

Cambodia SUPPORT for INACTIVATED POLIO VACCINE (IPV)

This Decision Letter sets out the Programme Terms of a Programme.

1. Country: Cambodia				
2. Grant Number: 1518-KHM-25b-X / 15-KHM-08h-Y				
3. Date of Decision Letter: 10 February 2015				
4. Date of the Partnership Framework Agreement: 6 November 2013				
5. Programme Title: New Vaccine Support				
6. Vaccine type: Inactivated Polio Vaccine (IPV)				
7. Requested product presentation and formulation of vaccine¹: Inactivated Polio Vaccine, 5 dose(s) per vial, LIQUID				
8. Programme Duration²: 2015 - 2018				
9. Programme Budget (indicative) (subject to the terms of the Partnership Framework Agreement): <i>Please note that endorsed or approved amounts for 2018 will be communicated in due course, taking into account updated information on country requirements and following Gavi's review and approval processes.</i>				
	2015	2016	2017	Total ³
Programme Budget (US\$)	US\$267,500	US\$1,025,000	US\$729,500	US\$2,022,000
10. Vaccine Introduction Grant: US\$312,000				
11. Indicative Annual Amounts (subject to the terms of the Partnership Framework Agreement):⁴				
Type of supplies to be purchased with Gavi funds in each year	2015	2016		
Number of IPV vaccines doses	130,200	499,100		
Number of AD syringes	125,800	478,500		
Number of re-constitution syringes				
Number of safety boxes	1,400	5,275		
Annual Amounts (US\$)	US\$267,500	US\$1,025,000		

¹ Please refer to section 18 for additional information on IPV presentation.

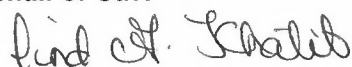
² This is the entire duration of the programme.

³ This is the total amount endorsed by Gavi for 2015 to 2017.

⁴ This is the amount that Gavi has approved.

12. Procurement agency: UNICEF.	
13. Self-procurement: Not applicable	
14. Co-financing obligations: Gavi's usual co-financing requirements do not apply to IPV. However, Cambodia is encouraged to contribute to vaccine and/or supply costs for IPV.	
15. Operational support for campaigns: Not applicable	
16. The Country shall deliver the following documents by the specified due dates as part of the conditions to the approval and disbursements of the future Annual Amounts:	
Reports, documents and other deliverables	Due dates
Annual Progress Report 2014	15 May 2015
17. Financial Clarifications: Not applicable	
18. Other conditions: Not applicable. If Cambodia envisages a switch in product presentation, it is encouraged to incorporate elements for both IPV presentations in your initial introduction preparations, in order to minimise the need for later interventions and facilitate the switch. In those circumstances, in principle, no product switch grant will be provided to Cambodia	

Signed by,
On behalf of Gavi



Hind Khatib-Othman
Managing Director, Country Programmes
10 February 2015

Appendix A

Country name: Cambodia

Type of support requested: NVS

Vaccines requested: IPV vaccine

Independent Review Committee (IRC) Country Report

Gavi Secretariat, Geneva • 10 - 24 November 2014

Country: Cambodia

1. Type of support requested

Type of support requested	Planned start date (Month, Year)	Duration of support	Vaccine presentation(s) (1 st and 2 nd choice, if applicable)
JE Preventive Campaign	January 2016	2016	5 doses/vial LYOPHILISED
IPV	October 2015	2015-2018	1 dose/vial 5 dose/vial 10 dose/vial

2. In-country governance mechanisms (ICC/HSCC) and participatory proposal development process.

An advisor to the MOH prepared the proposal for both JE & IPV. PATH has been a key partner for JE vaccine and provided the majority of support for preparation of the JE proposal, while key focal points from the NIP were involved with the preparation of the IPV proposal. In addition, WHO and UNICEF provided inputs into the development of both proposals.

Signatures from the MOH and the MOF were provided for both the JE preventive campaign and IPV applications. In Cambodia, the Technical Working Group for Health (TWGH) functions as the national coordinating body for health related issues, including immunization activities. The TWGH has been in place since 2004 and meets monthly. Minutes from the last three TWGH meetings indicate a functional and well-organized ICC/HSCC. Although a formal membership list for the TWGH was not included, a list of meeting participants from the most recent meeting were provided and, included individuals from various government departments, UNICEF, USAID, WHO, UNAIDS, UNFPA US-CDC, JICA, KOICA, GIZ and more. It was difficult to ascertain the degree of CSO membership or representation in the TWGH and no information was provided in the JE/IPV application on CSO involvement.

The application for both JE and IPV were discussed during a TWGH session held on Aug 7, 2014. According to the minutes, both proposals were fully endorsed and signatures of the attendees were present at the meeting were provided. At the current time, Cambodia does not have a NITAG.

3. Situation analysis – Status of the National Immunisation Programme

Cambodia is a low-income country with a population of approximately 14.3 million and a GNI per capita of \$880 USD. The majority of the population (80.5%) resides in rural areas, practicing traditional wet rice cultivation and other forms of agriculture. Administratively Cambodia is divided into 24 municipalities and provinces, 185 districts, 1609 communes, and 14,073 villages.

The Cambodian EPI was initiated in 1986, reaching all provinces across the country by 1998. In recent years Cambodia introduced penta vaccine (2010) and a second dose of MR vaccine (2012). In addition to the planned JE (early 2016) and IPV introductions (Oct 2015) for this application, the country also plans to introduce PCV in Jan 2015. Official country estimates in 2013 was 92% for DTP3 and 90% for MCV1, both in line with WUENIC estimates and slightly decreased from 2012 estimates. The last immunization survey in the country was the 2010 DHS; the survey estimated DTP3 coverage of 85% and MCV1 of 82%.

The government and WHO conducted a comprehensive DQA in 2012. The assessment found that the reporting system in Cambodia is well functioning, and has shown steady improvement over time. Key outstanding issues highlighted in the assessment included issues pertaining to the denominators and possible over-reporting of numerators for immunization indicators and the contribution of the private sector remaining unknown; although increasing numbers of private facilities are being included in the web-based HIS. The country submitted both the DQA improvement plan and a progress report on the implementation of the DQA plan.

In 2010, a review of the EPI in Cambodia was conducted. The review revealed that communities can still be found throughout Cambodia where infants and women are still not accessing any immunization services

including: mobile worker populations, ethnic Vietnamese and other minorities, urban poor and the poorest within communities, geographically remote areas, unofficial or new settlements which are not included in planning, and those that fear vaccination, usually because of the perception of associated pain or fever. Key action points to address these findings were provided in the application. In addition, the country provided detailed lessons learned from recent campaigns (JE-2013; MR-2013; Measles SIA-2011) that will be used during the planning of the JE campaign.

4. Overview of national health documents

The current cMYP covering the period from 2008-2015 is linked to broader health sector planning and provides an adequate situational analysis of the status of the immunization program in the country. The current cMYP does not include plans for introduction of IPV but the country has indicated that the document will be updated in early 2015 to include the Oct 2015 IPV launch.

Plans to develop a new cMYP for the period starting in 2016 are underway. To address the discordance between the timeline of the current cMYP and JE activities starting in 2016, the country has developed an addendum to the 2008-2015 cMYP that includes the JE campaign and routine introduction along with updated costing information. However, no update of the overall vaccination costs was provided, so there is a lack of clarity of the overall cost of the Cambodia EPI both in terms of traditional and new vaccines costs and operational and co-financing costs.

5. Gender and Equity

Sex disaggregated data are not collected in the routine immunization reporting system in Cambodia, however 2010 DHS survey shows a minimal gap in gender disaggregated coverage rates. Both proposals recognize high-risk communities identified through 2010 EPI review and during measles SIA activities. In order to try and improve the use of the high-risk strategy for routine immunization,

the "Implementation guideline for high risk communities" was produced in 2014. It is stated that this strategy will be the focus of strengthening routine immunization in coming years.

6. Proposed activities, budgets, financial planning and financial sustainability

NVS (JE):

Cambodia funds all traditional vaccines and co-financing obligations for Gavi funded vaccines have been met. Co-financing is not required for the JE vaccine in the catch-up campaign; however, the government is expected to cover the full cost of the introduction of JE vaccine into the routine immunization system. As evidence that the country can finance the introduction of JE into the routine program the country provided a budget line in cMYP costing document that indicates funding for JE vaccine. The application also states that the signatures of the MOH and MOF endorsing the application constitute commitment of the government to finance the vaccine.

The government of Cambodia is requesting Gavi **support for a JE campaign** to cover vaccine and supplies amounting to **US\$ 1,983,545.08**. In addition, it is requesting Gavi operational support for the JE campaign amounting to **US\$ 2,664,563.00**. US\$20,000 will be provided by partners for surveillance and monitoring and TA activities. The vast majority of the Gavi operational support for the campaign has been earmarked for human resources, incentives and transportation of staff (42.5%). Per Diem for the NIP is provided with a lump sum, making it difficult to judge its appropriateness. The country has included \$30,000 in the Gavi VIG for customs clearance costs, a cost ineligible for Gavi VIG funding.

Introduction of JE into routine immunization is planned immediately subsequent to the JE campaign. To support this introduction, Cambodia is requesting Gavi support for a Vaccine Introduction Grant of **US\$ 269,430 using the 2016 birth cohort**. The total introduction related costs is estimated to be **US \$409,430**. The funding from Gavi will be used mainly for social mobilization activities including designing, printing IEC materials (53%) and human resources incentives and transportation of staff (40.6%). The remaining funding will be provided by the government for document production (\$100,000 US\$) and by partners for surveillance and monitoring activities (\$40,000 US\$).

IPV

Cambodia has estimated that the total cost of IPV introduction will be \$797,577. The country does not plan to co-finance IPV (this is not mandatory for IPV). There is a logical flow of activities in the timeline provided. Gavi VIG amounts to US\$ 312,000 and the unit costs in the budget appear reasonable. The cost of reprinting and distributing new immunization cards (US\$315,400) will be paid by the government and is a joint activity with PCV and JE. WHO and UNICEF have committed support of \$55,000 and \$50,000 respectively to provide technical assistance, monitoring support, social mobilization, cold chain investments and other support. Finally, the remaining \$65,000 will be funded by anticipated HSS funds, which have been allocated to trainings and meetings and vaccine distribution costs.

Clarification is required as to whether the financial modalities including bank details as previously agreed with Gavi are still applicable for this one-time IPV grant or if the FM for this grant should be changed in line with the new HSS grant. The country will also be required to provide an external audit report for annual expenditures exceeding \$250,000 but the fees for the required audit have not been included in the budget.

7. Specific comments related to requested support

NVS (JE)

New vaccine introduction plan

In October 2009, Cambodia initiated routine immunization against JE for children aged 10 months to 25 months, in four provinces. The program was stopped in January 2013 due to interruption of JE

vaccine supply, however a vaccine donation resolved this issue and JE vaccination will resume in these four provinces plus an additional 2 provinces in Q4 2014. In addition, in 2013 a JE vaccination campaign was carried out during the month of February in Battambang province (In the context of a CDC study) targeting children age between 9 months to 12 years. The campaign vaccinated 309,549 children achieving coverage of 91%.

The application provides good justification regarding the burden of JE disease. The Current JE/AES surveillance in the country is supported by 13 sentinel sites in 6 provinces and one national laboratory in Phnom Penh located at the National Institute for Public Health. The sentinel system was designed to provide a platform to incorporate laboratory testing for other CNS infections in children. AES cases reported in the last four years from six provinces found that 10-20% were JE positive, and all of these cases were below 15 years. Data suggest a seasonal pattern with a marked increase in cases from July through August with 90% cases in children 10 years of age or under. In addition, the application provided results from a cost effectiveness study indicating introduction of the vaccine would be highly cost-effective.

The proposed campaign will take place from Jan-Mar 2016 and use the live-attenuated SA 14-14-2 prequalified WHO vaccine; this is the same vaccine used in previous JE immunization activities. The vaccine for the SIA will be procured through UNICEF SD. The JE campaign will target children from 9 months to <15 years, in line with WHO recommendations. The campaign will be nationwide, with the exception of most of Battambang province where a campaign was already conducted (2 health centers not included in the 2013 campaign will be included in the Gavi campaign). In provinces where routine immunization has already started, it is recognized that a portion of children (estimated not to exceed 40% of the target population in these provinces) may receive two doses of JE vaccine by the end of the campaign. The decision to include the full target population age groups in these provinces was considered in consultation with relevant stakeholders and partners and is not in contradiction with the WHO position paper. Using the population data from the 2008 census from the National Institute of Statistics, the target population for the JE campaign in 2016 has been estimated to be 4,100,013, which corresponds to 4,551,050 doses of vaccine using the indicative 10% wastage rate.

The campaign will roll out in three phases within the first quarter of 2016. The campaign will utilize 2 co-ordinated approaches: 1: Health Centres and Outreach, with a focus on children under 5 years of age using both fixed site and outreach posts; 2) School based delivery (collaboration with the Ministry of Education) will focus on children from 6 years old through 14 years and 11 months. Cambodia has high rates of school attendance, and past measles and measles-rubella SIAs have successfully used this delivery option to improve coverage and reduce costs. The country, however, does not indicate strategies to reach out of school children.

After completion of the campaign, one dose JE vaccine will be included in the routine immunization schedule at 9 months in line with WHO recommendations; this will coincide with an MR dose at the same visit. JE vaccine for routine immunization from 2016 onwards will also be procured through UNICEF SD. To ensure high coverage children between 9 months and up to and including 12 months of age will be given the vaccine at any visit, if they have not previously received it.

Although no concurrent introductions are being planned with JE, because PCV, IPV, and JE will all be introduced in the next two years, opportunities to capitalize on these concurrent introductions will include the concurrent updating of immunization cards, tally sheets, and immunization registry will all be revised at one point in time. The application indicates several ways in which the proposed JE campaign is expected to strengthen routine immunization including improving the capacity of health workers through training activities; further strengthening of strategies to improve equitable access to vaccines building upon efforts already initiated in identifying and reaching hard-to-reach populations.

A comprehensive communications strategy will be conducted in both schools and villages. In areas where Khmer is not well understood, information materials containing explanations in local languages/dialects will be prepared and printed to make sure the messages reach the hard to reach and ethnic minorities. A nationwide media plan using the continuous broadcast scheduling technique

will be prepared by MOH. In addition, the development and implementation of a crisis communication plan for JE campaign that will include establishing a coordination mechanism and a communication task force at different level, foster and mobilize partnerships for communication, conduct a communication analysis, train staff and partners in different aspects of communication programming and management, set up a spokesperson system and prepare to work with the media.

AEFI guidelines have been developed, a Causality Committee has been established and basic AEFI monitoring systems are in place. The training for health workers for JE SIA and routine introduction will further strengthen the capacity in recognizing, reporting, and responding to any issues relating to vaccine safety.

Success of the JE SIA will be measured using administrative coverage data at HC, operational district, province and national level [target 100%]. In addition, rapid coverage assessments (RCAs), especially in areas with large populations or uncertain population targets, will be conducted. JE vaccine RCAs will be conducted at every site to confirm the quality of implementation, using random samples of 20 children in the target age ranges. This will be conducted by local level supervisors or other non-vaccination team members, and will provide a pass/fail assessment of the area. Areas that fail the RCA will require further mop up activities and additional RCAs to confirm that no children have been missed. Finally, a post-campaign coverage survey will be conducted in May or June 2016.

IPV:

New vaccine introduction plan

The New Vaccine Introduction Plan for IPV clearly outlines the justification for the introduction of one dose of IPV into the routine immunization program in Cambodia, in line with the Polio Eradication and Endgame Strategic Plan and the 2014 WHO SAGE position paper. The last case of wild poliovirus was detected in Cambodia in 1997 and the Western Pacific Region was certified polio-free in 2000. In 2005-2006, three cases of circulating vaccine-derived poliovirus (cVDPV) were detected in Cambodia. Immediately following detection, an OPV campaign was conducted and the transmission of cVDPV was halted.

Cambodia is planning for a nationwide introduction of IPV in October 2015. IPV vaccination will occur at 14 weeks along with Penta3, OPV3 and PCV3. IPV will be administered in the left thigh, 2.5 cm apart from the injection site for PCV vaccine, while Penta will be administered in the right thigh. For children who start the immunization schedule late, IPV will be given at the first immunization contact after 14 weeks. In alignment with the national Policy on immunization, IPV should be given by the first birthday, but if a child over one year is not fully immunized, doses may be given up to the second birthday. The country recognizes that "catch-up" policies such as this will not be funded by Gavi.

IPV is WHO pre-qualified and will be procured through UNICEF, and as a result the registration process is simplified. To register the vaccine, the necessary documents will be sent to the Department of Drugs and Food (DDF) by the NIP. The country has indicated that the preferred vaccine presentation is the 1 dose/vial, the second preference is for the 5 dose/vial and the third preference is the 10 dose/vial. For the single dose vial, data from Cambodia has shown that wastage in routine immunization is approximately 3%, lower than the indicative wastage rate of 5%, while for the 10 dose vial the country has provided estimated wastage data from their measles experience as 62%, above the indicative wastage rate of 50%. Following IPV introduction, Cambodia will collect data on wastage in order to determine the true wastage. However, Gavi will use indicative wastage rates to calculate initial allocations of IPV doses.

As mentioned previously, although no concurrent introductions are being planned with IPV, because PCV, IPV, and JE will all be introduced in the next two years, opportunities to capitalize on these concurrent introductions will include the synchronized updating of immunization cards, tally sheets, and immunization registry will all be revised at one point in time.

Training, Community Sensitisation & Mobilisation Plans

Training materials will be developed in early 2015 with trainings taking place the four months before introduction (June-Sept 2015) using a ToT/cascade approach. Following introduction, supervisory visits will be conducted to monitor the status of IPV introduction.

A communication plan that includes key messages will be developed and communicated at all levels. This will include explaining the need for IPV to high-level decision makers and also for health care workers and mothers. Furthermore, communication will be a key focus of ToT and the case trainings for IPV introduction at all levels. NIP will create a small booklet containing key messages about IPV introduction and other new vaccines (PCV and JE) that will be tailored to different stakeholders.

Monitoring and evaluation plans

The Technical Working Group on Health (TWG-H) will be the primary oversight body monitoring the implementation of IPV introduction. The National Immunization Program (NIP) will be responsible for coordinating, planning, and implementing IPV introduction. A small-scale post-introduction evaluation will be conducted following the introduction of IPV. AEFI guidelines will be updated to include information on AEFI for PCV, IPV, and JE.

Vaccine management, cold chain capacity, and waste management: JE & IPV

An EVM conducted in 2012 indicates good supply chain performance with the notable exception of maintenance standards that were less than adequate at all levels of the supply chain except at the central store. The EVM performance ratings for maintenance were only 50%. This problem is further compounded since the HSS2 application informs that two thirds of cold chain equipment is more than 10 years old and frequent maintenance intervention is required. A cold chain impact assessment conducted for the introduction of PCV, indicates that 36% additional storage space is required at central level and that frequency of shipments should be adjusted, and vaccine distribution frequency should also be adjusted at provincial and peripheral levels. This document was not provided to reviewers.

The present cold room capacity of the 4 cold rooms at the central store is 29m³ net, and just adequate with a 6 months shipping cycle to accommodate the inclusion of PCV. If the shipping cycle is reduced to 4 months 7m³ of space will be available to accommodate IPV. The 5-dose presentation of JE requested for a 2016 campaign at 4.2cc/dose and VVM14, with a target population of 4,1 million and 10% wastage rate will require an additional 19m³ net. 2 additional cold rooms of 40m³ will be adequate as budgeted in the HSS proposal.

The HSS budget of \$1,048,000 for cold chain equipment includes only \$51,000 provision for spare parts and maintenance. The IPV/VIG also budgets \$45,000 for spare parts for the 98 compression refrigerators (8% of national inventory) of which more than 50% are more than 10 years old, but makes no provision to support maintenance costs. The bulk of HSS funds for cold chain equipment are used for the procurement of 624 refrigerators and 2 cold rooms.

Concerns are also raised the about minimal Government budgetary allocations for maintenance and insufficient staff to respond to demands for servicing equipment, and updating an inventory database. A UNICEF independent consultant in 2014 also highlighted the inadequacy of adequate resources for maintenance of cold chain equipment.

An EVM improvement plan progress report was developed in Aug 2014. This report responded to each of the improvement plan recommendations of the EVM assessment. Progress in implementing the EVM recommendations is modest. The cold chain inventory of 2013 lists 1198 vaccine refrigerators of which 1072 are Gas/Electric absorption refrigerators. These are notorious for freezing

vaccines if not well maintained and regulated. Only 96 AC compression refrigerators/freezers are listed in the inventory.

\$1,700 is allocated to waste management in the HSS2 proposal and \$15750 in the JE application to cover the transportation and disposal of 42,000 safety boxes. More than 30% of district facilities do not have waste disposal equipment.

8. Country document quality, completeness, consistency and data accuracy

There was relatively good consistency between proposal documents and all required documents were submitted with the application.

9. Overview of the proposal

Strengths:

- Strong justification was provided for the introduction of JE backed by an AES surveillance system with JE laboratory confirmation capability
- Government funds traditional EPI vaccines and has met co-financing requirements
- Country conducted a successful JE campaign with high coverage in one province in 2013 and will be initiating routine JE vaccination in 6 provinces in Q4 of 2014
- Country has made good use of lessons learned in previous introductions/campaigns
- JE campaign includes plans for RCAs with mop-up activities and post campaign coverage survey
- Strong support of in-country partners, specifically PATH in the case of JE. Proposals were comprehensive and well written.
- Some synergies for upcoming introductions of PCV, JE and IPV were outlined

Weaknesses:

- Strategies for reaching out of school children aged 6 yrs. to less than 15 yrs. were not provided in the proposal,
- No information was provided in the applications on CSO involvement through CSO platforms/coalitions.
- The current cMYP (2008-2015) does not correspond with the timelines for JE campaign and RI. Country has provided an addendum to the current cMYP that includes the 2016 plans for JE but updated costing information for the overall immunization program was not provided
- Explicit MOH/MOF support to introduce JE into the routine system was not provided
- No estimation on the absolute numbers of children that may receive 2 doses of JE vaccine in the six provinces that have introduced JE into the routine immunization system

Risks:

- The resubmission decision for the HSS application may result in a funding gap for IPV as well as implications for cold chain equipment required for the introduction of JE

Mitigating Factors

- School enrolment in the country is very high, making the choice of a school based approach for the JE campaign appropriate

10. Conclusions

Cambodia has requested support for a JE catch-up campaign prior to the introduction of JE into the routine immunization system as recommended by WHO. In addition, the country has requested one dose of IPV into their routine immunization system in-line with the GPEI Endgame Strategic Plan and recent WHO Sage recommendations. The country has provided adequate justification and documentation to recommend approval of their proposal with recommendations as outlined in the below section.

11. Recommendations

NVS (JE) and IPV:

Recommendation:

Approval with Recommendations

Recommendations to the Country:

1. Outline strategies for reaching out of school children aged 6 yrs. to less than 15 yrs. during the JE campaign.
2. Submit information on the participation of CSOs in the TWGH meeting that approved the JE and IPV applications or involvement of CSOs through other platforms/coalitions or explain reasons for lack of involvement
3. Include in the budget external audit fees for the Gavi requirement to provide an external audit report for annual expenditures exceeding US\$ 250,000.
4. Remove the \$30,000 budget line for customs clearance requested from Gavi for the JE campaign as this is an ineligible expense
5. Provide the unit costs for each category of per diems in the JE campaign budget.
6. Submit signed documentation from the government that explicitly supports the introduction of JE into the routine immunization program following the JE campaign.
7. Clarify why only 1 additional cold room is proposed to store the 19m³ of JE vaccine and the source of funds for the procurement of additional cold room space as proposed in the JE application.
8. Indicate how the potential \$65,000 funding gap for the IPV budget will be addressed given the resubmission decision for the submitted Gavi HSS proposal

Recommendations to the Gavi Secretariat:

1. Verify that the cold rooms planned for procurement in 2015 are sufficient to accommodate JE.