Vietnam VACCINE SUPPORT

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

1. Country: Vietnam

2. Grant Number: 1115-VNM-04a-X

3. Date of Decision Letter: 19 December 2014

4. Date of the Partnership Framework Agreement: 9th October 2013

5. Programme Title: NVS, Pentavalent Routine

6. Vaccine type: Pentavalent

7. Requested product presentation and formulation of vaccine: DTP-HepB-Hib, 1 dose(s) per vial, LIQUID


9. Programme Budget (indicative) (subject to the terms of the Partnership Framework Agreement):

<table>
<thead>
<tr>
<th></th>
<th>2010-2014</th>
<th>2015</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Programme Budget (US$)</td>
<td>US$64,123,127</td>
<td>US$12,135,500</td>
<td>US$76,258,627</td>
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</tbody>
</table>

10. Vaccine Introduction Grant: Not applicable

11. Indicative Annual Amounts (subject to the terms of the Partnership Framework Agreement):^1

<table>
<thead>
<tr>
<th>Type of supplies to be purchased with GAVI funds in each year</th>
<th>2010-2014</th>
<th>2015</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of Pentavalent vaccines doses</td>
<td></td>
<td>4,578,600</td>
</tr>
<tr>
<td>Number of AD syringes</td>
<td></td>
<td>4,812,400</td>
</tr>
<tr>
<td>Number of re-constitution syringes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Number of safety boxes</td>
<td></td>
<td>52,975</td>
</tr>
<tr>
<td>Annual Amounts (US$)</td>
<td>US$64,123,127</td>
<td>US$12,135,500</td>
</tr>
</tbody>
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^1 This is the entire duration of the programme.
^2 This is the total amount endorsed by GAVI for the entire duration of the programme.
^3 This is the consolidated amount for all previous years.
^4 This is the amount that GAVI has approved.
^5 This is the consolidated amount for all previously approved years.
12. **Procurement agency:** UNICEF shall procure vaccines using GAVI funds.

13. **Self-procurement:** Self-procurement applies to co-financed portion.

14. **Co-financing obligations:** Reference code: 1115-VNM-04a-X-C According to the Co-Financing Policy, the Country falls within the Graduating group. The following table summarises the Co-Financing Payment(s) and quantity of supply that will be procured with such funds in the relevant year.

<table>
<thead>
<tr>
<th>Type of supplies to be purchased with Country funds in each year</th>
<th>2015</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of vaccine doses</td>
<td>961,600</td>
</tr>
<tr>
<td>Number of AD syringes</td>
<td>1,010,700</td>
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<tr>
<td>Number of re-constitution syringes</td>
<td></td>
</tr>
<tr>
<td>Number of safety boxes</td>
<td>11,125</td>
</tr>
<tr>
<td>Value of vaccine doses (US$)</td>
<td>US$2,429,488</td>
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<tr>
<td>Total Co-Financing Payments (US$)(including freight)</td>
<td>US$2,548,500</td>
</tr>
</tbody>
</table>

15. **Operational support for campaigns:** Not applicable.

16. **Additional documents to be delivered for future disbursements:**

<table>
<thead>
<tr>
<th>Reports, documents and other deliverables</th>
<th>Due dates</th>
</tr>
</thead>
<tbody>
<tr>
<td>Annual Progress Report or equivalent</td>
<td>To be agreed with Gavi Secretariat</td>
</tr>
</tbody>
</table>

17. **Financial Clarifications:** The Country shall provide the following clarifications to GAVI*: Not applicable

*Failure to provide the financial clarifications requested may result in GAVI withholding further disbursements.

18. **Other conditions:** Not applicable.

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Signed by

On behalf of the GAVI Alliance
Hind Khatib-Othman
Managing Director, Country Programmes
19 December 2014
Appendix A

Internal Appraisal
Geneva, October 2014

Country name: Viet Nam
Type of support requested: Pentavalent and HSS
Vaccines requested: DTP-HepB-Hib, 1 dose(s) per vial, LIQUID

Viet Nam
Internal Appraisal 2014

1. Brief Description of Process
This Internal Appraisal was conducted for GAVI by independent technical expert Gordon Larsen, in close cooperation with GAVI CRO for the country Raj Kumar, and is based on reports and documentation supplied to GAVI by the national authorities and institutions in the country for the year 2013. Inputs were also received from in-country UNICEF and WHO pre-assessment of HSS window of the support.

2. Achievements and Constraints
The immunization programme was seriously disrupted in 2013 by a series of adverse events (AEFIs) that occurred following immunization of infants with the Pentavaccine 'Quinvaxem', and the resulting temporary suspension in use of this vaccine that was ordered by the Ministry of Health. A total of 43 AEFIs were reported in the early months of the year, and use of the vaccine was suspended for a period of 5 months, from May to September 2013 while a detailed investigation into the causes of the events was carried out.

Following safety checks on the remaining Pentavaccine batches and reassurances on quality and safety of all new batches from WHO and the vaccine manufacturers, Penta immunization was eventually re-started in October 2013 using the same vaccine, amid intense efforts to catch up as much of the lost ground from the year as possible. However, many of the immunizations that should have been given in 2013 inevitably had to be deferred into 2014 and this may eventually have an impact on 2014 programme results also. With the AEFI crisis hopefully resolved, it is anticipated that coverage rates for both traditional and NVS vaccines will return to the high levels that are shown by the long-term trend for the country. Vietnam is now actively considering introduction of more new vaccines with increased domestic financing.

National Penta3 coverage rates were dramatically reduced as a consequence of this suspension of immunization, and coverage declined from the 97% achieved in 2012 to only 59% in 2013. Similar declines occurred in the coverage rates to a smaller extent for Penta1 and DPT1. 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.

The main technical assistance used during 2013 was that provided by WHO in relation to the AEFI crisis and the resulting suspension of the ‘Quinvaxem’ Penta vaccine. WHO provided technical input to minimize gaps in vaccination due to the suspension of the vaccine. Quality of this TA was seen to be high and very supportive of programme activities.

As a result of the above disruption, the 2013 DPT1-DPT3 drop-out increased to 28%, from 3% in 2012. Dropout rates for 2014 and 2015 are set at 1%, but these are highly ambitious targets and are unlikely to be achieved. It is recommended that the target ‘Number of infants to be vaccinated with DTP3’ be reduced for both 2014 and 2015 to a more realistic target for DPT1-DPT3 drop-out rates.

For marginalised and hard-to-reach populations, the APR notes that ‘DPT3 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 DPT3 coverage <50%. With support from UNICEF and WHO and together with the specific activities carried out under the HSS project, the country is focusing attention on improving access to and the immunization coverage in, the remote and hard-to-reach areas.

Findings from many EPI programme review evaluations show no significant difference for boys and girls for access to vaccination. Results from a 2009 EPI review indicate that gender is not a significant factor affecting immunization service utilization, i.e 1% difference in DPT3 and FIC coverage between boys and girls (99% for boys vs 98% for girls and 96% for boys vs 95% for girls respectively). No other equity issues are highlighted.

3. Governance

An ICC for EPI has been long established in the country and has a membership comprising a cross-section of government, bilateral and international organizations, including some members from Civil Society Organisations (CSOs). There was only 1 CSO member in 2012, (PATH), but this increased to 2 members in 2013. (PATH and AMP). The ICC meets occasionally rather than regularly, with 2 meetings held in 2012 and 2 in 2013. This is considered to be just sufficient for
providing effective support to the EPI programme. There is also a functioning HSCC, with members from a cross-section of government and international organizations, although without bilateral organizations or CSOs. It operates as a high-level committee and also meets occasionally rather than regularly, with only one meeting held 2012 and 2 in 2013. Again, this is considered to be just sufficient for providing effective support to the EPI programme.

The minutes provided show the conclusions and actions to be taken and it is clear from EPI programme achievements that these are followed up and implemented. There is no information provided on the opinions of members on the effectiveness or otherwise of their roles and actions.

The NITAG, though recently established, is gradually proving to be an influencer in decision making in immunization in Viet Nam. It is only comprised of national officials mainly from Ministry of Health, who unfortunately have limited influence on government budget allocation for immunization.

There has not yet been participation of Civil Society Organization in the HSCC or NITAG. Representatives from provinces do not participate in the meetings of ICC or HSCC. Active attempts were made to harmonize implementation of Gavi and Global Fund HSS support through a common PMU. The activities across two support mechanisms are similar and are mapped geographically to avoid overlaps.

4. Programme Management

The national annual EPI Plan is developed and its budget is approved and allocated by the Ministry of Health in consultation with and overall directions made by the Ministry of Finance and the Ministry of Planning and Investment. ICC has very limited role in influencing such decision-making process and does not approve the annual budget for EPI.

An annual EPI work plan for 2014 specifically covers the HSS project for strengthening health systems in selected provinces. The plan is costed and budgeted for under the GAVI support programme. It contains a review of the previous year's results and achievements and uses these to plan for future activities.

Apart from the disruptions caused by the Penta vaccine AEFI crisis described above, the activities are generally implemented in accordance with the schedule and budget, and particularly with the various forms of GAVI support.

Baseline data, performance indicators and future targets cover the period 2013 up to 2015, the end date of all currently-approved GAVI support programmes. However, there is no data or estimates for numbers of infant deaths by year. UN Population Division estimates are available which indicate approximately 25,000 deaths per year for 2013, based on the reported number of births. A further error occurs with the number of pregnant women reported, where with one exception, the figures provided for 2013, 2014 and 2015 are the same as the projected number of births. If country data is not available for this indicator, UN Population Division estimates may be used in the short term.
5. Programme Delivery

The GAVI HSS is project based and managed by the Department of Planning and Finance of Ministry of Health with limited participation of the EPI which is managed by the other departments. EPI is under the direct management of the National Institute of Hygiene and Epidemiology and the General Department of Preventive Medicine of Ministry of Health. Thus, overall, GAVI HSS’s contribution to immunization improvement throughout the country other than the 10 provinces being supported by GAVI HSS is difficult to attribute for. In addition, the current setting and structure of the healthcare system in Viet Nam makes it difficult to promote effective coordination and collaboration between the GAVI HSS and GAVI NVS. As a graduating country, the current HSS grant may turn out to be the last GAVI support for this window.

Health centers have very limited budget to conduct outreach vaccinations in hard to reach areas. Budget for outreach sessions is from the programme rather than EPI. Thus, it would be good in having the outreach sessions to provide immunization services plus e.g. malnutrition screening and health behaviour communication. The RED/REC approach should be used for this purpose, taking immunization as a backbone to deliver.

Reaching Every Child/ District activities are in the stage of being formulated and implemented prior to scale-up. However, due consideration should be given how the RED/REC could be best deliver in the context of integration, primary healthcare level strengthening, and addressing inequity not just in immunization silos but in other healthcare services. There are pros and cons in moving the RED/REC with immunization only and with a service package and decision would be up to the long term and short term strategies of the Ministry of Health and NEPI. A step wise approach would be worth considering.

Social mobilization is a gap in immunization system and a communication strategy for immunization should be developed. This is particularly important considering the AEFI in the past and related community confidence in vaccination.

The most recent EVM assessment was carried out during March/April 2012, with the next one planned for April 2016. An EVM Improvement Plan Status Report dated 31 December 2013 indicates 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. GAVI HSS is not contributing directly to the EVM Improvement activities but these are adequately covered with Government and WHO funding.

Some stock-outs of Penta vaccine were experienced during 2013, although details of how frequently, for how long and at what level these occurred are absent. No stockouts were reported in 2012, but in 2011 there was number of stock-outs leading to insufficient supply for lower levels or insufficient amounts for use at the facilities (ie, the commune level).

There have been no recent routine vaccine introductions or campaigns and the last new vaccine (Penta) were introduced in 2010.
The country had to postpone a planned campaign with MR vaccine as the vaccine was not registered for use in Viet Nam by the manufacturer. Since then this issue has been resolved and the campaign has begun in September 2014.

6. Data Quality

There are differences between country data and UN Population Division estimates – for births, country data is 25.2% higher than UN figures, and for surviving infants, country data is now 27.0% higher than UN estimates.

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 DPT3 coverage. It also found a greater gender difference in coverage than shown in the 2009 EPI review mentioned in section 2 above, with a 3.7% disparity (72.5% male vs 76.2% female) compared to only 1% reported by the EPI review.

The Country has no discrepancy between DTP3 admin data and WUENIC 2013 but has low (1 star) GoC on DTP3 WUENIC 2013 estimates. MICS round 5 conducted in 2014, preliminary report released end August 2014 is available. GAVI contributed to the MICS with partial financial support. The results from a recent MICS were released. DTP3 coverage has been estimated as 87.5% which is 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 relatively strong robust information system as compared to other similar countries.

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

For improving administrative data systems, a handbook with guidelines for EPI staff on the collection, calculation and use of EPI data has been printed and distributed, and training courses for EPI staff based on this document were conducted during 2012. For other types of programme data, efforts are continuing to develop tools for internal M&E, with revised forms, checklists and tables for improved data collection on all activities under the HSS project framework. There was a specific focus in 2013 on improved data for gender and ethnicity which is gathered for training related activities, and follows on recommendations from the HSCC members on the issue.

7. Global Polio Eradication Initiative, if relevant

The last reported case of wild polio virus in the country was in 1997, so polio immunization is fully integrated into routine immunization in the country and no specific polio eradication activities are carried out. Maintenance of polio-free status is a main objectives and priority action for EPI in 2014 to 2015, but no specific actions are indicated for achieving this and none are considered necessary. There are no polio-supported field staff engaged in the country and there is no need or justification for having any. There is only one, fully integrated annual work plan developed for routine immunization activities.
8. Health System Strengthening

Progress in achieving targets and intermediate results is considered to be satisfactory, even though only a small proportion of the planned activities were completed by 31 December 2013. Because transfer of GAVI funds occurred very late in the reporting year, (30 Nov. 2013), many project activities originally planned for 2013 could not be achieved during that year and had to be delayed into 2014. However, most of the delay had been recovered by April 2014, and the project is now generally back on track. The challenges created by the late receipt of funds appear to have been overcome in an efficient and satisfactory manner.

At this moment, the immunization outreach session of GAVI HSS has not yet applied the RED/REC and there is still opportunity in the remaining project timeline to introduce RED/REC. UNICEF CO is willing to provide technical support and additional budget for capacity building for RED/REC.

There were no NGO/CSO co-implementers under GAVI-HSS, however these organizations do play important role reaching out to mothers and children. There is involvement of CSOs - Women's Union, Fatherland Front, Farmers Association and Youth Union for few activities like organizing immunization activities in outreach and mobilizing mothers and children services. Also the Red Cross Association along with above stated CSOs played active part in IEC activities on immunization, MCH and other HSS activities. All the support activities provided by the CSOs were voluntary in nature.

CSOs have been participating in implementation of the HSS grant as key stakeholders rather than official co-implementers. These are mainly related to implementing and supervising health care activities, especially at the local level, and they have evidently been well-received by the communities, as it is reported that the HSS project has received ‘great support from these organizations’. No funds were provided to CSOs under the HSS project and all activities carried out by these organisations are voluntary.

Reporting of HSS results is considered to be satisfactory. Baselines, impact, process and outcome indicators are reported together with the results achieved for 2013. For indicators that were not met, explanations and justification are given and where appropriate, revised targets are indicated. The proposed future HSS activities are described in detail and are considered to be logical and appropriate continuations of the activities already being implemented. They are believed to fit in well within broader HSS activities and other donors’ initiatives (e.g., those of The Global Fund for period 2012-2016).

9. Use of non-HSS Cash Grants from GAVI

No new ISS funds were received in 2013, but US$480,723 was carried forward from 2012. Total expenditure during the year was US$330,350, leaving a balance of US$150,373 carried forward to 2014. An external audit was conducted on the use of ISS funds in April 2014, and according to activities described in the audit report and detailed in the APR, the use of these funds appears to be appropriate and reasonable, with activities implemented to schedule. GAVI ISS support is reported within the national health sector budget.

A new VIG was awarded in 2013 for introduction of MR vaccine and funds received from GAVI amounted to US$1,357,500. No balance was carried forward from previous VIGs, so funds available for the year was the same amount. However, actual introduction of the vaccine is scheduled for 2014, with MR campaigns to be conducted in 2014 and 2015, so there was no
expenditure made from this grant during the current year and the amount carried forward into 2014 remains unchanged at US$1,357,500.

The country reports on Campaign Operational Support (COS) fund utilization in 2013, but no information is given on any use of COS funds and as noted above, these activities are scheduled to be conducted in 2014 and 2015.

For these 3 types of support, the completeness and quality of the country’s reporting is considered to be satisfactory. Vietnam is not reporting on CSO support fund utilisation (neither Type A or B) for 2013.

10. Financial Management
APR section 9.1.3 gives a comprehensive description of the financial management arrangements and processes used for HSS funds, including the type of bank accounts used, how budgets are approved, how funds are channelled to sub-national levels, financial reporting arrangements at sub-national and national levels and the role of the HSCC in the process. This is considered to be a very satisfactory management process. A cash program audit is being carried out by Gavi secretariat in November 2014.

The PFO team keeps track of the pending requirements and clarifications for financial management. The current status, as provided by PFO, is appended at end of Section 14 of this report.

11. NVS Targets
Proposed future NVS targets as shown in Baseline table 4 are considered to be realistic and likely to be achievable. It is noted however, that the target set for Penta in 2015 is slightly lower than that set for 2013 and 2014, (94% vs 95%) although no discussion or rationale for this somewhat unexpected reduction is provided.

EPI Financing and Sustainability
The government continues to fund all traditional vaccines, and its share of the EPI budget was 55% of the total for 2013, up from 49% in 2012, so has increased a little over this year. The total EPI budget decreased by just over US$ 1 million over the period however, from US$24.2 million in 2012 to around US$23 million in 2013, so the dollar value of Government’s share actually increased by more than 8%, from some US$11.7 million in 2012 to just over US$12.7 million in 2013.

GAVI is the other main contributor to the EPI budget, supporting 48.7% of costs in 2012, almost exactly equal to Government’s share, with the balance being covered by UNICEF, WHO, PATH, JICA and the Government of Luxembourg. For 2013, GAVI’s contributions decreased slightly to 42% of total costs, with other partners maintaining similar levels of support. None of these figures appear to reflect the total extent and proportions of the EPI budget however, as no personnel costs at all are included in the 2013 data. There was a very similar situation in the 2012, where only a very minimal amount of the total EPI budget was allocated to personnel costs (only 0.14%) This is in marked contrast to most GAVI-supported countries, where personnel costs often
represent a very substantial part of Government’s input and often, it is the major portion of the national contribution.

Support from GAVI, in the form of NVS and injection supplies is reported in the national health sector budget.

With the Penta vaccine AEFI crisis hopefully resolved, it is anticipated that coverage rates for both traditional and NVS vaccines will return to the high levels that are shown by the long-term trend for the country. It is believed that EPI performance is likely to continue improving after eventual graduation from GAVI support, with increasing attention on equity of access and the addition of further NVS vaccines. There is a clear commitment from Government to continue and probably expand its contributions to the EPI budget, and also the likelihood of continued support from the partner agencies.

12. Renewal Recommendations

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<th>Topic</th>
<th>Recommendation</th>
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<td>NVS</td>
<td>Renewal – Country does not require any change in vaccine presentations.</td>
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<tr>
<td>HSS</td>
<td>Renewal – next tranche</td>
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</table>

13. Other Recommended Actions

<table>
<thead>
<tr>
<th>Topic</th>
<th>Action Point</th>
<th>Responsible</th>
<th>Timeline</th>
</tr>
</thead>
<tbody>
<tr>
<td>Financial Management</td>
<td>Country to report on use of MR campaign funds (US$ 8,159,650, transferred by GAVI in May 2013)</td>
<td>Country</td>
<td>Next APR</td>
</tr>
<tr>
<td>Graduation assessment</td>
<td>Conduct cash program audit</td>
<td>PFO</td>
<td>November 2014</td>
</tr>
<tr>
<td></td>
<td>Conduct the assessment</td>
<td>SCM, IFS, Partners</td>
<td>Q4 of 2014</td>
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