

TIMOR LESTE SUPPORT FOR INACTIVATED POLIO VACCINE (IPV)

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

1. Country: Timor-Leste				
2. Grant Number: 1518-TLS-25d-X / 15-TLS-08h-Y				
3. Date of Decision Letter: 10 February 2015				
4. Date of the Partnership Framework Agreement: 24 January 2014				
5. Programme Title: New Vaccine Support				
6. Vaccine type: Inactivated Polio Vaccine (IPV)				
7. Requested product presentation and formulation of vaccine¹: Inactivated Polio Vaccine, 1 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\$44,500	US\$128,000	US\$114,000	US\$286,500
10. Vaccine Introduction Grant: US\$100,000				
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	14,900	43,200		
Number of AD syringes	15,800	45,500		
Number of re-constitution syringes				
Number of safety boxes	175	525		
Annual Amounts (US\$)	US\$44,500	US\$128,000		

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, Timor Leste is encouraged to contribute to vaccine and/or supply costs for IPV.					
15. Operational support for campaigns: N/A					
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:					
<table border="1"> <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>		Reports, documents and other deliverables	Due dates	Annual Progress Report or equivalent	To be agreed with Gavi Secretariat
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Annual Progress Report or equivalent	To be agreed with Gavi Secretariat				
17. Financial Clarifications: Not applicable					
18. Other conditions: Not applicable. If Timor-Leste 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 Timor-Leste.					

Signed by,
On behalf of Gavi



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

Appendix A

IRC NVS COUNTRY REPORT Geneva, November 2014

Independent Review Committee (IRC) Country Report Gavi Secretariat, Geneva • 10 - 24 November 2014 Country: Timor Leste

1. Type of support requested: IPV

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

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

The country has an active HSCC functioning as an ICC. The committee includes NGO representatives as well as WHO and UNICEF and other stakeholders. The HSCC approved IPV, DPT and DT in the immunisation schedule and the application for Gavi IPV support on 18th August 2014. Minutes and members signatures as well as signatures of the Ministry of Health and Finance are provided. Currently there is no NITAG. WHO is providing support to the country to establish a NITAG.

3. Situation analysis Status of the National Immunisation Programme

The country has an estimated 47,385 live births annually. The NIP appears to be well managed, overseen by a highly committed government working in close coordination with WHO, UNICEF and other partners.

National immunisation declined (to around 50%) during the transition to independence from Indonesia (1999-2000), but appears to have climbed since 2003. However, without a reliable denominator it is difficult to assess the coverage with great accuracy. Penta3 coverage was 83% and 82% in 2012 and 2013 respectively according to administrative estimates which have been endorsed by WUENIC. However, the WUENIC report shows the last survey to have been in a DHS in 2009/2010 which found DPT3 to be 66%.

Pentavalent introduction in October 2012 was well planned and appears to have gone smoothly. However, the proposal does not discuss findings from any PIE. The country has not conducted an EPI review in the past five years.

Timor Leste will graduate from Gavi support in January 2018. The government is currently financing 92% of the costs of all vaccines and paying co-financing for Pentavalent vaccine. The country is not planning to co-finance IPV but will begin assume responsibility to pay for IPV in 2019.

The last reported polio case was in 1996, when the country was still a province of Indonesia.

4. Overview of national health documents

The cMYP 2011 – 2015 does not include introduction of IPV. This is to be included in the next cMYP for the period 2016 – 2020.

5. Gender and Equity

GII rank and value = NA; HDI rank = 128; MMR = 300/100,000. The HMIS collects routine data that is disaggregated by sex and no difference in coverage. The 2009/2010 DHS found no significant difference in DPT3 coverage by sex (66% and 64% DPT3 for males and females respectively).

On the other hand, the survey found significant variation in DPT3 coverage by wealth (from 52.5% for children of the poorest quintile to 81.3% for children of the wealthiest quintile) and geographic district (from 51.8% to 86.4%). Eighty percent of the population *lives in rural dispersed communities in mountainous areas in the northern part of the country*. These population groups are also economically disadvantaged. The programme is planning to address these disparities over the next 4 to 5 years with inputs from a Gavi HSS grant that will support micro-planning by community health centres, extension of outreach services and increasing demand through community participation.

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

The country submitted a comprehensive plan to introduce IPV in Sept 2015. Advocacy, training of staff and development of IEC materials will commence in January 2015, using the Gavi V.I.G. The activities appear feasible and the timeline reasonable.

The introduction plan has detailed activities for pre-introduction, introduction and post introduction activities including PIE. The introduction will be paid for from the V.I.G. (US\$ 100,000), Gavi HSS (US\$ 178,000 for cold chain equipment), and UNICEF (US\$ 37,000 for the communication plan). The V.I.G. will be allocated for Advocacy Communication and Social Mobilisation (ACSM) (51%), training (25%), and printing (24%). The government will pay \$400,000 for design and printing of monitoring tools. The budget does not include the costs of a PIE or costs associated with transportation of vaccines/supplies.

The country has requested that the grant be transferred to the government using the same bank account as agreed with Gavi in the Aide Memoire (resulting from an FMA).

7. Specific comments related to requested support

New vaccine introduction plan

The country introduced Pentavalent vaccine in 2012 and appears to have achieved 80% coverage. Timor Leste plans to achieve 80% IPV coverage in 2015 (September to December) and 85% coverage in 2016.

The New vaccine introduction plan includes all the required elements. The vaccine introduction plan for IPV clearly outlines the justification for the introduction of one IPV dose in line with the Polio Eradication and Endgame Strategic Plan and the recent WHO SAGE position paper. IPV will be given with DPT3 at 14 weeks of age 0.5 ml IM in the right thigh. The booster dose of DTP will be introduced for children at 18 months of age while DT will be introduced at 6 years of age.

The proposed schedule of IPV in the routine immunisation system is in line with the SAGE recommendations. In its meeting on 26th May 2014, the EPI Working Group decided to synchronize the introduction of IPV, DPT and DT booster dose to synergize with the efforts and resources available for IPV vaccine introduction, from 1st of September 2015.

The government has yet to establish a regulatory body and a mechanism to ensure the safety, efficacy and quality of vaccines imported into the country. Until the country develops its own capacity, WHO pre-qualified IPV and other supplies will be procured through UNICEF SD. Only vaccines containing "Vaccine Vial Monitors" could be used in the National Immunisation Programme. The preferred product is the 10 dose vial.

Vaccine management and cold chain capacity

The EVM assessment conducted in 2011 showed that there were improvements in cold chain capacity. However stock management and distribution were rather weak at most levels. With on-going WHO and UNICEF support, the progress has been good and is still on going. The central store has been overhauled, and a manager appointed. Further strengthening is planned through Gavi HSS, to provide 92 refrigerators to districts and health centres as required. Gavi HSS funding will also be used for procurement of motorcycles and hiring of support staff for EPI.

With the Government's vigorous rural electrification scheme, the intention is to provide cold chain to all health posts in the near future and this will further strengthen the cold chain capacity and access to immunisation in the country. With Gavi HSS inputs and improved supportive supervision, the stock management system is expected to improve at district and CHC level.

In urban settings incinerators are used for injection waste disposal and in rural settings waste is burned in open pits.

Training, Community Sensitisation & Mobilisation Plans

Training:

Health workers will be trained on the new schedule, cold storage of the new vaccines, injection techniques, immunisation safety, AEFI surveillance and waste disposal. The NIP will use the existing Gavi HSS resources from the previous grant to support capacity building activities.

Communication strategies for vaccine introduction and demand creation are being developed with UNICEF support, based on lessons learnt from penta introduction. The programme is preparing for a well-publicized launching.

Monitoring and evaluation plans

There is an established system for reporting and monitoring for NIP activities. The programme is aware of the weakness of feedback and plans to address with MLM trainings, supportive supervision and the monthly/quarterly reviews which will be conducted with the Gavi HSS inputs.

There is no functional AEFI surveillance system in place. However, AEFI guidelines and reporting forms had been developed, and AEFI surveillance and response will be addressed in all training activities. A national AEFI Expert Review Committee is yet to be established.

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

Documents presented for this application are complete, detailed and consistent.

9. Overview of the proposal

Strengths:

- Highly committed government and strong national programme, working closely with Gavi and different partners.
- Country managed to introduce Pentavalent vaccine in 2012, apparently achieving 80% coverage.
- The programme is aware of its weaknesses and has plans to address them, capitalizing on the opportunity of IPV introduction.
- The IPV Introduction Plan is comprehensive and complete.

Weaknesses:

- No major weakness identified in the introduction plan, except in the area of AEFI surveillance, where the programme is aware and planning to cover it in trainings
- Recent increases in immunisation coverage need to be validated with a high quality coverage survey.
- There was no comprehensive EPI review in the previous five years, the last EPI review was in 2008.
- No information about post introduction evaluation (PIE) after the pentavalent vaccine introduction in 2012
- No budget estimated for supportive supervision, PIE and transportation of vaccines and other logistics.
- Vaccine stock management and distribution may be issues

Risks:

- Dispersed communities may be hard to reach
- Parents may resist two injections at one visit at 14 weeks of age.

Mitigating strategies:

- An effective communication strategy with support from UNICEF

10. Conclusion

The country submitted a clear proposal to introduce one dose of IPV into their routine immunisation system in-line with the GPEI Endgame Strategic Plan and the recent WHO SAGE recommendations (to infants 14 weeks of age). The country has had good experiences with previous vaccine introductions, and is planning to synchronize IPV introduction with the introduction of DPT and DT booster dose. Based on the past performance and track record of new vaccine introduction, Timor Leste is capable of smoothly introducing IPV. The country has provided adequate justification and documentation for the IRC to recommend approval of their proposal.

11. Recommendations:

Approval with recommendations

Recommendations to the Country:

1. Make efforts to reach hard to reach areas during the IPV introduction.
2. Consider conducting a comprehensive national EPI review in the coming years.
3. Consider conducting a PIE for pentavalent (if not done) to derive lessons for IPV introduction.
4. Consider modifying the IPV introduction budget to cover the costs of a post introduction evaluation (PIE).

Recommendations to the Gavi Secretariat & Partners:

1. Ensure that the country has technical assistance in the area of Advocacy, Communication, and Social Mobilisation and the development of the cMYP 2016 - 2020 as requested.
2. Support the extension of outreach activities before Timor Leste graduates.