Myanmar Vaccine Support for
PNEUMOCOCCAL VACCINE (PCV)

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

1. **Country:** Myanmar
2. **Grant Number:** 16-MMR-12b-X / 16-MMR-08c-Y
3. **Date of Decision Letter:** 23 June, 2015
4. **Date of the Partnership Framework Agreement:** 4 April 2014
5. **Programme Title:** NVS, Pneumococcal Routine
6. **Vaccine type:** Pneumococcal
7. **Requested product presentation and formulation of vaccine:** Pneumococcal (PCV10), 2 dose(s) per vial , LIQUID
8. **Programme Duration**[1]**:** 2016
9. **Programme Budget (indicative) (subject to the terms of the Partnership Framework Agreement):**

	2016	Total[2]
Programme Budget (US$)	US$19,225,500	US$19,225,500

10. **Vaccine Introduction Grant:** US$1,211,000 payable up to six 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	2016
Number of Pneumococcal vaccines doses	4,898,000
Number of AD syringes	5,498,900
Number of re-constitution syringes	
Number of safety boxes	60,500
Annual Amounts (US$)	US$19,225,500

12. **Procurement agency:** UNICEF. The Country shall release its Co-Financing Payments each year to UNICEF.
13. **Self-procurement:** Not applicable.

[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 amount that Gavi has approved.

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14. **Co-financing obligations: Reference code:** 16-MMR-12b-X-C
According to the Co-Financing Policy, the Country falls within the *Low* Income 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	2016
Number of vaccine doses	299,200
Number of AD syringes	
Number of re-constitution syringes	
Number of safety boxes	
Value of vaccine doses (US$)	US$1,009,554
Total Co-Financing Payments (US$) (including freight)	US$1,039,500

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	15 May 2016

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.

Signed by,
On behalf of Gavi

P.O. Nigel

Hind Khatib-Othman
Managing Director, Country Programmes
23 June, 2015

NEW PROPOSALS IRC COUNTRY REPORT
GAVI Secretariat, Geneva, 7 – 22 November 2013

Country: MYANMAR

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1. Type of support requested

Type of support requested	Planned start date *(Month, Year)*	Duration of support	Vaccine presentation(s) *(1st and 2nd choice, if applicable)*
Pneumococcal	January 2016	1 year	1st: PCV10; no 2nd preference given
MR campaign	November 2014	6 months (3rd,4th qtrs)	10-dose lyophilised

Amounts of Support Requested:
Operational funds for MR campaign @0.65 US$ per child = **US$ 14,932,791**
MR vaccine introduction grant @0.80 US$ per child = **US$ 1,216, 846**
PCV vaccine = **US$ 17,991,000**
PCV vaccine introduction grant @0.80 US$ per child = **US$ 1,210,746**

2. In-country Governance Mechanisms (ICC/HSCC)

The ICC was established in 2001 and is chaired by the Director General Health, DOH and MOH. Membership was revised in 2012 to include additional partners, i.e. Myanmar Maternal and Child Welfare associations. The committee generally meets 3-4 times/year. TOR for the ICC and 3 sets of minutes were provided. The plan to introduce rubella and PCV vaccines were discussed at a meeting in May 2013, where it was noted that considerable planning would be needed to be ready for the introductions. It was decided to resume HepB birth dose in all hospitals, which would cover about 10% of the birth cohort (this had been temporarily suspended in 2009 when GAVI funding for it ended). Further discussions on the present application took place at a meeting on 3rd July 2013, and the proposals for introduction of both MR and PCV vaccines were approved. Attendance and signature lists for all meetings are provided, and it was noted that the key meeting on 03 July 2013 attracted a very large attendance.

3. Situation Analysis (Burden of Disease and Health System bottlenecks)

The National EPI Programme

2012 was declared the "Year of Intensification for Routine Immunisation" in the country. Many activities were undertaken to improve access to routine immunisation, although there were problems reaching some areas due to insecurity. Some 70 townships are defined as being physically and socioeconomically hard-to-reach, especially some in mountainous areas. Immunisation is currently given only during the first week of each month due to cold chain constraints, but with the planned expansion during 2014-2015, this is due to increase. Even so, coverage is generally high and has remained so in recent years. A coverage survey in 2009 found a DPT3 coverage of 98%, which is even higher than routinely reported data suggests, although it is noted there has been no population census for the past 30 years, and thus there is much uncertainty over figures used as the denominator in calculations. No specific references are made to bottlenecks or problems that need to be

resolved in EPI in the application, but this is consistent with a proposal for introduction of new vaccines.

Burden of Disease
All available data from studies on rubella and CRS are summarised in the proposal, and based on this evidence; the NCIP and ICC recommended that EPI introduce MR vaccine for all infants as from 2015.

4. Overview of National Health Documents

Only the cMYP covering the period 2012-2016 was provided for this review, and although the application refers to a Myanmar National Health Plan, (also for the period 2012- 2016), it was not attached. The cMYP was updated in September 2013 to include the proposed introduction of the 2 new vaccines, and following a WHO/SEARO meeting on regional disease control, to include the goal of measles elimination by 2020. Thus, activities planned for the vaccine introductions are aligned with at least this national document.

Lessons Learnt from Previous Vaccine Introductions
Hepatitis B vaccine was introduced in 2003, followed by a switch to pentavalent vaccine in 2012. There was a successful national measles campaign in 2007 and a follow-up campaign in 2012. Some key lessons were learnt from these various experiences, and these will be used when planning for introduction of MR and PCV into the routine EPI.

5. Proposed activities, budgets, financial planning & financial sustainability

The choice of MR vaccine is the 10-dose lyophilised presentation. PCV10 in a 2-dose vial with a volume of 4.8 cm3 /dose was identified as the vaccine of choice, based on the available cold chain capacity and the likely need for expansion and replacement of existing equipment in all parts of the country.

Activities Introduction of the MR vaccine in 2015 is to be preceded by a wide age-range catch-up campaign in late 2014, and based on measles and rubella prevalence this will target all children 9 months to below 18 years. Under current guidelines, only the age range 9 months to below 14 years can receive GAVI support, and the MOH and partners will fund the remainder to cover the full age range. The campaign target is given as 22,973,525 children, but this is based on a birth cohort of 1,510,745 in 2012, which is more than 60% higher than the UN population division figures for 2012. On the WHO website Myanmar surviving infants are reported to be 877,000 in 2012: http://apps.who.int/immunization_monitoring/globalsummary/countries?countrycriteria%5Bcountry%5D%5B%5D=MMR&commit=OK.

In addition, figures for 2013 and 2014 in the application indicate that birth cohorts are assumed to be increasing year-to-year, whereas most sources show that birth cohorts have been falling for more than 10 years. Based on the UN data population data, the IRC estimated the MR campaign target at only some 10.7 million children for the 9 months to below 14 years group, or 13.8 million for the range 9 months to below 18 years, and such discrepancies will have a large impact on the funds requested from GAVI. Following the campaign, MR vaccine will replace the current measles 1st dose given at 9 months under to the national schedule, but it appears measles 2nd dose at 18 months will remain unchanged, and not be replaced by MR vaccine.

PCV10 will be introduced in 2016 as a single, nationwide event, following a 6-month preparation phase and intensive promotion. All children born after 1st November 2015 will be eligible for 1st dose PCV10 as from 1st January 2016, but children born before 1st November 2015 will not be eligible. The application gives a projected target of 1,466,516 surviving infants in 2016, with 3 doses given /child on a schedule of 2, 4 and 6 months alongside pentavalent. This target is based on 1,454,842 surviving infants in 2012. However, and again, this is more than 60% higher than UN population division figures, and contrary to most projections, assumes the cohort increases year-by-year. Introduction will aim at 90% coverage of the target population with a wastage factor of 1.05 and a buffer stock of 25%. The request to GAVI is for 5,196,966 doses of vaccine for 2016, but for the same coverage and assumptions, IRC estimated the need to be only around 3,065,000 doses for 2016 if the UN population division data is used.

Budgets UNICEF procures all vaccines for routine EPI (OPV, BCG, TT and measles). The HepB birth dose is planned to be funded by government or donors, and the MOH has been co-financing pentavalent with GAVI since 2012. The country is a good co-financing performer, with timely payments and an early payment in 2013. The MOH now agrees to fully fund the rubella part of the MR vaccine as from 2015 with support from UNICEF, who will fund the measles component. The country applies for GAVI support of the operational costs of the MR campaign, and requests US$ 14,932,791 based on a target population of 22,973,525 as mentioned above. This is already incorrect, as it is refers to the entire 9 months to <18 year group that GAVI cannot support, but also, it is based on a very high estimated birth cohort as already described. Using the UN population division figures, the IRC estimated a campaign target of 10.7 million for children 9 months to <14 years, making the amount that should be requested from GAVI to US$ 6,955,000. The country is also applying for an introduction grant for the MR vaccine amounting to US$ 1,216,846, but again, this is based on a very high estimated birth cohort, and if using the UN population division estimated birth cohort for 2014, the amount requested should only be around US$ 731,200.

For PCV vaccine, the government will co-finance the costs with GAVI, and the proposal states that contributions will be at the rate of US$ 0.20 per dose. It was noted that co-funding PCV vaccine will almost double the national vaccine budget, increasing from some US$18 million in 2015 to US$ 36 million in 2016. The amount requested from GAVI for PCV vaccine and injection supplies is US$ 17,991,000, but this is based on a projected surviving infant cohort of 1,466,516 in 2016, and as before, this seems a high estimate and would need to be justified. Using UN population division data, he IRC estimates a surviving infant cohort of 865,000 in 2016, and thus, requested support from GAVI should be around US$ 10,611,725. The government is also applying for a GAVI introduction grant for the PCV vaccine, and requests US$ 1,210,746, based on a projected target population of 1,513,433 in 2016. Again, this is based on a target population higher than UN population division data and the issue of data quality should be discussed and explained.

Financial Sustainability The government is strongly committed to co-financing PCV and the rubella component of the MR vaccine. Evidence-based advocacy will remain a main strategy to encourage it to honour its existing commitments, and increase support for other immunisation expenses. These include items such as staff, transport, building maintenance, vaccine distribution and operational costs for accessing the hard-to-reach areas. Several partners, including WHO, UNICEF, Japanese Committee for Vaccine (JCV) and AusAid, as well as the GAVI Alliance, have supported EPI through the ICC over many years. The EPI will continue to seek additional partners, reinforce coordination among current and future partners in supporting the programme and move towards financial sustainability.

6. Equity and Gender

Equity Although the EPI is provided for all children, some 70% of the population lives in rural areas where mortality may be at least 25% higher than in urban areas. There are also hard-to-reach areas with geographical and social barriers, and on-going ethnic conflicts in Eastern and Western border areas. The EPI has brought services to many such communities using the Reaching Every Community (REC) approach, engaging with local and international NGOs, and by integrating EPI with other health programmes. Social mobilisation takes place in all parts of the country using IEC materials in major dialects to address local needs, especially for border areas. Under REC, extra funds are provided to deliver services in hard-to-reach and remote populations, and micro-plans are regularly included in township annual plans. Many NGOs are becoming active and assist in reaching remote and conflict-affected areas, while new government policies also contribute to achieving equity of access in health services.

Gender There is no gender discrimination and EPI provides free vaccination to all children irrespective of sex, religion, ethnicity and location. Surveillance data for VPDs shows no significant gender differences in disease prevalence. However, no recent DHS or MICS surveys were conducted that could provide sex dis-aggregated data on vaccination and other information on gender, such as the frequency of early marriage.

7. Specific comments related to requested support

New Vaccine Introduction Plans An 'MR Catch up Campaign Plan and Rubella Vaccine Introduction Plan 2014 -2015' is submitted. This sets clear objectives, strategies, and priority activities for introduction of the new vaccine, and provides realistic guidelines. An 'Introduction Plan for PCV Pneumococcal Vaccine in 2016' is also submitted, although much of this is identical with the MR plan, and it is not clear why activities needed for introducing this vaccine are assumed to be exactly the same as those for MR. It could for instance be considered to have different social mobilisation and training activities for the routine MR introduction compared PCV, taking into consideration that MR is "only" a switch to a combination vaccine, which does not imply an additional injection. Furthermore, the cold chain implications of introducing PCV10 are significantly different from those of MR, and although the plan acknowledges this, no attempt is made to quantify or even outline what these differences might be. The plan simply notes that another EVM assessment will be carried out in mid-2014, and implies that the cold chain needs for introducing PCV will be identified at that time. Apart from these shortcomings, this is also a generally good plan.

Vaccine Management and Cold Chain Capacity MR will replace the current measles vaccine in 2014, and as volumes/dose of the two vaccines are similar, this will not have a great impact on routine cold chain needs. For the MR catch-up campaign, however, there will be substantial extra short-term storage needs which are not discussed, although the proposal abstract mentions renting extra cold storage space in Yangon. This may be a solution at central level, but less likely at lower levels, where hiring extra capacity may not be possible. Existing aging and worn-out equipment will still need to be replaced as per the 2011 EVM assessment, and will be carried out with support from UNICEF and other partners.

By comparison to the routine MR vaccine, introduction of PCV10 in 2016 will need significantly increased cold chain capacity. The PCV10 vaccine occupies 4.8 cm3 /dose and for 3 doses, will need around 40% extra storage space compared to all the current vaccines. The next EVM is scheduled for mid-2014, and a key task will be to review the available cold chain capacity in the light of introducing 2 new vaccines, and to update the improvement plan to take account of these developments. Costing and financing of this plan will also be an important component of the 2014 assessment.

Surveillance Rubella and CRS surveillance will be integrated with the case-based measles surveillance that is already in place. CRS surveillance will be established at 5 sentinel sites in Yangon city areas commencing in 2014, and will comprise 2 children's hospitals and 3 specialist hospitals with paediatric wards. One sentinel site will also be established in Mandalay Children's Hospital. All 6 of these sites will be associated with the WHO sentinel sites surveillance network, and will benefit from capacity strengthening support for surveillance and laboratory quality assurance.

Waste management Nothing is said about plans for dealing with huge amounts of extra medical and sharps waste that will be generated at all levels by the MR campaign. This campaign will target around 40% of the total population, according to figures provided.

8. Quality, Completeness, Consistency & Accuracy of Documents & Data

Some inconsistencies were noted within the application and between the various documents submitted. The most important issue is the lack of discussion on differences between UN population data and sources used for the target population estimates in the application. The cold chain capacity issues are inconsistently addressed. In the abstract of the proposal it is mentioned that "additional space will be hired from private sector to temporarily store the MR vaccine in Yangon". However, in the MR introduction plan no cold chain storage plans are mentioned at all. It is also an inconsistency that the MR introduction grant is estimated for the 9 months – 18 years target population, even though GAVI only provides support for the 9 months – 14 years target population.

9. Overview of the proposal

Strengths:

- Good progress shown in the EPI over recent years. It is encouraging that hepatitis B birth dose will be resumed.

Weaknesses:

- Inconsistency in the amount of GAVI MR campaign cash support requested
- Birth cohort used is >60% higher than UN population division figures with no explanations given
- Application assumes a rising birth cohort, but most data sources show births and surviving infants have been falling for the past 10 years
- No mention of cold chain 'surge' capacity needed at sub-national levels for huge amounts of extra vaccine during the MR campaign
- No mention of plans for disposal of huge amounts of sharps waste from a campaign targeting between one third and half the total population
- No mention of the US$ 30 million 2008 – 2014 HSS proposal and how it is being used for reaching hard to reach

- The vaccine introduction plans for MR and PCV are largely identical. We would expect differences in the activities being planned for to support the two vaccine introductions, but this has not been planned for.

10. Conclusions

In light of the relatively large differences between the population data used in the application and those reported by the UN Population Division, the data sources used should have been discussed in the proposal. No adequate discussion or plans were seen for managing the large increase in cold chain space needed at all levels for the MR campaign. The proposal abstract speaks of hiring extra storage space in Yangon, but no details are given and there is no mention of plans for other levels, where hiring more space is unlikely to be an option.

11. Recommendations Conditional approval

Conditions:

1. Differentiate PCV and MR vaccine introduction plans so that activities are better suited to introduction of the respective vaccines (refer to section on new vaccine introduction plans for details)

PCV:
2. Justify PCV target population
3. Explain plans for ensuring cold chain expansion for PCV introduction

MR:
4. Justify the MR campaign target population
5. Justify MR routine target population (for calculation of introduction grant amount)
6. Explain calculations of cold chain capacity for the MR campaign and how any expansions likely to be funded
7. Provide an injection waste management plan for the MR campaign

IRC Review of Country Response to Conditions

Reviewed: **Geneva, 27 February – 7 March 2014**

12. Review of Country Response to Conditions

Condition 1: Differentiate PCV and MR vaccine introduction plans so that activities are better suited to introduction of the respective vaccines (refer to section on new vaccine introduction plans for details).

Comments: In November, Myanmar submitted a plan for each vaccine, but the problem was that the planned activities were largely identical, even though the mode of introducing the two vaccines is quite different. Two revised introduction plans have now been submitted. However, they are still dated as in November 2013 on the front page. The new MR has an adequate updated introduction budget for MR introduction. The revised PCV introduction plan provides new and pertinent information on cold chain expansion and maintenance, communication and social mobilization, and AEFI risk communication.

Conclusion: Condition 1 met.

Condition 2: Justify PCV target population

Comments: Myanmar has now provided a detailed justification and source of the population figures used in the two applications and report that a national population census will be conducted later in 2014. If the latter shows a different figure from the one provided in the vaccine introduction applications, the country has expressed its readiness to revise the targets accordingly.

Conclusion: Condition 2 met.

Condition 3: Explain plans for ensuring cold chain expansion for PCV introduction.

Comments: Myanmar reports plans to conduct an EVM assessment in 2014 and have an EVM improvement by 2015. The currently available information shows no cold chain capacity gap at central level, however there are gaps at sub-national levels. A cold chain inventory is in process in the country, to be followed by a comprehensive cold chain assessment; which will determine the existing gaps and the required additional capacity. The assessment will inform the development of the cold chain replacement and expansion plan.

Conclusion: Condition 3 partially met. The IRC commends the efforts of the Government of Myanmar and her development partners, and requests that the country submits to the GAVI Secretariat a report of the cold chain assessment as well as the replacement and expansion plan, when these become available.

Condition 4: Justify the MR campaign target population.

Comments: Similar to comments to condition 2.

Conclusion: Condition 4 met.

Condition 5: Justify MR routine target population (for calculation of introduction grant amount)

Comments: Similar to comments to condition 2.

Conclusion: Condition 5 met.

Condition 6: Explain calculations of cold chain capacity for the MR campaign and how any expansions are likely to be funded

Comments: Myanmar supplied convincing information about a number of partners willing to support managing the cold chain for the campaign, including details from a recent co-ordination meeting for cold chain investments.

Conclusion: Condition 6 met.

Condition 7: Provide an injection waste-management plan for the MR campaign.

Comments: Myanmar informs the IRC of her experience with adequate waste management during the 2012 nationwide measles vaccination campaign, and provides a two-page waste-management plan for the scheduled MR campaign.

Conclusion: Condition 7 met.

13. Updated Recommendations

Amounts of Support Requested:

Vaccine: **MR campaign (10-dose lyophilised MR vaccine)**

Recommendation: Approval

Vaccine: **Pneumococcal (PCV10)**

Recommendation: Approval, with clarification

Clarification

Myanmar is requested to submit a report of the comprehensive cold chain assessment as well as the replacement and expansion plan.