

# Internal Ex-Post Evaluation for Technical Cooperation Project

conducted by Vietnam office: March, 2014

Country Name	Project for Strengthening Capacity for Measles Vaccine Production
Socialist Republic of Vietnam	

## I. Project Outline

Background	<p>Prior to the Project, morbidity and mortality rate of measles was high in Vietnam, especially for children. The Vietnamese government started provision of two doses of measles vaccine per child following the strategy of WHO. Accordingly, the domestic demand for the vaccine was expected to increase. On the other hand, international vaccine manufacturers had tended to shift from low-profit measles vaccine production to more profitable vaccines production, so there was a concern about a stable supply of imported measles vaccines at a reasonable price in Vietnam. Under these circumstances, domestic production of measles vaccine to secure stable supply was an important issue for reducing prospective financial burden of the Ministry of Health. In order to cope with the above issues, "the Project for the Construction of the Facilities for Measles Vaccine Production (2003-2006)" was implemented under Japanese grant aid to construct measles vaccine production facility as a part of Center for Research and Production of Vaccines and Biologicals (POLYVAC). Since POLYVAC did not have experience in measles vaccines production, capacity development of POLYVAC was also necessary.</p>										
Objectives of the Project	<ol style="list-style-type: none"> <li>Overall Goal: Measles Infection Rate in the Socialist Republic of Vietnam will be decreased from the level of 2005.</li> <li>Project Purpose: Center for Research and Production of Vaccines and Biologicals (POLYVAC) will be capable to produce necessary amount of measles vaccines for use of measles control activities in the Socialist Republic of Vietnam complying with Vietnam-GMP <sup>(Note 1)</sup> which complies with WHO-GMP standard.</li> <li>Assumed steps for achieving the project goals: The project implements technical training and establishes quality management system for measles vaccines production complying with WHO standard. Through these activities, the project improves the capacity of POLYVAC to produce necessary amount of measles vaccine in Vietnam complying with WHO-GMP standard. As POLYVAC's measles vaccine becomes widely utilized for measles control activities in Vietnam, the domestic supply of measles vaccine will be increased. As a result, immunization rate of measles vaccine in Vietnam will be increased, and ultimately, measles infection rate in Vietnam will be decreased from the level of 2005. (Note 1) GMP: Good Manufacturing Practice: a system that those who are engaged in pharmaceutical and biotech production must follow to ensure that products are consistently produced and controlled according to quality standards appropriate to their intended use and as required by the product specification.</li> </ol>										
Activities of the project	<ol style="list-style-type: none"> <li>Project site: Hanoi</li> <li>Main activities Technical transfer of mass production of the measles vaccine to POLYVAC staff, establishment of Performance Qualification (PQ) and Process Validation (PV) systems complying with Vietnam-GMP which has met WHO-GMP standard, and preparation of various GMP related documents.</li> <li>Inputs (to carry out above activities) <table style="width: 100%; border: none;"> <tr> <td style="width: 50%;">Japanese Side</td> <td style="width: 50%;">Vietnamese Side</td> </tr> <tr> <td>1) Experts: 38 persons for Short term</td> <td>1) Staff allocated: 68 persons</td> </tr> <tr> <td>2) Trainees received: 12 persons</td> <td>2) Land and facilities: Measles vaccine production facility, project office</td> </tr> <tr> <td>3) Equipment: Calibration and validation equipment</td> <td>3) Others: Cost for low materials, salaries to counterpart personnel, energy bill, facility maintenance cost, etc.</td> </tr> </table> </li> </ol>			Japanese Side	Vietnamese Side	1) Experts: 38 persons for Short term	1) Staff allocated: 68 persons	2) Trainees received: 12 persons	2) Land and facilities: Measles vaccine production facility, project office	3) Equipment: Calibration and validation equipment	3) Others: Cost for low materials, salaries to counterpart personnel, energy bill, facility maintenance cost, etc.
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Project Period	March 24, 2006 – March 23, 2010	Project Cost	485 million yen								
Implementing Agency	Center for Research and Production of Vaccines and Biologicals (POLYVAC)										
Cooperation Agency in Japan	The Kitasato Institute, Research Center for Biologicals										
Related Projects	<p>Japanese cooperation:</p> <ul style="list-style-type: none"> <li>Project for the Construction of the Facilities for Measles Vaccine Production (Grant aid, 2003-2006)</li> <li>Follow-up cooperation on the Project for Construction of the Facilities for Measles Vaccine Production (Technical cooperation, January 2011-August 2011)</li> <li>The Project for Strengthening Capacity for Measles – Rubella Combined Vaccine Production in the Socialist Republic of Vietnam (Phase II) (Technical Cooperation, 2013-2018)</li> </ul> <p>Other donors' cooperation:</p> <ul style="list-style-type: none"> <li>Assistance for measles vaccine immunization (GAVI, UNICEF, WHO etc.)</li> </ul>										

## II. Result of the Evaluation<sup>1</sup>

### 1 Relevance

This project has been highly relevant with Vietnamese development policy (“decrease of infant mortality rate and control of infection diseases by vaccine immunization” in the Strategy for Public Health Care and Protection 2001-2010 and the Health Vietnamese Long-term Healthcare Policy 2010-2020), development needs (“establishment of domestic production system for measles vaccine complying with WHO-GMP standard”), as well as Japan’s ODA policy for Vietnam with the priority area of improvement of lifestyle and social aspects including health and medical care, at the time of both ex-ante evaluation and project completion. Therefore, relevance of this project is high.

### 2 Effectiveness/Impact

This project focuses on establishment of domestic production system for measles vaccines complying with WHO-GMP standard at POLYVAC. POLYVAC was equipped to produce measles vaccines at a rate of 300,000 doses x 2.5 batch annually (i.e.7.5 million doses/year) by the Project. In 2009, POLYVAC achieved a production rate of 5 contiguous batches (1.5 million doses) in 2 months. It indicates that POLYVAC has acquired the production capability of more than 8 million doses annually. As requested by the Ministry of Health who purchases the POLYVAC vaccines, POLYVAC duly produced 2.4 million doses of measles vaccines in 2010.

Due to the recent increase of rubella infection in Vietnam, MOH decided to replace the second dose of measles vaccine by measles and rubella vaccines (MR vaccines) in and after 2018. Under this circumstance, MOH also decided to expand the POLYVAC’s capacity to produce MR vaccine by utilizing technology transferred by the Project. In accordance with the request from MOH, JICA launched a new project for technology transfer of MR vaccines production in 2013. In addition, POLYVAC successfully obtained clearance on the production and quality management of measles vaccines complying with WHO-GMP standard from the National Regulatory Authority (NRA) and a license was granted in December 2009. As a result, two indicators were fulfilled and the project purpose is deemed to be achieved.

As for overall goal<sup>2</sup> which was redefined as “domestic supply of measles vaccine complying with WHO-GMP standard is improved in Vietnam”, before the project implementation 100% of imported vaccines were utilized for EPI in Vietnam. However, MOH started to utilize domestic measles vaccines produced by POLYVAC for EPI in 2009 and the domestic supply ratio of measles vaccine has subsequently reached 100% in 2012. MOH estimates necessary measles vaccines as 3.2 million doses/year. The in-stock vaccine of 4.9 million of 2011 was used for 2012 and the vaccines purchases in 2012 have been used for 2013. According to the production plan of POLYVAC, they will maintain production of 2-2.5 million doses of measles vaccines per year until 2020 even after they start to produce MR vaccines in 2018 with the assistance of ongoing Phase II of this project<sup>(Note 1)</sup>. Epidemiological information shows that surveillance was strengthened and more clinical measles cases were reported but virologically confirmed cases were decreased obviously so that the incidence of measles among children was lower in 2012 than 2005<sup>3</sup>. Therefore, this project has achieved the project purpose and overall goal in terms of the indicators set in the project design matrix (PDMver2).

On the other hand, at the terminal evaluation, the evaluation team evaluated impact of the project based on “Probability of MV production covering domestic demand” and “Probability of MV export for neighboring countries via UN Agencies”. (Joint Terminal Evaluation Report (13 Nov 2009) p19, ) Then, this ex-post evaluation also examined those two indicators to measure achievement of the overall goal, and found that MV export for neighboring countries has not been realized because NRA’s functions have not been accredited by WHO, which is a precondition to export measles vaccines produced by POLYVAC. Therefore, overall effectiveness/impact of the project is fair.

(Note 1) JICA’s technical cooperation “the Project for Strengthening Capacity for Measles – Rubella Combined Vaccine Production in the Socialist Republic of Vietnam” (2013-2018).

Measles Vaccines Production in Vietnam

(Unit: 1,000 doses)

	2009	2010	2011	2012
1) Measles vaccines production by POLYVAC	2,670	2,390	3,200	2,700
2) Purchased amount of POLYVAC measles vaccines by MOH	1,300	2,000	3,200	2,700
3) Imported vaccines supplied by GAVI <sup>(Note 2)</sup>	1,740	1,580	1,700	0
4) Imported vaccines supplied by UNICEF/WHO <sup>(Note 3)</sup>	0	8,100	0	0
5) Total (=2+3+4)	3,040	11,680	4,900	2,700
6) Ratio of POLYVAC vaccines against the total supply in Vietnam (=2/6)	43%	17%	65%	100%

(Note 2): GAVI: Global Alliance for Vaccines and Immunization.

(Note 3): To respond to outbreak of measles in 2009, UNICEF/WHO had supplied measles vaccines in 2010.

Achievement of project purpose and overall goal

Aim	Indicators	Results
(Project Purpose) POLYVAC will be capable to	Measles vaccines are produced in POLYVAC at a rate of 0.3 million	(Project Completion) POLYVAC is able to produce measles vaccines at a rate of 7.5 million doses/year, but only 2.39 million measles

<sup>1</sup> Constraint of Evaluation: Since there is a logical discrepancy between the project purpose and overall goal, the ex-post evaluation redefined the overall goal as “domestic supply of measles vaccine complying with WHO-GMP standard is improved in Vietnam” and its indicator was set as “domestic supply ratio of measles vaccine complying with WHO-GMP standard”.

<sup>3</sup> Number of children reported as measles was 410 clinically but 175 was confirmed in laboratory among them in 2005. In 2012, children reported as measles clinically was 578 but only 6 cases among them were confirmed in laboratory. (Source: WHO/UNICEF Joint Report Form)

produce necessary amount of measles vaccines for use of measles control activities in Vietnam complying with Vietnam-GMP which has met WHO-GMP standard.	doses x 25 batch (i.e. 7,5 million doses)/year	vaccines were produced in 2010 according to the target set by MOH. (Ex-post Evaluation) POLVAC plans to produce 2.2 million measles vaccines in 2013 according to the target set by MOH.
	Clearance on the production and quality management by NRA which has met WHO-GMP	(Project completion) License was granted by NRA in December 2009. (Ex-post Evaluation) License is still effective until October 2014.
(Overall goal) Measles Infection Rate in Vietnam will be decreased from the level of 2005	Rate of children infected with measles in Vietnam	(2005) 0.48 (410/8,4948,000 × 100,000) (2012) 0.64 (578/90,796,000 × 100,000) * 410 and 578 are the numbers of children reported as measles clinically (Note 4)
	Number of children immunized with measles vaccine in Vietnam	Number of children immunized with measles vaccine in 2005 was 1,448,721 among target population (1,545,475), The immunization coverage was 95.2%. (Note 4) (Ex-post Evaluation) Number of children immunized with measles vaccine in 2012 was 1,711,096 among target population (1,775,756). The measles vaccine immunization coverage of children was 96.3% in 2012. (Note 4)

Source : Project Completion Report, Interviews with counterparts  
(Note4): WHO/UNICEF Joint Report Form

### 3 Efficiency

Although the project was implemented within the planned period (ratio against the plan: 100%), the project cost exceeded the plan (ratio against the plan: 131%). This stems largely from a difficulty to estimate budget accurately at the stage of project design due to technical constraints. Through cooperative efforts between POLYVAC and the Project, the inputs were appropriate for producing the outputs of the project. Therefore, efficiency of this project is fair.

### 4 Sustainability

From the policy aspect, even after the Vietnamese Government introduces MR vaccine for EPI, both Measles and MR vaccine will be used for EPI. Therefore this project is still given importance in the current development policy of the Five-Year Plan for Health Sector (2011-2015), which prioritizes the promotion of the domestic production of EPI vaccines. Regarding the institutional aspect, POLYVAC has sufficient number of staff with 129 employees, of which one third of staff are categorized in level A4 who are able to work by themselves and can retrain others. Regarding the technical aspect, POLYVAC has been conducting training for staff to maintain and improve their knowledge and technical skills on routine measles vaccines production complying with GMP standards. Also GMP related documents including Standard Operating Procedure (SOP) have been properly utilized. POLYVAC currently has been receiving technical support to produce MR vaccines under Phase II of this project. Regarding the financial aspect, POLYVAC experienced a deficit in 2010 because sales of measles vaccines remained at 2 million doses, and the counterpart funds from the MOH were terminated along with the completion of this project. The actual production cost is estimated twice or more than the planned costs because the annual production quantity remains as little as two to three million doses per year. Importing many kinds of test reagents from Japan is another factor to push up the production costs. However, after 2011 POLYVAC recovered to produce a profit. In order to secure the stable profitability of POLYVAC, the annual production quantity must be increased. It is considered that POLYVAC can remain profitable as long as they maintain present production and their production is purchased by MOH as planned. Additionally, although POLYVAC is financially independent, POLYVAC is considered to be able to receive finance support from government in case of financial difficulty because POLYVAC is a MOH affiliated company. .

From these findings, sustainability of this project is high.

### 5 Summary of the Evaluation

The project has achieved the project purpose and overall goal. POLYVAC was able to produce measles vaccines at a rate of 7.5 million doses/year by the project. Although their actual production quantity remains less than half of its' target value after the project completion in 2010 because the annual production quantity depends on the demand of EPI. The project achieved a ratio of 100% of domestic supply of measles vaccine in 2012. POLYVAC successfully obtained clearance on the production and quality management of measles vaccines complying with WHO-GMP standard from NRA in 2009. Regarding sustainability, although profitability of POLYVAC is of a concern due to high production costs, it is considered that financial support from government is to be given when POLYVAC faces financial difficulty. Therefore, sustainability is high. As for efficiency, the project cost exceeded the plan due to increase in number of Japanese experts dispatched. In the light of above, this project is evaluated to be satisfactory.

## III. Recommendations & Lessons Learned

Recommendations for Implementing agency:

- It is strongly suggested that POLYVAC continues staff training in order to strengthen and maintain the knowledge and skill regarding GMP standard.
- It is desirable if MOH could make more efforts to promote NRA to receive accreditation by WHO so that POLYVAC will be able to export its vaccines.

Lessons learned for JICA:

The production capacity was set at 7.5 million per year when designing the plant while the current domestic demand of measles vaccine is about 3-3.2 million x 1.5 times per year and the total quantity of domestic demands and export does not

reach 7.5 million. Thus, the manufacturing plant could not run as fully as designed, resulting in i) high unit cost and ii) high operation costs. Therefore, it is necessary to forecast the needs of vaccine carefully by taking into consideration of the changes of the demand and other factors before construction of a facility under Grant Aid. Additionally, the current technical cooperation project, which is planned to utilize the constructed facility, needs to review its production capacity to respond to changes periodically, so that project effectiveness and sustainability are ensured.



Staff members work in manufacturing process



Measles Vaccine produced by POLYVAC