



GAVI/13/349/MK/RK

The Minister of Health
Department of Health
PO Box 807
Waigani NCD
Papua New Guinea

10 June 2013

Dear Minister,

Papua New Guinea's Proposal to the GAVI Alliance

I am writing in relation to Papua New Guinea's proposal to the GAVI Alliance for New Vaccines Support for **pneumococcal vaccines**, which was submitted to the GAVI Secretariat in February 2012.

Following our correspondence 13 April 2012, we are now able to confirm the availability of vaccine supply to support an introduction starting in October 2013. Based on data provided in the original application and the new introduction timeline, we have recalculated the number of doses to be supported by GAVI and updated the co-financing requirements. Appendix B provides this information.

Please note that this document contains the following important attachments:

Appendix A: Description of approved GAVI support to Papua New Guinea

Appendix B: Financial and programmatic information for pneumococcal vaccine

Appendix C: The report of the Independent Review Committee for reference

Appendix D: GAVI Alliance Terms and Conditions

The following table summarises the outcome for each type of GAVI support applicable to Papua New Guinea:

New Vaccines Support	Approved for 2013	Approved for 2014
Pneumococcal vaccines	US\$1,138,500	US\$3,624,500
Vaccine Introduction Grant	US\$ 188,000	N/A

Please do not hesitate to contact my colleague Raj Kumar raj कुमार@gavialliance.org if you have any questions or concerns.

Yours sincerely,

Hind Khatib-Othman
Managing Director, Country Programmes

cc: The Minister of Finance
Director of Medical Services
Director Planning Unit, MoH
The EPI Manager
WHO Country Representative
UNICEF Country Rep.

Regional Working Group
WHO HQ
UNICEF Programme Division
UNICEF Supply Division
The World Bank

Description of GAVI support to Papua New Guinea (the “Country”)

New Vaccines Support (NVS)

The GAVI Alliance has approved the Country’s request for supply of vaccine doses and related injection safety material which are estimated to be required for the 2013 and 2014 immunization programme as set out in Appendix B. Financing provided by GAVI for vaccines will be in accordance with:

- The GAVI Alliance Guidelines governing Papua New Guinea’s proposal application; and
- The final proposal as approved by the Independent Review Committee (IRC), including any subsequent clarifications.

The vaccines provided will be used for routine immunisation of children under 12 months of age. The principles of the WHO-UNICEF-UNFPA joint statement on safety of injections (WHO/V&B/99.25) shall apply to all immunisation provided with these vaccines.

Item number 11 of Appendix B summarises the details of the approved GAVI support for vaccines in 2013 and 2014.

Any required taxes, customs, toll or other duties imposed on the importation of vaccines and related supplies can not be paid for using GAVI funds.

GAVI is not responsible for any liability that may arise in connection with the distribution or use of vaccines and related supplies after title to such vaccines and related supplies has passed to the country, excluding liability for any defect in vaccines and related supplies, which remain the responsibility of the applicable manufacturer.

Country Co-financing

In accordance with the GAVI Co-financing Policy, the Country has agreed to make the required contribution to co-financing vaccine doses in 2013 and 2014.

Item number 14 of Appendix B summarises the budget and the quantity of supply that will be procured with country’s funds in 2013 and 2014. The total co-financing amount indicates costs for the vaccines, related injection safety devices and freight.

Countries may select to co-finance through UNICEF Supply Division, PAHO’s Revolving Fund, or self-procure their co-financing requirement following their own procedures, except for the Pneumococcal vaccine that needs to be procured through UNICEF.

If the purchase of the co-financed supply is carried out through UNICEF or PAHO, the payment is to be made to UNICEF or PAHO (whichever is applicable) as agreed in the Procurement Services Memorandum of Understanding between UNICEF or PAHO (whichever is applicable) and the country, and not to the GAVI Alliance. Please keep in contact with UNICEF or PAHO (whichever is applicable) to understand the availability of the relevant vaccine(s) and to prepare the schedule of deliveries.

The total co-financing amount expressed in item number 14 of Appendix B does not contain costs and fees of the relevant Procurement Agency, such as contingency buffer and handling fees.

Information on these extra costs and fees will be provided by the relevant Procurement Agency as part of the cost estimate to be requested by the country. UNICEF/PAHO will share information with GAVI on the status of purchase of the co-financed supply. In accordance with the GAVI Co-financing Policy (<http://www.gavialliance.org/about/governance/programme-policies/co-financing/>), the co-financing contribution is payable annually to UNICEF/PAHO.

If the purchase of the co-financed supply is carried out by the Government, following its own procurement procedures and not procuring from UNICEF Supply Division or PAHO, the Government must submit to GAVI satisfactory evidence that it has purchased its co-financed portion of the vaccines and related supplies, including by submitting purchase orders, invoices, and receipts to GAVI. GAVI strongly encourages that countries self-procuring co-financed products (i.e. auto-disable syringes and syringe and needle disposal boxes) ensure that products appear on the applicable WHO list of pre-qualified products or, for syringe and needle disposal boxes, that they have obtained a certificate of quality issued by a relevant national authority.

GAVI support will only be provided if the Country complies with the following requirements:

Transparency and Accountability Policy (TAP): Compliance with any TAP requirements pursuant to the GAVI TAP Policy and the requirements under any Aide Memoire concluded between GAVI and the country.

Financial Statements & External Audits: Compliance with the GAVI requirements relating to financial statements and external audits.

Grant Terms and Conditions: Compliance with GAVI's standard grant terms and conditions (attached in Appendix D).

Country Co-financing: GAVI must receive proof of country co-payment from the Country such as invoices or shipment receipts if neither UNICEF nor PAHO is the procurement agent for country co-financed vaccine for the prior calendar year.

Monitoring and Annual Progress Reports: Papua New Guinea's use of financial support for the introduction of new vaccinations with pneumococcal vaccine is subject to strict performance monitoring. The GAVI Alliance uses country systems for monitoring and auditing performance as well as other data sources including WHO/UNICEF immunization coverage estimates. As part of this process, National Authorities will be requested to monitor and report on the numbers of children immunised and the delivery of funds to co-finance the vaccine.

Papua New Guinea will report on the achievements and request support for the following year in the Annual Progress Report (APR). The APR must contain information on the number of children reported to have been vaccinated with DTP3 and 3 doses of pentavalent vaccine by age 12 months, based on district monthly reports reviewed by the Immunisation Coordinating Committee (ICC), and as reported to WHO and UNICEF in the annual Joint Reporting Form (JRF). The APRs will also contain information on country's compliance with the co-financing

arrangements outlined in this letter. APRs endorsed by the ICC, should be sent to the GAVI Secretariat no later than 15 May every year.

Continued funding beyond what is being approved in this letter is conditional upon receipt of satisfactory Annual Progress Reports and availability of funds.

Financial and programmatic information for Pneumococcal vaccine support

This sets out the terms of a Programme.

1. Country: Papua New Guinea				
2. Grant Number: 1315-PNG-12c-X / 13-PNG-08a-Y /				
3. Decision Letter no: 2				
4. Date of the Partnership Framework Agreement: N/A				
5. Programme Title: New Vaccine Support (NVS)				
6. Vaccine type: Pneumococcal				
7. Requested product presentation and formulation of vaccine: Pneumococcal (PCV13), 1 dose(s) per vial , LIQUID				
8. Programme Duration¹: 2013 -2015				
9. Programme Budget (indicative): (subject to the terms of the Partnership Framework Agreement)				
	2013	2014	2015	Total²
Programme Budget (US\$)	US\$1,138,500	US\$3,624,500	US\$2,821,000	US\$7,584,000
10. Vaccine Introduction Grant: US\$ 188,000 payable up to 6 months before the introduction.				
11. Indicative Annual Amounts (subject to the terms of the Partnership Framework Agreement):³				
Type of supplies to be purchased with GAVI funds in each year	2013	2014		
Number of Pneumococcal vaccines doses	180,000	714,600		
Number of AD syringes	192,200	761,000		
Number of re-constitution syringes				
Number of safety boxes	2,150	8,450		
Annual Amounts (US\$)	US\$1,138,500	US\$3,624,500		
12. Procurement agency: UNICEF. The Country shall release its Co-Financing Payments each year to UNICEF.				
13. Self-procurement: Not applicable				
14. Co-financing obligations: Reference code: 1315-PNG-12c-X-C According to the Co-Financing Policy, the Country falls within the Intermediate 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.				
Type of supplies to be purchased with Country funds in each year	2013	2014	2015	2016
Number of vaccines doses	12,600	54,000	55,800	

¹ This is the entire duration of the programme.

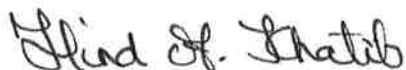
² This is the total amount endorsed by GAVI for the entire duration of the programme. This should be equal to the total of all sums in the table.

³ This is the amount that GAVI has approved. Please amend the indicative Annual Amounts from previous years if that changes subsequently.

Number of AD syringes	12,500			
Number of re-constitution syringes				
Number of safety boxes	150			
Value of vaccine doses (US\$)	US\$41,105			
Total Co-Financing Payments (US\$) (Including freight)	US\$44,500	US\$200,000	US\$206,000	
15. Operational support for campaigns: Not applicable				
16. Additional documents to be delivered for future disbursements: Not applicable				
Clarifications: Not applicable				
17. Other conditions: Not applicable				

Signed by

On behalf of the GAVI Alliance



Hind Khatib-Othman

Managing Director, Country Programmes

10 June 2013

The report of the Independent Review Committee for reference

IRC NVS COUNTRY REPORT

Geneva, June 24 – July 08 2011

Country name: PAPUA NEW GUINEA
Type of support requested: NVS
Vaccines requested: PCV13, 1 doses/vial, Liquid

Country profile/Basic data

Population (2011)	7.112.628	Infant mortality rate (2006)	57/1000LB
Birth cohort**	216,637	Govt. Health expenditure/total Govt. budget (2011)	3.20%
Surviving infants (2010)	204,288	GNI/capita (2010)	US\$ 1,200
DTP3 coverage (administrative)	2010: 70% (5.3 JRF) 2010: 56% (5.4 Table 1)	Co-financing country group*	Intermediate

**Inconsistencies in AF:
or graduating

5.1 Surviving Infants 216.637

5.4 (Table 1) Total births 216,637, Surviving Infants 204,288

*low income, intermediate

1. Type of support requested/Total funding/Implementation period

PCV13, 1 doses/vial, Liquid

US\$ 9,400,000 to be funded by GAVI

Implementation period: 2012-2015

2. History of GAVI support

ISS: 2006-2010

DTP-Hib: 2007-2008

Penta: 2009-2015

3. Composition & Functioning of the ICC

The ICC was established in 2006. It is a stand-alone committee with participation of MOH, multilateral agencies (WHO, UNICEF), bilateral organizations (JICA, AusAID, CSO (Society of paediatrics, Churches medical council), that meets quarterly. In its meeting of May 5, 2001, the ICC reviewed and endorsed the proposal. Three more minutes are attached in which ICC reviewed the APR to submit to GAVI as well as other considerations related to the vaccine program. There is no NITAG.

4. Status of the National Immunisation Programme

The EPI was launched in 1977, initially with TBC, polio and DPT. Measles vaccination was introduced in 1982, HepB in 1989 and Penta in 2009. The Penta introduction was successful.

Low immunization coverage explains the outbreaks of pertussis (2009, 2010) and the high number of NN tetanus cases (125, 32 respectively).

There is a decreasing trend in DTP3 coverage, from 75% in 2006 to 60% in 2008 (cMYP). Historically the DTP drop-out rate is 30%, and the proposal targets decrease from 13% to 2% (2012-2015).

Lessons have been learned from the Penta introduction:

- 9 years delay in introducing pentavalent vaccine,
- research results do not reach decision makers,
- training health personnel in vaccine management,
- adverse events reporting.

The introduction was fairly successful in the country, however the national department of health (NDOH) is taking effective measures including the implementation of the reaching every district strategy (RED) in all provinces and districts, and institutionalizing the role of supportive supervision with a possible integration of maternal and child health to address the concerns identified by the National EPI unit in reaching the unimmunized children in the country.

Sex-disaggregated data is recorded but not reported. There is no information on gender equality because it is not considered an issue in the country

5. *Comprehensive Multi Year Plan (cMYP) overview*

The cMYP was prepared for 2011-2015 and is aligned with the National Health Plan (NHP) 2010-2020, which is in turn is aligned with the Long Term Development Strategy (LTDS) 2010-2030, which is guided by the National Strategic Plan 2010-2050.

Targets are set for different EPI preventable diseases. Based on the current levels these targets are reasonably reachable. It is pointed out that integration to other PHC delivery services will be implemented, especially with the malaria program. But there is as yet no integration with other PHC programs.

6. *New vaccine introduction plan*

There is neither a stand-alone Introduction Plan in the attached documents, nor described in the cMYP (2.4.6). In other documents the following information is available:

- The Burden of disease is very well stated when describing the prevalence of pneumococcal disease in bacterial meningitis as well as in the mortality and case fatality rates.
- The volumes requested are 2,687,300 doses for 4 years, for a nationwide introduction, 93.4% of which will be supported by GAVI
- A wastage factor of 1.05 is assumed for each of the 4 years of implementation that is in agreement with the minimum required for this vaccine
- The procurement mechanism will be through UNICEF.
- The cost of the introduction is \$726,000, \$100,000 of which is covered by PNG-

7. *Improvement plan*

"There are twenty five (25) priority tasks requiring immediate implementation in 2009".

This is not an improvement plan. It has activities to be performed, but not a plan. For example, *"(2) There is no automatic temperature recording device"*. The corresponding recommendation states *"Install three automatic temperature recording devices to the three chillers"*. There is no evidence that this has been implemented.

A new EVM should have been performed in May 2011. The report is awaited.

8. *Cold chain capacity*

According to the UNICEF report, there is sufficient capacity for the introduction of the new vaccine, at central as well as district level. It should be explained why is a WIC required in 2011 when the space is adequate.

The national department of health, based on the national updated inventory and baseline data of cMYP towards the cold chain requirement, has submitted the cold chain request for support to AusAID and JICA. JICA in its commitment to the cold chain support has agreed

to support the country for the next five years. AusAID has already committed to procure the cold chain equipment for the year 2010.

The government of Papua New Guinea will bear the cost of the installation and distribution of the cold chain equipments and ensure the national department have annual a maintenance contract with a reliable in-country agency for both preventive and curative maintenance.

9. Financial Analysis

On the issue of financial sustainability, it is noted that the country accounts for 77% of the EPI budget. The Government and GAVI afford the program.

It is noted that Table 5.5 of the proposal, personnel cost, and the figures in tables 18 and 19 of the cMYP do not coincide.

10. Co-financing arrangements

The source of co-finance is the government. Co-financing will be the minimum required (0.20, 0.23, 0.26, and 0.30) for each year of implementation.

PNG started voluntary co-financing in 2009, has done so in a timely manner, and its current co-financing obligation is partially completed.

11. Consistency across proposal documents

In general there is consistency across documents. There are a few inconsistencies (personnel budget) that have been pointed out above.

12. Overview of the proposal: Strengths & weaknesses

Strengths:

- Burden of disease is well described
- Cold chain is adequate
- PNG co-financing of EPI is high (77%)

Weaknesses:

- Improvement plan does not state status of implementation of the recommendations
- No introduction plan
- Results of May 2011 EVM to be known
- Inconsistencies in some figures (coverage, budget)

13. Recommendations

Vaccine: PCV13, 1 doses/vial, Liquid

Recommendation: Approval with conditions

Conditions:

PNG is requested to provide:

1. an implementation status report demonstrating that major issues highlighted in the EVM of May 2011 are being resolved.
2. an Introduction Plan (either as a stand-alone document or integrated into cMYP) that shows clearly:
 - a. Rationale for PCV introduction
 - b. Programmatic implications of the introduction of PCV vaccine
 - c. Key activities necessary for the introduction of PCV vaccine with timeline, milestones, and responsible agencies
 - d. New vaccine introduction budget

14. Review of response to conditions

Independent Review Committee, Geneva, February 6 – 10 2012

Condition 1:

PNG is requested to provide an implementation status report demonstrating that major issues highlighted in the EVM of May 2011 are being resolved.

Response:

The significant weaknesses of cold chain supply as identified during the EVM in Papua New Guinea are temperature monitoring, stock management, distribution management and vaccine management.

Procurement of continuous temperature devices, standby generating set and freeze indicators, training in stock and vaccine management practices and improved supervision and monitoring are all required to address these weaknesses.

The EVM report includes a detailed improvement plan with a timeline and budget. PNG has incorporated the specific improvement actions identified in the EVM assessment into a table which provides the status of improvements as of October 2011. Significant action has been taken, or is in progress and other actions are planned for completion by December 2012. The table responds well to the condition requiring an improvement plan status report.

Condition 1 is met.

Condition 2:

PNG is requested to provide an Introduction Plan (either as a stand-alone document or integrated into cMYP) that shows clearly:

- a. Rationale for PCV introduction
- b. Programmatic implications of the introduction of PCV vaccine
- c. Key activities necessary for the introduction of PCV vaccine with timeline, milestones, and responsible agencies
- d. New vaccine introduction budget

Response:

As a part of PNG's response, a vaccine introduction plan was provided which demonstrates the rationale for PCV introduction and a good understanding of the programmatic implications of introduction of the vaccine. Key activities were presented with responsible agencies and a timeframe but no milestones. A budget for introduction was prepared but no funding sources were identified. The plan is somewhat superficial but does however respond specifically to the conditions.

Condition 2 is met.

Recommendation: Approval

The IRC appreciates receiving sufficient response from the country in regard to the conditions raised. However, the committee has some concerns regarding the quality of the PCV introduction plan which needs more details that it deems necessary for the monitoring of implementation. Special consideration has to be given to the financing gap that might exist and implementation of appropriate strategies that mitigate any programmatic implications.

GAVI Alliance Terms and Conditions

Countries will be expected to sign and agree to the following GAVI Alliance terms and conditions in the application forms, which may also be included in a grant agreement to be agreed upon between GAVI and the country:

FUNDING USED SOLELY FOR APPROVED PROGRAMMES

The applicant country ("Country") confirms that all funding provided by the GAVI Alliance for this application will be used and applied for the sole purpose of fulfilling the programme(s) described in this application. Any significant change from the approved programme(s) must be reviewed and approved in advance by the GAVI Alliance. All funding decisions for this application are made at the discretion of the GAVI Alliance Board and are subject to IRC processes and the availability of funds.

AMENDMENT TO THIS PROPOSAL

The Country will notify the GAVI Alliance in its Annual Progress Report if it wishes to propose any change to the programme(s) description in this application. The GAVI Alliance will document any change approved by the GAVI Alliance, and this application will be amended.

RETURN OF FUNDS

The Country agrees to reimburse to the GAVI Alliance, all funding amounts that are not used for the programme(s) described in this application. The country's reimbursement must be in US dollars and be provided, unless otherwise decided by the GAVI Alliance, within sixty (60) days after the Country receives the GAVI Alliance's request for a reimbursement and be paid to the account or accounts as directed by the GAVI Alliance.

SUSPENSION/ TERMINATION

The GAVI Alliance may suspend all or part of its funding to the Country if it has reason to suspect that funds have been used for purpose other than for the programmes described in this application, or any GAVI Alliance-approved amendment to this application. The GAVI Alliance retains the right to terminate its support to the Country for the programmes described in this application if a misuse of GAVI Alliance funds is confirmed.

ANTICORRUPTION

The Country confirms that funds provided by the GAVI Alliance shall not be offered by the Country to any third person, nor will the Country seek in connection with this application any gift, payment or benefit directly or indirectly that could be construed as an illegal or corrupt practice.

AUDITS AND RECORDS

The Country will conduct annual financial audits, and share these with the GAVI Alliance, as requested. The GAVI Alliance reserves the right, on its own or through an agent, to perform audits or other financial management assessment to ensure the accountability of funds disbursed to the Country.

The Country will maintain accurate accounting records documenting how GAVI Alliance funds are used. The Country will maintain its accounting records in accordance with its government-approved accounting standards for at least three years after the date of last disbursement of GAVI Alliance funds. If there is any claims of misuse of funds, Country will maintain such records until the audit findings are final. The Country agrees not to assert any documentary privilege against the GAVI Alliance in connection with any audit.

CONFIRMATION OF LEGAL VALIDITY

The Country and the signatories for the government confirm that this application is accurate and correct and forms a legally binding obligation on the Country, under the Country's law, to perform the programmes described in this application.

***CONFIRMATION OF COMPLIANCE WITH THE GAVI ALLIANCE
TRANSPARANCY AND ACCOUNTABILITY POLICY***

The Country confirms that it is familiar with the GAVI Alliance Transparency and Accountability Policy (TAP) and will comply with its requirements.

ARBITRATION

Any dispute between the Country and the GAVI Alliance arising out of or relating to this application that is not settled amicably within a reasonable period of time, will be submitted to arbitration at the request of either the GAVI Alliance or the Country. The arbitration will be conducted in accordance with the then-current UNCITRAL Arbitration Rules. The parties agree to be bound by the arbitration award, as the final adjudication of any such dispute. The place of arbitration will be Geneva, Switzerland. The language of the arbitration will be English.

For any dispute for which the amount at issue is US\$ 100,000 or less, there will be one arbitrator appointed by the GAVI Alliance. For any dispute for which the amount at issue is greater than US \$100,000 there will be three arbitrators appointed as follows: The GAVI Alliance and the Country will each appoint one arbitrator, and the two arbitrators so appointed will jointly appoint a third arbitrator who shall be the chairperson.

The GAVI Alliance will not be liable to the country for any claim or loss relating to the programmes described in this application, including without limitation, any financial loss, reliance claims, any harm to property, or personal injury or death. Country is solely responsible for all aspects of managing and implementing the programmes described in this application.

USE OF COMMERCIAL BANK ACCOUNTS

The eligible country government is responsible for undertaking the necessary due diligence on all commercial banks used to manage GAVI cash-based support, including HSS, ISS, CSO and vaccine introduction grants. The undersigned representative of the government confirms that the government will take all responsibility for replenishing GAVI cash support lost due to bank insolvency, fraud or any other unforeseen event.