

## Ex-Ante Evaluation (Science and Technology Research Partnership for Sustainable Development)

Date: November 07, 2011

JICA Division in Charge: Health Division 1, Human Development Department

1. Project Title: The Project for Development of Rapid Diagnostics and the Establishment of an Alert System for Outbreaks of Yellow Fever and Rift Valley Fever in Kenya

2. Background and the Justification of the Project

(1) Current Situation and Agenda of the Health Sector of the Country:

In the Republic of Kenya and the neighboring Eastern African countries, Arboviruses (multiple types of arthropod-borne viruses) often cause disease outbreaks, adversely affecting human beings and livestock respectively. In particular, damages caused by Yellow Fever (YF) and Rift Valley Fever (RVF) are often serious. In the year 2005, 555 YF cases were reported in the north western region of Kenya and the southern region of Sudan (with 142 casualties—case fatality rate of 25.6%). As for RVF, in the year of 2006-2007, 1,062 RVF cases were reported in Kenya, Somalia, and Tanzania (with 315 casualties—case fatality rate of 29.7%). In addition, 12,500,000 head of cattle, 11,000,000 head of sheep, and 850,000 head of camels were also infected. Although YF and RVF outbreaks in developing countries have been recognized as an important social issue, the development of the diagnostic techniques as well as the early vigilance and rapid response for control of YF and RVF diseases are considered to be significantly delayed with comparison to “Neglected Tropical Diseases: NTDs” as defined by the World Health Organization (WHO).

Arboviruses are found primarily in natural environment such as jungles and make sudden invasion into human communities, causing widespread infection. Taking countermeasures such as early detection of viruses and emergency vaccination and elimination of vector mosquitoes (aggregately referred to as “early containment”) in areas where human contact with the viruses is frequent is thought to be more cost effective than a usual vaccination program. However, response to NTDs including researches of YF and RVF targeted by this project is lagging far behind. Rapid diagnostics have already been developed on a commercial level in pandemic diseases or those attracting high interest of economically advanced countries and are made available even in developing countries. On the other hand, inexpensive rapid diagnostics for NTDs such as YF and RVF are not made available on a commercial level, and in reality, companies in developed countries do not show any signs of producing them for use in developing countries. Kenya and other developing countries where these NTDs are widespread are in urgent need to come up with an inexpensive diagnostics on their own.

Alert system models of developed countries cannot be utilized due to differences in infrastructure between the countries. Thus, development of a sustainable alert system model that is well adapted to the social and economic infrastructure of developing countries is highly anticipated.

Under these circumstances, the promotion of studies is strongly required with regard to development of rapid diagnostics including introduction of POC (Point-of-Care) testing, strengthened referral functions for diagnosis, and establishment of early vigilance system towards the cost-effective “early containment” of patients for early response to the outbreaks of Arboviruses such as YF and RVF.

Arboviral infection control is a common issue for all East African countries. As the diagnostic technique and the alert system model developed by this project will be well designed for social and economic infrastructure of not only Kenya but all the East African countries, it is expected that the benefits derived from the project will be able to contribute to each country’s fight against the infection.

(2) Development Policy of the Health Sector of the Country and the Position of the Project.

In “the Second National Health Sector Strategic Plan (2005-2010) (NHSSP II)” and “the Strategic Plan of the Ministry of Public Health and Sanitation (2008-2012)”, capacity development in disease surveillance and research for infectious diseases covering not only HIV/AIDS, Malaria and Tuberculosis but YF and RVF is mentioned as areas of priority. The interviews conducted by JICA with the leadership of the Ministry of Public Health and Sanitation (MOPHS) brought out the importance of responses to YF and RVF for the reasons that RVF is regarded as a zoonotic infection threatening people’s health and that YF has negative impact on the tourism industry. Moreover, as the Strategic Plan includes improvement of access to health services and strengthened functions of health facilities; this project aiming at

establishment of early vigilance system is affirmed to contribute indirectly to the implementation of the plan.

(3) Japan's and JICA's Aid Policy and Achievements for Health Sector

In "the *Yokohama Action Plan*" adopted by the fourth Tokyo International Conference on African Development (TICAD IV) in 2008, infectious disease control is listed on the priorities of the health sector. The Government of Japan revealed its commitment to encourage medical studies and researches for combating infectious diseases in Africa by dispatching Japanese researchers especially for facilitation of joint researches of infectious diseases. At the G8 Toyako Summit of the same year, global effort for infectious disease control was agreed on together with maternal and child health and human resource for health in the concept of "the Health Systems Strengthening (HSS)". "*Japan's Global Health Policy 2011-2015*" (September 2010) presented at the United Nations Millennium Development Goals (MDGs) at the World Summit, also, showed the vision; "*in order to help achieve the MDGs through realizing human security, Japan's new policy aims to deliver results effectively and efficiently by addressing bottlenecks impeding progress on the health MDGs*".

Kenya is playing a critical role for Japan's diplomacy in East Africa and is considered to be one of the priority countries for Japanese ODA. Health sector has a priority in the country assistance policy for Kenya. "*JICA's Cooperation in Health Sector – Present and Future*" published in September 2010 also highlights the fight against infectious diseases that have impact beyond borders as a priority global issue.

(4) Assistance of Other Development Partners

In view of the strategic importance of Kenya in East Africa, many development partners have continued supporting the country. Especially, health sector support is considered to be critical by many development partners. U.S. Center for Disease Control and Prevention (CDC) and World Health Organization (WHO) are potentially inter-complementary collaborators without any duplication of activities observed.

3. Project Overview

(1) Purpose of the Project

This project, through its scientific joint research activities, aims at supporting the Kenya Medical Research Institute (KEMRI) in developing rapid diagnostics which includes introduction of POC (Point-of-Care) testing and in improving referral functions in the arbovirus infection high-risk provinces. Furthermore, this project also aims at strengthening early containment system by establishing an early vigilance and rapid response system for YF and RVF, which connects the local health facilities, KEMRI and MOPHS, based on the results from the joint research.

(2) Period of Cooperation

The project period is five (5) years starting from January 2012

(3) Beneficiaries of the Project (Target Groups)

Residents at risk of arbovirus infection in Kenya: Central Province: Approx. 3.9 millions, Coast Province: Approx. 3.0 millions, Nairobi Province: Approx. 2.8 millions, North Eastern Province: Approx. 1.3 millions, Western Province: Approx. 4.0 millions

(4) Total Cost (JICA's budget)

The project has budget of approximately three hundred and sixty millions (360,000,000) Japanese Yen from JICA.

(5) Research Institution and Implementing Organization on the Kenyan side

KEMRI serves as the research institution of the Project with its Production Department (PD), Centre for Virus Research (CVR) in HQ, and Centre for Infectious and Parasitic Diseases Control Research (CIPDCR) in KEMRI-Alupe.

MOPHS serves as the implementing organization of the Project with its Department of Disease Prevention and Control, Division of Disease Control and Surveillance, National Public Health Laboratory Services.

(6) Research Institution on Japanese side

Institute of Tropical Medicine of Nagasaki University (NUITM) serves as the Japanese research

institution of the Project.

(7)Inputs

① Japanese Side

<Dispatch of Experts >

- (i) Chief Advisor/Development of Rapid Diagnostics And Alert System (Short-term Experts)
- (ii) Research Management (Long-term Expert)
- (iii) Researchers (Long-term Expert)
- (iv) Project Coordinator (Long-term Expert)
- (v) Genetic Engineering (Short-term experts)
- (vi) Viral Experiments (Short-term Experts), etc.

<Training in Japan >

- (i) Virology (Recombinant Viral Protein Expression)
- (ii) Monoclonal Antibody Development
- (iii) Laboratory Diagnosis
- (iv) Quality Management System (QMS) for production
- (v) Molecular Epidemiology
- (vi) Other Necessary Training

<Provision of Equipment >

- (i) Necessary equipment for research and development activities in the Project
- (ii) Necessary equipment and/or devices for development of the bidirectional early vigilance and rapid response mechanism.

<Local Costs >

Running expenses necessary for implementation of the project activities other than those that are borne by the Kenyan side.

② Kenyan Side

<Counterparts >

- (i) Project Director
- (ii) Project Manager
- (iii) Project Co-managers
- (iv) Researchers (Ph.D., MSc.) in Virology, Immunology, and Communicable disease surveillance.
- (v) Health Personnel engaged in early vigilance and rapid response for disease outbreaks

<Land, Facilities, equipment and materials >

- (i) Office space at KEMRI headquarters and KEMRI-CIPDCR (Alupe)
- (ii) Laboratory space at KEMRI-PD
- (iii) BSL-3 laboratory at KEMRI
- (iv) BSL-2 laboratory at KEMRI-CIPDCR (Alupe)
- (v) Clinical specimens from YF and RVF suspected cases

<Local Costs >

Running expenses necessary for implementation of the project activities such as personnel costs of researchers, research activity costs including travel expenses, consumables, and supplies, utility costs such as water, electricity and communication, etc.

(8)Special Considerations for Environmental Society, Poverty Reduction, Social Development

Through the research activities conducted by the project, experimental waste disposal must be properly processed both at KEMRI Headquarters and KEMRI-CIPDCR (Alupe). Solid waste is generally disposed at KEMRI HQ with its own incinerator, but KEMRI-CIPDCR (Alupe) is using an incinerator of a neighboring medical facility. Construction of appropriate incinerator within the space available at the KEMRI-CIPDCR (Alupe) should be considered. Regarding the liquid waste, wastewater sewerage system of both facilities are placed independently from the general sewerage system, and designed not to affect the general environment. In the KEMRI Headquarters, special liquid waste is segregated and processed in accordance with the regulation. KEMRI-CIPDCR (Alupe) will have to take proper disposal procedures in accordance with the same regulation in waste treatment as the KEMRI HQ.

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## (2) Related Aid Activities

## ① Japan's Aid Activities

JICA Expert (Dr. Shingo INOUE) was dispatched in 2008 by Nagasaki University to KEMRI-PD for development of new diagnostics in Arboviruses and assisted JICA and KEMRI in keeping up preparation of this project.

## ② Aid Activities of Other Development Partners

CDC has a base in KEMRI, and provides the KEMRI-CVR with technical assistances including confirmed diagnosis on YF and RVF (viral antibody detection-ELISA<sup>1</sup> and genetic detection -PCR<sup>2</sup> method) for suspected cases and supporting KEMRI-RD to obtain the WHO accreditation.

## 4. Framework of the Project

## (1) Project Outline

## ① Project Purpose

Outbreak containment system of YF and RVF is strengthened in Kenya through the development of rapid diagnostics and establishment of a sustainable outbreak vigilance and response mechanism.

## &lt; Objectively Verifiable Indicator (OVI) &gt;

1. Rapid diagnostic test kits for YF and RVF are stably available in the target area.
2. The Operational Manual is integrated by the MOPHS into the national surveillance and response system for priority diseases by the end of project period.
3. The time taken from the first clinical suspicious cases to confirmation of diagnosis is 1 week or less.

## ② Outputs and Activities

## &lt; Output 1 &gt;

Rapid diagnostics (test kits) for YF and RVF are developed in collaboration between researchers from Kenyan and Japanese sides.

## &lt; OVI for Output 1 &gt;

1. Rapid diagnostic test kits and ELISA test kits using viral antigens with more than 90% sensitivity and specificity are produced in KEMRI by the end of 2013.
2. Rapid diagnostic test kits using genetically engineered antigens with more than 90% sensitivity and specificity are produced in KEMRI by the end of 2014.
3. KEMRI-PD receives the qualification of ISO 13485: 2003 by the end of 2014.

## &lt; Activities under Output 1 &gt;

- 1-1. Preparation of reference antigens of YF and RVF by large-scale cell culture systems.
  - 1-1-1. Establish a large-scale viral antigen preparation system using eukaryotic cells in KEMRI-PD.
  - 1-1-2. Prepare viral antigens by purifying virus particles from the system.
- 1-2. Preparation of genetically-engineered antigens of YF virus and RVF virus for development of antibody-detecting rapid diagnostic test kit.
  - 1-2-1. Establish a large-scale expression system of viral protein antigens with cultured prokaryotic cells in KEMRI-PD.
  - 1-2-2. Prepare genetically-engineered diagnostic antigens, designed on the basis of preliminary study, by affinity chromatography technique.
- 1-3. Production of conjugated monoclonal and polyclonal anti YF virus and RVF virus antibodies.
  - 1-3-1. Purify polyclonal antibodies from sera of experimental animals sensitized by YF and RVF viral antigens prepared by activity 1-1.
  - 1-3-2. Prepare monoclonal antibodies from large scale culture of hybridoma cells provided from the Institute of Tropical Medicine, Nagasaki University.
  - 1-3-3. Label polyclonal and monoclonal antibody by conjugating with Horseradish Peroxidase

<sup>1</sup> ELISA: Enzyme-Linked Immunosorbent Assay

<sup>2</sup> PCR: Polymerase Chain Reaction

(HRP) or colloidal gold particles.

- 1-4. Production of rapid diagnostic test kits for POC testing of YF and RVF using immunochromatography technology.
  - 1-4-1. Coat each antigen on immunochromatography membrane using spraying machine.
  - 1-4-2. Fabricate rapid diagnostic test kits by assembling relevant parts produced in KEMRI-PD.
  - 1-4-3. Evaluate specificity, sensitivity and stability of the YF- and the RVF-rapid diagnostic test kits by comparative reviewing with advanced reference diagnostics of ELISA.
  - 1-4-4. Validate the rapid diagnostic test kits for POC testing at field level, developed by the Production Department, using clinical specimens at KEMRI-CVR and KEMRI-CIPDCR (Alupe).
- 1-5. Preparation of ELISA tests for YF and RVF as higher reference diagnostics.
  - 1-5-1. Fabricate ELISA test kits by assembling relevant parts produced in KEMRI-PD.
  - 1-5-2. Validate the ELISA kits, developed by the Production Department, by using clinical specimens at KEMRI-CVR and KEMRI-CIPDCR (Alupe).

< Output 2 >

Advanced rapid and accurate reference activities are in place and functional in KEMRI headquarters as well as KEMRI-CIPDCR (Alupe) in collaboration between Kenyan and Japanese sides.

< OVI for Output 2 >

1. Entire KEMRI receives the qualification of ISO 9001: 2008 by the end of 2012.
2. Sensitivity and specificity of laboratory diagnosis by ELISA and gene amplification technique in KEMRI are as same level as that in WHO collaborating centers by the end of 2014.

< Activities under Output 2 >

- 2-1. Strengthening reference capacity for rapid confirmation of YF and RVF at KEMRI headquarters.
  - 2-1-1. Enhance the function of existing Biosafety Level (BSL)-3 laboratories in the KEMRI headquarters by renovating it and supplying necessary research instruments.
  - 2-1-2. Set up safe virus isolation system in BSL-3 laboratories targeting on YF virus and RVF virus for monitoring of antigenic variation and genetic mutation.
  - 2-1-3. Set up and standardize gene amplification and detection system (e.g. real-time PCR) of YF virus and RVF virus as reference diagnostics at field laboratories.
  - 2-1-4. Collect and analyze specimens for monitoring of antigenic variation and genetic mutation of YF virus and RVF virus.
- 2-2. Establishment of primary reference capacity for confirmation of YF and RVF at KEMRI-CIPDCR (Alupe)
  - 2-2-1. Enhance the function of existing BSL-2 laboratory in KEMRI-CIPDCR (Alupe) by renovating it and supplying necessary research instruments.
  - 2-2-2. Set up safe virus inoculation and RNA extraction system in the BSL-2 laboratory targeting on arboviruses.
  - 2-2-3. Set up and standardize gene amplification and detection system at field laboratory level (e.g. real-time LAMP<sup>3</sup>, conventional PCR).
  - 2-2-4. Collect and analyze clinical specimens for diagnosis of YF and RVF at field laboratory level.

< Output 3 >

Bidirectional early vigilance and rapid response mechanism model for YF and RVF outbreaks is established and evaluated in collaboration with MOPHS officials, selected health facilities officials and JICA Experts.

< OVI for Output 3 >

1. Sensitivity/specificity, completeness and timeliness of reporting are improved in comparison to the baseline data. (*target values will be determined on the basis of baseline investigation by the Joint Coordinating Committee meeting in 2014*).
2. Results from POC testing for YF and RVF are reflected in the DDSR Weekly Bulletin by the end of 2015.

<sup>3</sup> LAMP: Loop-Mediated Isothermal Amplification

3. Ratios of laboratory confirmed cases of YF and RVF reach 80% among all the suspicious cases in the target areas of the Project by the end of 2016.
4. The Operational Manual is officially authorized by the MOPHS by the end of 2016.

< Activities under Output 3 >

- 3-1. Integration of YF and RVF outbreak response network model into the existing communicable diseases response system in MOPHS/DDSR (Division of Disease Surveillance and Response).
  - 3-1-1. Set up a working group for development of YF and RVF outbreak response network model, composed of representatives from MOPHS, KEMRI, health facilities, other relevant agencies and Japanese experts.
  - 3-1-2. Develop a mobile networking system using verbal and Short Message Service (SMS) communication for communicable diseases vigilance and response system including YF and RVF.
  - 3-1-3. Develop a draft Operational Manual of mobile phone-based bidirectional early vigilance and response for YF and RVF outbreaks.
  - 3-1-4. Distribute mobile phones to health personnel engaged in communicable diseases outbreak vigilance and response system, followed by test operation of reporting system in accordance with the draft Operational Manual in a limited scale.
- 3-2. Set up the mobile phone linked to network of selected health facilities and laboratories in Central, Coast, Nairobi, North Eastern, and Western, Provinces.
  - 3-2-1. Enroll 200 selected health facilities and laboratories in the pilot areas identifying responsible personnel for each institution.
  - 3-2-2. Provide trainings for manipulation of the rapid diagnostic test kits after its distribution to relevant facilities.
- 3-3. Conduct outbreak report and response simulation including table-top exercises in collaboration with DDSR, KEMRI, selected health facilities and other relevant agencies.
- 3-4. Verify the effectiveness of the novel outbreak vigilance and response system on spreading rate of communicable diseases and its responses by evaluating the data from the simulation in 3-3.
- 3-5. Revise and finalize the Operational Manual on the basis of the assessment results from the test operations and the simulations.

③ Considerations for Project Implementation

1. The application for this technical cooperation project was submitted by MOPHS, but this project will be managed jointly among chiefs of the participating institutions and organizations. They are Director of KEMRI, Director of KEMRI-CIPDCR (Alupe), Director of Department of Diseases Prevention and Control (MOPHS), while the initiative is taken by Director of KEMRI. Whether this project goes smoothly or not will have an influence on the success of the project from the viewpoint of efficiency. Thus, in order to coordinate the activities among the implementers and to monitor the progress of the research activities, a Project Steering Committee (PSC) will be established under the Joint Coordinating Committee. Additionally, research teams will be set up under the PSC and each researcher will be required to submit a quarterly research progress report. It is necessary to check whether this system will function after the project starts.
2. It is important for MOPHS to purchase the rapid diagnostic test kits produced through the project and to materialize the domestic distribution in Kenya from the viewpoint of sustainability and impact on the infection control in Kenya as well as other East African countries. Thus, the quality evaluation of the rapid diagnostics by the National Public Health Laboratory Service, MOPHS and accreditations by the third party including ISO certification of the KEMRI-PD must be conducted appropriately. The Kenyan side took note of the fact that these evaluation and accreditation should be adequately processed.
3. Originally, Central, Nairobi, Western and Coast Provinces, were considered as target areas for establishing an alert system for outbreaks. However, the Kenyan side strongly requested the addition of North Eastern Province that borders Somalia for reasons that the province is geographically important to monitor the invasion of infectious diseases from the neighboring countries, and that previously the province had an outbreak of RVF. The detailed planning survey team agreed to add the North Eastern Province, but the implementation of the concrete activities need to be discussed on the basis of the latest JICA personnel safety measures after the project starts,

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<p>because access to parts of the province is still restricted by JICA's safety regulations,.</p> <p>4. There is an existing surveillance system in which the reports are sent up to the central level from health facilities via district disease surveillance coordinators. The early vigilance and rapid response system will be established in line with the existing one and eventually integrated because of sustainability of the Kenyan side. Therefore, it is important to obtain the right understanding and support by administrative organizations in charge of district and provincial health services.</p> <p>(2) Other Impacts</p> <p>Basic techniques of rapid diagnostics of YF and RVF to be developed by the Project will be available to other diseases. Joint research activities of the Project will focus on only the two diseases, but it is highly expected that diagnostics of other arboviruses and infectious diseases will be strengthened if capacities of researchers are developed. Also, if the rapid diagnostic test kits are produced and commercialized in East Africa after receiving third-party accreditation, significant positive impacts in the region will be realized with regard to control of YF and RVF</p>
<p>5. Pre-conditions and Important Assumptions (Risk Control)</p> <p>① Pre-conditions</p> <ol style="list-style-type: none"> <li>1. Approval is obtained by the Scientific Steering Committee (SSC) and the Ethical Review Committee (ERC) for the research subjects conducted in the Project.</li> <li>2. Approval is obtained from relevant ministry/authority for genetic engineering.</li> <li>3. Clearance for animal use is obtained from SSC, ERC and the Animal Care and Use Committee: ACUC of KEMRI.</li> <li>4. Clearance for material transfer or export/import is obtained from relevant ministry/authority.</li> </ol> <p>② Important Assumptions for Outputs</p> <ol style="list-style-type: none"> <li>1. Kenyan side allocates an adequate budget and personnel for the project activities.</li> <li>2. Trained counterparts do not leave their position so as to affect the outputs of the Project.</li> <li>3. Necessary cooperation is obtained from health facilities and relevant agencies for the project activities.</li> </ol> <p>③ Important Assumptions for Project Purpose</p> <ol style="list-style-type: none"> <li>1. Kenyan side properly proceeds with third-party accreditation, in terms of quality evaluation of diagnostics by National Public Health Laboratory Services (NPHLS) as well as ISO certification for KEMRI, necessary for official use of the rapid diagnostic test kits in Kenya.</li> <li>2. Cooperation from relevant authorities for official authorization of the Operational Manual as a part of the national surveillance response system is gained.</li> </ol>
<p>6. Evaluation Results</p> <p>The project is fully aligned to the development policy and needs of Kenya as well as Japan's assistance policy to Kenya. Accordingly, significance of implementing the Project is highly recognized.</p> <p>Kenya and neighboring East African countries have suffered tremendous loss of not only human lives but also those of livestock caused by Arbovirus outbreaks such as YF and RVF. As expressed in NHSSP II and MOPHS Strategic Plan, though measures against the three major infectious diseases HIV/AIDS, malaria and tuberculosis are being coordinated with other development partners, YF and RVF are way behind in all areas of surveillance, diagnosis and treatment. However, MOPHS officials added emphasis on enforcing the measures against YF and RVF not only in protecting the people's health but also in terms of zoonosis and its effect on tourism. There are high expectations for the implementation of this project notably in developing rapid diagnostics, strengthening referral functions for diagnosis and establishing outbreak alert system for YF and RVF. This project is in line with the needs of the Kenyan government's health policy and fulfills the needs of the Kenyan population residing in the endemic area. It is also highly consistent with the Japan's ODA policy, which values the importance of infectious disease control, and;</p> <p>This project aims at improvement of capacity for "early containment" (Project Purpose) of YF and RVF, by developing rapid diagnostics that enable POC testing (Output 1), strengthening referral diagnostic functions including confirmed diagnosis conducted after field-level diagnosis (Output 2) and strengthening bidirectional outbreak alert system starting from the POC testing (Output 3). These</p>

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Outputs efficiently cover all the elements necessary for “early containment” such as rapid and accurate diagnosis and bidirectional information system, responding to the global demand for research on infectious disease control. This project is theoretically feasible without logical discrepancy between the project purpose and outputs. Commercialization of YF and RVF rapid diagnostics within the project period is strongly expected for not only domestic sales but to other endemic areas in East African countries in the future.

#### 7. Lessons Learned from Past Project

*‘The Research and Control of Infectious Diseases Project’* (Technical Cooperation Project) and *‘The Project for Improvement of Facilities for Control of Infectious and Parasitic Diseases at Kenya Medical Research Institute’* (Grant Aid Project) were implemented in Kenya for effective control of HIV/AIDS, and viral hepatitis as well as strengthened research capacity and production of test kits by KEMRI. As a result of these projects, blood-screening kits for HIV and hepatitis B were developed and produced. Subsequently, KEMRI obtained a marketing license of succeeding rapid diagnostic test kits for HIV and hepatitis B for domestic sales in Kenya, and started production of the kits.

The post evaluation reports of the two projects revealed that foreign-made test kits occupied a great deal of marketing shares in HIV and hepatitis B because the Project had been slow in responding to change of MOPHS procurement policy that suppliers were required to have pre-qualification by WHO, and due to insufficient sales capacity of KEMRI. On the other hand, the reports concluded that the capacity in technical research and the production of KEMRI were found to be reinforced.

The project will proceed for acquiring the WHO pre-qualification by establishing system of quality management regarding the production process of rapid diagnostic kits of YF and RVF by utilizing strengthened capacity in technical research and the productivity of KEMRI. Consequently, the kits will be available on domestic and regional market for sales after they are purchased by MOPHS.

#### 8. Future Evaluation Plan • Mid-term Review; June, 2014 • Terminal Evaluation; June, 2016

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