



GAVI/12/047/sk/rh

The Minister of Public Health
Ministry of Public Health
Vientiane
Lao PDR

3 May 2012

Dear Minister,

Lao PDR Proposal to the GAVI Alliance

In a letter of 29 February 2012, we informed you that the Independent Review Committee (IRC) recommended "Approval" of your proposal for pneumococcal vaccine introduction.

We are pleased to inform you that the GAVI Executive Committee (EC), at its meeting on 12 April 2012, considered and **endorsed the IRC recommendation** of your 2013-2015 proposal for the introduction of pneumococcal vaccine. For your reference, the IRC summary report is attached in Appendix A.

As specified and agreed in the submitted application form, Lao PDR will co-finance the procurement of pneumococcal vaccine. The level of co-financing is determined by GAVI's co-financing policy where Lao PDR is classified in the low-income group based on the 2010 GNI per capita data released by the World Bank. Therefore, Lao PDR's co-financing requirement is US\$ 0.20 per dose in the first year, followed by an annual increase of 15%. Please note that the requirement to co-finance this vaccine will begin only once the supply of the vaccine commences.

GAVI is keen to support you to make the earliest possible introduction of pneumococcal vaccines. However, due to an unprecedented demand for pneumococcal vaccines and the lead time required by manufacturers to increase vaccine production, it is possible that the global vaccine supply will not meet all country requirements approved by GAVI in the short term.

As a consequence, the actual amount of doses and the vaccine introduction timeframe may differ from that requested in your proposal. The final total dollar amount of Lao PDR's co-financing requirement and the allocated number of doses will be communicated to you in a separate letter in due course.

Please do not hesitate to contact my colleague Dr Raj Kumar at rajkumar@gavialliance.org if you have any questions or concerns.

Yours sincerely,

A handwritten signature in blue ink, appearing to read "Helen Evans".

Helen Evans
Deputy Chief Executive Officer

GAVI Alliance

2 Chemin des Mines
1202 Geneva
Switzerland

Tel. +41 22 909 6500
Fax +41 22 909 6555

www.gavialliance.org

Attachments: **Appendix A: IRC country report, February 2012**

cc: **The Minister of Finance**
The Director of Medical Services
Director Planning Unit, MoH
The EPI Manager
WHO Country Representative
UNICEF Country Representative
Regional Working Group
WHO HQ
UNICEF Programme Division
UNICEF Supply Division
The World Bank
The GAVI Finance Unit

IRC NVS COUNTRY REPORT
Geneva, June 24 – July 08 2011

Country name: Lao PDR
Type of support requested: NVS
Vaccines requested: PCV-13

Country profile/Basic data (year)

Population	6,395,218
Birth cohort	175,359
Surviving infants	169,445
DTP3 coverage (administrative)	74%

Infant mortality rate (y2005)	70
Govt. Health expenditure as percent of total government expenditure	5.50%
GNI/capita (2009r)	880\$
Co-financing country group*	Low income

*low income, intermediate or graduating

1. Type of support requested/Total funding/Implementation period

Lao PDR has requested for PCV-13 in single dose/vial liquid presentation, from 2013 to 2015. The second preferred presentation is PCV-10, 2 doses per vial liquid.

2. History of GAVI support

ISS: 2002-2006
DTP-HepB: 2002-2009
Penta: 2009-2011
INS: 2002-2004
HSS: 2010

3. Composition & Functioning of the ICC

The ICC and the Technical Working Group meet regularly. It has active participation from the donors and ownership by the government. Inter-Agency Coordination Committee on immunization (ICC) established in 1992 as a stand-alone body, meeting 3-4 times per year (at least). It is composed of 8 members: government officials plus WHO and UNICEF.

The application was presented by WHO EP officer to the ICC at the May 12th (2011) meeting. According to the minutes APR was approved by ICC (to be signed by MoH, WHO and UNICEF). There is no mention of the PCV application to GAVI.

4. Status of the National Immunisation Programme

The National Immunization Program was launched in 1979 as the "Expanded Program on Immunization (EPI)" with introduction of six vaccines (BCG, Diphtheria, Tetanus, Pertussis, Polio and Measles). The program was started as a pilot in two provinces and 10 districts and was gradually extended to all provinces by 1989.

Since 2002, GAVI Alliance has supported Lao PDR with Immunization Services Support (ISS), injection safety support and with introduction of hepatitis B vaccine as tetravalent (DTP-HepB) vaccine, followed by DTP-HepB-Hib vaccine in 2009. The DTP-HepB vaccine was rolled out to all districts by 2004 along with injection safety improvements (100% utilization of AD syringes and safe disposal). Monovalent Hepatitis B birth dose (HBBD) was piloted in 2004 and as of 2007 is being given in three central hospitals and two provincial hospitals. The joint NICEF/WHO/UNFPA initiative for maternal and neonatal tetanus elimination (MNTE) has also been introduced to all provinces. Vitamin A supplementation and de-worming services were added to the routine immunization program in 2005.

The immunization coverage as measured by DPT3 has increased from 49% in 2005 to 74% in 2010 (an increase in 25% coverage). WHO/UNICEF coverage, however, reports 57% for 2009. Measles coverage has increased from 41% to 64%. BCG coverage however has increased from only 65% to 72% (an increase of 7%), indicating that many families are either are not being reached in the first place and/or that there are fundamental problems with demand. National drop-out rate for DPT1/DPT3 for 2010 is 9%, indicating that once first contacts are made the services are for the most part continuing to be utilized.

5. *Comprehensive Multi Year Plan (cMYP) overview*

This cMYP is developed to ensure the progressive improvement and long-term sustainability of immunization services and coverage with increasing ownership by the government and improved donor coordination.

The Plan used the basic framework outlined in the Global Immunization Vision and Strategy (GIVS). It includes strategic activities to address geographic and social inequities in immunization coverage.

The plan puts immunization services in the overall context of child survival delivered as a core package of preventive and primary health care services along with services for safe motherhood, reproductive health, newborn-care, improved nutrition, and IMCI.

6. *New vaccine introduction plan*

WHO estimates that in 2008, pneumonia accounted for 27% and meningitis accounted for 4% of under 5 mortality in Laos (WHS 2010). According to these estimates, pneumonia is by far the most common disease or syndrome causing child death in Laos. In the absence of vaccination, *Streptococcus pneumoniae* and *Haemophilus influenzae* are the most common causes of pneumonia death in children, and are also an important cause for childhood meningitis and sepsis. Hib vaccine has already been introduced. WHO estimates that in 2000, pneumococcus caused 25,605 cases of pneumonia, 109 cases of meningitis and 541 cases of other invasive diseases among children under 5 years of age in Laos, causing 1114 deaths. Hence introduction of pneumococcal vaccine is likely to make substantial contribution to achievement of MDG-4 goal in Lao PDR. However, no country specific studies have been conducted to ascertain the burden of disease.

There is a very detailed introduction plan that has been developed after learning all the lessons from the introduction of pentavalent. Some of the important lessons were as follows:

Print new materials for the new vaccine; consider decreasing the amount of cascade training; use competency based training for health center workers; teach to supervise; reward good performance.

The detailed introduction plan has taken into account all these learning from the assessment of penta introduction.

7. Improvement plan

According to the EVM report (August 2010), Vaccine Management, Distribution and Stock Management scored <50%. Section 4 of the report lists recommendations to address issues revealed during the assessment. As a matter of fact it cannot be considered as an improvement plan because each recommendation needs a set of activities with the timeline and milestones.

Application Form states that "The report and improvement plan have just been released and the action will take place in the near future. Refer to cMYP section 2.1.4 for more information." More detailed report ought to have been provided as to the action taken on the assessment.

8. Cold chain capacity

Based on an EVM analysis conducted in 2010, the cold room and freezer room have sufficient cold storage space to store routine vaccines in net positive storage capacity. However, the capacity needs to be expanded if more than one new vaccines is introduced simultaneously such rotavirus, pneumococcal, pandemic vaccines or human papilloma virus (HPV). The recommendation from the assessment was to add six freezers for ice pack freezing and to add a new walk-in cold room, as the current room is not well ventilated.

Vaccination activities are mostly done through outreach services due to unavailability of cold chain systems at health centers. This has limited the coverage and community's access to immunization services. Vaccinators/health workers collect vaccines in the district vaccine store using a cold box or vaccine carrier. Vaccines in a cold box or vaccine carrier are packed with unconditioned icepacks or frozen ice in plastic bags. The practice of using frozen ice and unconditioned icepacks can put the freeze sensitive vaccines at risk. However, with the expansion of the cold chain system, there is now an increased opportunity to expand utilization of immunization services at the health centre. In fact, the percentage increase in the number of health centres with refrigerated cold chain from 22% in 2006 to 80% in 2010 is likely to have been one reason as to why routine immunization coverage has increased over the last 5 years.

The promotion of a fixed site strategy is identified by the government and its partners as the key condition to improving the performance of the immunization services. It is planned to extend the cold chain equipment to 100% of health centers during this plan period. Adequate cold chain systems at the health centers will improve both the accessibility and quality of immunization services.

9. Financial Analysis

The total cost for traditional four antigens (BCG, MCV1, OPV3, HepB0) for children under 1 years of age and for tetanus immunization for pregnant and CBA women as per the current immunization schedule in the base year 2012 is estimated to be about \$ 500,000 per year (Table 26). The funding of these vaccines

comes from the government, UNICEF, Government of Korea, and Government of Luxembourg. Though the vaccine financing is secured for 2012, the funding is still tentative in the subsequent years. The government has committed \$200,000 or at least 10% of all traditional vaccine cost each year. It is expected that Lux-Development will start a new funding cycle after 2012 and may continue to support a significant portion of the vaccine as they have in 2009-2011.

Among new planned introductions in the current five year plan, Lao PDR is planning to introduce pneumococcal conjugate vaccine in 2013. The cost of new introduction of pneumococcal vaccine, assuming price of one dose at \$3.50 during the whole plan period, will range from \$2,118,528 in 2013 to \$2,342,835 in 2015. The cost of pentavalent vaccine will be shared with GAVI, with government co-financing at the rate of \$0.20 per dose. In addition to GAVI, the government will continue to fund pentavalent vaccine introduced in 2009 for between \$ 123,652 in 2012 and \$136,501 in 2015. Also it is planned that the government will contribute \$ 50,000 per year for introduction of Japanese Encephalitis vaccine.

The proposed introduction of new vaccines will increase the cost of vaccines from \$ 2,355,465 in 2010 to \$ 4,128,093 in 2015—a 75% increase.

It is noteworthy that resource requirements, financing by sources and funding gaps are described separately in details for major cost categories (vaccines, injection supplies, operational costs, investment in cold chain and campaigns. Though the structure of funding gap of \$4 million (~17% of the total resource requirements) is not described and analyses, some of its aspects are described in previous sections (by major cost categories). Unfortunately, the funding gaps are not presented and analysed by type of financing (secure or secure + probable).

Sustainability strategies are general without quantitative projections of outcomes (in terms of decreasing the funding gap). It is noteworthy that switching to more fixed site delivery as well as sharing costs with other primary health programs are listed as financial sustainability strategies (along with traditional ones).

The Government of Laos is committed to increase its total health sector financing to meet its effort to strengthen the overall health system and to create greater sustainability in the health sector. This provides opportunities to increase government commitment for immunization services as well. Firstly, the government will steadily increase government commitment to vaccine financing by including a budget line to buy traditional vaccines (BCG, Measles, OPV and TT). This c-MYP includes government contribution towards traditional vaccines and injection supplies for at least 15% of total cost. The GoL has committed to spending \$ 949,000 for new vaccines over the new multi-year plan period. In addition, government will put domestic resources to meet some of the operational costs towards outreach. Regular advocacy meetings will be held with Minister of Health and Minister of Finance to advocate for increase in financing of different costs associated with immunization services to reduce the donor dependence.

10. Co-financing arrangements

There is a clear commitment to provide co-finance.

11. Consistency across proposal documents

The proposal is consistent across documents.

12. Overview of the proposal: Strengths & weaknesses

Strengths:

- Introduction and improvement plans are well developed.
- Post-introduction assessment of penta is useful.
- Commitment to step-up domestic funding for immunization.
- Strong integration of NIP with a broader package of MNCH services and alignment with the sectoral goals for 2015.

Weaknesses:

- Status of the implementation of the Improvement Plan (or EVM recommendations) cannot be assessed. This is critical.
- The costing tool used for financial projections does not allow analysis of the funding gap by the type of financing (secure or probable).
- Burden of disease is not very well supported

13. Recommendations

Vaccine: PCV

Recommendation: Approval with conditions

Conditions:

1. The country should provide an improvement plan with a set of necessary actions addressing major issues highlighted in the EVM report:
 - a. timeline,
 - b. responsible agencies,
 - c. budget and milestones, and
 - d. the implementation status report.
2. The country should revise its resource requirements for vaccines, indicate the financial risks (probable or secure funding), provide a detailed analysis of the funding gap, showing implications of the unfilled gap on the different programmatic areas of the NIP implementation. The country should propose an alternative funding scenario, matching resource requirements with the financing projections.

14. Review of response to conditions

Independent Review Committee, Geneva, February 6-10 2012

Condition 1:

The country should provide an improvement plan with a set of necessary actions addressing major issues highlighted in the EVM report:

- a. timeline,
- b. responsible agencies,
- c. budget and milestones, and
- d. the implementation status report.

Response:

A cold chain improvement plan based on the findings of the 2011 EVM assessment was submitted. This gives a list of cold chain items and areas that need improvement, the corresponding necessary actions in each case, the agencies responsible for taking these actions, the budget required and budget available for each improvement, and the status of implementation of each action. The plan shows that USD232,000 of the required USD424,000 is available to make the improvements listed, but there is no indication how or from where the balance of USD192,000 will be obtained. All improvements are scheduled for completion by December 2012, although progress is indicated on less than 50% of the activities listed on the plan. The plan is not dated however, so it is unclear whether the status is current, or whether it reflects the situation as it was at some point in the past. However, apart from these omissions, it appears that the IRC's condition 1 has been satisfied.

Condition 1 is met.

Condition 2:

The country should revise its resource requirements for vaccines, indicate the financial risks (probable or secure funding), provide a detailed analysis of the funding gap showing implications of the unfilled gap on the different programmatic areas of the NIP implementation. The country should propose an alternative funding scenario, matching resource requirements with the financing projections.

Response:

A revised, comprehensive financial analysis of the NIP has been carried out based on the GAVI template, and a new funding scenario has been developed. This is submitted as part of the response to IRC, and shows secured and probable funding, and the resulting funding gaps. The analysis details the implications of the funding gap by sector, and shows that only recurrent costs and logistics will be impacted by the shortfall. Figures generated are used to update the on-line GAVI application form, and to completely re-write section 5 of the cMYP. This is also submitted, and it thus appears that condition 2 has been met.

Condition 2 is met.

Recommendation: Approval