of technical, material and financial support to the community sector to enable them to participate fully in service delivery as well as mobilization, monitoring and advocacy.

G6.2   Human Rights

The Global Fund's mandate - to direct resources to support the fight against HIV, TB and malaria - is grounded in a commitment to human rights. It supports governments in their obligation under the *International Covenant on Economic, Social and Cultural Rights* and the *Universal Declaration of Human*

Rights to progressively realize the right to the highest attainable standard of health. The Global Fund made this commitment to human rights explicit in its 2012-2016 strategy, which has as one of its five objectives: "To protect and promote human rights in the context of the three diseases".

Protecting and promoting human rights in the context of the Global Fund involves three components:
- Ensuring that the Global Fund does not support programs that infringe human rights;
- Integrating human rights considerations throughout the grant cycle; and
- Increasing investment in programs that address rights-related barriers to access.

The Global Fund encourages countries to place human rights at the core of their planning and development process by adopting a human rights-based approach. In other words, disease programs should be designed in consultation with the communities for whom they are intended and should be tailored to the specific needs of those communities.

This means that, for example, the country dialogue process must specifically reach out to and include key populations in the planning and development process, as this is the best way to ensure that programs that are implemented will both be effective and will show impact on the diseases.

The country dialogue also serves as an opportunity for civil society and community participants, working together with government, to identify any legal barriers to accessing services that may exist and which may also impede the effectiveness and impact of the response to the diseases.

Ensuring the human right to health cannot be achieved without addressing legal barriers which prevent people from accessing health care. Generally speaking, there are five actions which can be taken to address human rights barriers. Although interlinked, each approach can be undertaken independently, and country context will determine whether or not all five approaches are needed in a given situation.

1. One essential element is an understanding of the status quo. This can be achieved through an assessment of the country's legal environment with respect to key populations and barriers to health care. This assessment can then serve as the basis for advocating for legal reform and for countries to uphold their human rights commitments through the international treaties that the country is a party to.

2. The second area of work is to share this understanding by educating individuals as to the law and their rights within the law. This is often best managed through programs that provide legal literacy and legal aid when and where needed.

3. Thirdly, understanding the issues and human rights in general must also become widespread within government structures, which requires a program of human rights training for police officers, government officials, and health workers.

4. Fourth, while much of this work can be considered the remit of government, communities too have their role to play in addressing barriers to accessing health care. Communities can take on a "watchdog" role through community-based monitoring, ensuring that program activities as well as breaches of human rights are noted, recognized, and responded to.

5. The fifth action involves communities coming together to support advocacy around policy issues.

Human rights have also been integrated into the Global Fund's risk management framework. Human rights risks can be categorized as either contextual risks or programmatic risks. Contextual human rights risks include such items as widespread and systematic discrimination, abusive law-enforcement practices, and gender-based violence, among others. Programmatic human rights risks refer to the possibility that Global Fund-supported programs will directly infringe human rights in delivering services.

To address the programmatic risk, the Global Fund has recently revised its grant agreement to include a clause on human rights. The article sets out minimum expectations of human rights standards in Global Fund programs, specifically addressing non-discrimination; reliance on informed consent and confidentiality in testing and treatment; use of only scientifically proven medical treatment; not employing methods that constitute torture or cruel, inhuman or degrading treatment; and use of medical detention only as a last resort. It also requires Global Fund grant recipients to notify the Secretariat if there is a risk or an identified violation of these standards, and to work with the Secretariat to address the issue through an agreed work plan or other actions. In addition, any human rights violations which are reported are to be investigated by the Office of the Inspector General.

G6.3   Gender

Gender inequalities drive the spread of the three diseases, not only because they mean that people become more vulnerable and, most often, more affected both as patients and as caregivers by the diseases, but also because unless these inequalities are specifically addressed, the effectiveness of programs to respond to the diseases will be affected. Gender inequalities primarily affect the vulnerability and access to services of women and girls; however those same inequalities and norms often also have a negative effect on men and boys, and are also particularly harmful for transgender people and others who do not fit into culturally accepted gender roles and definitions.

The Global Fund encourages funding for programs that address gender inequalities and strengthens the response for women and girls in all their diversity. This includes scaling up services and interventions that reduce gender-related risks and vulnerabilities to infection; decreasing the burden of disease for those most at risk, mitigating the impact of the three diseases; and addressing structural inequalities and discrimination against women and girls in all their diversity, as well as men and boys.

The Global Fund has a *Gender Equality Strategy* and a *Sexual Orientation and Gender Identity Strategy.* These have been supplemented by a *Gender Equality Strategy Action Plan* and a *Key Populations Action Plan.* In July 2013, the Secretariat also began on an eighteen-month timeline to develop policies and procedures to put the human rights commitment in the strategy into operation and to outline how the Global Fund will work with countries to enshrine human rights principles at every stage of the grant life cycle.

Reference Documents

Information, guidelines and requirements for Country Coordinating Mechanisms can be found on the dedicated website http://www.theglobalfund.org/en/ccm/ including information on CCM funding, oversight tools and thematic reports.

The Global Fund dedicated website for Operational Policies, Guidelines and Tools http://www.theglobalfund.org/en/documents/operational/ contains tools and guidance documents, including

- The Operational Policy Manual
- The Global Fund Guidelines for Grant Budgeting and Annual Financial Reporting
- Guidelines For Annual Audits of Global Fund Grant Program Financial Statements

The Global Fund M&E website http://www.theglobalfund.org/en/me/ contains requirements, guidelines and tools for M&E related assessments and verifications, including partner resources.

Information on procurement and supply management can be found on the dedicated website http://www.theglobalfund.org/en/procurement/. This includes Quality Assurance policies and guidance on quality monitoring, lists of prequalified products and relevant partner resources.

The Global Fund list of publications http://www.theglobalfund.org/en/publications/ and the Access to Funding website http://www.theglobalfund.org/en/fundingmodel/support/infonotes/ contain thematic guidance and information notes, including on gender, community and human rights issues.