

## VIETNAM SUPPORT for INACTIVATED POLIO VACCINE (IPV)

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

<b>1. Country: Vietnam</b>				
<b>2. Grant Number:</b> 1518-VNM-25c-X / 15-VNM-08h-Y				
<b>3. Date of Decision Letter:</b> 11 February 2015				
<b>4. Date of the Partnership Framework Agreement:</b> 9 October 2013				
<b>5. Programme Title:</b> New Vaccine Support (NVS)				
<b>6. Vaccine type:</b> Inactivated Polio Vaccine (IPV)				
<b>7. Requested product presentation and formulation of vaccine<sup>1</sup>:</b> Inactivated Polio Vaccine, 10 dose(s) per vial, LIQUID				
<b>8. Programme Duration<sup>2</sup>:</b> 2015 - 2018				
<b>9. Programme Budget (indicative) (subject to the terms of the Partnership Framework Agreement):</b>				
<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 <sup>3</sup>
Programme Budget (US\$)	US\$379,500	US\$1,443,500	US\$1,213,000	US\$3,036,000
<b>10. Vaccine Introduction Grant:</b> US\$1,111,000				
<b>11. Indicative Annual Amounts (subject to the terms of the Partnership Framework Agreement):<sup>4</sup></b>				
Type of supplies to be purchased with Gavi funds in each year	2015	2016		
Number of IPV vaccines doses	326,500	1,242,900		
Number of AD syringes	301,700	1,137,000		
Number of re-constitution syringes				
Number of safety boxes	3,325	12,525		
Annual Amounts (US\$)	US\$379,500	US\$1,443,500		
<b>12. Procurement agency:</b> UNICEF				

<sup>1</sup> Please refer to section 18 for additional information on IPV presentation.

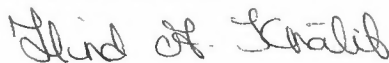
<sup>2</sup> This is the entire duration of the programme.

<sup>3</sup> This is the total amount endorsed by Gavi for 2015 to 2017.

<sup>4</sup> This is the amount that Gavi has approved.

<b>13. Self-procurement: N/A</b>	
<b>14. Co-financing obligations:</b> Gavi's usual co-financing requirements do not apply to IPV. However, Vietnam is encouraged to contribute to vaccine and/or supply costs for IPV.	
<b>15. Operational support for campaigns: N/A</b>	
<b>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:</b>	
<b>Reports, documents and other deliverables</b>	<b>Due dates</b>
Annual Progress Report	15 May 2015
<b>17. Financial Clarifications: N/A</b>	
<b>18. Other conditions:</b> If Vietnam 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 Vietnam.	

Signed by,  
**On behalf of Gavi**



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

## Appendix A

### Independent Review Committee (IRC) Country Report Gavi Secretariat, Geneva, 10 - 24 November 2014 Country: Viet Nam

#### 1. Type of support requested: IPV

Planned start date (Month, Year)	Duration of support	Vaccine presentation(s) (1 <sup>st</sup> , 2 <sup>nd</sup> , and 3 <sup>rd</sup> choice)
October 2015	2015-2018	10 dose, 5 dose, 1 dose

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

An ICC for EPI has been long established in the country and has a membership from UNICEF, WHO, JICA, AMP, PATH, NIHE-EPI, MOF, MPI, General Department of Preventive Medicine (GDPM), Drug Administration, Department of Planning and Finance, Department of International Cooperation of MOH, Gavi HSS, NICVB, Biotech, Polivac, and relevant stakeholders. There is no mention of CSOs as participating members, as is customary in this political environment. At its meeting on 5 September 2014, the ICC supported and approved the IPV application for GAVI support. Full minutes of ICC meetings are provided. There is a functioning NITAG, although no details are provided about it.

#### 3. Situation analysis – Status of the National Immunisation Programme

Viet Nam will become a graduating country in January 2015. The coverage of fully immunized children (FIC) varies across provinces, and the coverage difference between the provinces with the highest and lowest rate was 27% in 2013. Out of 63 provinces, 39 had a coverage level of higher than 90% for FIC.

Viet Nam has experienced a number of reviews recently and has identified important messages from them. Following the EPI review in 2009 and EVM assessment in 2012, the MOH made great efforts in addressing the programmatic gaps identified and implementing key recommendations, including incorporating key findings and recommendations from the 2009 EPI review into the current cMYP and developing an Improvement Plan (IP) following the 2012 EVM assessment.

With continued improvements in recent years, the strong immunisation system has built a solid foundation for introducing IPV and achieving high coverage. Meanwhile IPV introduction can potentially provide a strategic opportunity to accelerate or strengthen implementation of some critical recommendations from the past reviews, and also offers a good chance to implement the operational guidelines for reaching the hard-to-reach populations, through incorporating the strategies/tools into nationwide training, social mobilisation and active supervision.

Given that the hard-to-reach populations are at the greatest risk of contracting polio and there will be only one chance for IPV vaccination, achieving uniformly high coverage throughout the country will become crucial for ensuring successful introduction of IPV and securing the gains made in sustaining polio-free status in the country.

National Penta3 (DTP3) coverage rates were dramatically reduced as a consequence of the decision of the government to suspend immunisation following an AEFI crisis, and coverage declined from the 97% achieved in 2012 to only 59% in 2013. Similar declines occurred in the coverage rates for Penta1. OPV3 coverage decreased somewhat from the 2012 level



achieved and failed to reach its target of 96% for 2013. The only EPI antigens for which the annual targets were reached for the year 2013 were BCG, measles and TT2 plus. As a result of this disruption, the DTP1-DTP3 dropout rates increased from 3% in 2012 to 28% in 2013. DTP1-DTP3 dropout rates for 2014 and 2015 are set at 1%, but these are highly ambitious targets and are unlikely to be achieved.

For marginalized and hard-to-reach populations, DTP3 coverage in some remote districts is very low (<50%) and for 2013, the JRF data shows that many more non-remote districts suffered this same problem, with 46% of all districts (320 districts) reporting a DTP3 coverage <50%.

The last independent survey was a household survey conducted in 2011, and this showed a substantial difference (21%) between the administrative and survey data for DTP3 coverage. However, there is little discrepancy between DTP3 administrative data and WUENIC 2013 DTP3 coverage, which has been estimated as 97% - consistent with routine reporting. The fully immunized child coverage stands at 76%. In general the findings from the latest survey match the earlier information. It is concluded that Viet Nam has a relatively strong and robust information system as compared to other similar countries.

No assessment of the national administrative data system has been conducted in recent years, but in general, it is found that official country-reported data on immunisation performance is consistent with that estimated by WHO/UNICEF on the JRF database.

#### **4. Overview of national health documents**

The introduction of IPV into the national immunisation schedule will be incorporated into the next cMYP (2016-2020), and the choice of the vaccine (single dose vs in combination) will be reflected in this important guiding document. The MOH has planned to start the process of developing the next cMYP from the mid-2015, ideally following a comprehensive EPI review. The last national EPI review was conducted in 2009, followed by development of the current cMYP (2011-2015) in 2010. A working group for development of cMYP will be established at national level involving the representatives from MOH, NIHE and Gavi HSS project management team, supported by the development partners.

An interesting aspect of this proposal is the planning for introduction of a multi-antigen IPV presentation in phase 2 of the roll-out. This will be at a date yet to be finalized and has considerable resource constraints associated with it.

#### **5. Gender and Equity**

G.I.I. value - 0.32; G.I.I. rank – 58; MMR - 59 /100,000

Gender coverage: The EPI review of 2009 found that there were no significant differences between the sexes in immunisation coverage. This was also the finding of the recent household survey (2011) reporting DTP3 coverage of 72.50% for boys and 76.20% for girls.

A review in 2013 revealed that children from ethnic minority communities often had lower immunisation coverage. Also children whose mothers had low education or no education are less likely to be vaccinated. In response to those challenges, the NIHE, with support from UNICEF, developed operational guidelines by adapting Reaching Every Community Strategy into the country context. The guidelines provide practical strategies/tools to systematically map underserved communities and prioritize those communities for actions (e.g. micro-planning, supervision), in the urban and rural settings.

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

The country estimates that 3.5 million US\$ will be needed to support critical activities at various stages of IPV introduction, including planning, preparation, implementation and evaluation. The Government (\$1.7M) and Gavi (\$1.1M from the IPV V.I.G. + \$0.4M from the HSS grant) will co-share a large proportion of the total costs, with a few areas to be covered through HSS (mainly training, cold chain equipment and reaching the hard-to-reach areas in 10 supported provinces) or by the development partners (e.g. WHO and UNICEF; \$0.3 M). There is cost sharing between the government, Gavi and other partner. The MOH is committed to meeting the funding needs beyond the contributions from Gavi and partners. Though there is no immediate concern related to financing IPV vaccine introduction in the near future, the situation may change in years to come. Once a decision is made to shift to combination (multi-antigen) IPV vaccine, funding needs will dramatically increase, covering relevantly expensive vaccine and upgrading cold chain storage capacity nationwide.

The country should consider including this IPV grant into the annual audit by an external audit firm and accordingly should make sure that the corresponding audit costs are budgeted for.

## 7. Specific comments related to requested support

### New vaccine introduction plan

As preliminary activities are already under way, there should be no difficulty in starting the introduction in October 2015 – so long as the appropriate presentation has been licensed for use in the country. According to the current national immunisation schedule, the Pentavalent vaccine (DTwP-HepB-Hib) and OPV are both given at 2, 3 and 4 months. In line with WHO guidelines, the NITAG has recommended to administer one dose of IPV at 4 months of age. IPV will be given intramuscularly at the same visit as Penta3, in the opposite thigh. This decision avoids the discussion about how far apart two injections should be if given in the same thigh.

The planned date of October 2015 should give the planners sufficient time to finalize arrangements. This is especially true in light of the fact that preparations are well under way already. Planned activities will include development of detailed work plans, guidelines, and a communication strategy/ action plan; preparation of training materials and IEC materials; revising, printing and distributing reporting instruments; training and social mobilisation targeting all levels; and supportive supervision.

The country is planning to introduce MR in March 2015 and HPV in January 2016 and has not described synergies with these initiatives in their application. The planners, however, do seem properly aware of the advantages of using IPV introduction to support other aspects of immunisation.

The licensure of IPV in Viet Nam is not without problems. The National Regulatory Authority (NRA) is not yet fully functional, but it has been improved a lot with a strong government commitment and the support of WHO. The Government expects a formal NRA assessment by WHO in late 2014. There is no expedited review procedure applying to any vaccine registration, and the Drug Administration Department of Viet Nam (DAV) requires that a full registration process must be followed for any vaccine registration and a clinical trial in the country settings must be conducted. The requirements equally apply to the WHO pre-qualified vaccines. The government's regulations on vaccine licensing are strict; and the full process can take 6-9 months or even more than one year, as experienced with the recent registration of MR vaccine (a WHO pre-qualified vaccine).



There are currently four types of IPV vaccines registered in the country, including a single dose IPV by Sanofi Pasteur (Imovaxm). None of the three IPVs that are prequalified and procured by UNICEF is yet registered in the country. Thus in the IPV introduction planning, lead time required for licensing IPV vaccine will need to be taken into considerations.

### **Vaccine management and cold chain capacity**

Background: Viet Nam introduced Pentavalent vaccine in 2010 and plans to introduce MR (routine) in 2015, IPV (10 dose) in October 2015 and HPV (demo) in January 2016.

**Status of EVM & Implementation Plan (IP)** -- Gavi HSS is not contributing directly to the EVM Improvement activities but these are adequately covered with Government and WHO funding. The last EVM was conducted in July 2012. The IP has been updated in September 2014. The EVM performance is excellent (well above 80%) at all levels and for all parameters with few exceptions. Important recommendations from the last EVM refer to the implementation of continuous temperature recorders, improvement of ordering forms, and retraining of staff in VVS use. The EVM Improvement Plan Status Report of December 2013 indicated that the majority of the recommendations have been carried out according to the planned schedule, with a few that had no specific deadline for completion still on-going. A new EVM is being considered for the first quarter of 2015.

The country will be easily able to accommodate the marginal increase in storage space required by the 10-dose presentation. During the 2010 measles campaign the country did not face any limitations in the vaccine storage capacity even at province level.

Only about 40% Health Centres (HCs) have refrigerators installed. These will not have any problem with regard to vaccine storage capacity. In the remaining commune HCs, refrigerators should be procured and installed in the next couple of years. Some proportion of HSS funds will be used to improve this situation in ten HSS-supported provinces; however there are funding constraints to support the remaining 53 provinces that should be considered in the next HSS grants as a priority. It is important to note that although many health centres have not had cold chain equipment, they have still managed to reach high levels of coverage by holding monthly immunisation sessions when the whole village turns out in a festival atmosphere.

Based on the 2012 EVM assessment in the area of stock management, scores of at least 80% were achieved at all levels except regional level. The few limitations were related to diluents which were managed differently from the relevant vaccines; vaccine inventories were not updated in a timely way.

Auto-disable syringes and safety boxes are now used for all the injectable EPI vaccines throughout the country (except BCG) and are funded by the government (except the proportion co-financed by Gavi for Pentavalent vaccine). Immunisation-related health waste is managed in a number of ways including incineration, burning and burying, or other means. Incinerators are available in most provincial hospitals; and at commune health centres where sometimes burying without burning has been observed. Further improvement in health waste management is emphasized in the current cMYP 2011-2015. The proposed activities include development of national guidelines on safe disposal of AD syringes and safety boxes and advocating for a national health care waste management plan.

## **Training, Community Sensitisation & Mobilisation Plans**

There are competent health personnel in place to deliver immunisation services in the country, who have received pre-service and in-service training. Also Gavi's support through Health System Strengthening (HSS) has been contributing to building capacity of health workers in delivering immunisation and other essential health services in 10 supported provinces. On the other hand, staff turnover at commune HCs is reported as one of the programmatic constraints in some provinces.

IPV introduction will offer another valuable opportunity for nationwide orientation and training, which will not only improve knowledge of HC staff about IPV vaccination, but also upgrade their overall knowledge and management skills to deliver immunisation services (e.g. vaccine and cold chain management, micro-planning, defaulter tracking, reaching the unreached).

Adverse Events Following Immunisation (AEFIs) pose a potential threat to the introduction of IPV because this will follow soon after a highly publicized confidence failure in immunisation. The declining confidence around vaccination followed directly after the extensive media reports on a suspected AEFI events following vaccination with pentavalent vaccine. This is because IPV will be administered at the same visit as penta-3 (4 months of age). To tackle this emerging challenge, MOH and NIHE, working closely with UNICEF and WHO, have developed and are implementing a national communication action plan. A well function AEFIs surveillance system is in place and any reported case of AEFI will be dealt with promptly. Recently new AEFI surveillance guidelines have been approved. The national training of AEFI surveillance and response at all level will start soon and this will further enhance the AEFI system in the country.

### **Monitoring and evaluation plans**

Supervision, monitoring and assessment, by national, regional, province and district levels, are planned before, during and after the launching of IPV introduction. Immunisation recording and reporting instruments (immunisation cards, registers, tally sheets, immunisation cards, and coverage monitoring charts) were to be revised to accommodate the adding of IPV vaccine. Improving knowledge, skills and practice on data management will be key focus areas during the nationwide training and supportive supervision in the course of IPV introduction. AEFI monitoring is dealt with separately. No specific mention is made of a Post Introduction Evaluation.

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

There is no obvious internal inconsistency within the various reports. However the current cMYP does not include mention of the introduction of IPV yet, but the application reports that the introduction of IPV into the national immunisation schedule will be incorporated into the next cMYP (2016-2020). The main unknown factor is the licensure of the vaccine in time for the start of introduction (see above).

### **9. Overview of the proposal**

The proposal is very well written and reflects a competent leadership. It is of the high quality we have come to expect from Viet Nam staff.

#### **Strengths:**

- The proposal demonstrates a long-term perspective with the plan to introduce IPV in a multi-antigen presentation at a later date.
- An excellent EVM with positive results regarding the cold chain.
- The proposal displays an understanding of the opportunities for wider strengthening immunisation systems with the introduction of IPV, e.g. training.

- There is a strong reporting system.
- Coverage is overall very high.
- Low coverage areas will be reached using a modified “Reaching Every Community” approach.

**Weaknesses:**

- There are pockets of low coverage.
- The programme was halted temporarily due to media coverage of a suspected AEFI related to Pentavalent vaccine administration.
- No external audit is planned.
- There does not appear to be planned synergy with the introduction of other new vaccines.
- Licensure is difficult and prolonged.
- There is high staff turnover in some areas.
- 60% of the commune HCs does not have CC equipment. There are funding constraints to support the remaining 53 provinces that should be considered in the next HSS grants as a priority.
- With regard to a potential future roll out of IPV in a combination vaccine, Viet Nam may want to consider the current Gavi position, which reads as follows: “With the WHO/SAGE recommendation that countries using wP should continue using this vaccine, Gavi does not offer financial support for national procurement of any aP containing vaccines. This includes financial support provided in lieu of Gavi-procured wP containing pentavalent vaccine and/or IPV for any self-procured combination vaccines containing aP. This decision will be reviewed in light of WHO’s final guidance on aP in the updated position paper to be published in 2015.”

**Risks:**

- The declining confidence around vaccination following the extensive media reports on suspected AEFI events following vaccination with pentavalent vaccine is a potential threat to achieving high coverage with IPV.
- Health staff at all levels face competing priorities, as nationwide catch-up MR SIAs will be implemented from October 2014 through June 2015. Currently there is a large MR campaign that will last through March 2015. This will require a detailed activity plan with timelines in every district.

**10. Conclusions**

The proposal competently describes how IPV will be introduced. The proposal is not without its difficulties, and recommendations regarding these are offered below.

**11. Recommendations**

**Approval with Recommendations**

**Recommendations to the Country:**

1. Cold chain equipment should be distributed to those HCs that are lacking it.
2. Please provide an update on the status of implementation of the REC strategy.
3. Please consider organising a workshop for senior staff on how to anticipate a crisis of confidence following a possible AEFI and how to handle communication with the media. WHO has resources that would be very suitable for this purpose.



4. Please consider ways to synergize activities related to any new vaccine that may be introduced such as HPV, Rotavirus pneumococcal and rubella vaccines.

**Recommendations to the Gavi Secretariat:**

1. Please check the financial data and confirm that unit prices are reasonable.
2. Please ensure that an external audit is carried out and the VIG budget takes this into account to cover its cost, if required.
3. Please consider working with partners to support national workshops for senior staff on how to anticipate a crisis of confidence following an AEFI and how to handle communication with the media. Please promote the WHO/EURO publication: "Vaccine safety events: managing the communications response" that can be downloaded at [http://www.who.int/vaccine\\_safety/publications/aevi\\_manual.pdf?ua=1](http://www.who.int/vaccine_safety/publications/aevi_manual.pdf?ua=1). Details of the training course using this manual can be found at: <http://www.euro.who.int/en/media-centre/events/events/2014/02/inter-country-training-workshop-on-vaccine-safety-management-and-communications>