**NEW PROPOSALS IRC COUNTRY REPORT**

**GAVI Secretariat, Geneva, 7 – 22 November 2013**

**Country: Papua New Guinea**

1. **Type of support requested**

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| Type of support requested | Planned start date  *(Month, Year)* | Duration of support | Vaccine presentation(s)  *(1st and 2nd choice, if applicable)* |
| MR campaign | April to Sept. 2015 | 6 + months | MR, 10 dose(s) per vial, lyophilised |
| Measles second dose | September 2015 | 1 year | Measles |

1. **In-country governance mechanisms (ICC)**

There is an ICC presided by the Deputy Minister of Health and includes NDoH, multilateral agencies (WHO, UNICEF), bilateral agencies (AusAID, JICA), CSO (Society of Paediatrics, Churches of PNG) and Medical School. The terms of reference (functions) and minutes of three last meetings are attached to the proposal.

Minutes are provided of the meeting where the proposal was “in principle” endorsed by the ICC. The proposal notes that “Significant support was provided by all ICC members including technical assistance and providing specific input during the review of the documents.” However, the minutes are cursory and do not permit assessment of the extent of discussions.

There is no NITAG. However, development of the proposal was supported by the Paediatrics Society of PNG and the Child Health Advisory Committee of the MoH.

1. **Situation analysis**

PNG has for many years officially accepted DTP3 and MCV1 coverage of roughly 60%. WHO/UNICEF have themselves endorsed these official estimates.

By these estimates, PNG would not normally qualify for GAVI support for MSD. However, WHO staff have communicated with GAVI to endorse evidence from a hepatitis B sero-survey suggesting that PNG’s true MCV1 coverage is 86%. The survey had a nationally representative sample of 2,160 children of 4 to 6 years old. Coverage was estimated by card or (in the absence of a card) mother’s recall (of an event up to 5 years previously). The IRC is uncertain whether this qualifies as “a recent high-quality coverage survey completed after the most recent WHO/UNICEF estimate” (as required by GAVI guidelines).

Other evidence that has been submitted (from sub-national surveys, from surveys conducted more than 6 years ago, from an insufficiently sensitive surveillance system in the setting of frequent measles SIAs, findings from a non-representative sample of health facilities showing under-reporting of MCV1) does not provide sufficient justification to satisfy GAVI requirements.

SIAs in 2008/2009, 2010/2011 and 2012 each covered 83% to 88% of the target populations. The proposal explicitly notes that the coverage estimate for the 2012 SIA is based upon “administrative coverage” rather than a survey. Note: GAVI guidelines specify that, unless MCV1 > 80%, a country must have achieved with the most recent SIA either administrative coverage >= 90% or survey coverage >=80%.

Laboratory surveillance for fever with rash has confirmed between 7 and 37 cases of rubella per year in PNG. The country does not have an established Congenital Rubella Syndrome (CRS) surveillance to assess the burden of CRS in the country although a retrospective review at Port Moresby General Hospital found a significant number of probable cases of CRS.

In the surveillance of acute fever and rash (AFR), progressive increase of rubella positivity was found (2010: 19%; 2011: 25%; 2012: 32%), mostly in those youngsters younger than 15 years of age. Following an outbreak of rubella in children, 24% of pregnant women were IgM positive (2012). The outcome of the pregnancies is still to be known. Another study (2012) reported that more than 90% of women older than 15 years of age had acquired natural immunity. The susceptible population has an annual risk of 23% of acquiring rubella.

## Overview of national health documents

PNGV50 is a long-term planning of the country. NHP 2011-2020 is aligned with PNGV50, and is the only sector plan to do so. cMYP 2011-2015 is, therefore, aligned with NHP and the long-term PNGV50.

The cMYP covers the period from 2011 to 2015. The costing tool does not reflect the costs of the proposed MR SIA nor introduction of rubella vaccine into the immunisation schedule. The narrative of the cMYP is equivocal about whether and when to introduce rubella vaccination into the immunisation schedule. The narrative of the cMYP makes no mention of any plan to introduce a second dose of measles after 12 months of age.

## Gender and Equity

Papua New Guinea at the national level has not routinely collected sex disaggregated data for routine immunisation although the proposal states that such information is available at the level of the local health facility. According to the MR Proposal, the National Health Information System in consultation with all development partners and with technical advice from the Child Health Advisory Committee has started the process to incorporate the reporting of routine vaccine doses by sex of the child. The data when made available by the National Health Information System will be analysed by the National EPI unit and steps will be taken to address any disparity.

According to a report commissioned by UNICEF, PNG has very high numbers of men to women at every age group. There are almost 331,000 boys aged 10 to 14, and only 290,000 girls in the same age category.[]](http://www.wikigender.org/index.php/Gender_Equality_in_Papua_New_Guinea#cite_note-53) Papua New Guinea also has high rates of child marriage, with higher rates in rural areas. The Rapid Coverage Monitoring evidence in the Report on Integrated Measles Supplementary Immunisation Activity, 2012 was “gender neutral” in that it did not identify whether the caretaker responsible for taking children for immunisation was male or female nor did it dig deeply into why 12% of children were not vaccinated during this particular campaign in this region (“knew about campaign but were too busy” 31%; “other reasons” 21%). It is highly likely that gender equity barriers need to be addressed.

It is recommended that PNG undertake a study to determine whether the low status of women affects their ability as mothers to take their children for routine or campaign immunisation.

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

**Total budget is defined for the cMYP**. The cMYP 2011-2015 financial plan shows a gap of U$18.5 million (10.4%) of the total cost of US$178 million. How the government plans to address this gap should be clarified.

**Financing for the MR campaign and MR routine**:

The template specifies that GAVI funding to support the campaign will be limited to US$1,952,549. In contrast, the narrative of the proposal asks GAVI to provide US$2,920,000 for operational cost of MR campaign. A note from the ICC has been inserted into the proposal: “The support of US$ 0.65 is far less than the actual cost per beneficiary in PNG. The operational cost in conducting campaigns in PNG is considerably higher due to cost of transportation to remote locations.”

In addition to GAVI support for MR campaign operations, PNG is also eligible for an MR Vaccine Introduction Grant (VIG). This should be the same size as the VIG for MSD (US$187,328). However, the proposal calls for an MR VIG of US$ 201,835. The budget for GAVI support to the MR campaign includes US$1,400,000 for transportation. The proposal specifies that an additional US$1,250,000 will be required from other sources (GoPNG, AusAID, WHO, UNICEF) to cover training (gap = US$128,000), IEC (US$54,000), surveillance and monitoring (US$50,000) and planning (US$80,000). Remarkably, the entire budget for the post-campaign survey ($500,000) is to come from as yet unknown non-GAVI sources.

As evidence that the country will finance the introduction of RCV into their routine programme, the proposal includes a letter from the Secretary for Health but none of the supporting documentation specified by GAVI guidelines (commercial contract, integration of RCV into the cMYP, an MoU committing donors to finance procurement, a letter from the Minister of Finance).

**MSD:**

GAVI is to support US$187,328 as VIG for MSD.This is budgetedfor appropriate activities. The proposal specifies that an additional US$380,000 will be required from other sources (GoPNG, AusAID, WHO, UNICEF) to cover training (gap = US$40,000), programme management (gap = US$230,000), surveillance and monitoring (gap = US$108,000).

## Specific comments related to requested support

**MR campaign:**

The proposal justifies the age group to be targeted for the MR campaign by noting a study that found that 90% of women more than 15 years of age have acquired natural immunity.

A phased approach will take place in two phases: from April to June 2015 then from July to September 2015.

The proposal includes appropriate plans for the campaign, for introduction of RCV into the routine schedule and for developing CRS surveillance. The proposal includes a relatively strong plan for assuring that the MR campaign will benefit routine immunisation.

Post campaign evaluation: It has not been the practice in PNG to conduct nationwide coverage surveys either to assess routine vaccination (the most recent DHS or MICs was in 2006) or for any of the numerous SIAs that have been conducted. This is clearly unfortunate, given the current uncertainty about vaccination coverage. A post-campaign coverage survey is a priority. A document accompanying the proposal notes that “an independent post-campaign coverage survey using a standardised methodology would be conducted after the completion of the planned MR campaign. This will also encompass the assessment of all routine immunisation coverage. The findings from the survey will be used to strengthen the routine immunisation programme.” Yet the budget for GAVI support of the MR campaign includes no funding for such a survey. Funds for such a survey (estimated to cost US$500,000) will have to be raised from as yet unspecified sources (GoPNG vs. AusAID vs. UNICEF or WHO). To assure high quality sampling and data collection, the coverage survey should be done entirely separately from the rapid convenience assessment performed during the campaign.

**MSD:**

The proposal calls for “Introduction of MSD in the National Immunisation Schedule in Q4 2015 as MR vaccine.” As this is to start in September an MSD coverage target of 33% is proposed for 2015. The GAVI financed vaccines and logistics will be procured and supplied through UNICEF.

A document that accompanies the proposal notes that “Measles-rubella case-based surveillance in PNG has low sensitivity, not yet meeting the target indicator of >2 non-measles febrile rash cases per 100,000 population.” The proposal notes that the national EPI Unit is taking steps to strengthen this surveillance.

The proposal notes plans for “Formulation of AEFI policy and guidelines on AEFI. Reporting of AEFI will be strengthened”.

**Vaccine management and cold chain capacity:**

PNG conducted its last EVM in May 2011. The scores on various criteria were relatively low. The progress report shows that as of April 2013, 47% of 17 tasks in the improvement plan at national level had been completed and 55% of 20 tasks at provincial/district levels had been completed. The proposal notes that “An analysis of the cold chain capacity for the introduction MR was undertaken which found that there was sufficient cold chain storage capacity at all levels of vaccine storage to absorb the requirements of the MR.”

**Waste management:**

Some health facilities (unspecified percentage) have incinerators whereas others (unspecified percentage) burn and bury vaccination waste.

## Country document quality, completeness, consistency and data accuracy

1. The cMYP needs to be updated to reflect addition of MR and MSD after 12 months.
2. The proposal indicates in several places that “Measles second dose, 10 dose(s) per vial, Lyophilised” is the preferred vaccine for the MSD. This contradicts repeated statements in the proposal such as “Introduction of MSD in the National Immunisation Schedule in Q4 2015 as MR vaccine”.
3. The country is requesting a larger grant for operational support of the MR campaign than is permitted by GAVI guidelines.
4. The VIG for MR (US$201,835 requested) should be the same as the VIG for MSD (234,160 births x US$0.80 = US$187,328).

## Overview of the proposal

**Strengths:**

1. GAVI support for MSD after 12 months will enable PNG authorities to update their immunisation schedule to make measles immunisations more effective and consistent with international recommendations.
2. During previous measles SIAs, PNG has achieved coverage of more than 80% by administrative statistics.
3. PNG has plans to strengthen surveillance for CRS and measles/rubella (which now falls short of targets) and acknowledges the need to strengthen surveillance and response to AEFI.
4. The proposal includes a relatively strong plan for how the proposed MR campaign may strengthen routine immunisation activities.

**Weaknesses:**

1. Many years of official estimates and WHO/UNICEF estimates have suggested that MCV1 is < 80% based upon administrative statistics. It is unfortunate that a high quality nationwide coverage survey using standard methods has not been performed for more than 6 years.
2. Data from the 2012-2013 hepatitis B sero-survey suggest that the MCV1 is greater than 80%. However, the resulting immunisation coverage estimates depend in part upon recall of immunisation events that took place up to 5 years before the survey. A full report from this survey (including an adequate description of the questionnaire and sampling methodology) is not yet available. The IRC must decide whether this is an acceptable methodology. Other evidence presented (sub-national surveys, surveys older than 5 years, findings from an insufficiently sensitive surveillance system in a setting of frequent SIAs, findings from a non-representative sample of health facilities showing under-reporting of MCV1), while supporting the argument that MCV1 has been under-reported, does not explicitly satisfy the requirements of GAVI guidelines.
3. Administrative estimates from recent SIAs have suggested that coverage has been less than 90%. In the absence of findings from a survey documenting SIA coverage (of at least 80%) these administrative estimates do not, by themselves, satisfy the GAVI requirements for MR campaign support. Note that WHO SAGE and GAVI requirements for at least 80% MCV1 or at least 80% SIA coverage (by survey; or 90% by administrative data) are designed to protect against the possibility of a “paradoxical effect” whereby pockets of girls go unimmunised for many years and then become infected with rubella during pregnancy.
4. PNG has indicated that it will find it difficult to finance the MR campaign with the funds specified by GAVI guidelines. The funding gap of US$1,250,000 is substantial.
5. Funding for an essential post-campaign coverage survey remains uncertain.
6. The application lacks the minimum documentation required to demonstrate that the country can finance the introduction of RCV into their routine programme.
7. The cMYP narrative and costing tool do not reflect plans for MSD after 12 months and for an MR campaign.

## Conclusions

In most cases, the IRC defers to the standard WHO/UNICEF process to determine whether a country has met GAVI requirements for immunisation coverage. However, the guidelines specify certain exceptions. The IRC must decide whether the hepatitis B sero-survey of 2012-2013 satisfies GAVI criteria for a “high-quality coverage survey”. A high quality immunisation coverage survey is clearly a priority to assess true coverage with all antigens.

## Recommendation

**NVS: MR campaign, MSD**

**Recommendation:**Approval with conditions

**Conditions:**

1. To approve either proposal (MR campaign; MSD), the IRC and those advising the IRC require further documentation from the 2012-2013 hepatitis B sero-survey to determine whether the survey meets WHO/UNICEF standards for a high-quality coverage survey and whether it provides sufficient evidence that MCV1 coverage of PNG is >= 80%. In particular, the percentage of children for which immunisations were assessed by card vs recall should be reported on.

**Reply: The Government of PNG would like to clarify that the measles coverage data from the recent Hepatitis B sero-prevalence survey was shared with GAVI to complement the available enumerated evidences about the reported measles coverage in the country as discussed in the original proposal. The collection of coverage data for all antigens which was done along with the sero-prevalence survey was not the primary aim of the survey; but the government decided to use the opportunity to collect data on coverage from field while the field investigators visited the assigned areas and that no recent evaluated coverage survey exists in the country. The Government of PNG is preparing a detailed report on the recently concluded sero-survey. The report will discuss separately the primary aim of the survey which is to determine the Hepatitis B sero-prevalence and other secondary aims including the detail of coverage levels with other agreed indicators and the report will be made available to stakeholders including GAVI.**

**The national EPI unit conducted this survey with technical support from WHO with sampling for cluster selection. Provinces were selected based on probability proportionate to size (PPS) while areas (provinces/districts) that definitely need to be part of the survey due to expected high prevalence of HBsAg (based on local knowledge) were over-sampled in the study. The sampling frame was a three stage sampling wherein within each province, the districts and local level governments were selected based on PPS. The inaccessible districts due to local security issues were excluded a priori and a PPS method used for selection of the villages thereafter. In the final implementation stage of the survey, a few villages could not be reached due to either harsh climatic condition during the time of visit and/or local security issues which were beyond the control of the investigators. A more detailed description will be included in the final report that is being prepared by the National EPI unit.**

**As for the percentage of children for which immunizations were assessed by card vs recall in the Hepatitis B Sero-survey, 54% of children were assessed by card while for the rest were assessed by recall.**

1. To approve the proposal for the MR campaign, the IRC needs to review a revised proposal that clearly commits members of the ICC to mobilising sufficient funding for a high quality MR campaign including a high-quality post-campaign coverage survey. GAVI can fund only US$0.65 per child.

**Reply: The Government of PNG has effectively mobilized all the funds required for conducting all the past supplementary immunization activities (measles, polio and tetanus toxoid) in the country using all available financial resources from the national and provincial governments. Also, the in-country donor partners as AusAID, NZAID including our development partners such as WHO and UNICEF have always supported the Government of PNG to attain the established goals of the Government of PNG. The National government has identified “outreach immunization” as one of the priority activities for all health centres. Designated funds are provided to all provinces and districts for this activity. The provision of this fund along with the financial allocation of provincial and district sector improvement funds by the National government clearly indicates the intention of the government to cater to the financial needs of its committed programmes.**

**Thus, it is imperative that the Government of PNG will make all provisions for the funding gap (both for the MR campaign and post-campaign survey) and that the required funds will be borne by the Government and in-country donor partners as needed. The existing mechanism in the country as the established ICC will be used to make those decisions. The ICC meets periodically once every quarter in Papua New Guinea and this will be discussed in the next ICC meeting planned by the end of quarter 1 of 2014.**

**The request to GAVI to consider higher costs for the campaign was made, based on the statement from GAVI in the application that the support provided (USD$0.65) by GAVI for the conduct of the campaign would cover 80% of the campaign costs. In PNG, USD $0.65 will not cover 80% of the campaign costs due to PNG's unique geo-topography. In the event the IRC does not provide the requested higher costs, the Government of PNG will mobilize resources within the country conduct the planned campaign and achieve high coverage.**

**A comment has been made by IRC on the post-campaign evaluation that the application does not specify the exact source of funding for the planned evaluation survey including non-inclusion of the cost of the survey in the vaccine introduction grant (VIG) to be provided by GAVI. As the government has made its commitment in the original application to conduct an independent post-campaign survey, the required fund will be mobilized as part of the financial gap highlighted in the application. As for the inclusion of the cost of the survey in the VIG, it was understood that the planned survey is a post-introduction activity. Also, the cost involved in conducting the survey in PNG is substantial and if this would have been included in the VIG, it would have compromised the other essential activities for the vaccine introduction. If GAVI wishes to extend its financial support to the Government of PNG towards conducting this survey, the Government will welcome this decision. The Government of PNG will be glad to hear from GAVI on their decision to support this survey.**

**The Government of PNG is committed towards ensuring availability of the financial resources for the quality MR campaign and the post-campaign survey.**

1. Please submit an update of the cMYP costing tool and a narrative document summarising updates to the cMYP that reflect PNG plans to drop measles immunisation at 6 months, begin MCV2 immunisation after 12 months of age, combine rubella immunisation with measles immunisation and conduct an MR campaign. (first dose MR, before 12 months of age, MSD only measles, because GAVI will not pay for R second dose).

**Reply: The Government of PNG is planning to update its current cMYP (2011-2015) in 2014 to reflect the changes planned in the immunization schedule. The updating of cMYP is a consultative process and involves meeting with all stakeholders including consultation with professional societies, development partners and donors. The Government of PNG feels that the cMYP should be reviewed/ updated in entirety and an isolated activity of revising one component of the immunization programme in the country.**

**The Government of PNG would like to inform IRC that the Child Health Advisory Committee (CHAC), the highest committee in the country to advice the Department of Health on all technical issues related to child health made a conscious decision to introduce the Measles 6-month dose in 1992. This decision was based on the evidences from in-country evidence of the benefits of this 6-month dose in wake of repeated measles outbreaks at that period of time and the age group affected in those outbreaks. The decision to review its immunization policy on its 6-month dose is being reviewed by the CHAC in 2013 again based on the current epidemiology and also in the light of the introduction of the measles second dose vaccine. However, the technical group would like to further consider the recommendations of the SAGE special working group on the non-specific effects of vaccines.**

**Following the completion of the MR campaign, rubella vaccine will be introduced as the second dose of measles at 18-24 months. The recommendations of CHAC on revising the immunization schedule to include two MR doses at 9 months and 18-24 months will be integrated in the revised cMYP costing tool and also in the EPI manual and policy of the country. The Government of PNG will share the final version of the revised cMYP with all stakeholders including GAVI.**

**The Government of PNG is aware that GAVI will not support the “R” component of the of the measles second dose. The Government procures all vaccines using Government funds and resources and is prepared will bear the additional expense.**

**We trust that this will suffice as a commitment by the Government of PNG ensuring that the proposed changes will be reflected in the revised costing tool and cMYP on advice from the Child Health Advisory Committee and other development partners in the country.**

1. The revised proposal and all supporting documents should consistently specify whether rubella vaccine will be administered with MCV2.

**Reply: The Government of PNG plans to introduce 10-dose measles-rubella combination lyophilized vaccine as the second dose of measles as indicated in the original application. Suitable changes in the online application have been initiated to reflect the changes as required in respective sections.**

1. GAVI guidelines require that one or more of the following be provided as evidence that the country can finance the introduction of RCV in their routine programme:
   1. A commercial contract for purchase of MR vaccine with or without shipping documents, invoice, etc.;
   2. Integration of RCV into the cMYP with a corresponding increase in the budget line for vaccines in the health sector budget adequate to cover purchase of RCV;
   3. A Memorandum of Understanding between the government and donor(s) (or other written document) committing the donor(s) to support for at least one year the purchase of RCV for use in the routine programme;
   4. A letter from the Minister of Finance or Budget ensuring additional funding for RCV purchase.

**Reply: A commitment letter from the Secretary of Health indicating the plan to introduce rubella vaccine in the country was provided as an attachment with the original application. This is to inform the IRC that the Secretary for Health is responsible for seeking allocation for the planned activities on the annual health budget and further allocate the government funds for all health related activities within the National Department of Health. The procurement of vaccines is a central responsibility of the National Department of Health and the National Procurement unit and the National EPI unit are its technical unit for the process. The commitment letter from the Secretary of Health should be respected by IRC as the evidence document that Papua New Guinea will finance the introduction of rubella vaccine in its national immunization schedule.**

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| |  | | --- | | **The procurement system of the National Department of Health is used by the National EPI unit for vaccine procurement as per the laid down regulations. The requested commercial contract for the purchase of MR vaccine will be issued following the approval of this proposal from GAVI and thereafter a concurrence by the Senior Executive Management headed by the Secretary for Health. The Government of PNG procures all its traditional vaccines, and hence a memorandum of understanding does not exist with any donor for procurement of its routine vaccine. The Government of PNG would also like to indicate that the government’s expenditure on health has increased considerably in the last three years. This clearly highlights the commitment of the Government of PNG towards financing and sustainability of its priority immunization programme to which it accords top priority under its National Health Plan.** | |

**Please note** that the letter from Secretary for Health, Government of PNG will be shared with GAVI by next week on the commitments outlined for clarifications under point 2 and 3.