

Papua New Guinea Inactivated Polio Vaccine Support
This Decision Letter sets out the Programme Terms of a Programme.

1. Country: Papua New Guinea															
2. Grant Number: 1518-PNG-25b-X / 15-PNG-08h-Y /															
3. Date of Decision Letter: 03 June 2015															
4. Date of the Partnership Framework Agreement: 29 November 2013															
5. Programme Title: NVS, IPV Routine															
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															
<p>9. Programme Budget (indicative) (subject to the terms of the Partnership Framework Agreement): Please note that the endorsed or approved amount for 2018 will be communicated in due course, taking into account updated information on country requirements and following Gavi's review and approval processes.</p> <table border="1"> <thead> <tr> <th></th> <th>2015</th> <th>2016</th> <th>2017</th> <th>Total³</th> </tr> </thead> <tbody> <tr> <td>Programme Budget (US\$)</td> <td>US\$181,000</td> <td>US\$408,500</td> <td>US\$299,500</td> <td>US\$889,000</td> </tr> </tbody> </table>		2015	2016	2017	Total ³	Programme Budget (US\$)	US\$181,000	US\$408,500	US\$299,500	US\$889,000					
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10. Vaccine Introduction Grant: US\$172,000															
<p>11. Indicative Annual Amounts (subject to the terms of the Partnership Framework Agreement):⁴</p> <table border="1"> <thead> <tr> <th>Type of supplies to be purchased with Gavi funds in each year</th> <th>2015</th> <th>2016</th> </tr> </thead> <tbody> <tr> <td>Number of IPV vaccines doses</td> <td>88,200</td> <td>198,900</td> </tr> <tr> <td>Number of AD syringes</td> <td>85,200</td> <td>189,700</td> </tr> <tr> <td>Number of safety boxes</td> <td>950</td> <td>2,100</td> </tr> <tr> <td>Annual Amounts (US\$)</td> <td>US\$181,000</td> <td>US\$408,500</td> </tr> </tbody> </table>	Type of supplies to be purchased with Gavi funds in each year	2015	2016	Number of IPV vaccines doses	88,200	198,900	Number of AD syringes	85,200	189,700	Number of safety boxes	950	2,100	Annual Amounts (US\$)	US\$181,000	US\$408,500
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12. Procurement agency: UNICEF															
13. Self-procurement: Not applicable															
<p>14. Co-financing obligations: Not applicable Gavi's usual co-financing requirements do not apply to IPV. However, Papua New Guinea is encouraged to contribute to vaccine and/or supply costs for IPV.</p>															

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.

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 or equivalent	To be agreed with Gavi Secretariat

17. Financial Clarifications: The Country shall provide the following clarifications to Gavi*:

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

18. Other conditions:

If Papua New Guinea 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 Papua New Guinea.

On behalf of Gavi



Hind Khatib-Othman
Managing Director, Country Programmes

03 June 2015

**Independent Review Committee (IRC) Country Report
Gavi Secretariat, Geneva • 16-27 March 2015
Country: Papua New Guinea**

1. Type of support requested: IPV

Table 1

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

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

The government re-established the EPI Interagency Coordinating Committee (ICC) in 2012. Besides members from NDoH, it includes representatives from WHO, UNICEF, DFAT, CHAI, Pediatric society and Christian Health services. The ICC is headed by the Secretary of NDoH. A recent Gavi internal assessment in 2014 of Papua New Guinea (PNG) found that it meets occasionally. PNG's IPV application was endorsed by ICC with comment to improve surveillance systems in low coverage areas.

3. Situation analysis – Status of the National Immunisation Programme

PNG has a population of around 7.6 million with approximately 87% residing in rural areas. PNG is divided into 22 provinces and 98 districts. The GNI of PNG is US\$ 2,010 (2013) and is eligible for support from Gavi until 2018. Within the national government, immunization falls under NDoH and is managed by NDoH's Expanded Program on Immunization (EPI). Immunisation coverage in PNG is low with DTP3 coverage of 68% in 2013, up from 55% in 2001. DTP1 coverage was estimated at 88% in 2013, suggesting a 20% dropout rate. Papua New Guinea was declared poliomyelitis free in 2000 with last reported case on 1996. Due to low vaccination coverage (68% in 2013) and a weak AFP (acute flaccid paralysis) surveillance system, the Western Pacific Regional Certification Commission for Polio has classified PNG at high risk of polio re-importation within the region. The country has recently developed a plan for a Special Integrated Routine EPI Strengthening Programme (SIREP) to be launched by the Prime Minister in July 2015 coinciding with the launch of MR campaign. Subsequently IPV is expected to be introduced in Q4 2015 with MR in routine EPI.

4. Overview of national health documents

- PNG has a cMYP for a period of 2011-2015. The introductions of IPV and the eventual switch from tOPV to bOPV are not outlined in the current plan, however there are plans to include these elements in the cMYP 2016-2020.
- An Effective Vaccine Management assessment conducted in May 2011 revealed that there were various and serious quality and logistics challenges. A new EVM is planned for Q2, 2016.
- There has been an EPI review in 2013. The main areas of concerns identified were maintenance of cold chain equipment, temperature monitoring processes, lack of qualified HR and deficiencies in knowledge on vaccine management.
- PNG plans to do a DHS in 2016.

5. Gender and Equity

Gender Inequality Index for Papua New Guinea⁵

61.7%

Female adolescents currently married⁶/ in union

14.8%

Although the population of Papua New Guinea is small, 87% of the population lives in remote rural areas. The population is divided by ethnic barriers (over 800 languages) and local security issues are an obstacle to the delivery of health services. Due to the high service delivery costs and the incentives to health staff for SIAs, most immunization is delivered through campaigns instead of routine services. Sex disaggregated data is not collected either by the government health services or the faith-based organizations that deliver more than half the health services. The country is reintroducing a child health register that may capture such information.

PNG states that there are no gender barriers to vaccination but the 2006 DHS found that for all vaccinations, coverage for boys (49.7%) is lower than for girls (55.1%). PNG ranks very low on the United Nations Gender Equality Index and acknowledges high rates of violence against women. This should be recognized as a barrier to women and children visiting clinics for routine services and immunization. In addition, the children of illiterate mothers have a lower coverage at 37.7% compared to children of mothers who have secondary education at 93.6%. The main bottleneck is presented as geographic equity; as a result, there is no information in the proposal or in the 2006 DHS on socio-economic quintiles. While the proposal notes "local security issues", PNG is not regarded as a fragile state.

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

The cost of IPV and syringes is requested from Gavi and the cost is estimated by GoPNG to be an additional US\$ 96,000 for 2015 and around US\$ 600,000 for each subsequent year. GoPNG has also requested a VIG of US\$ 172,000 for training of health care workers, the reproduction of print materials and other essential activities. The total budget for the introduction of IPV is US\$ 567,282 of which US\$ 38,000 (7%) is from the Government, US\$358,000 (63%) from other partners and US\$ 172,000 (30%) from Gavi contributions respectively. The breakup of the budget is given below:

Activity	Budget in US\$ from all sources	Budget in US\$ from Gavi as VIG (% of total VIG budget)
Coordination meeting with Partners and Program management	250,000	30,000 (17%)
Social mobilization, IEC, advocacy	43,282	40,282 (23%)
Training	100,000	60,000 (35%)
Cold chain equipment and upgrade	Nil	Nil
Waste Management	3,000	3,000 (2%)

⁵ The Gender Inequality Index (GII) is a composite measure which captures the loss of achievement within a country due to gender inequality. The GII is interpreted as a percentage and indicates the percentage of potential human development lost due to gender inequality.

⁶ Generally early marriage indicates that girls are being taken out of school and married to significantly older men. This raises questions around inequality within these relationships and the ability of young women to make decisions about their own and their children's wellbeing.

Surveillance & Monitoring	126,000	10,000 (6%)
TA (Introduction planning and for cold chain review and implementation)	30,000	18,000 (11%)
Data Management	15,000	10,718 (6%)
TOTAL	567,282	172,000 (100%)

* TA is also requested to improve some of the shortcomings in the system.

7. Specific comments related to requested support

New vaccine introduction plan

- IPV will be introduced into routine immunisation program nationally across PNG in November 2015, in conjunction with the introduction of Measles Rubella (MR) vaccine after the completion of campaign.
- IPV is registered for use in PNG from pharmaceutical regulatory unit (PNG's national regulatory authority).
- The procurement of the vaccine would be through UNICEF SD.
- Throughout the introduction of IPV, the National Certification Committee for Polio Eradication, Inter agency Coordination Committee and the Child Health Advisory Committee will continue to monitor and provide technical advice.
- The Paediatric Society of Papua New Guinea will provide the required technical support along with WHO and UNICEF. Other donor partners at the national level as DFAT Australian Government and others at the provincial and districts level will provide the required support.
- The Provincial Family Health Coordinators through the involvement with the Provincial Governors and the Provincial Administrators will provide the ground for introduction of the vaccine in their respective provinces.

Vaccine management and cold chain capacity

Vaccine wastage rate: Indicative wastage rates for IPV depend on whether or not the country will apply the WHO multi-dose vial policy (MDVP):

- **If the MDVP will be implemented:** indicative wastage rates are 20% for 10-dose vials, 15% for 5-dose vials and 5% for single-dose vials
- **If the multi-dose vial policy for IPV will NOT be implemented:** indicative wastage rates are 50% for 10-dose vials, 30% for 5-dose vials and 5% for single-dose vials

In its application PNG did not indicate whether or not it will apply the WHO MDVP (PNG used the 2014 application form rather than the 2015 one which includes MDVP questions). In response to Secretariat clarifications, PNG confirmed that the MDVP will be implemented, however, the wastage rate was not subsequently reduced as the country indicated that based on their past experience the wastage rate may be higher. This is a concern as it could lead to stock outs and the situation should be further clarified.

Stock management system: PNG intends to use current stock management system for IPV though in 2014 there was a stock out of OPV and measles vaccines for a couple of months followed by an outbreak of measles.

The last EVM was conducted in 2011. The next one is planned for 2016. The last EVM highlighted critical problems in the supply chain at all levels and all EVM criteria. The IPV application states that most of the recommendations have been implemented. An updated report on vaccine supply management report only describes the ideal process of distribution. The EPI review 2013, the internal appraisal of 2014 and the trip report of May 2014 highlights persisting problems of ageing equipment, stock-outs and distribution. Introduction

of PCV has further added to the existing strain. The 5 dose vial will strain the system further in terms of capacity, and management of the supply chain.

A cold chain assessment was planned in Q4 of 2014, but has now been pushed to 2016.

Conclusion

In the absence of the recent cold chain assessment it is difficult to have confidence in the supply chain – especially considering the 2013 EPI findings and other appraisal reports. The quality and quantity of IPV reaching the child may be compromised without appropriate attention to the supply chain.

Waste management:

Current waste management practice in PNG includes incinerators that are used for waste disposal when available. Where there is no availability, sharps and waste are burnt and buried. This procedure is outlined in the EPI manual and is followed nationwide.

Training, Community Sensitisation & Mobilisation Plans

PNG has a national EPI program to train immunisation providers nationwide on use of IPV and will be incorporated with the health facility level, competency-based training including basics of EPI, cold chain, vaccine stock management, AEFI and micro planning. To improve coverage of RI, PNG has planned re-introduction of the child health register, the promotion of defaulter tracking and improved micro planning through the RED-REC (reaching every district to reach every child) strategy. The communication and social mobilization material production, technical support will be sought from UNICEF and WHO in consultation with the Health promotion unit of National Department of Health. The Church Health Services will be mobilised for introduction of IPV.

Monitoring and evaluation plans

To improve surveillance new recruitment is planned to strengthen this component. The coverage for IPV will be monitored and reported using the established monthly routine immunization report to the National Health Information System. The reporting of the coverage will be done by each district. SMS reminder system for AFP reporting is also planned. NDoH is currently working to develop the national AEFI policy.

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

The documents provide information as required for introduction of IPV though there is an ambiguity in request for IPV presentations.

9. Overview of the proposal

Strengths:

1. There is wide stakeholder support including partners and government for the introduction of the vaccine.
2. Training, mobilization and M&E plan has been well planned.

Weaknesses:

1. As per Gavi internal assessment in 2014 of PNG, the ICC is not meeting regularly as planned.
2. Current cMYP has a specific reference to the maintenance of polio-free status and but still the Pol3 coverage is 69%.

3. EVMA of 2011 revealed various quality and logistics challenges and again EPI review of 2013 identified gaps in same area.
4. Timelines proposed are quite aggressive and delays may be encountered. This is a risk given that all countries should introduce IPV by the end of 2015 in order to meet the Polio Endgame Strategy timelines.
5. PNG intends to use its current stock management system for IPV though in 2014 there was a stock out of OPV and measles vaccines for a couple of months.
6. Engagement of partners is real for IPV and other new vaccine introductions but support is relatively fragmented and uncoordinated

Risks:

1. Immunization coverage in PNG is low with DTP3 coverage of 68% in 2013, lowest among Gavi graduating countries.
2. Country has agreed to follow MDVP though they do not appear to be confident to meet this; failure to use the MDVP could lead to stock outs.

Mitigating strategies:

1. Ensure more regular ICC engagement
2. Ensure proper cold chain systems and stock management systems are in place.
3. Careful coordination of TA with partners and country

IRC comments for consideration:

Comments for consideration
1. Country and ICC should carefully review all the recent reports to check and monitor what progress is done to overcome the serious weaknesses highlighted in different areas including stock management, distribution implementation plans, data quality and supervision
2. A more intensive and regular technical support from partners and ICC involvement is desired to address the gaps in the supply chain and assure delivery of viable vaccines as well as in monitoring immunization coverage and immunization program performance.

10. Conclusions

The country needs to implement the IPV in their immunisation programme since it is one of the high risk countries in the WPRO region. The proposal has been well conceived and the country's intent to improve the vaccine coverage is evident from the extensive training and mobilization plan. The area of concern for PNG is effective vaccine management. They have budgeted for TA, but their timelines are aggressive and it may not be possible to implement all of the necessary improvements before the introduction of the vaccine.

11. Recommendation:

Approval

Table 3a

Issues to be addressed	Action points
1. Many deficiencies in the supply chain and vaccine management have been identified and vaccine stock outs observed.	1. Since EVM will not be conducted until 2016, a supply chain plan and monitoring need to be put in place. Provide a roadmap and person responsible for how the implementation plan will be followed.
2. Introduction activities and timeline are also inconsistent including for TA.	2. Country should revise and resubmit timelines for IPV introduction plan.
3. Engagement of partners is real for IPV and other new vaccine introductions but support is relatively fragmented and uncoordinated.	3. Country and Partners should develop and implement a more coherent and coordinated plan of engagement as well as a set actionable points to be undertaken preferably by May 2015.
4. The country has provided mixed information about the expected wastage rates for IPV. PNG has indicated that it will apply the MDVP although it indicated a need for higher wastage rates.	4. Country to clarify whether the indicative wastage rates of 20% for 10-dose vials, 15% for 5-dose vials and 5% for single-dose vials will be sufficient and if not, to provide data to support a request for higher wastage rates.