ATTACHMENT 1: DRAFT PROGRAM DESCRIPTION

I. PROGRAM DESCRIPTION

1. PURPOSE

The goal of MedQAPS is to sustainably strengthen medical product quality assurance and production systems in low- and middle-income countries (L/MICs) for improved access to quality-assured medical products[1]. To achieve this goal, medical product regulatory systems must be strengthened through regional harmonization, convergence[2], reliance[3], improved capacity of medical product regulatory authorities, efforts to sustain advanced performance, and resilience to acute shocks and prolonged stressors. Manufacturing of quality-assured essential medical products must be strategically increased through building the technical capacity and ensuring the operational sustainability of manufacturers of priority medical products. The ecosystem for responsible pharmaceutical industry needs improvement by supporting the enabling environment for the pharmaceutical sector and integrating climate risk adaptation and mitigation activities into medical product manufacturing.

MedQAPS has the following three Objectives and related Sub-objectives.

Goal: Sustainably strengthen quality assurance and production systems in L/MICs for improved access to quality-assured medical products		
Objective 1 Medical product regulatory systems strengthened	**Objective 2** Manufacturing of quality-assured essential medical products increased	**Objective 3** Ecosystem to support responsible pharmaceutical industry improved
Sub-objective 1.1: Capacity of medical product regulatory system, including national quality control laboratory, improved	**Sub-objective 2.1:** Technical capacity institutionalized across manufacturers of priority medical products	**Sub-objective 3.1:** Pharmaceutical sector enabling environment supported

[1] The term "medical products" refers to medicines, vaccines, biologics/other emerging modalities, and devices, including diagnostics and supplies, and includes both active pharmaceutical ingredients (API) and finished pharmaceutical products (FPP).

[2] Regulatory "harmonization" refers to the process by which technical guidelines are developed to be uniform across participating authorities, whereas regulatory "convergence" refers to the process of gradually aligning regulatory requirements through the adoption of internationally recognized standards and technical guidance. https://www.ncbi.nlm.nih.gov/books/NBK174226/#:~:text=PANDRH's%20approach%20more%20closely%20approximates,%2C%20standards%2C%20and%20best%20practices

[3] Regulatory "reliance" refers to the practice whereby a regulatory authority in one jurisdiction may give significant weight to work performed by another regulator in reaching its own decision. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9395591/#R1

Sub-objective 1.2: Advanced medical product regulatory system performance sustained	**Sub-objective 2.2:** Operational sustainability and commercial viability for manufacturing of quality-assured medical products enhanced	**Sub-objective 3.2:** Climate risk adaptation and mitigation activities integrated into medical product manufacturing and regulation
Sub-objective 1.3: Regional harmonization, convergence, and reliance supported		

2. BACKGROUND

Shortages of quality-assured medical products — including those required to prevent deaths and combat and control infectious diseases — are still common in many countries as well as the proliferation of poor-quality products that are ineffective, and otherwise harmful. Despite efforts by the US Government to ensure the availability of safe, effective, quality-assured medical products, the COVID-19 pandemic and extreme weather events highlighted vulnerabilities in the global health supply chain. These include an overreliance on a small number of suppliers for key active pharmaceutical ingredients (APIs), and a concentration of medical product manufacturing in Asia. However, reliable access to medical products is only part of the challenge; in L/MICs, at least one in ten medical products is estimated to be substandard[4] or falsified[5] (SF) with the true number likely much greater. Consequently, this jeopardizes the health of the public and contributes to the emergence and spread of antimicrobial resistance (AMR).[6] In addition to representing a significant public health threat, poor quality medical products waste scarce resources, undercut the market for manufacturers of quality-assured medical products, erode the public's confidence in the health system, and risk undermining past, current, and future investments.

SF medical products represent a threat to public health worldwide but pose a particular problem in developing countries. To a large extent, this is due to a lack of technical, human, institutional, and financial capacity in L/MICs to fully regulate their markets for medical products and protect their supply chains. Fewer than one third of WHO member states have well-functioning and integrated medical

[4] Also called "out of specification", these are authorized medical products that fail to meet either their quality standards or specifications, or both. Approved during the Seventieth World Health Assembly; https://www.who.int/news-room/fact-sheets/detail/substandard-and-falsified-medical-products

[5] Medical products that deliberately/fraudulently misrepresent their identity, composition or source. Approved during the Seventieth World Health Assembly; https://www.who.int/news-room/fact-sheets/detail/substandard-and-falsified-medical-products

[6] https://www.who.int/news-room/fact-sheets/detail/substandard-and-falsified-medical-products

product regulatory systems, only a few of which are in L/MICs.[7] According to the WHO, "weak regulatory capacity limits the ability of national regulatory agencies to ensure the quality, safety and efficacy of medicines and vaccines and regulate new products [... and] creates a risk that poor-quality or SF medical products enter markets."[8] This also applies to medical devices. In addition to low capacity, L/MICs are more vulnerable to climate change and are less equipped to address its impacts, which could compromise the quality of the medical products due to exposure to extreme heat or loss of reliable electricity. Also, many L/MICs import finished products and/or APIs from countries like China and India, where increased climate-driven risks such as temperature extremes could impact the active ingredients.[9]

Good quality medical products contribute to improving not only health but also productivity, economic growth, and social stability – all outcomes consistent with USAID's development goals. For example, the availability of quality-assured medical products plays a critical role in building well-governed states, in so far as quality-assured medical products promote trust and participation in health services, which in turn promote trust in government.

WHO cites the presence of SF medical products in L/MICs as one of the leading sources of inefficiency in health systems. Significant resources are wasted on inefficient and poorly defined medical product quality assurance operations, which also are chronically underfunded and understaffed. As countries move to expand coverage of essential health services as part of their commitments toward achieving Universal Health Coverage (UHC) and meeting the U.N. Sustainable Development Goals (SDGs), optimizing the allocation and use of sustainable domestic resources for the strengthening of regulatory systems and other quality assurance-related practices is critical.

The US Government (USG) and other donors make considerable investments to assure the quality medical products are donated to country health programs. USAID and other global agencies are actively pursuing ways to procure more products from local sources while continuing to assure their quality. This goal requires reliable manufacturing practices, and a strong regulatory system anchored by a functional independent national regulatory authority.

Although USAID has been involved in strengthening medical product quality assurance systems in L/MICs, including systems for local production, since the mid-2000s, recent evidence is drawing attention to new challenges. For example, the production of lifesaving medical products (e.g. for HIV, tuberculosis, and malaria) is contributing to climate change as the energy needed to produce raw materials and final products produces large amounts of emissions.[10] However, innovative interventions can improve manufacturing processes and facilitate a shift to renewable energy sources that not only reduce carbon emissions but do so at no additional cost.[11]

As the demand and need for access to quality-assured medical products increases, focused technical assistance to manufacturers and regulatory authorities to ensure the quality, safety, and efficacy of these products becomes even more critical. This is especially true for USAID-supported countries pursuing ambitious plans toward UHC with less mature regulatory systems. As such, MedQAPS represents an

[7] https://joppp.biomedcentral.com/articles/10.1186/s40545-021-00299-7
[8] http://apps.who.int/gb/ebwha/pdf_files/EB142/B142_13-en.pdf
[9] https://unitaid.org/assets/Report_From-milligrams-to-megatons_A-climate-and-nature-assessment-of-ten-key-health-products.pdf
[10] Ibid.
[11] Ibid.

enhancement in strengthening technical assistance for medical product quality assurance systems supporting countries and regions in their efforts to build resilient, high-performing health systems. In response to high-level concern regarding global health supply chain vulnerabilities; the increased evidence of SF medical products in L/MICs; and the need to ensure continuity of access to quality-assured medical products during times of routine service provision and times of crises or emergencies, MedQAPS is designed to work across three interrelated and complementary objectives. These objectives aim to sustainably strengthen quality assurance and production systems in L/MICs for improved access to quality-assured medical products.

3. FOCUS AREAS AND RESULTS

3a. **Objective 1: Medical product regulatory systems strengthened**

Functional regulatory systems that ensure health commodity safety, quality, and efficacy are essential to self-reliant supply chains, high-performing healthcare and public health programs, as well as healthy commodity markets in both the public and private sectors. The efficiency and quality of regulatory work has a direct impact on the speed with which needed products are made available to the supply chain and information is made available to providers and the public regarding appropriate use. Critical resource efficiencies are gained through reliance, collaboration, and capacity strengthening among regulatory authorities, for example through regional regulatory harmonization efforts.

Functional regulatory systems are equally essential for protecting the public from the harms of SF products. While the supply of SF medical products is a global challenge, "the populations most vulnerable are those in countries who do not have the facilities or the regulatory authorities to regulate and police the drug supply."[12] According to WHO, in many L/MICs, national regulatory authorities "are often overburdened and under-staffed, with fragmented structures or insufficient legal frameworks systems which may be difficult to reform."[13] Furthermore, regulatory systems that do not function optimally can be a barrier to trade (e.g., due to longer than necessary lead times for registration decisions, delays in quality-assurance testing), further limiting access to quality-assured products and disincentivizing entrants to the market, whether domestic manufacturers or importers.

As mandated by World Health Assembly Resolution 67.20 on regulatory system strengthening for medical products[14], WHO's Global Benchmarking Tools (GBT) for evaluation of national regulatory systems are the globally recognized standard for objectively assessing the maturity of regulatory systems for medicines and vaccines, medical devices[15], and blood products. The GBT process allows countries to identify

[12] https://www.ndm.ox.ac.uk/paul-newton-poor-quality-medicines

[13] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7466745/

[14] https://apps.who.int/gb/ebwha/pdf_files/WHA67/A67_R20-en.pdf

[15] The WHO Global Benchmarking Tool + Medical Devices (GBT+MD) for evaluation of national regulatory systems of medical devices including in-vitro diagnostics is undergoing significant revision

strengths and gaps within the various regulatory functions[16], assign a corresponding maturity level (ML)[17], and facilitate coordinated, complementary efforts to address identified gaps through a single institutional development plan, thereby prioritizing areas of strategic support and investment, avoiding duplication of effort, and leveraging available resources. USAID works in concert with countries, regional bodies, and other donors and development partners to facilitate coordinated L/MIC regulatory systems strengthening, including through support for the GBT.

In 2021, WHO introduced a separate but related regulatory performance evaluation framework used by WHO to designate countries as a WHO Listed Authority (WLA). Whereas the GBT benchmarks static *capacity* by maturity level, WHO uses the WLA evaluation framework to measure regulatory *performance* in terms of how the regulatory system operates "through an extended set of measurements targeting key regulatory outputs and consistent adherence to international standards and good regulatory practices."[18]

USAID aligns its regulatory technical assistance (TA) activities with, and builds upon, WHO regulatory benchmark indicators as described in the WHO GBT, and related country regulatory institutional development plans, as well as country efforts to attain WLA designation, and related international standards and best practices (e.g., ICH, IMDRF, PIC/S, ISO17025).

In complement, USAID recognizes that not all cross-cutting operational areas of regulatory TA are explicitly addressed in WHO's GBT or WLA framework, for example comprehensive or transparent regulatory information management systems (IMS), budgeting and financing for regulatory functions, aspects of resilience in times of crisis or emergency, and engagement of multisectoral actors with a direct or indirect impact on medical product quality assurance. USAID considers such areas as additionally important to identify and support through TA, in alignment with the WHO GBT and/or WLA performance evaluation framework.

Sub-objective 1.1: Capacity of medical product regulatory system, including national quality control laboratory, improved

To fulfill the mandate of controlling the quality, safety, and efficacy of the medical products circulating within national markets and exported across borders, functional regulatory systems must conduct various regulatory functions and operate with well-governed and efficient institutions with skilled staff, information systems and data transparency, and sufficient financial resources. Core regulatory functional areas include: clinical trial oversight, registration, licensing, inspection, post-marketing surveillance [product quality], laboratory testing, vigilance [patient safety], advertising and promotion control, and lot

[16] Registration and Marketing Authorization (MA), Vigilance (Vl), Market Surveillance and Control (MC), Licensing Establishments (LI), Regulatory Inspection (RI), Laboratory Testing (LT), Clinical Trials Oversight (CT), and Lot Release (LR).
[17] The GBT uses the concept of 'maturity level' or (ML) to assess the overall maturity of the regulatory system on a scale of 1 (signaling the existence of some elements of a regulatory system) to 4 (operating at advanced level of performance and continuous improvement), with many L/MICs aiming to reach ML3, indicating a stable, well-functioning and integrated regulatory system.
[18] https://www.who.int/initiatives/who-listed-authority-reg-authorities

release [for biologics], underpinned by a sound regulatory framework of laws and policies aligned with international and/or regional standards.

USAID strengthens medical product regulation by engaging at the country, regional, and global level with regulatory authorities, regulatory networks and harmonization efforts, and other stakeholders. USAID will expect applicants to adapt proposed tools and approaches to enhance existing systems while taking into account current capabilities and local and regional contexts. Additionally, USAID will expect applicants to include integration of the private sector and local stakeholders in the process for developing locally-relevant strategies for strengthening regulatory capacity development.

Core Regulatory Functions

Regulatory framework and governance

Country medical product regulatory systems require that roles, responsibilities, and relationships be specified in laws, policies, regulations, and standard operating procedures (SOPs) to codify lines of authority and accountability. Legislation supports implementation of national medicines policies and includes provisions for the establishment of national regulatory agencies responsible for assuring that only medical products meeting acceptable standards for quality, safety, and efficacy are registered and available in a country. Many countries lack adequate regulation regarding manufacturing of medical products (including medical devices and biologics), clinical trial oversight, post-marketing surveillance, and many other regulatory functions. Poor governance can occur within medical product quality assurance operations (e.g., product registration/pre-marketing authorization, procurement/payment decisions that fail to account for quality, product quality testing decisions and information sharing) and in the legislation and regulation of medical products. Efforts of countries and international stakeholders to combat SF medical products will continue to be hindered if data on the true extent of the problem are not available.[19] To be effective, laws and regulations should also set out legal sanctions that allow for transparent and appropriate enforcement actions.

Illustrative activities include:

- Working with host country, local and regional stakeholders to identify and undertake needed legal, policy, regulatory, and other governance reforms in the medical product quality assurance arena.
- Supporting countries to increase transparency and accountability throughout medical product quality assurance systems, including structures for data collection and dissemination and mechanisms for oversight and enforcement, particularly as interventions are designed and implemented.

Clinical trial oversight

[19] https://www.nap.edu/catalog/18272/countering-the-problem-of-falsified-and-substandard-drugs

Regulatory capacity to oversee the scientifically-rigorous and ethical conduct of clinical trials is an essential part of bringing products to market and ensuring their safety and efficacy, including for specific populations such as pregnant and nursing women, children, and the elderly. This includes for products developed and tested in one region and submitted for authorization in another, particularly where significant genetic differences occur. For certain high-risk products or for products authorized for use on an emergency basis, additional clinical trials to further establish safety and efficacy after the product is authorized for use (Phase IV studies) may be required and regulators need to have appropriate procedures in place to determine when this is needed and when the requirements have been satisfied.

Illustrative activities include:

- Supporting country regulators and regional networks to improve regulatory capacity for clinical trial oversight.

Market Authorization / Registration

Common challenges that L/MIC NMRAs face in executing the market authorization function include delayed registration decision times and publication of product assessment reports; skilled staffing shortages particularly for review of complex products; lack of clear national legal provisions and documented processes; absence of reliance mechanisms and/or procedures for timely national registration following joint review; lack of transparency and accountability to industry for timely reviews. Many NMRAs lack procedures for expedited review and emergency use authorization decisions for products needed in a health emergency, including stringent safety, quality, and efficacy monitoring and reassessment of the risk-benefit determination.

Illustrative activities include:

- Supporting NMRAs to improve and streamline systems for market authorization, both for simple and complex products, to ensure the establishment of a consistent, transparent, and efficient review process leading to timely decisions regarding approval of safe, effective, and quality-assured medical products. This includes setting appropriate pre- and post-marketing requirements, formal reliance arrangements to facilitate joint reviews among NMRAs, and ensuring NMRAs can execute emergency use authorization procedures when appropriate, including guidance for providers.

Furthermore, regulators need to control claims made by manufacturers and others about approved medical products and ensure alignment with the production information approved by the regulatory authority (i.e., summary of product characteristics, product label). This is a challenge in L/MICs where laws and procedures to control advertising and promotion may be limited, allowing false or misleading information to reach providers and the public.

Illustrative activities include:

- Strengthening L/MIC regulatory capacity for the control of promotion, marketing, and advertising of medical products, including effective engagement with industry and the public to promote compliance and address unapproved claims.

Licensing and Inspection

The licensing of manufacturing establishments and the periodic inspection of those establishments to ensure compliance with current Good Manufacturing Practice (GMP) is critical to ensuring that producers meet quality standards and that those failing to meet best practices are identified and informed of their deficiencies and/or removed from the market. In some countries, the regulatory authority also oversees pharmacy practices and the licensing of pharmacy establishments. Skilled staff as well as sound governance procedures are needed to execute these regulatory functions and avoid vulnerabilities to corruption.

Illustrative activities include:

- Strengthening national regulation systems and regional collaboration to apply rigorous licensing and inspection practices that introduce reliance and cooperation, transparency and accountability, and application of risk-based methods to ensure compliance.

Post-marketing surveillance [product quality]

Regulatory systems in many USAID-supported countries are hindered by vertical, donor-dependent, fragmented, and/or under-resourced post-marketing surveillance (PMS) and laboratory systems for quality testing. Surveilling the quality of medical products on the market is an essential function of a regulatory system both within the public and private sectors among donated, imported, and locally-produced products, from the manufacturing facility and to point of use. While recognizing limitations in resources, international best practices encourage the use of risk-based approaches in the implementation of various regulatory functions, including PMS.

Illustrative activities include:

- Supporting countries to develop sustainable, integrated post-marketing surveillance systems to routinely monitor for product quality, identify SF medical products, and enable appropriate and effective regulatory action against these products.
- Supporting countries to deploy a risk-based PMS approach effectively using limited resources by allowing national regulatory authorities to target sampling activities to geographic areas and outlets that are most vulnerable and to prioritize medical products that represent the greatest risk to the patient.
- As an intermediate step toward sustainable PMS, supporting monitoring the quality of specific medical products such as for disease control programs on a short-term basis to demonstrate and raise awareness of quality issues where they exist and make the case for routine post-marketing surveillance including all product categories. This may include product quality testing on an ad hoc basis (e.g., within a particular locality, provider or drug outlet, national disease program, or

specific product category such as those for use in animals). However, the applicant should note that USAID employs other mechanisms to routinely test for the quality of products donated by USAID to host countries and it is not intended for MedQAPS to engage in quality testing for such purposes.

Laboratory Testing

A fully functional medicines regulatory system includes quality testing capabilities both for initial screening and for advanced laboratory testing to detect SF products. The use of screening technologies, including portable analytical devices used to detect SF products, provides an initial indication about the quality of products and flags potential problems requiring confirmatory product testing. Compendial testing in laboratories that are ISO 17025 accredited and/or WHO prequalified meet international standards and provide results about product quality that are reliable and can be used as the basis for regulatory actions.

Illustrative activities include:

- Assisting countries to develop appropriate, integrated screening and laboratory testing scheme(s) to support both pre-marketing authorization and post-marketing surveillance for domestically-produced and/or imported products that meet international standards and are operationally and financially sustainable.

Vigilance [patient safety]

All medical products have the potential to cause harm. Prior to market authorization, regulators are responsible for reviewing clinical trial data and determining whether the benefits (efficacy) of the product outweigh potential risks, and whether post-market safety studies are required. Once the product is authorized for use, regulators must collect, analyze, and communicate safety information in culturally relevant ways, while taking appropriate regulatory action to ensure patient safety.

Illustrative activities include:

- Strengthening national regulatory authority capacity for safety monitoring (aka vigilance/pharmacovigilance) for medicines, vaccines, and/or medical devices, in alignment with international standards and approaches.

NOTE: It is intended that the applicant work on the regulatory aspects of pharmacovigilance *only* and NOT intended for the applicant to work on improving vigilance practices among providers at the service delivery level. This is covered by other USAID mechanisms.

Lot release [for biologics]

Lot release is a regulatory function that additionally ensures the quality, safety and efficacy of biological products through additional regulatory release procedures, taking into account the inherent variability of

biological products; this regulatory function does not apply to all products. The lot release function is needed for countries that wish to be certified by WHO as maturity level 3 or 4 for vaccine production.

Illustrative activities include:

- Supporting national regulatory authorities to strengthen their capacity for lot release of relevant products, including through tapping into capacity strengthening and collaboration efforts at a regional level.

Cross-Cutting Regulatory Capacities

In addition, there are multiple operational elements that must be in place in order for medical product regulatory systems to function effectively and sustainably, including, but not limited to a skilled workforce, adequate financing, functional regulatory information management systems, and effective engagement with industry and local stakeholders.

Human resources

A country's medical product quality assurance system requires an adequate number of skilled staff capable of managing the key functions of the regulatory system, as well as other members of the pharmaceutical workforce with medical product quality assurance requirements (e.g., those that work in manufacturing, procurement, and supply chain). The pharmaceutical workforce, including quality assurance professionals (e.g., regulatory affairs professionals, quality control specialists, and laboratory personnel), is a critical part of the health system but is frequently overlooked, including in health sector workforce strategic planning. Training programs within educational institutions may be deficient and not linked to workforce demand and to operational needs of the regulatory system. Efforts to optimize the performance of the pharmaceutical workforce should consider not only staffing and skills, but also working conditions and motivation, collecting and incorporating feedback from members of the pharmaceutical workforce.

Illustrative activities include:

- Seeking opportunities to sustainably increase the competence and efficiency of quality control, regulatory, and laboratory personnel at the national and regional levels, including through identification of opportunities to outsource select regulatory functions as appropriate.
- Seeking to work with educational and training institutions to sustainably improve their capability and/or undertake reforms to produce a qualified workforce responsive to demand to address the needs of the country's medical product quality assurance systems.
- Engaging with professional associations and/or accreditation efforts to establish appropriate standards of practice and continuing education programs.
- Supporting government and industry to design and operationalize effective human resource practices and training programs.

Financing for regulatory system

National regulatory authorities require support for analysis of investments (e.g., costing of medical product quality assurance operations within laboratory, market authorization/approval, licensing, and surveillance units), use of risk-based approaches to inform and prioritize medical product quality assurance systems improvements in line with internally-accepted best practices (e.g., as identified through implementation of the WHO GBT), resource mobilization, financial management and planning, and consideration of reliance and work sharing through regional harmonization efforts. Efforts to sustainably strengthen medical product quality assurance systems should ensure that waste is reduced and efficiencies are introduced in the allocation and use of resources for medical product quality assurance operations.

Illustrative activities include:

- Supporting NMRAs to draw upon international experience and best practices to adopt sustainable approaches to mobilize and use resources (e.g., regular budget allocations, monitoring of timely budget executions) and introduce appropriate cost-recovery approaches that are reinvested in the regulatory system (e.g., product application fees, drug quality laboratory testing fees).

Regulatory Information Management Systems

Fragmented information systems generate data that is not connected, coherent, and/or interoperable, and is not standardized. The information flow does not enable decision making that is evidence-based, timely, transparent, and accountable and inhibits the efficiency of operations. Even when there is adoption of international standards, they are not necessarily implemented. For country regulatory information management systems (RIMS) to be effective, adoption of and compliance with international standards is required. Such information systems support the mutual reliance of various actors within the regulatory system as well as between country regulators.

Illustrative activities include:

- Promoting the linkage and interoperability of regulatory and other quality assurance-related information systems, building on USAID's investments to develop a set of minimum common standards to support digitization of RIMS across each of the nine GBT regulatory functions identified, allowing for information sharing, data aggregation, coordination of efforts, work sharing, and improved regulatory practices.

Engagement with Industry

Regulatory systems benefit from some level of engagement with industry, such that rules and regulations are clearly understood and accessible (e.g., up-to-date and publicly available industry guidelines, constructive pre-submission meetings between the regulator and the manufacturer), that fair and transparent pathways exist for industry voice to inform aspects of the regulatory system (e.g., public comment periods on relevant proposed regulatory reforms), and that procedures are in place for industry

to hold the regulatory authority accountable (e.g., to timelines set for registration decisions), while avoiding bias and/or undue influence (including outright corruption) related to any one manufacturer or group of manufacturers.

Illustrative activities include:

- Supporting the regulatory authorities' formal policies and procedures for effectively engaging with industry to increase regulatory compliance, inform regulatory reforms, and receive regulatory decisions/responses within predictable timelines, while maintaining a level, inclusive playing field and avoiding undue influence and corruption.

Sub-objective 1.2: Advanced medical product regulatory system performance sustained

Achievement of WHO GBT Maturity Level 3 for medicines, vaccines, medical devices, and/or blood product regulation and other international standards such as ISO accreditation and/or WHO Prequalification of National Quality Control Laboratories (NQCLs) is a substantial milestone for a regulatory authority and a reflection of advanced regulatory capacity. Many L/MICs are actively working to reach these capacity levels, and some countries receive substantial donor support (technical and/or financial) to achieve these designations. Once attained, reassessment is required to ensure capacity is maintained at this level.

Illustrative activities include:

- Supporting countries that have achieved WHO ML3, ISO accreditation and/or WHO prequalification for their NQCLs, or other similar designations to sustain their capacity gains such that reassessments are successful.

As USAID and other global procurers as well as procurement units in country look to increasingly rely on quality products produced in L/MICs, the WHO's WLA designation offers an important indication of regulatory systems that are consistently and reliably performing with advanced capacity and in doing so, assuring the quality of products in their markets.

Illustrative activities include:

- Supporting countries to demonstrate and maintain advanced regulatory performance through achievement of the WLA designation based on WHO's evaluation framework.

Sub-objective 1.3: Regional harmonization, convergence, and reliance supported

WHO and others recognize that L/MIC medical product regulatory systems operate in under-resourced environments, requiring prioritization of efforts and solutions to gain efficiencies in their work to ensure they can meet their public health mandate. Regional harmonization and/or convergence of regulatory requirements (e.g., application of model laws, use of common technical documents) and coordination of regulatory processes (e.g., joint dossier reviews, collaborative registration procedures, regional post-marketing quality surveillance, Good Manufacturing Practices (GMP) inspections) among countries are

promising approaches to introduce efficiencies in the regulatory process, establish platforms to improve regulatory capacity, avoid unnecessary duplication of efforts, and reduce the cost and uncertainty of market entry for producers, accelerating access to quality, safe, and effective health commodities and promoting their appropriate use.

USAID's partnerships with regional institutions and networks, such as the Association of Southeast Asian Nations (ASEAN), the Southeast Asian Regulatory Network (SEARN), and AUDA-NEPAD's African Medicines Regulatory Harmonization Initiative (AMRH), aim to improve collaboration among NMRAs and across regions, supporting NMRAs to converge technical approaches and guidelines for medicines regulation and reliance and to adopt international and regionally-endorsed standards. This can speed up the introduction of quality-assured, safe, and effective medical products into the market, thereby promoting greater access and improving practices for ongoing safety and quality monitoring across borders and populations.

In Africa, the AMRH initiative has made progress in regional regulatory harmonization efforts, such as the development of the AU Model Law on Medical Products Regulation and many other accomplishments.[20] AMRH is implemented by NMRAs through Medicines Regulatory Harmonization (MRH) programs in six Regional Economic Communities (RECs)[21], eleven Regional Centres of Regulatory Excellence (RCoREs)[22], and various Technical Committees[23] to facilitate information sharing, capacity strengthening, and dissemination of best practices among NMRAs in Africa. The existing AMRH structures are planned to be transferred to the African Medicines Agency (AMA), once operational. The AMA has both continental level aims as well as plans for engaging with country national medicines regulatory authorities to provide technical guidance, reduce duplicative efforts, and ensure cost-effective use of limited resources.

In Asia, several forums support regional efforts for strengthening regulatory and quality assurance systems, including the South-East Asia Regulatory Network (SEARN)[24] and the Association of Southeast Asian Nations (ASEAN)[25]. SEARN aims to build capacity of NMRAs by developing and strengthening regulatory collaboration, convergence, and reliance in the South-East Asia region. Despite the different levels of maturity among NMRAs in SEARN, significant progress has been made by some member countries to strengthen the capacity of their NMRA. ASEAN's Pharmaceutical Product Working Group (PPWG) has similarly supported regional regulatory harmonization efforts, such as the introduction of the ASEAN Common Technical Dossier[26], among many other accomplishments.

Illustrative activities include:

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[20] https://www.nepad.org/publication/au-model-law-medical-products-regulation

[21] https://amrh.nepad.org/amrh-recs

[22] https://amrh.nepad.org/regional-centres-of-regulatory-excellence-rcores

[23] https://amrh.nepad.org/amrh-microsite/our-focus#amrh_technical_committees

[24] SEARN includes Bangladesh, Bhutan, Democratic People's Republic of Korea, India, Indonesia, Maldives, Myanmar, Nepal, Sri Lanka, Thailand, and Timor-Leste.

[25] ASEAN includes Brunei, Cambodia, Indonesia, Laos, Malaysia, Myanmar, Philippines, Singapore, Thailand, and Vietnam.

[26] https://asean.org/book/asean-common-technical-dossier/

- Supporting L/MIC regional regulatory harmonization, convergence, and/or reliance efforts within and across regions, through both formal and informal channels, aided by the adoption of common standards and procedures. This may include providing support to countries for the joint registration of medical products, for example through the WHO Collaborative Registration Procedure.[27]

Within the area of medical product quality assurance, countries are additionally challenged to tackle the movement of poor-quality products (e.g., unregistered, SF) across borders and cross-country collaboration is required.

Illustrative activities include:

- Supporting countries to share standardized information on SF products, rely on/use information from other countries for appropriate regulatory actions, and collaborate with regional and/or international efforts such as the WHO Global Surveillance and Monitoring System or other networks.

Furthermore, regulatory and manufacturing expert "hubs" or technical networks, including those set up within academic settings or professional associations not formally a part of regulatory harmonization initiatives, can serve a critical role in building up the skills and opportunities for technical exchanges among regulators as well as within the industry workforce.

Illustrative activities include:

- Identifying promising regulatory and industry hubs and/or networks as centers of technical expertise and support such entities to become sustainable providers of technical assistance within and among USAID-priority countries.

Objective 2: Manufacturing of quality-assured essential medical products increased

By building manufacturing capacity closer to where the supply is needed and supporting markets in USAID partner countries to become more competitive, countries can ensure a reliable and uninterrupted supply of life-saving commodities, continued progress toward epidemic control, and adequate preparedness for eventual pandemics.

Much of the world relies on APIs manufactured in Asia[28], and on imported FPPs to meet their public health needs. Therefore, they are at the mercy of the price setting strategies of the producing countries, which may not be feasible for L/MICs, and these costs are often transferred to the patient and linked to high out-of-pocket expenditures. In many Sub-Saharan African countries, 70-90% of drugs consumed are imported into a "highly fragmented landscape of distributors, wholesalers, and retailers, who all add their

[27] https://extranet.who.int/prequal/medicines/collaborative-procedure-accelerated-registration

[28] https://www.mckinsey.com/~/media/mckinsey/dotcom/client_service/Pharma%20and%20Medical%20Products/PMP%20NEW/PDFs/778886_India_Pharma_2020_Propelling_Access_and_Acceptance_Realising_True_Potential.ashx

individual markups to the product…. In addition to raising the price of drugs, this system also has the effect of compromising quality assurance, since each additional step creates the potential for improper storage, tampering, or delay, even as drugs near their expiration dates."[29] Such reliance on a limited geographic source makes L/MICs vulnerable to shortages, potential quality issues, and supply chain disruption. Sub-Saharan African countries in particular face a high burden of disease, such as HIV and malaria, for which medicines are nearly entirely procured from generic manufacturers in Asia despite significant demand and market opportunities in Africa. Furthermore, manufacturing practices and quality requirements for less well-regulated markets are often less rigorous than for markets such as the United States.

Having a diversified supply base for essential medicines, vaccines, diagnostics, and medical supplies (such as PPE) is critical for meeting the public health challenges of today and responding to the pandemics and health needs of the future. In line with the Agency's commitment to localize its investments across our development programs[30] and support meaningful engagement with the private sector[31], USAID endeavors to support strategic local and regional manufacturing of safe and effective medical products in L/MICs to diversify the supply base and promote greater access to quality-assured medicines and health products that are closer to the end-user, and potentially more affordable for them and more economical for the country. This includes building the technical capacity of manufacturers of priority medical products and supporting their operational sustainability and commercial viability. Strategic support for local and regional manufacturing of medical products may also align with the Agency's commitment to reduce greenhouse gas emissions[32] by helping to reduce shipping distance of medical products.

Sub-objective 2.1: Technical capacity institutionalized across manufacturers of priority medical products

Various factors influence whether manufacturers of medical products can meet the international standards required to produce quality-assured essential medical products for domestic and global markets. The WHO Prequalification Program is considered a standard for prequalification of some, but not all, priority medical products by many international agencies and requires manufacturers to meet defined standards of acceptable quality, safety, and efficacy for their products to become prequalified. USAID has played a part in helping manufacturers in partner countries meet these standards, by providing technical assistance in the areas of GMPs, quality management systems, bioavailability/bioequivalence (BA/BE) studies, and technology transfers. It is anticipated for this type of support to be continued under MedQAPS. Furthermore, as countries improve their regulatory systems and introduce more rigorous quality requirements for domestic production and exports, manufacturers will need to meet these standards.

[29] https://www.mckinsey.com/industries/public-sector/our-insights/should-sub-saharan-africa-make-its-own-drugs
[30] https://www.usaid.gov/sites/default/files/2022-12/USAIDs_Localization_Vision-508.pdf
[31] https://www.usaid.gov/sites/default/files/2022-05/usaid_psepolicy_final.pdf
[32] https://www.usaid.gov/policy/climate-strategy

Illustrative activities include:

- Supporting selected manufacturers of medical products to comply with GMPs as defined by national and/or internationally accepted standards.
- Providing assistance in the preparation of dossiers required for national registration and/or pre-qualification at the international level for essential medicines and health technologies for country health systems and of priority to USAID health programs.

To obtain market authorization, including in L/MICs, BA/BE studies are frequently required to demonstrate therapeutic equivalence for generic products. Because BA/BE studies only approximate larger clinical trials conducted on the innovator product that established safety and efficacy, it is critical that BA/BE studies are conducted appropriately and their results are reliable,[33] whether by a contract research organization (CRO) or the manufacturer itself. This is particularly needed in L/MIC settings with limited regulatory capacity.

Illustrative activities include:

- Improving the capacity of CROs and/or manufacturers to conduct BA/BE studies where relevant for priority health products.

Innovation and advances in technology (e.g., continuous manufacturing, robotic technology, GS1, and AI) have led to more cost-effective and efficient manufacturing approaches, which improve drug quality, address shortages of medicines, and increase time-to-market speed. Advanced manufacturing technologies (AMTs) include innovative technologies and processes which have the potential to further advance domestic manufacturing by improving efficiencies and lowering overall production costs.[34] There is also new emphasis on achieving climate targets set by countries and the pharmaceutical industry, by reducing greenhouse gas emissions during medical product manufacturing through improved sourcing of energy and raw materials. USAID partner countries where domestic manufacturing is nascent may be well positioned to adopt such innovations and technologies, leapfrogging current manufacturing methods to adopt new hybrid approaches and cutting-edge technologies.

Illustrative activities include:

- Working within the local and/or regional context to explore and implement viable AMTs where and when appropriate.
- Supporting manufacturers of medical products to identify opportunities to reduce environmental and climate impact.

Sub-objective 2.2: Operational sustainability and commercial viability for manufacturing of quality assured medical products enhanced

A number of USAID-priority countries are developing local pharmaceutical industries with two main aims:

[33] https://www.who.int/publications/m/item/annex-9-trs-966

[34] https://www.marketlinks.org/blogs/opportunities-advanced-manufacturing-technologies-local-production-health-commodities

public health security and economic growth. The manufacturers in these countries face challenges both reaching country and international quality standards as well as competing in the local and global pharmaceutical market. This is compounded when markets for quality-assured medical products are undercut by SF medical products.

Increasing regional or local production will not increase local access to medical products by itself. Building sustained manufacturing capacity requires manufacturers to focus not only on increasing production (the supply side) but also on demand and enabling environmental factors (i.e., trade, regulation, policy context). When not functioning optimally, these factors hinder the development and integration of the pharmaceutical sector in global/regional trade and overcoming them requires that cost-effective incentives be defined and put in place. Investments in local and/or regional production should always involve the selection of the appropriate product, a realistic look at the timeline for bringing product to market, and whether sufficient demand will exist relative to the global supply at that time to support commercial viability.

The most impactful investments serve not only country but also regional markets and ensure that supply meets demand to ensure commercial viability. As such, a careful and comprehensive analysis of business and market opportunities, support which MedQAPS is anticipated to be able to provide, is critical for minimizing risk and ensuring the sustainable manufacturing of critical medical commodities. This includes the selection of the appropriate products based on the market, engaging with both the public and private sector, including relevant health sector entities, regulators, and end-users, to gauge current and future demand, and developing a contingency plan to adapt to market changes. Strategies may also include market diversification, such as geographic expansion and extending the product line, to support operational sustainability and potential growth of the manufacturer. Finally, supporting industry collaboration and strategic partnerships, including those with financial institutions, is key to facilitating market entry, mitigating risk and ensuring sustainability. Raw material needs and constraints also need attention and investment.

Illustrative activities include:

- Supporting manufacturers to identify, prioritize and implement strategies that will position them for success in a competitive and ever-changing landscape. This may include supporting them to understand the local and global market potential for priority medical product(s), identify any market barriers that exist, including informational barriers whenever pharmaceutical market data are missing, and prioritize solutions using relevant models that meet international best practices.

Objective 3: Ecosystem to support responsible pharmaceutical industry improved

Enhancing reliable, equitable access to quality-assured medical products is key to building resilient health systems globally. Investing in manufacturing in L/MIC markets and the supporting systems and infrastructure required for production of quality-assured products can help strengthen local/regional economies and protect public health. Any efforts to diversify or scale-up manufacturing of health products, requires development of a sustainable ecosystem at the national, regional, and global levels.

Technical leadership and engagement with global, regional, and country stakeholders is essential to moving the agenda for local and/or regional production forward, given the sizable and growing pharmaceutical markets for both imported and locally produced products in L/MICs, plans to expand coverage of health services and products, and recognition that poor quality medical products contribute to the emergence and spread of AMR. National and international investments for increasing and strengthening the capacity for local and/or regional manufacturing of quality-assured products must be strategic, market-based, and carried out with multi-sectoral coordination. This includes supporting the creation of a conducive enabling environment and an enhanced focus on climate risk adaptation and mitigation in medical product manufacturing.

Sub-objective 3.1: Pharmaceutical sector enabling environment supported

Pharmaceutical industries require supportive enabling environments to ensure products reach the market in a timely manner and are safe, effective, consistent, of high-quality, and available when and where needed. In addition to the regulatory system, the pharmaceutical sector enabling environment - sometimes referred to as the "manufacturing ecosystem" - includes elements such as: institutionalized governance structures and policies, innovative solutions to improve business intelligence, supportive procurement policies that foster quality and sustainable industry, affordable and sustainable financing, incentives, market information/analysis, collaboration between sectors, and structures aligned with demand.

Medical product quality assurance is a complex domain that brings to the fore political sensitivities among national policy makers and also directly affects economic interests. Governance structures supporting medical product quality assurance systems must be flexible to adapt to contextual changes such as increased volume of local production, development of relationships with regional economic communities, introduction of new medicines and other health technologies, and need for multi-sectoral collaboration to combat criminal activities related to falsified medical products and to address the product quality drivers of AMR.

L/MICs are making substantial investments in the growth of their pharmaceutical industries, requiring intervention both within and external to medical product quality assurance systems to ensure alignment and success. Regulators and other stakeholders in the medical product quality assurance systems are challenged to collaborate with other sectors including law enforcement, education, customs (e.g., ensuring only registered medical products enter the country and that customs procedures do not compromise product quality), finance (e.g., budget allocations, public financial management, tax incentives), agriculture (e.g., quality-assurance of products for use in animals), and economic development (e.g., pharmaceutical industrial development plans, business enabling environment). Countries' trade commitments or obligations also have a bearing on national regulatory authorities, which have responsibility for developing standard operating procedures (SOPs) that codify these trade obligations within the regulatory framework.

Illustrative activities include:

- Supporting countries to increase transparency and accountability throughout medical product quality assurance and production systems, including mechanisms for oversight and enforcement. Identify opportunities to support stakeholders in the medical product quality assurance system to effectively engage with other sectors.
- Identifying country policies related to reliance and utilization of international best practices and/or regional or bilateral trade agreements and supporting country implementation of international standards and alignment of domestic standards with regional/international standards.
- Identifying country gaps in compliance with international trade commitments as related to regulation of medical products, including those related to Good Regulatory Practices and technical barriers to trade.

National or regional pharmaceutical sector strategies can support efforts to create a conducive enabling environment, develop the workforce, strengthen the national regulatory authority, and identify partnership opportunities, including for technology transfers. Governments may also introduce supportive procurement policies and incentives to foster quality and sustainable industry by setting aside a portion of tenders for local manufacturers and/or offering preferential pricing for local manufacturers in public tenders, helping ensure that local manufacturers maintain quality standards while producing medicines efficiently.

The pharmaceutical sector along with collaboration from governments are employing various strategies such as public-private partnerships, subsidies and price controls, and innovative financing mechanisms like health bonds or funds, to bolster affordable and sustainable financing in L/MICs. Additionally, initiatives such as pooled procurement and technology transfers can be promoted to enhance access to essential quality medicines while keeping costs manageable.

Illustrative activities include:

- Supporting the development of national or regional pharmaceutical sector strategies.
- Working with host country and regional stakeholders to identify and undertake needed legal, policy, regulatory, and other governance reforms to support the pharmaceutical sector enabling environment.

Sub-objective 3.2: Climate risk adaptation and mitigation activities integrated into medical product manufacturing and regulation

As pharmaceutical industries continue to expand, they should aim to do so in a way that is climate smart and minimizes damage to the environment. Manufacturers of medical products in L/MICs often face production challenges such as a lack of reliable and renewable energy supplies and options for ecologically friendly treatment of pharmaceutical waste, causing negative environmental impacts. When coupled with weak regulations, L/MICs often face relatively higher environmental risks and generate an outsized contribution to climate change from their pharmaceutical sector. There is a need to further

develop and utilize the existing evidence base to address current impacts of medical product manufacturing on climate change.

Illustrative activities include:

- Assessing and addressing environmental risks and climate impacts related to medical product manufacturing, including regulatory aspects.
- Strengthening regulation and compliance with country policies to meet climate adaptation or mitigation targets where relevant, including effectively tracking, monitoring, reporting, and reducing greenhouse gas emissions of medical product manufacturers.

Advanced manufacturing technologies may offer options for more cost efficient and environmentally friendly manufacturing that not only increases capacity for scale-up and yields cost efficiencies, but also reduces greenhouse gas emissions. For example, continuous manufacturing represents a transformative approach in pharmaceutical production by enabling the production of pharmaceuticals within a single facility, thereby reducing the manufacturing footprint, energy consumption, and waste generation.[35] It will be critical for L/MICs to harness opportunities to incorporate such technologies and climate- smart and environmentally responsible manufacturing processes as appropriate to support the development of sustainable local manufacturing capacity, as outlined in sub-objective 2.1. Similarly, the regulatory workforce must have the necessary capacity and frameworks to effectively regulate and support developments in manufacturing technology.

Illustrative activities include:

- Identifying opportunities to increase reliability of clean energy and environmentally friendly practices in medical product manufacturing.
- Providing support to develop expertise in advanced manufacturing technologies among the workforce for both medical product manufacturers and regulatory authorities.
- Identifying opportunities to reduce the environmental impact of medical product waste disposal directly associated with manufacturing and quality assurance/quality control activities.

NOTE: It is NOT intended that the applicant address climate impacts throughout the supply chain, such as during warehousing and distribution.

4. Guiding Principles

1. **Systems Strengthening Approach**
   Address all five health system functions (governance, human resources, information, financing, and service delivery) in relation to the medical products, vaccines, and technologies function. Emphasize sustainability and self-reliance by considering interactions among health system components within the country context.

[35] https://www.marketlinks.org/blogs/opportunities-advanced-manufacturing-technologies-local-production-health-commodities

2. **Build on Existing Systems**
   Enhance and strengthen existing systems, adapting tools and approaches to local and regional contexts to improve sustainability and scalability. Engage the private sector and local stakeholders in development of strategies for strengthening medical product quality assurance and production systems.

3. **Support Integration**
   Promote integration across disease-specific programs, medical product quality assurance systems actors and functions. Align with USAID's cross-cutting health systems strengthening (HSS) investments to sustain global health progress, enhance health coverage, prepare for emerging threats, and prevent and address non-communicable disease prevention.

4. **Country-Led Coordination and Governance**
   Strengthen governance frameworks and support country-led coordination involving governments, civil society, and private sector stakeholders. Enhance transparency, communication, accountability, and participation to foster effective collaboration and system improvements.

5. **Local Capacity Strengthening**
   Build capacity of local and regional organizations, prioritizing technical, governance, financial, and monitoring and evaluation competencies. Promote south-to-south learning, institutionalization of medical product quality assurance approaches into counterpart practices, and transition to direct awards for local entities.

6. **Resource Optimization and Prioritization**
   Assist stakeholders in increasing efficiency in the allocation and use of resources for quality assurance and production systems and improving processes for cost-benefit analyses and investment decisions.

7. **Strategic Partnerships**
   Foster partnerships with USG entities, donors, private sector, and international stakeholders. Leverage USAID's Private Sector Engagement Policy to align efforts and harmonize approaches.

8. **Collaborating, Learning, and Adapting (CLA)**
   Apply CLA principles to coordinate global technical leadership efforts, evaluate innovative approaches, and advance improvements and efficiencies in medical product quality assurance through collaboration among stakeholders.

9. **Diversity, Equity, Inclusion, and Accessibility (DEIA)**
   Apply USAID's DEIA and inclusive development policies throughout activities to strengthen medical product quality assurance and production systems as appropriate. Focus on equitable

access to quality-assured medical products and services for at-risk populations and propose context-specific solutions to reduce disparities.

5. Relationship to Other USAID Awards

This Award is intended to complement other USAID global health mechanisms working in health systems strengthening and specific areas of the medical products, vaccines, and technologies health system function. Related USAID mechanisms include:

Promoting the Quality of Medicines Plus (PQM+): Awarded to United States Pharmacopeial Convention (USP) and its consortia of partners (2019–2025), this cooperative agreement focuses on strengthening medical product quality assurance systems in L/MICs by providing technical assistance to manufacturers of priority health products and to Medicines Regulatory Authorities to improve product registration, inspection, and post-marketing surveillance for product quality. This includes accreditation of national drug quality control laboratories and expanding the supply of essential medical products for diseases like tuberculosis, malaria, and neglected tropical diseases, and to improve maternal, newborn, and child health.

Medicines, Technologies, and Pharmaceutical Services (MTaPS): Managed by MSH (2018–2025), this contract strengthens pharmaceutical systems in L/MICs to ensure access to and appropriate use of safe, effective, quality-assured, and affordable essential medicines and other health technologies and medicines-related pharmaceutical services.

NextGen Comprehensive TA IDIQ: Awarded in 2024 to multiple contractors, strengthens systems to ensure sustainable access to and appropriate use of safe, effective, quality-assured, affordable health commodities. Excludes technical assistance for medical product quality assurance systems strengthening and support for local and regional manufacturing.

NextGen Qualifying, Testing, and Issuing (QTI): Awarded to FHI 360 (2024), implements quality assurance for USAID-procured health commodities, including vendor qualification, testing, and issue management.

Integrated Health Systems Strengthening (IHSS): An upcoming five-year cooperative agreement under procurement, aims to strengthen primary health care (PHC) and accelerate progress toward universal health coverage (UHC) through evidence-driven, locally-led approaches.

Local Health System Sustainability (LHSS): A six-year task order (2019–2025) managed by Abt Global , helps countries achieve sustainable, self-financed health systems that offer quality health care through increased financial protection, service coverage, and quality of essential health services.

Country Health Information Systems and Data Use (CHISU): Managed by JSI (2020–2026), strengthens health information systems to improve the quality, availability, and use of health data globally.

WHO Consolidated II: A five-year agreement (2019–2026) advancing shared USAID-WHO goals to strengthen health systems, improve population health, and foster resilience in public health services.

USAID has a vast array of awards outside of the Bureau for Global Health related to MedQAPS such as economic growth, public financial management, customs reform, and engagement of local organizations.

6. Relevant USAID Strategies and Policies

USAID's Office of Health Systems (OHS) works across the Agency's entire global health portfolio and provides technical leadership and direction in health systems strengthening. This includes the critical component of strengthening country systems to ensure the quality and safety of medical products (i.e., drugs, vaccines and other biologics, and devices) and protect against the harms of SF medical products. USAID's approach is to ensure that its investments support sustainable local change and improve system performance in a way that facilitates country transition away from reliance on donor aid and technical assistance.

USAID's Vision for Health Systems Strengthening[36] highlights the importance of strengthening health systems and provides guidance to achieve four strategic outcomes: financial protection, quality essential services, equitable population coverage, and responsiveness. According to USAID's Vision, "A health system is defined as consisting of all people, institutions, resources, and activities whose primary purpose is to promote, restore, and maintain health." HSS comprises the strategies, responses, and activities that are designed to sustainably improve health system performance. Strengthening a health system means working across and improving the six internationally accepted and interrelated HSS functions: human resources for health; health finance; health governance; health information; medical products, vaccines, and technologies; and health service delivery. USAID focuses its HSS approach on integrated programs and projects that will help meet USAID's Global Health goals of Preventing Child and Maternal Deaths, Controlling the HIV/AIDS Epidemic, and Combating Infectious Diseases.

USAID's Vision includes priority objectives for each of the six HSS functions. Under the medical products, vaccines, and technologies function, these include: 1. Strengthen supply chain components to ensure the uninterrupted supply of quality-assured medical products; 2. Strengthen medical product regulatory capacity and pharmaceutical sector governance to promote transparency and accountability; and 3. Increase and enhance human and institutional capacity to manage pharmaceutical systems and services including ensuring efficacy, projecting patient safety, and combating antimicrobial resistance (AMR), all of which are affected by medical product quality.

[36] https://www.usaid.gov/policy/vision-health-system-strengthening

Other relevant Agency policies, initiatives, and strategies include:

- USAID, HSS Learning Agenda
- USAID, HSS Resource Center
- USAID, 2023 Gender Equality and Women's Empowerment Policy
- USAID, Youth in Development Policy
- USAID, A Vision for Action in Digital Health
- USAID, USAID Climate Strategy 2022-2030
- USAID, Position Statement on One Health
- USAID, USAID Disability Policy Paper
- USAID, LGBTQI+ Inclusive Development Policy
- USAID, Policy on Promoting the Rights of Indigenous Peoples
- USAID, Diversity, Equity and Inclusion Strategy
- USAID, Non-Discrimination for Beneficiaries FAQs
- USAID, CLA Framework (pg. 2), USAID Learning Lab
- USAID, Localization.

Note: The term "program" as used in 2 CFR 200 and this NOFO is typically considered by USAID to be an Activity supporting one or more Project(s) pursuant to specific Development Objectives. Please see 2 CFR 700 for the USAID specific definitions of the terms "Activity" and "Project" as used in the USAID context for purposes of planning, design, and implementation of USAID development assistance.