USAID
FROM THE AMERICAN PEOPLE

Patrick Lukulay
U. S. Pharmacopeia
12601 Twinbrook Parkway
Rockville, MD 20852

September 18, 2009

Reference: Promoting the Quality of Medicines RFA

Subject: Cooperative Agreement No. GHS-A-00-09-00003-00

Dear Dr. Lukulay:

Pursuant to the authority contained in the Foreign Assistance Act of 1961, as amended, the U.S. Agency for International Development (USAID) hereby awards to U. S. Pharmacopeia, hereinafter referred to as the "Recipient", the sum of $35,000,000.00 to provide support for a program as described in the Schedule of this award and in Attachment B, entitled "Promoting the Quality of Medicines (PQM)."

This Cooperative Agreement is effective and obligation is made as of the date of this letter and shall apply to expenditures made by the Recipient in furtherance of program objectives during the period beginning with the effective date September 18, 2009 and ending September 17, 2014. USAID will not be liable for reimbursing the Recipient for any costs in excess of the obligated amount.

This Cooperative Agreement is made to the Recipient, U. S. Pharmacopeia, on condition that the funds will be administered in accordance with the terms and conditions as set forth in Attachment A (the Schedule), Attachment B (the Program Description), Attachment C (Branding Strategy and Marking Plan), Attachment D (Initial Environmental Examination), and the Standard Provisions, all of which have been agreed to by your organization.

Please sign the original and all enclosed copies of this letter to acknowledge your receipt of the Cooperative Agreement, and return the original and all but one copy to the Agreement Officer.

Sincerely,

Bruce Baltas
Agreement Officer
USAID

PROMOTING QUALITY OF MEDICINES (PQM)

DETAILED PROGRAM DESCRIPTION

I. ABSTRACT

II. PROGRAM DESCRIPTION

- A. Development Challenge
- B. USAID and Medicines Quality Assurance
- C. Program Objectives
- D. Statement of Expected Results
- E. Core Operating Principles
- F. Program Tasks
- G. Geographic Coverage
- H. Gender Considerations

III. PROGRAM MANAGEMENT

- A. Responsibility for Performance
- B. Implementation Planning
- C. Reporting Requirements
- D. Substantial Involvement
- E. Authorized Geographic Codes for Procurement
- F. Support to Police and Other Law Enforcement Activities
- G. Buy-In from Other Stakeholders

IV. AWARD INFORMATION

- A. Available Funding and Awards
- B. Cost Sharing

I. ABSTRACT

The proposed program, Promoting Quality and Safety of Medicines (PQSM), will function as U.S. Agency for International Development (USAID)'s primary mechanism to help assure the quality, safety, and efficacy of medicines of relevance to USAID health programs. Good-quality, safe, and efficacious medicines are essential to achieve desired health outcomes.

PQSM is USAID's response to the growing development challenge posed by substandard and counterfeit medicines worldwide. Sub-standard/counterfeit medicines increase morbidity and mortality because they cause treatment failure and adverse reactions, and they contribute to antimicrobial resistance. They thus represent not only a waste of scarce resources but also a substantial risk to public health. They further risk undermining decades of health investments, including by USAID.

In order to achieve the overall objective of helping assure the quality, safety, and efficacy of medicines of relevance to USAID priority health programs, a set of four intermediate objectives will be pursued:

1. Strengthen national quality assurance systems
2. Increase the supply of good-quality medicines of direct relevance to priority USAID health programs
3. Combat the availability of counterfeit and sub-standard medicines
4. Provide technical leadership and global advocacy regarding the importance of medicines quality assurance

Each of the four intermediate objectives corresponds to an intermediate result (I.R.)

Overall Objective: To Ensure the Quality, Safety, and Efficacy of Medicines of Relevance to USAID Health Programs	
Intermediate Objectives	**Intermediate Results**
1. To strengthen national quality assurance systems	1. More developing countries have a better functioning/ fully operational medicines quality assurance system in place
2. To increase the supply of good-quality medicines of direct relevance to priority USAID health programs	2. Increased availability of good quality medicines of direct relevance to priority USAID health programs
3. To combat the availability of sub-standard and counterfeit medicines	3. Reduced presence of substandard and counterfeit medicines in the supply chain of developing countries
4. To provide technical leadership and global advocacy regarding the importance of medicines quality	4. Improved medicines quality assurance tools and mechanisms, increased awareness of their importance, and

assurance	increased funding for their implementation and use

The pursuit of these objectives involves interventions and activities of a highly technical nature - at the local, national, regional, and/or international levels. In addition to the in-depth technical expertise required, an even more critical issue is the inherently sensitive political nature of pharmaceutical sector interventions. The availability of substandard and counterfeit medicines in a country, and/or the need for compliance with specific quality standards by manufacturers, invariably bring to the fore political and other sensitivities regarding governance, political will and capacity, and even sovereignty. For these reasons, it is absolutely essential that the Awardee be an organization with international credibility and recognition as an independent technical authority in the field of quality assurance. Without it, Ministries of Health, regulatory authorities, manufacturers and other international stakeholders will have no economic or political interest in working with USAID in this field. Consequently, it will be impossible for USAID to have the desired impact in terms of reducing the harmful effects of substandard/counterfeit medicines on public health.

PQSM will be implemented as a five year Cooperative Agreement, with USAID funding totaling $35 million. The Awardee will work in partnership with USAID-supported efforts in all four USAID regions. The Awardee is also expected to work in synergy with other stakeholders, including international organizations.

The Detailed Program Description serves as a framework and platform for response by the Applicant.

- Section II (Program Description) lays out the development challenge as well as past and ongoing USAID involvement in activities where medicines quality assurance is relevant. This forms the basis for the delineation of the overall and intermediate objectives of the proposed program, as well as the expected results. The Program Description further lists the core operating principles, program tasks, and gender considerations.
- Section III (Program Management) addresses performance and reporting requirements as well as other practical considerations related to implementation.

II. PROGRAM DESCRIPTION

A. THE DEVELOPMENT CHALLENGE

Over the last years, development and health organizations have increasingly sounded the alarm about the harmful health impacts of the widespread availability of substandard and counterfeit medicines in developing countries. Since the 1990s, the globalization of trade, the abundance of medicines entering developing countries through global health initiatives, and the persisting lack of transparency in the pharmaceutical sector, have

contributed to an increase in the availability of these medicines. According to WHO and the US-based Center for Medicines in the Public Interest, counterfeit drug sales will reach $75 billion globally in 2010, an increase of more than 90% from 2005.

From a public health perspective, counterfeits and substandard medicines are a cause of treatment failure and adverse reactions, contribute to antimicrobial resistance, and thus increase morbidity and mortality. As such, they undermine decades of investments in public health: without good quality, efficacious, and safe medicines, the impact of other health investments is negated.

In order to protect public health and safeguard the impact of past and future health investments, it is thus not sufficient to only secure the quality, safety and efficacy of the medicines procured directly by USAID programs; it is equally important, and in the long run essential, to ensure the quality, safety, and efficacy of the (same) medicines available on the market or in the public sector supply chain of beneficiary countries.

Counterfeits and substandard medicines represent a threat to public health worldwide but pose a particular problem in developing countries. This is due to a large extent to the fact that most developing countries do not have the technical, human, managerial and financial capacity to protect their supply chains.

In order to address this development challenge in an effective manner and to achieve sustainable results, several complementary strategic approaches are in order. These strategic approaches are presented as intermediate objectives in the context of this Program Description:

1. Strengthen national quality assurance systems
2. Increase the supply of good-quality medicines of direct relevance to priority USAID health programs
3. Combat the availability of counterfeit and sub-standard medicines
4. Provide technical leadership and global advocacy regarding the importance of medicines quality assurance

The four intermediate objectives are presented in detail in Sections C and D below. However, at this point, it is worth noting that the intermediate objectives involve a multi-layered process of interventions of technical, financial, and managerial nature, at local, national, regional, and international level. These interventions will require from the implementing organization more than simply in-depth technical expertise, though that is of course indispensable. In order to gain access to the sensitive pharmaceutical sector in developing countries, it will also be crucial that the implementing organization is recognized internationally as an independent and respected authority in the medicines quality assurance arena.

B. USAID AND MEDICINES QUALITY ASSURANCE

USAID has been supporting medicines quality assurance for the last decade. An overview of how past activities and the proposed program fit within the context of the USG Foreign Assistance Framework and the corresponding health elements follows below.

The current USG Foreign Assistance Framework identifies "Investing in People" as one of five priority objectives. Investing in People includes "Improving Global Health", which in turn includes eight Program Elements: HIV/AIDS, Tuberculosis (TB), Malaria, Avian Influenza (AI), Other Public Health Threats, Maternal and Child Health, Family Planning and Reproductive Health, and Water Supply and Sanitation.

Health challenges and issues vary from country to country depending on the burden of disease and the stage of development of health systems. The USG Foreign Assistance Framework provides a useful perspective by identifying various classes of countries: rebuilding; developing; transforming; and sustaining partnership countries. The conditions of the health systems in these categories of countries will need to be taken into consideration in designing solutions to address pharmaceutical challenges, including quality assurance of medicines.

Past and Current Activities Focused on Medicines Quality Assurance in Support of the Health Program Elements

USAID has long recognized that access to good-quality essential medicines and other health commodities is essential to achieving improved health outcomes. Over the past three decades, USAID has financed a range of projects and programs to strengthen pharmaceutical management systems to promote such access - from large-scale global programs to smaller scale Mission bilateral programs. These programs have addressed a wide spectrum of issues, including contraceptive availability, logistics and supply systems development, provision of unbiased drug information, and promotion of the rational use of medicines. In this context, the importance of medicines quality assurance has increasingly gained attention and USAID has become progressively more engaged in targeted activities to strengthen medicines quality assurance in support of the health program elements. This is described in more detail below.

In maternal and child health, USAID supports the increased availability and use of proven life-saving interventions that address the major causes of maternal and childhood morbidity and mortality. The success of these interventions depends among other things on the availability and distribution of good-quality health commodities - for example, oral rehydration salts and zinc supplements to help prevent dehydration and death from diarrheal disease. USAID has been instrumental in increasing the supply of good quality zinc products through supporting technical assistance in Good Manufacturing Practices (GMP) compliance for selected manufacturers. The technical assistance has improved

the local supply of good quality zinc in several countries; it has also enabled some manufacturers to be pre-approved as suppliers for UNICEF.

In the area of malaria, the objective of the President's Malaria Initiative (PMI) to reduce malaria related mortality by 50% in 15 target countries is contingent upon, among other things, access to good quality antimalarials, particularly ACTs, and other essential health commodities. In this context, USAID has developed guidance to countries to help them plan and manage the complex process of introducing ACTs. USAID has also supported the strengthening of medicines quality control laboratories as well as post-marketing surveillance capabilities. As access to antimalarials increases, it is important that national authorities monitor the quality of the medicines in the market and be in a position to take corrective actions against substandard and/or counterfeit products. This is necessary to help preserve the effectiveness of the antimalarial medicines, upon which the impact of the PMI Program depends to a large extent. USAID has also engaged with WHO in a 10 country in-depth study of the quality of antimalarial medicines in Sub-Saharan Africa, which is ongoing.

One third of the world's population is infected with tuberculosis (TB). USAID's goal for TB is to reduce the number of deaths by increasing case detection to at least 70% and by successfully treating at least 85% of detected cases, as well as addressing issues of multi-drug resistant TB and TB-HIV co-infection. In this context, USAID supports for example the Global Drug Facility (GDF) and the Green Light Committee (GLC), two multilateral groups with the prime responsibility of providing quality first- and second-line TB medicines. USAID is also directly supporting efforts to increase the number of manufacturers of second line medicines that are prequalified by WHO.

In HIV/AIDS, USAID supports the President's Emergency Plan for AIDS Relief (PEPFAR) and integrated prevention, care and treatment programs, including the prevention of mother-to-child transmission (PMTCT) and administration of life-extending therapy. Various GH implementing mechanisms have provided ARVs and other health commodities to PEPFAR country programs. As in the case of PMI, the PEPFAR program has a vested interest in ensuring that beneficiary countries are in a position to undertake effective quality control of HIV/AIDS medicines in the market, to monitor trends, and to undertake corrective actions against substandard products and illegal operators. USAID has supported post-marketing surveillance of HIV/AIDS medicines in several countries and is anticipating increased support to the strengthening of PEPFAR countries' medicines quality control capabilities.

New infectious diseases such as avian influenza (AI) pose enormous health challenges on a global scale. Through collaborative efforts with other USG partners, USAID has focused on strengthening capacity to rapidly detect and respond to current AI problems in animals and humans, among other things by mapping distributors of oseltamivir in specific countries and by developing a sampling and testing protocol to determine the quality of oseltamivir products, both stockpiled and in medical facilities.

Finally, the GH Bureau is focusing on the containment of antimicrobial resistance, which is listed as a sub-element under several of the health program elements. Preserving the effectiveness of currently available treatment options and therapies is directly tied to the reliable supply and use of good-quality medicines as well as to the behaviors of health care providers and consumers. USAID supported the development of the WHO Global Strategy for Containment of Antimicrobial Resistance, on the basis of which it has further supported the development of guidance to countries and USAID Missions on how to implement the Global Strategy. In the area of quality assurance, USAID has supported among other things regional networks to exchange information and best practices among regulatory authorities and national quality control laboratories of different countries, in addition to strengthening national quality assurance capabilities.

Relationship to Main Other Pharmaceutical Programs

The new program will build on the quality assurance work undertaken by the current US Pharmacopeia Drug Quality and Information (DQI) Program. As such it will also continue to play a complementary role to medicines quality assurance activities under other existing medicines-related GH programs, in particular the Strengthening Pharmaceutical Systems (SPS) cooperative agreement, the Supply Chain Management System (SCMS) contract, and both of the commodities, security and logistics contracts, i.e. Central Contraceptive Procurement (CCP) and the USAID/DELIVER Project.

The SPS Program is designed to provide specialized technical support to address new and evolving pharmaceutical challenges through a systemic approach (i) to promote the availability and use of good-quality essential medicines, including through cooperation with the private sector; (ii) to increase accountability and transparency in pharmaceutical management; (iii) to contain antimicrobial resistance; and (iv) to address the problem of scarce human resources as well as financing and economic issues. The pharmaceutical management systems that SPS introduces and strengthens cover quality assurance-related issues. However, the SPS program does not offer the in-depth technical assistance required for example to ready a national medicines laboratory for WHO prequalification or ISO certification; or to assist manufacturers in achieving Good Manufacturing Practices (GMP) compliance and WHO prequalification. SPS also does not include activities such as post-marketing surveillance and in-depth research of the quality trends of essential medicines on the market. These areas of technical assistance will be covered by the new program.

SCMS is designed to provide one-stop shopping for HIV/AIDS supplies and supply-related services for use by HIV/AIDS programs that are funded by PEPFAR and other USG entities combating HIV/AIDS. SCMS also assists in improving capacity of national supply chains in order to ensure long-term sustainability of distribution systems in participating countries. With regard to quality assurance, SCMS has developed and implemented standard operating procedures (SOPs) and policies to ensure the quality of the procured products, including sample management and quality control incident management. Specific quality requirements are enforced (e.g. FDA approval or tentative

approval) and the sampling and testing mechanisms include protocols for action in case of non-conforming test results. SCMS has started the process of prequalifying pharmaceutical vendors and as part of this effort it provides feedback to aid the manufacturer in improving performance on GMP standards.

The USAID/DELIVER Project works with host-country governments and non-governmental and private voluntary organizations to develop, strengthen, and operate safe, reliable, and sustainable supply systems to provide essential health supplies through public and private services. This includes improving systems for forecasting and information collection as well as procurement, storage, and distribution systems in which quality assurance plays an important role. The Project also supports USAID's provision of health commodities in the context of the President's Malaria Initiative.

The purpose of the Agency's Central Contraceptive Procurement (CCP) project is to provide an efficient mechanism for consolidated USAID purchases of contraceptives, including condoms. CCP also administers the Commodity Fund, which serves HIV/AIDS prevention activities worldwide. The CCP provides a mechanism for independent testing of the contraceptives purchased by USAID. The contraceptive quality assurance component of CCP has two features: (i) pre-acceptance surveillance and testing of contraceptives purchased by USAID and (ii) testing the quality of contraceptives already in the field.

As is clear from the above descriptions, quality assurance activities form an important part of the SCMS, CCP and USAID/Deliver projects. However, in all three projects, the focus of these activities tends to be predominantly on the medicines procured by USAID only, on one particular type of health commodities only, or on quality assurance within the context of procurement and distribution systems only. The new program will complement the SCMS, CCP and USAID/Deliver programs among other things by (i) providing in-depth technical assistance and leadership in the area of building countries' national capacity in quality assurance of the medicines on the market from laboratory testing and registration to post-marketing surveillance and pharmacovigilance; (ii) improving the supply of good-quality medicines through public standard development and working with prequalification mechanisms; and (iii) combating the availability of substandard and counterfeit through national, regional, and international initiatives.

C. PROGRAM OBJECTIVES

The overall objective of this program is to **help assure the quality, safety, and efficacy of medicines of relevance to USAID health programs**. Good quality, safe, and efficacious medicines are essential to achieve desired health outcomes.

The pursuit of the overall objective involves a complex process of interventions and activities of technical, financial, and managerial nature, at local, national, regional, and/or international level. In all these contexts, there is a continuing unmet need for knowledge and expertise, tools and mechanisms, and technical leadership and advocacy.

Achieving the overall objective is dependent on achieving several intermediate objectives. The activities under the intermediate objectives not only contribute to the strengthening of the quality of medicines in general but they often also feed into supporting the Global Health Bureau's different sub-elements and pathways.

(1) **To strengthen national quality assurance systems in developing countries**.

A key obstacle to promoting good quality medicines and combating substandard/ counterfeit products is the lack of institutional, financial, technical and human resource capacity among medicines regulatory authorities in developing countries to protect their respective supply chains. Medicines quality assurance worldwide depends to a large extent on the capacity of national authorities – in essence, each country needs a capable authority to safeguard the quality, safety, and efficacy of the medicines in the market. This forms the basis for the first intermediate objective and first component of the project, namely to strengthen the drug quality assurance systems in developing countries.

(2) **To increase the supply of good-quality medicines of direct relevance to priority USAID health programs**.

In many instances, good quality medicines are not available and Ministries of Health, health facilities and/or patients have little choice but to use medicines that have not necessarily undergone rigorous quality control. This is currently and most strikingly the case for 2nd line TB medicines for example. The Green Light Committee and the Global Development Fund identify the lack of good quality products and prequalified manufacturers as the main challenge to their continued success. In general, and as mentioned before, without good quality, efficacious, and safe medicines, the impact of other health investments is negated. This forms the basis for the second intermediate objective, namely to increase the supply of good-quality medicines of direct relevance to priority USAID health programs.

(3) **To combat the availability of counterfeit and sub-standard medicines**.

In parallel to increasing the supply of good quality medicines, the program will also seek to combat the growing threat of substandard and counterfeit medicines in the supply chain of developing countries. While it is essential that countries strengthen their national quality assurance systems, combating trade in substandard and counterfeit medicines also requires interventions at regional and international level. The latter implies coordination and cooperation among national authorities, relevant regional mechanisms, international organizations, and other stakeholders. This forms the basis for the third intermediate objective, which thus serves to strengthen and/or complement the health/quality assurance system strengthening activities undertaken at national level (1st intermediate objective).

(4) **To provide technical leadership and global advocacy regarding the importance of medicines quality assurance in terms of health outcomes and containment of AMR.**

Over the last decade, improving medicines quality assurance and combating counterfeits have increasingly gained attention from policy makers. USAID has been involved in the field since the mid-2000s. As medicines quality assurance continues to gain in importance, USAID expects to play an active role in the continued development and implementation of strategic approaches, interventions and tools through the new program. The program will undertake significant efforts to raise awareness of the dangers of counterfeit and substandard medicines and to promote medicines quality assurance strengthening, including funding and supporting medicines quality assurance strengthening activities through global health initiatives. The main target audience includes both international and national policy makers, as well as international organizations active in pharmaceutical procurement.

D. STATEMENT OF EXPECTED RESULTS

As stated earlier, the ultimate goal of the proposed program is to ensure the quality, safety, and efficacy of essential medicines of relevance to USAID priority health programs. Good quality medicines contribute to improving not only health but also quality of life, productivity, economic growth, and social stability – all outcomes consistent with the goals and objectives of USAID's Strategic Framework and of the U.S. Foreign Assistance Act on which the Strategic Framework is based.

The availability of good quality medicines, it is important to note, also plays a critical role in building well-governed states, in so far that pharmaceuticals promote trust and participation in health services, which in turn promote trust in government.

Below follows a systematic overview of the expected results and illustrative activities under each of the four intermediate objectives presented in Section C. Note: The expected results under the different components are often expressed in the form of "an increased number of …" The Applicant is invited to provide a target number that can be achieved based on available program funds.

Intermediate Objective 1: To strengthen national quality assurance systems in developing countries.

As mentioned, medicines quality assurance depends first and foremost on the capacity of national authorities to safeguard the quality, safety, and efficacy of medicines on the market and in the public sector supply chain. In order to achieve this objective, it is necessary to address the myriad points in the pharmaceutical supply system where quality can be affected. This varies from ensuring adequate quality assurance considerations in registration, to training national quality control laboratories in Good Laboratory Practices, to introducing a post-marketing surveillance system and/or pharmacovigilance

network. Furthermore, South-South collaboration and support to strengthening national quality assurance systems can also play an important role in strengthening national capacity. In this context, the program is also expected to build sustainable regional capacity, where appropriate in Latin America, Africa, and South East Asia by establishing regional centers of excellence that can serve as a technical resource in quality assurance for the respective region. It is expected that this intermediate objective will represent the bulk of the activities under the new program. A more detailed list follows below under the "Illustrative Activities".

Note: In order to achieve impact, the component will require first of all in-depth technical knowledge – e.g. to shepherd a laboratory to meet WHO prequalification or ISO certification; to ensure a Ministry of Health has the technical capacity to introduce a GMP certification scheme in the country; and/or to ensure that post-marketing surveillance is done according to international pharmacopeial standards. Furthermore, in addition to the in-depth technical assistance, successful implementation requires recognized expertise in the policy aspects of medicines quality assurance. The Awardee will need to work with Ministries of Health and policy makers, as well as with scientists, health professionals, and private sector stakeholders. Medicines quality assurance is a complex domain that brings to the fore political sensitivities, among the national policy makers first and foremost; it also directly affects economic interests. It is indispensable that the Awardee commands international recognition as an independent and respected authority in the field to move the many processes forward in the given political and economic context. Without international recognition and credibility, Ministries of Health and other policy makers are unlikely to be open to active engagement into the field, i.e. moving forward with the necessary measures, and their enforcement, to improve quality, safety and efficacy of medicines in the country.

Expected Results

- Increased number of countries with strengthened quality assurance systems as defined by a minimum set of indicators[1]
- Increased number of quality control laboratories that operate according to Good Laboratory Practices (GLP) or reach WHO prequalification or ISO certification
- Increased number of countries with increased knowledge of the quality of the medicines available in the different sectors of the national supply chain
- Strengthened capacity for regional or South-to-South support in medicines quality assurance

Intermediate Objective 2: To increase the availability and supply of good-quality medicines

In the case of medicines of direct relevance to USAID priority health programs, such as zinc supplements and 2nd line TB medicines, targeted interventions are often required to

[1] The list of illustrative activities serves as a guide for determining relevant indicators for strengthened medicine quality assurance system outcomes. The Applicant is welcome to propose additional indicators.

increase the availability of good quality medicines. These targeted interventions include working with selected manufacturers of medicines of particular relevance to USAID programs to achieve compliance with internationally accepted Good Manufacturing Practices as well as supporting international pre-approval or prequalification programs. The premier prequalification program currently in existence is the WHO prequalification program. It is considered "the gold standard" by many international agencies and imposes significant quality assurance requirements on manufacturers. Furthermore, USAID programs may need expert technical advice or require independent quality testing on an ad hoc basis. Finally, targeted interventions may also include establishing public quality standards, as well as chemical reference standards, for medicines of priority relevance to USAID programs if no other internationally recognized public standards are available.

Note: The international recognition and credibility of the Awardee is expected to play an important role in convincing manufacturers to work with international prequalification or pre-approval programs. By the same token, international procurement programs are unlikely to seek support in improving their quality assurance mechanisms unless the implementing agency is recognized as authoritative by virtue of its standard setting role and demonstrated technical expertise. Finally, when no internationally recognized public standards exist for medicines of direct relevance to USAID priority health programs, the Awardee will be expected to be in a position to fill the gap.

Expected Results

- Increased number of new pharmacopeial monographs and reference standards to allow for quality control testing
- Increased number of additional manufacturers that comply with Good Manufacturing Practices, as defined within the national context or by so-called stringent authorities
- Increased number of medicines of direct relevance to USAID priority health programs that have gained pre-approval or prequalification
- Informed procurement decisions based on the availability of independent expertise regarding medicines quality related technical issues
- Access to independent medicines quality testing capacity for procurement purposes, as needed

Intermediate Objective 3: To combat the availability of counterfeit and sub-standard medicines.

While strengthening national quality assurance systems in general and increasing access to good quality medicines may be expected to have an impact on the availability and use of counterfeit and substandard medicines (SCM), the challenge posed by substandard and counterfeit medicines is of such magnitude that directly targeted interventions are indispensable. Furthermore, strengthened national systems will allow for actions within national borders but such activities will often not suffice, as illegal operators are known to work across borders.

The focus of this component is on concrete anti-SCM activities – both in the context of national quality assurance programs and in the context of regional and international initiatives against these types of medicines. The initiatives can be organized by regional networks or spearheaded by international organizations such as the International Medical Products Anti-Counterfeiting Taskforce (IMPACT) or Interpol. The initiatives require exchange of information and best practices, as well as effective collaboration. The role of the program will vary from helping a country strengthen its human resources in this area through training programs to setting up institutional mechanisms for corrective actions. A key consideration in this context is that successful combating of SCM products requires not only sufficient human and technical resources but also actual legislative/regulatory powers for the medicines regulatory authorities in the respective countries and true political willingness on their part to make use of their powers.

Expected Results

- Increased number of countries that undertake corrective actions against counterfeit/substandard medicines in their supply chains
- Increased number of confiscated SCM products and reduction of illegal operators in the medicines markets
- Improved availability and sharing of information about SCM findings and operations
- Increased coordination/cooperation of national governments in regional and international anti-SCM operations

Intermediate Objective 4: To provide global technical leadership and undertake global advocacy regarding the importance of medicines quality assurance in terms of health outcomes and containment of AMR.

Technical leadership in moving the medicines quality assurance agenda forward on behalf of USAID is essential, given the abundance of medicines entering developing countries through USAID programs such as PMI and PEPFAR and other global health initiatives. Global technical leadership and advocacy are key as regional and international initiatives and partnerships in the health arena multiply. The activities include playing an active role in relevant policy discussions or initiatives among major partners to promote good quality medicines and fight substandard products; ensuring continued attention to that any ongoing and new international procurement mechanism includes appropriate quality assurance requirements and/or provisions to promote quality assurance in countries (see also intermediate result 2); undertaking high quality research where needed and developing efficient new quality testing techniques and approaches. This can be done independently as a representative of USAID or in operational partnerships with major players such as WHO, UNICEF, PAHO etc. The recognized technical leadership is expected to provide an excellent platform to undertake effective global advocacy about the importance of medicines quality assurance in terms of health outcomes and containment of AMR. Target audiences include both international and national stakeholders, who in turn can reach the patient population writ large.

Note: As under other intermediate objectives, the success of the activities is entirely dependent on both the technical expertise and the international recognition and credibility of the Awardee.

Expected Results

- Continued attention to, improved provision for, and increased investments in medicines quality assurance in international initiatives of relevance to USAID priority health programs, including initiatives such as GFATM, GDF, etc
- Representation of USAID viewpoint or approach in international fora
- A minimum number of operational partnerships with major players

- Availability and communication of reliable information and research related to quality of medicines of relevance to USAID priority health programs
- Access to, appropriate and/or state-of the art technologies and approaches in the field of medicines quality assurance, for use within a country context and/or at regional/international level