TA BPOM dengan USAID

TECHNICAL ARRANGEMENT
BETWEEN
THE NATIONAL AGENCY FOR DRUG AND FOOD CONTROL (BPOM)
AND
THE UNITED STATES AGENCY FOR INTERNATIONAL DEVELOPMENT MISSION TO INDONESIA
(USAID)
RELATING TO THE
IMPLEMENTATION OF INTERMEDIATE RESULTS 2.1 AND 3.1 OF USAID ASSISTANCE AGREEMENT No. 497-AA-030 ("THE AA HEALTH PORTFOLIO")

1. GENERAL

1.1 This Technical Arrangement (TA) expresses the intentions of the Technical Counterpart Agency (BPOM) and USAID (the Parties) pursuant to the USAID Assistance Agreement No. 497-AA-030 (AA) between the Ministry of Finance and USAID, and the Individual Arrangement (IA) between the Ministry of Health and USAID Office of Health to provide guidance to and facilitate cooperation on the implementation of Projects and Activities under the AA Health Portfolio.

1.2 Implementation Letter (IL) No. 3 designated the Ministry of Health (MoH) as the Executing Agency responsible for fulfilling the Government of Indonesia (GoI)'s commitments under the AA related to implementation of the AA Health Portfolio. This TA is executed under Section 2.d. of the IA, which provides that USAID will develop separate Technical Arrangements with the Technical Counterpart Agencies, including the National Agency for Drug and Food Control (BPOM). Furthermore, Section 2.c.2. of the IA designated BPOM as the Technical Counterpart Agency for the Promoting the Quality of Medicines (PQM) Program.

2. PURPOSE

2.1 This TA is intended to provide coordination between BPOM and USAID for the implementation of the PQM Program. The Parties acknowledge that the Ministry of Finance, as the signatory to the AA, and the Ministry of Health, as the Executing Agency, as designated in the IL, remain USAID's primary points of contact in the GoI for matters related to the implementation of the AA and the AA Health Portfolio, respectively.

2.2 The Parties to this TA will cooperate in providing assurance, guidance and facilitation to the implementation of activities under the PQM Program to support Indonesia's efforts to strengthen the capacity of the Indonesian National Health Care System to improve and sustain quality assurance and quality control of medicines.

3. SCOPE OF COOPERATION

The scope of cooperation among the Parties is intended to include:

a) Strengthen the National Medicines Regulatory Systems.
b) Increase the availability of quality-assured medicines.
c) Reduce the amount and availability of substandard and falsified medicines.
d) Enhance the technical capacity of the GoI to develop and implement inter-agency (MoH, BPOM, Donors, Professional Associations, other stakeholders) policies and procedures for medicines quality assurance.

4. COLLABORATING AGENCIES

4.1 Collaborating Agencies are other national and/or sub-national government agencies that have an interest and stake in activities implemented under the PQM Program.

4.2 The Collaborating Agencies for this TA will be:

a) BPOM as a signatory to this TA and the Technical Counterpart Agency for the PQM Program.
b) MoH Directorate of Direct Transmitted Disease Prevention and Control, including:
   1) Subdirectorate for HIV/AIDS, and
   2) Subdirectorate for Tuberculosis
c) MoH Directorate General of Pharmaceutical and Medical Devices (FARMALKES).
d) U.S. Agency for International Development (USAID) Office of Health.

4.3 USAID through the United States Pharmacopeial Convention (USP) will carry out its functions in support of this TA.

5. UNDERTAKING OF USAID

In accordance with applicable U.S. laws and regulations, and subject to the availability of funds pursuant to Section 3.1 of the AA, and in compliance with relevant articles of section 3 of the IA, USAID shall undertake the following:

a) Consult and Coordinate to reach consensus on PQM Program activities with the Technical Counterpart Agency and other Collaborating Agencies to determine necessity and compliance with related Ministry or Agency Programs.
b) Ensure USP prepares the subsequent fiscal year's annual work plans in close consultation with the Technical Counterpart Agency and other Collaborating Agencies.
c) Coordinate with the Technical Counterpart Agency prior to the implementation of agreed activities.
d) Together with USP, USAID shall submit quarterly progress and financial reports on activities to the Executing Agency and Technical Counterpart Agency, and brief monthly progress reports.

e) Promptly consult with the Technical Counterpart Agency of any significant changes related to the activities. Respect relevant GoI laws, regulations and policies in carrying out agreed activities. Work closely with the Technical Counterpart Agency and provide guidance to USP.

f) Ensure that projects and activities undertaken under the PQM Program are conducted in a manner consistent with the RPJMN and the terms of the AA and that they support the achievement of the AA Health Portfolio.

g) Provide the Executing Agency and Technical Counterpart Agency with data on an annual basis necessary to fulfill the Berita Acara Serah Terima (BAST) reporting requirements regarding the disbursements of USAID funds for agreed activities under the PQM Program.

h) Participate in yearly Steering Committee Meetings organized and co-chaired by Ministry of National Planning and Ministry of Finance to discuss activities under the IA for Health Portfolio in accordance to the IL No.3.

i) Publicize activities under the PQM Program as cooperative undertakings of the GoI and USAID.

j) Maintain responsibility for the financial management and the implementation of activities under the PQM Project.

k) The involvement of the Pharmaceutical Industry must be agreed by the Technical Counterpart Agency(ies) of related ministries and Executing Agency.

6. UNDERTAKING OF TECHNICAL COUNTERPART AGENCY

In accordance with applicable laws and regulations of the Republic of Indonesia, and budgetary resources available to the Technical Counterpart Agency, the Technical Counterpart Agency shall

a) Assure all activities under this TA are in line with and support the achievement of the RPJMN.

b) Work closely with and provide guidance to USP in preparing annual work plans. The work plan shall be made in writing and will include activities, objective, target and indicators, timeline, location of the agreed activities, mechanism of monitoring and evaluation as well as other necessary arrangement.

c) Prior to and during the implementation of agreed upon activities under this TA, the Technical Counterpart Agency shall discuss and report to the Executing Agency.

d) On behalf of the Executing Agency, provide GoI coordination and guidance required for the implementation of this TA to USAID and USP.

e) Prepare and be responsible for BAST reports and notify the final draft report to the Executing Agency.

f) Publicize the activities under this TA as cooperative undertakings of the GoI and USAID.

g) Monitor and evaluate the engagement of USP with other national and sub-national government agencies in the implementation of this TA to ensure all activities are in line with RPJMN and national priorities. Such activities shall be notified on a regular basis to the Executing agency.
h) Coordinate with USAID to nominate and approve GoI candidates for training financed under this TA.
i) In accordance with rules and regulations of Republic of Indonesia, the Technical Counterpart Agency will ensure that a recommendation letter for all administrative purposes is provided, where necessary. These administrative processes include, but are not limited to: work and stay permits, exit and re-entry permits, tax and customs exemptions.
j) Participate in biannual AA Health Portfolio Review Meetings co-convened by the Executing Agency and USAID's Office of Health to discuss progress and successes, and resolve implementation challenges.
k) Participate in yearly Steering Committee Meetings organized and co-chaired by Ministry of National Planning and Ministry of Finance to discuss activities under the IA Health Portfolio in accordance to the IL No.3.
l) Monitor and evaluate PQM Program activities together with USAID and USP.
m) Submit the implementation of activities and financial reports to the Secretary General of the Ministry of Health as the Executing Agency on a monthly basis.

7. PROGRAM DESCRIPTION

7.1 The Parties anticipate cooperating with USAID in this TA covering the implementation of Projects and Activities under the PQM Program.
7.2 USAID-financed projects and activities that may fall under the PQM Program are described in Annex 1, appended to this document.

8. DURATION OF THE ACTIVITY

8.1 The Parties anticipate the projects and activities will be implemented through the estimated completion date of the AA, currently designated as September 30, 2019. This date may be extended through mutual consent of both Parties.
8.2 The Parties acknowledge that the estimated completion date may change depending on, for example, legislative action affecting the availability by both the GoI, and USAID and subject to congressional approval of budget appropriations.

9. COORDINATION, MANAGEMENT AND TECHNICAL AUTHORITIES

9.1 The Coordination, Management and Technical Authorities for this TA will be:
The Permanent Secretary (SESTAMA) for BPOM
Co-chairs of Technical Team supporting the Technical Counterpart Agency

a) BPOM Representatives:
   1) Deputy Chairperson for Therapeutic Products and Narcotics, Psychotropic and Addictive Substance Control,
   2) Director of Drug and Biological Product Evaluation,
   3) Director of Therapeutic Product and Household Medical Supplies Standardization
   4) Director for Production Control of Therapeutic Product and Household Medical Supplies,
   5) Director for Distribution Control of Therapeutic Product and Household Medical Supplies,
   6) Head of National Quality Control Laboratory of Drug and Food,
   7) Head of Planning and Financial Bureau,
   8) Head of General Affairs Bureau,
   9) Head of International Cooperation Bureau,
   10) Head of Center of Drug and Food Investigation,
   11) Head of Center of Drug and Food Research.

b) Director of MoH Directorate of Direct Transmitted Disease Prevention and Control, including
   1) Subdirectorate for AIDS, and
   2) Subdirectorate for Tuberculosis.

c) Directorate General of Pharmaceutical and Medical Devices (FARMALKES).

d) Infectious Disease Team Lead, USAID/Indonesia Health Office and/or his/her designee.
   1) USP Country Representative/Chief of Party of PQM Program and/or his designee.

9.2 The Team will assist in the implementation of the PQM Program, as follows:

a) Coordination, assurance and guidance on activities under the PQM Program, to achieve the AA Health Portfolio.

b) Harmonization of the PQM Program with relevant GoI programs to support achieving RPJMN and Strategic Plan (Renstra) targets to strengthen the capacity of the Indonesian National Health Care System to improve and sustain quality assurance and quality control of medicines.

c) Preparation and documentation of Grantee Contribution (as stated in the AA).

9.3 Chair of the Team will convene a coordination meeting at least every six months (semi-annual). The Team may meet on other occasions as needed or appropriate, and may invite representatives of other line ministries or relevant stakeholders to participate in the meeting as resource persons.

9.4 The Technical Counterpart Agency, or designated representative, shall immediately notify the Team of any circumstances that may affect the performance of the PQM Program.

10. CONTRIBUTION

10.1 The total USAID contributions for the PQM Program are estimated to be up to **USD 11.5 million** over five years, details provided in Annex 2. The provision and disbursement of USAID contributions under the PQM Program will be subject to the availability of funds.

10.2 Pursuant to section 3.2 of the AA, the Indonesia national and sub-national agencies will provide cash and/or "in-kind" contributions required for the successful implementation of the AA Health Portfolio. Per the terms of Section 3.2 (b) of the AA, as further explained in Section C of the IL, the GoI's Contribution shall equal at least 25% of the total estimated cost of activities that directly benefit the GoI or are administered and reported as 'Grantee Contribution' as stipulated in the IL by the Executing Agency.

11. SETTLEMENT OF DISPUTES

Any disputes, controversy, or claim, which arise out of the interpretation or application of this TA will not be subject to adjudication or arbitration, but will instead be dealt with through amicable consultations and negotiations as the only method of achieving the peaceful settlement of that dispute, controversy, or claim.

12. AMENDEMENTS

This TA may be amended by mutual consent in writing through and an exchange of letters signed by the Parties.

13. COMMENCEMENT AND TERMINATION

13.1 This TA will take effect on signature by the Parties.

13.2 This TA is expected to be implemented until the Estimated Completion Date of the AA, as may be amended from time to time.

13.3 Any Party may terminate this TA by giving written notice of its intention to terminate to the other Parties.

In Witness whereof, the Executing Agency, the Technical Counterpart Agency and USAID have signed this Technical Arrangement in Jakarta, Indonesia as the date first below written.

Agreed by:

BPOM

Dra. Reri Indriani Apt., M.Si
Permanent Secretary
Date: Friday, June 2nd., 2017

USAID

Jonathan Ross
Director USAID Health Office
Date: Friday, June 2nd , 2017

Acknowledged by:
MoH:

Dr. Untung Suseno Soetarjo, MPPK
MoH Secretary General as Executing Agency
Date:

ANNEX 1

SCOPE OF ACTIVITIES UNDER PQM PROGRAM

Objective	Promoting the Quality of Medicines (PQM) 3.1 Strengthen the National Medicines Regulatory Systems 3.2 Increase the availability of quality-assured medicines 3.3 Reduce the amount and availability of substandard and falsified medicines 3.4 Enhance the technical capacity of the GoI to develop and implement inter-agency (MoH, BPOM, Donors, Professional Associations, Academia, public-private partnerships, and others) policies and procedures for medicines quality assurance in Indonesia.
Location	Priority locations as agreed upon by MoH, BPOM and USAID
Period	2015-2019
Funding	USD 11.5 million
Public-Sector Partners	BPOM, MoH P2M (Subdirectorate HIV and Subdirectorate TB), MoH (Farmalkes)
Implementing Partner	United States Pharmacopeial Convention (USP)

ANNEX 2

ESTIMATED BUDGET OF THE PROMOTING QUALITY OF MEDICINES PROGRAM

FOR FY 2015-2020 (in USD)*)

PORTFOLIO	FY 2015	FY 2016	FY 2017	FY 2018	FY 2019	FY 2020	Estimated Grant Total
Promoting the Quality of Medicines	$2,000,000	$2,000,000	$2,750,000	$2,750,000	$2,000,000	0	$11,500,000

*FY is the USG fiscal year October 1 to September 30.

Future funding is not guaranteed, as annual funding depends on approval by the U.S. Congress.