Technical Brief:

Support to Effective Regulatory Systems for Procurement and Supply Management of Health products

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The Global Fund

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1. Introduction

Access to safe, effective and quality medicines and vaccines for all is one of the targets of the Sustainable Development Goals. Achieving universal health coverage requires access to safe, effective, quality and affordable essential medicines and vaccines.

Substandard and falsified medical products represent a threat to public health worldwide but pose a particular problem in Low- and middle-income countries (LMICs). This is due largely because most developing countries do not have the technical, institutional and financial capacities to regulate their health products market. As per WHO, about a quarter of WHO member states have stable, well-functioning and integrated regulatory system; a fraction of which are in LMICs.

Efficient and effective national regulatory system is an essential component of any resilient health system and a critical enabler as assurance mechanism to health products (as shown in Figure 1).

Figure 1: National Regulatory Authority as HSS component

At the same time, efficient national and regional regulatory systems are also central to achieve the core mission of the Global Fund. The need to improve National and regional regulatory systems is aligned to the Global Fund 2017-2022 strategy “Investing to End Epidemics. The core objectives of the strategy are to:

a) Maximize impact against HIV, TB and Malaria
b) Build resilient and sustainable systems for health
c) Promote and protect human rights and gender Equality
d) Mobilize increased resources.

The Global Fund would like to acknowledge the fundamental role played by WHO in improving access to safe, effective and quality medicines and Diagnostics around the world through its strategic and normative work and technical support at the global, regional and national levels.

The WHO Regulatory Systems Strengthening (RSS) Programme provides guidance to countries in terms of the pillars of a robust regulatory system and core regulatory functions.

Applicants are encouraged to invest in improving their regulatory system. accurate and reliable diagnostic products are also critical for effective treatment and achieving the global targets in the fight against HIV, Malaria and Tuberculosis. Applicants should consider support to all health products which play a critical role in the quality of the health services as a whole such as In-Vitro Diagnostics products or other types of medical devices.

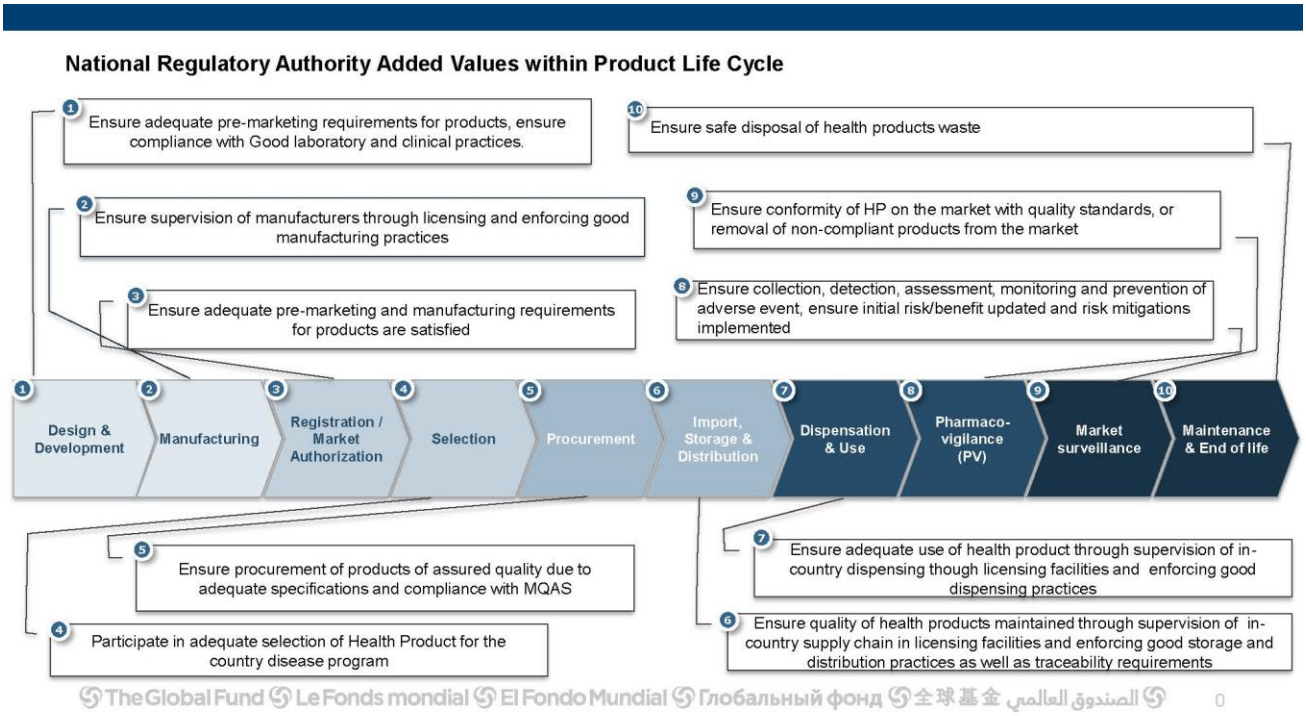
2. Essential Background Information

2.1 Rationale for Global Fund Investments in Regulatory Systems

In line with the definition of health system, the Regulatory System consists, for the purpose of this notice, of all organizations, people and actions whose primary intend is to ensure access to essential medicines and other health products of assured quality, safety and efficacy or performance[1]. A regulatory system is therefore more than the pyramid or the institutional arrangements of public institutions that deliver regulatory services but include private providers such as manufacturers or distributors

National regulatory authorities (NRAs) play a critical role in countries because they have received delegation from their parent Ministries to ensure the quality, safety and efficacy of health products. The institutional arrangements of regulatory authorities within a country is key to provide access to quality assured essential medicines, vaccines in-vitro diagnostics and health technologies of assured quality. The Figure 2 describes the whole spectrum of assurance mechanism under the mandate of a NRA.

Figure 2: Contribution of National Regulatory Authority to quality of essential health products



A weak regulatory system can have a direct impact on patient outcomes. Unfortunately, many low- and middle-income countries have limited capacity to assess and approve health products. Key challenges include inadequate financial resources, staff lacking scientific expertise, inefficient regulatory systems and inadequate regulatory frameworks. The underreporting of adverse reactions

[1] This is based on the definition given in the World Health Report 2000 Health Systems: Improving performance

and adverse events and very few regulatory decisions on medicines safety in LMICs are based on local data highlights the need for improved approaches to post-marketing surveillance. In addition, the rise in substandard and falsified products in all markets is hampering efforts to ensure the quality, safety and efficacy of health products. Substandard and falsified medical products endanger health, promote antimicrobial resistance, undermine confidence in health professionals and health systems.

2.2 Guiding Principles for investing in Regulatory Systems

a. Country-led coordination and Ownership

Support country-led coordination and ownership by working with partner country governments and other national stakeholders including civil society, industry and professional associations, and private sector to dialogue effectively with each other and with donors, cooperating agencies, etc. on national health priorities, proposed solutions and strategies, and resource requirements.

b. System strengthening approach

Utilize a system strengthening approach that considers the five health systems functions (governance, human resources, information, financing, and service delivery) as they relate to the sixth function: medical products, vaccines, and technologies, specifically within the context of quality assurance systems strengthening. By considering all health systems functions (not just medical products) and their interactions with each other within the country context, there is increased likelihood that improvements in medical product quality assurance systems performance will be sustained and country systems made more self-reliant.

c. Build on and strengthen existing systems

When and where appropriate, build on existing systems/processes and customize tools and approaches for strengthening medical product quality assurance to improve buy-in and acceptance from local governments and counterparts, the potential for sustainability, the scalability of health programs, and cost effectiveness from both a financial and human resource capacity perspective.

Priority will be given to identifying existing organizations (e.g., educational institutions and professional associations and networks) and strengthening their governance, technical competence, financial systems, and monitoring and evaluation capabilities.

d. Support integration

Where programmatically feasible, across disease-specific programs (e.g., routine post-marketing surveillance systems for product quality), medical product quality assurance systems actors and functions (e.g., addressing fragmentation of regulatory quality assurance responsibilities), and inclusion of medical product quality considerations in procurement, storage, distribution, recall, and national action plans.

e. Develop Partnership

In addition to country actors, multiple regional and international stakeholders are engaged in helping to assure the quality of medical products and combat substandard and falsified products. The Global Fund expects the applicant to leverage investments with other donors and other initiatives.

3. Scope of Global Fund Investments

Activities in this strategic area would support countries to deliver and implement regulatory framework that protects and promotes public health while enabling timely access to, and innovation of, quality products. Activities would focus on regulatory system strengthening based on WHO recommended models focusing on key regulatory functions such as marketing authorization,

regulatory inspection, market surveillance and control, pharmacovigilance. The support could broadly include the following:

- Support countries in implementing good practices in leadership and governance, including implementing quality and risk management systems;
- Support countries in developing or reviewing national health products policies, related regulation and operational plans to translate the policy goals;
- Support countries for improving prescribing, dispensing and rational use of health products;
- Strengthen the country institutional arrangements and capacity of the national regulatory system that oversee the implementation of health products regulation overall following a risk-based approach;
- Strengthen regulatory systems to organized post-market surveillance including pharmacovigilance and combat sub-standard and falsified health medical products; and
- Support increased interorganizational, regional collaboration to share best practices, exchange regulatory information to facilitate decision making, reliance to avoid duplication of efforts.

3.1 Implementing Good Leadership and Governance Practices

The leadership and governance of regulatory systems is the most complex but also the most critical of the building blocks. It is about having an effective regulatory framework well-articulated (e.g. policies, laws, regulations and related guidelines) avoiding fragmentation of responsibilities in the pharmaceutical and medical devices system. The delegated roles and responsibilities to the NRA and its relationship with other actors whose activities impact on quality, safety and efficacy of health products are key factors. It is ultimately the responsibility of the government to supervise the effectiveness of the institutional arrangement of NRAs and their functions, define goals and priorities and monitor performance.

Weak governance makes the pharmaceutical system vulnerable to undue influence, corruption, fraud and abuse. In addition, poor governance continues to be an issue for country due to lack of accountability, unclear distribution of roles and responsibilities and lack of oversight. Transparency is recognized as an essential element of ethical processes for governments.

Implementation of public sector reform can be a good opportunity for setting NRAs operating at arm’s length for government.

Activities that may be supported with Global Fund grants include:

- Support for legal, regulatory and policy reforms;
- Support for the establishment of more effective and efficient NRAs, based on WHO and other internationally recommended models,
- Support project for greater accountability and implementation of transparency principles at all levels of the Regulatory Systems.

3.2 Supporting delivery of efficient regulatory services to ensure quality safety and efficacy

The overall objective of a NRA is to ensure that medical products (medicines, vaccines, medical devices including in-vitro diagnostics and other health care products are of assured quality, safety and efficacy / provide the requested performances. In all countries, the roles and responsibilities of the NRA are organized under a set of regulatory functions such as

- Market authorization/registration of products,
- Licensing of the actors such as manufacturers, distributors and retailers,
- Laboratory testing of products and / or lot release of products,
- Inspection of manufacturing sites, distribution facilities until dispensing of end-users,
- Post marketing surveillance of quality and safety,

- Control of Clinical trials,
- Control of advertising and promotion.

Each regulatory functions implemented provided a different contribution to ensure quality, safety and efficacy. However, all are necessary to ensure impact of the regulatory echosystem. The Global Fund Quality Assurance Policies and other quality Assurance requirements provided already the basisi for selecting more specific regulatory functions which will be the focus for Grants funds.

- **Market authorization/registration of products**

The NRA has the critical responsibility to assess product submission to allow for the products to be marketed in their countries. Administrative, regulatory and scientific data submitted by the manufacturer to demonstrate quality, safety and efficacy and/or interchangeability are assessed as per internationally recognized guidelines. The time it takes for the applicant to be granted market authorization (MA) affects availability of the product on the market. Marketing authorization / registration is a core function allowing the other regulatory functions such as pharmacovigilance or quality control testing to be performed in an efficient way. This is also recognized by Global Fund Quality Assurance Policies for Pharmaceuticals and Diagnostics Products which requires authorization by the NRA of the receiving countries.

Activities aiming at strengthening, facilitating the registration mechanism in countries can be supported, such as:

- Support developent and revision of policy, legislation, regulation and guidelines
- Establish Registration committee / board
- Training of regulators on assessment of quality, safety and efficacy
- Development of Standard Operational Procedures

- **Licensing and inspecting actors such as manufacturers, distributors and retailers,**

Detailed knowledge of the actors involved in the design & manufacturing, distribution up to the dispensing is a major responsibility of the NRA. The licensing mechanism allows the regulator to have the detailed picture of stakeholders in the health sector from private, public or non-governemental. Setting and enforcing of best pratices is also in the remit of the regulator ensuring that product are adequatlty manufactured as per approved specifications, distributed in line with storage conditions and dispensing and use as per national treatment guidleines

Depending on the country context, dedicated inspection entities within the NRA or outside the NRA (regional inspectorate, Pharmaceutical council) can supervise differents stakeholders such as manufacturers, distributors and wholesalers and retailers. However, enforcement of best practices at all level of the supply chain should be supported such as for:

- Developing, promoting Good practices and road map for implementation
- Revising & updating regulations, guidelines and tools
- Supporting inspection units, development and implementation of operational procedures

- **Market surveillance of quality**

NRA has the critical responsibility for overseeing the quality of health products in countries. This activity has been supported with Global Fund funds as included in its Quality Assurance Policy. Based on market intelligent and implementing risk-based approach, NRA has to develop strategies and implement plans to identify potential non-compliant products circulating on their market. Market surveillance can be organized in different ways depending of the objectives. Routine sampling can be performed by inspectors when visiting manufacturing sites to check compliance with approved specifications. Market surveys can be organized on a specific regional area, dedicated period to give a snapshot of the medicines quality situation in certain settings.

There is a need to build a testing strategy which should not only envisaged full advanced laboratory testing but also use screening technologies as well as basic human skills, in collaboration with the

laboratory which will oversee the testing. Each activity should be well described with timeline and resources in relevant plan e.g. Inspection plan, sampling plan and testing plan…

Activities aiming at strengthening market control activities including detection of falsified products should be supported and may include:

- Developing overall risk-based post market surveillance strategy and programme;
- Developing and implementing market surveys based on risks
- Developing and implementing market surveillance program along the supply chain.

- **Pharmacovigilance**

Pharmacovigilance has become an essential component of medicines regulation. Depending on country history and context, surveillance of medicines safety can be co-ordinated by a specific institution namley the national pharmacovigilance centre or within the NRA itself. While the National Centres achieved to collecting and analysing case reports of ADRs and distinghuishing signals from background 'noise'. The NRA is responsible of making regulatory decisions based on signals detecded and alerting prescribers, manufacturers and the public to new risks of adverse reactions.

Stenghtening pharmacovigilance activities has already been highlighted as an area for support in particular in a Global Fund publication supporting the allocation of funds to reach a minima sets of requirements for functional pharmacovigilance system. However, the situation needs today greater attention. as a wide variety of novel or newly introduced medicines are now reaching patients in LMICs through global health programs including support from The Global Fund. All require adequate post-market safety surveillance, which does not yet exist in most of these countries.

Activities aiming at strengthening PV system for country decision making should be supported and may include the following activities:

- Support PV policy, legislation, guidelines development and revision
- Support the establishment of PV risk assessment committee
- Deliver training on PV to regulators and healthcare professionals
- Support implementation of Active surveillance/Pregnancy registry/ Sentinel sites

- **Laboratory testing of products**

Quality control testing of health products is a major tool to ascertain the non-compliance of health products to their specifications. Historicall, and because of the high level of expertise, the specific technology used and the specific environment, this component is in some countries implemented within one specialized institution namely the national quality control laboratory. The National national quality control laboratory performed the testing in line with the planned arrangements in order to identify non-compliant products. The NRA should be responsible for making regulatory decisions based on supporting evidence provided by the National Quality Control Laboratory (NQCL) in suspending or withdrawing the Marketing Auhtorization.

The Global Fund will support the following activities related to quality control:

- Support to implement of quality management system,
- Training staff/analyst
- Procuring, installation and maintenance equipment
- Procuring reference standards/materials

- **Appropriate prescribing, dispensing and use**

As per WHO, more than 50% of all medicines are prescribed, dispensed or sold inappropriately and 50% of patients fail to take their prescribed medicines correctly. Medicines continue to be inappropriatly prescribed and dispensed in many countries. The Global Fund would invest in:

- Support to revision of Essential Medicines List (EML) and Essential Diagnostics List (EDL)
- Support to revision of therapeutic and diagnostics guidelines;

- Support the surveillance of the consumption and use of antimicrobial medicines;
- Support to revision guidance to reinforce startegies for the rationale use of medicines e.g. selection, prescribing, dispensing and use
- Support the control of advertisement and promotional materials.

3.3 Increasing Human ressources

In many countries the human resources crisis within the NRA system is acute with an inadequate number of staff and inadequate skill sets. Retention in the public sector is also a challenge for well-trained specialists leave the country or migrate to better-paid positions in the private sector or research institute in the same country. Moreover, the skills and competencies needed to for performing the technical regulatory activities are not integrated in most of the curricula of pharmaceutical personnel in LMIC.

Activities that may be supported by the Global Fund include those that are aimed at improving the equitable distribution and retention of a skilled laboratory workforce.

This includes:

- Support for recruitment, definition of retention strategies for NRA and leadership development
- Support for curriculum revision and implementation to align with the required skills;
- Support capacity of educational, training institutions and professional associations to produce qyalified workforce.

3.4 Improving infrastructure & equipment

Appropriate building space and equipment are also essential to deliver effective regulatory services. Global Fund investments may be used for interventions aimed at supporting the upgrading infrastructure, including refurbishing facilities.

The availability and maintenance of IT equipment remains a challenge. Countries often do not have the minimum required equipment to work efficiently. back-up power and communication technology.

Considering these weaknesses, activities that may be supported by the Global Fund include the following:

- Support for equipment;
- Connectivity solutions for networking and internet access
- Promoting use of technology and electronic systems (e.g. establishment of text messaging/SMS systems of reporting,)

3.5 Implementing Quality Management Systems & Good Regulatory Practices

The implementation of Quality Management System (QMS) will provide assurance on the reproducibility of the quality and consistency of the outputs (products and services). The impact of the use of QMS has been recently confirmed by the publication by WHO of a draft guidance to support NRA in their approach.

Many mature regulators are currently making great progress in implementing QMS, which is leading to accreditation to international standards. Because substantial resources are needed for quality improvement towards accreditation, developing countries have not considered implementation of QMS as a priority which is quite understandable and justified. However, it is recommended that countries incorporate standards, comprehensive quality systems and goals for accreditation in their plans for development at later stage.

Activities that may be supported by the Global Fund include:

- Support for the establishment and implementation of quality management systems towards accreditation;

3.6 Support implementation of risk based principles

In all domain, policymakers are encouraged to learn more and more on how to better apply risk management tools to policymaking. Regulators should increasingly develop a common risk management process for their regulatory system; and incorporate risk management best practice into their regulatory work.

In particular NRAs should take increased benefits of these principles in particular to tailor their processes and proportionally allocate of appropriate resources to mitigate or manage them. This is even more critical for low- and middle-income countries (LMICs), many of which currently rely to some or a large degree on donor support that is not sustainable.

The Global Fund will support investments and technical assistance to support NRAs in performing their own initial risk assessment and subsequently implementing risk management activities.

3.7 Implementing Regulatory Information Systems

Regulators have to manipulate a huge amount of data for regulatory purpose. Most of the information system used by NRA in low and middle-income countries are not existing or fragmented inhibiting the functioning of regulatory activities. WHO and the Pan American Health Organization (PAHO) have developed a Model System for Computer-assisted Drug Registration (SIAMED) in consultation with several NRAs with technical and financial support from various partner organizations and donors. The main objective of the WHO model system was to improve the efficiency of NRAs enabling them to assure that marketing authorizations are issued in a robust manner.

Initially, the introduction of computerized-regulatory system will put an additional burden on staff, especially when existing information needs to be examined and organized. However, once the system is operational, staff will face less routine and clerical work, and will have more time available for technical and professional work because many frequent tasks, such as searching for information on similar items and producing certificates, will be simplified or automated

However, prior to engaging in computerization, it is required to perform a feasibility study to assess local specifications, the organizational structure and level of maturity of working procedures, the allocation of resources in order to better understand local needs. Computerization can contribute to improving the regulatory information management process and information retrieval. At the same time, it's efficiency and effectiveness are dependent on the existence of efficient drug regulatory system. The implementation of emerging international standards on the management of data for regulatory purpose should be encouraged to facilitate future interoperability of regulators. Such standards should critically improve the information sharing between NRAs within or without their regional approach.

The Global Fund supports the following interventions and activities:

- Feasibility study / Study on Customers needs / users requiremens
- Establishment, maintenance and strengthening of Information Management system for managing regulatory data e.g. registraion, Inspection, Pharmacovigilance,..
- Support the development of online platforms for dossier submission, reporting of safety signals or guideline consultation

3.8 Enhancing Regional Collaborationand networking towards Integration

Globally, there has been a growing trend towards increased regional multilateralism, integration, and cooperation in most sectors, including health. The scraricity of the ressources at home and pressing realities abroad necessitate a new form of foreign policy—one in which countries do not

tackle issues alone, but in strategic alliances with other like-minded. In Africa's health sector, regional bodies—such as regional economic communities and inter-governmental institutions, as well as regional professional associations and regional networks —have become active contributors to the development and health agendas during the last 10-15 years.

Established by a treaty ratified by the member states within a sub-region, a REC is the institution responsible for the planning, coordination, and monitoring of the integration or regionalization process. Their individual mandates aim at widening and deepening regional cooperation and integration among their member states and with other regional economic communities in political, economic and social areas for their mutual benefit. These processes were actively implemented since the emergence of African Medicines Regulatory Harmonization (AMRH) initiative in 2009.

Historically, The Global Fund has provided support to enhance regional collaboration and networking in Africa with different mechanisms and in various sub-regions. We will continue to work with regional economic communities towards standards harmonization; support regulatory coherence and transparency; improve infrastructure that strengthens regional regulation integration and harmonized policies and practices.

The Global Fund will support RECs to the following activities:

- Develop a regional policy, regulation and strategic plan for regulatory system
- Support organizational capacity of regional economic organizations
- Harmonization regulatory standards, norms and guidelines
- Regional human ressoucres planning including Standardized curricula on regulatory functions and establishment regional training center

3.9 Facilitating financial sustainability

Commensurate to the level of responsibilities of the National regulators, the governement must therefore allocate specific financial resources for medicines regulation. Provisions of fund must also be regular and uninterrupted to ensure oproper running of regulatory activities. Experience to date tells us that government ressources are unlikely to be sufficient for promoting effective regulation. A realistic fee system should faciliatete the path towards financial sustainability should be imposed for regulatory services provided and agency should have a power to collect them and use them. Traceability of of the usage of the funds is paramount and significant concern from manufacturers regading misues of fees. However, as per WHO guidance, total dependance on fees should be avoided.

The Global Fund supports the following interventions and activities:

- Evidence based analysis on financial sustainability of NRA including revision of fees structure.
- Support awareness campaign to governments developing rationale for increased allocation of domestic resources to regulatory activities.

3.10 Leverage convergence and reliance initiatives

Regulatory reliance refers to a sovereign authority using the work products by trusted authoritiies and reliable organizationd to inform on a regulatory decisison based on local settings considering also their own specific knowledge. The implementation of the reliance concept promoted by WHO is a great opportunity to provide immediate benefit of the expertise of more mature regulators to all members of a communicy of countries avoiding duplcation of efforts.

Operationalization of the reliance principles to other regulators within or without Regional mechanism can have a hugh impact to limit the cost of certains regulatory functions. This is in particular evident in case of testing pprdoucts where access to quality control testing activities via contratual agreement can be much cheaper than buidling and maintening a state of art quality control laboratory.

The Global Fund will support the development of infrastructure and tools to facilitate implementation of such principles.

4. Programmatic considerations

4.1 Creating lasting value

Strengthening capacity-building and the development of capabilities is a continued process and implies a step-by-step approach to provide long term impact and future sustainability. The applicant is strongly encouraged to follow a methodology such as the one described hereunder. Various tools are already existing and attuned to health sector or a specific areas of health products regulation. However, the methodology remains the same.

- Engage with stakeholders

An effective capacity building process must encourage participation by all those involved. If stakeholders are involved and share ownership in the process of development, they will feel more responsible for the outcome and sustainability of the development. Engaging stakeholder's who are directly affected by the situation allows for more effective decision-making, it also makes development work more transparent. The Global Fund and its partners use advocacy and policy advisory to better engage stakeholders.

- Evidence of baseline analysis

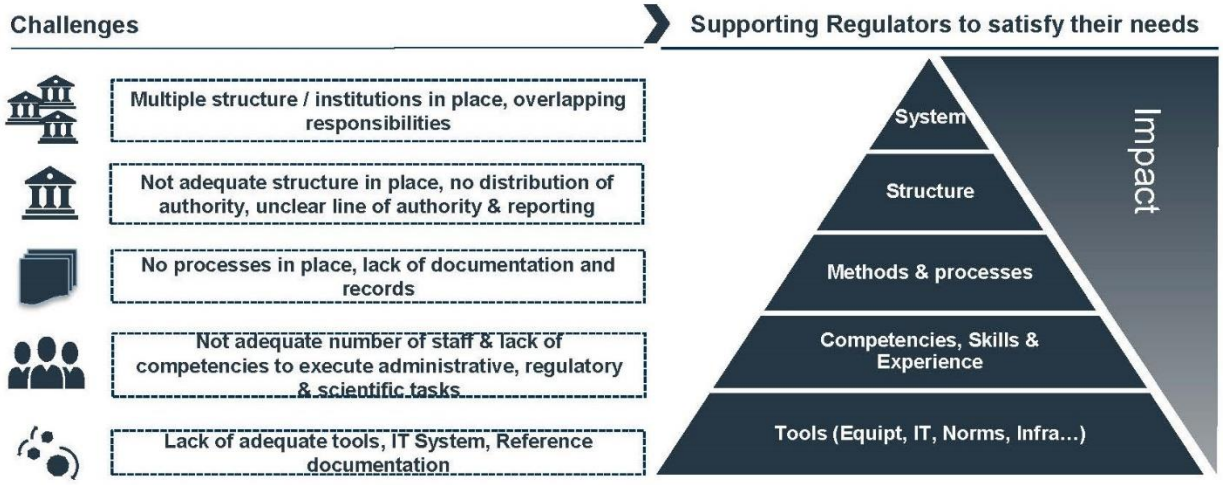
Assessing preexisting capacities allows to identify what areas require additional support, training or other interventions, what areas should be prioritized in what ways capacity building interventions supported by The Global Fund can be incorporated into local and current institutional development strategies. The Global Fund argues that capacity building that is not rooted in a comprehensive study and assessment of the preexisting situation will not ensure sustainability. The applicant should consider to what extend existing situation analysis should be considered in order to avoid duplication and endue multiplication of similar assessment. The use of existing tools which has demonstrated their efficacy should be encourage such as the World Health Organization (WHO) Global Benchmarking Tool (GBT) for regulatory systems assessment .

- Formulate a capacity development response

Once an assessment has been completed, a capacity building response under the format of an institutional development planning must be created taking into consideration a hierarchy of needs (see Figure 3). The supportive activities should consider that all areas of intervention are inter related. For bottom to up, they are easier to achieve but have less impact. While intervening and introduction practices at the highest level will bring more impact and have more chance to be sustainable.

The plan developed should make clear reference to the norms, standards or guidelines which serve as a support, milestone or objective for the activities. WHO has developed numerous guidelines in various field of regulatory systems. The critical ones are put as reference in this notice, but it was not possible to include a comprehensive list. However, other international harmonization initiative such as International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) or, International Medical Device Regulators Forum (IMDRF) are publishing specialized technical and scientific standards which should be considered as useful references.

Figure 3: Hierarchy of needs versus impact of intervention



- Implement a capacity development response

Implementing a capacity building program involves the inclusion of multiple systems; national, local, institutional. It involves continual reassessment and expect change depending on changing situations. It includes evaluative indicators to measure the effective of initiated programs.

- Monitoring & Evaluate capacity development

Evaluation of capacity building promotes accountability. Measurements is based on changes in an institutions performance. Evaluations are based on changes in performance based around the four main issues: institutional arrangements, leadership, knowledge, and accountability.

4.2 Aligning with country strategic planning

In many countries, the national Medicines policy leads to an implementation plan or master plan, which may cover a 3–5-year period. This implementation plan spells out for each component of the policy what needs to be done and who is responsible, estimates the budget requirement and proposes a rough time frame.

The master plan e.g. strategic should be broken down into annual action plans and work plans, which should be carefully developed with the various agencies involved in implementation on specific topics such as quality Assurance. The master plan facilitates monitoring and follow-up, and it is important that it is communicated to all parties involved.

The applicant is strongly encouraged to refer and integrate their plan and activities supported by the Global Fund funding within existing strategic or specific plan in line with national policy implementation including indications of any areas supported by other donors. In absence of national strategic plan, due considerations should be taken to support country to fill this gap.

4.3 Prioritization investments based on risks

The applicant should consider taking benefit of risk-based approach to implemented by regulators to analyze and strengthen medical product quality assurance systems (e.g., risk-based regulation, risk -based resources allocation systems) that increase efficiency in the allocation and use of resources. Investments priorities for strengthening regulatory systems should take into consideration the need to focus on risk-based and value-added services in view of the limited resources available.

Based on the above, the priority areas of intervention selected within the activities supported by Grant funds should be well articulated in the request.

4.4 Relationship with other areas supported by The Global Fund

Depending on the country context and existing Global Fund investments, supportive activities for strengthening regulatory system can be integrated in Resilient and Sustainable System for Health (RSSH) grant or in grant designed to support a specific disease program.

This can be the case for funds to be used to strengthen good governance, support Information Management System or support human resources within an NRA.

5. References and further readings

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