MYANMAR SUPPORT for INACTIVATED POLIO VACCINE (IPV)

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

1. **Country:** Myanmar
2. **Grant Number:** 1518-MMR-25c-X / 15-MMR-08h-Y
3. **Date of Decision Letter:** 11 February 2015
4. **Date of the Partnership Framework Agreement:** 04 April 2014
5. **Programme Title:** New Vaccine Support (NVS)
6. **Vaccine type:** Inactivated Polio Vaccine (IPV)
7. **Requested product presentation and formulation of vaccine[1]:** Inactivated Polio Vaccine, 10 dose(s) per vial, LIQUID
8. **Programme Duration[2]:** 2015 - 2018
9. **Programme Budget (indicative) (subject to the terms of the Partnership Framework Agreement):**

Please note that endorsed or approved amounts for 2018 will be communicated in due course, taking into account updated information on country requirements and following Gavi's review and approval processes.

	2015	2016	2017	Total[3]
Programme Budget (US$)	US$602,000	US$1,089,000	US$971,500	US$2,662,500

10. **Vaccine Introduction Grant:** US$723,500
11. **Indicative Annual Amounts (subject to the terms of the Partnership Framework Agreement):[4]**

Type of supplies to be purchased with Gavi funds in each year	2015	2016
Number of IPV vaccines doses	518,200	938,100
Number of AD syringes	478,800	848,500
Number of re-constitution syringes		
Number of safety boxes	5,275	9,350
Annual Amounts (US$)	US$602,000	US$1,089,000

12. **Procurement agency:** UNICEF

[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.

13. Self-procurement: N/A

14. Co-financing obligations:

Gavi's usual co-financing requirements do not apply to IPV. However, Myanmar is encouraged to contribute to vaccine and/or supply costs for IPV.

15. Operational support for campaigns: N/A

16. The Country shall deliver the following documents by the specified due dates as part of the conditions to the approval and disbursements of the future Annual Amounts:

Reports, documents and other deliverables	Due dates
Annual Progress Report	15 May 2015

***17.* Financial Clarifications:** N/A

18. Other conditions:

If Mynamar 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 Mynamar.

Signed by,
On behalf of Gavi

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

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Appendix A

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

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)*
IPV	July 2015	2015 - 2018	10 dose, 5 dose, 2 dose

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

The National Committee for Immunization Practices (NCIP) is the technical body mandated to consider the introduction of new vaccines, review epidemiological data, WHO guidelines and relevant studies. Based on NCIP recommendations and on programmatic issues the MoH decided to introduce IPV and a technical team (expert officers from MoH, WHO and UNICEF) prepared the application for Gavi support. The application for IPV introduction was presented, discussed and endorsed by the ICC at a meeting held on 10thSept 2014, attended by 16 officers from the MoH, 9 from WHO and UNICEF and 2 from CSOs. Minutes and signatures were provided.

The process of decision-making and proposal development appears to have been adequate. The ICC composition and inclusiveness can raise some concern, since the principle of representation is not properly considered. Myanmar has a number of coordination mechanisms for the health sector, some related to the big funds (GFATM, the "3 Diseases Fund", Gavi). There are moves to address such fragmentation. Myanmar signed the International Health Partnership (IHP+) in 2014. This seems to be part of an ongoing effort to better coordinate a wide range of partners – and coordination bodies – toward harmonization, alignment and aid effectiveness.

3. Situation analysis – Status of the National Immunisation Programme

The population of Myanmar is 51 million according to preliminary data from the 2014 census (break down data by age groups are not available yet). The population figures used in this proposal and in the cMYP 2012-2016 are projections from the past census (30 years ago).

Administrative estimates suggest that Myanmar has maintained DTP3 coverage of 82% to 90% for the past 8 years. This has been validated with surveys, although the last survey (a MICS in 2009/2010) appears to have been unreliable. WUENIC estimates have thus mirrored the administrative estimates. The coverage dropped in the past four years from 90% to 75% in 2013 due to a major increase in drop out from 3 % to 15%.

This decrease in coverage is attributed to dysfunction of primary health services in border areas with ethnic tensions, to population movements and changing distribution of health workers, and to poor coordination of multiple external interventions. There is marked variation in coverage among districts, with only 45% reaching above 80% coverage and 8% of districts having below 50% coverage. The MoH has developed an "intensification of

routine immunization plan of action" to increase services coverage. The application documents acknowledge some role of the private sector in immunization services, on both logistics and actual service delivery. This seems, however, to be still unregulated and not considered in its potential to increase coverage.

Myanmar has benefited from Gavi support since 2002. Most recent and current support is for Pentavalent and Measles (MSD) vaccines (both introduced in 2012) and MR campaign in 2014. Pneumococcal vaccine is to be introduced in 2014 along with an HSS grant. The country is also to introduce Rubella vaccine, funded from domestic and other sources. A post introduction evaluation (PIE) for Pentavalent vaccine was conducted and the findings were generally satisfactory.

The government of Myanmar increased its health budget 7 fold in the last three years. The traditional vaccines are still paid for by donors; while the government is contributing to the co-financing of Pentavalent vaccine and procures 100% of the Hep B vaccine. No co-financing is foreseen for IPV. The future resource requirements and financing gap analyses are detailed in cMYP 2012-2016. The Government recognizes the funding risks, and is exploring various additional funding sources for financial sustainability.

4. Overview of national health documents

The Myanmar "National Health Plan 2011/12 – 2015/16" is part of the "National Comprehensive Development Plan 2010/11 – 2030/31" that establishes the principles for development.

The cMYP 2012-2016 describes well routine immunization activities and the introduction of new vaccines. It also outlines the commitment of MoH in sustaining immunization and epidemiological surveillance and the contribution of Gavi support. IPV introduction is to be included in the cMYP 2016-20, to be developed in 2015.

The last EVM assessment was done in 2011 and the next one is planned for 2015.

5. Gender and Equity

Myanmar's GII value is 0.430; GII rank is 83; MMR = 200/100,000. The 2009/2010 MICS found no significant differences in DPT3 coverage by sex nor by wealth quintile but these survey findings have been discounted by WUENIC estimators as health workers participated in the survey and may have biased the findings.

In Myanmar there are hard-to-reach areas with geographical and social barriers. There are also on-going ethnic conflicts in Eastern and Western border areas. The "Reaching Every Community" (REC) strategy has been implemented since 2012 to deliver primary health services to marginalized communities. Intensification of Routine Immunization (IRI) was also done in areas of low coverage in 2012.

Some NGOs such as Myanmar Maternal and Child Welfare Association, Myanmar Red Cross Society and Myanmar Women Affairs Association have a role in health service delivery at community level.

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

The IPV Introduction Plan is well structured and detailed. The documents present activities in a logical sequence and within the background of the overall EPI programme. The timeline

and budget appear reasonable. Total operational costs for IPV introduction have been estimated at US$ 1,068,500. A VIG of US$ 723,500 contributing 68% of the total budget while 20% will come from WHO & UNICEF and the remaining 12% will be covered by the government. The unit costs and the allocations appear reasonable. Different programme components range from2% for data management to 13% for cold chain. There is a logical flow of activities in the timeline provided. According to the fiduciary management arrangements, the VIG will be transferred through partners.

7. Specific comments related to requested support

New vaccine introduction plan

The last cases of wild poliovirus were detected in May 2007 (11 cases; a re-introduction). Two isolated cases of vaccine-derived poliovirus (VDPV) infection have been reported in 2010 and 2012 in different states/regions in hard-to reach-areas of the country.

The IVP Introduction Plan clearly outlines the justification for the introduction of one dose of IPV into the routine immunisation programme, in line with WHO SAGE recommendations.
The 10-dose presentation of IPV is requested. This seems suitable given the size of the target population and the cold chain storage capacity. IPV will be introduced in the routine immunization schedule from 1st July 2015. The proposed schedule is to administer IPV at 4 months, along with OPV2 and Penta2 (that have a 2-4-6 month schedule), according to WHO guidelines.

All vaccines used so far in Myanmar have been registered by the "Food and Drug Administration" (FDA). One formulation of IPV has already been registered as a combined vaccine with DPT and Hep B in a single injection. The Gavi supported IPV vaccine still needs to be registered by the FDA. The process will start soon in order to finalize the registration before April 2015. As with other vaccines, IPV will be delivered to the country through UNICEF.

Vaccine management and cold chain capacity

The May 2014 update of the EVM Improvement Plan showed good progress. The inventory of all cold chain equipment has been recently updated. A cold chain expansion and replacement plan has been formulated. A comprehensive cold chain review was conducted in August 2014. It generated a clear list of requirements with a timeline of actions.
From the application documents it appears that the government is seriously taking steps to strengthen its cold chain system at all levels. Partners' support is high and consistent, with WHO and UNICEF providing technical assistance and traditional donors / new pooled funds ready to mobilize resources (Japanese Committee for Vaccines JCV, the "3 MDG Fund", others). In this context, financial support for the cold chain system is not expected to be challenging. High vaccine wastage rates were reported in the JRF (BCG 76%, Penta 24%), indicating weak vaccine management practices. According to the proposal, cMYP addressed many strategies and activities to reduce the vaccine wastage rates. A new EVM assessment is definitely needed in 2015.

The National Immunization Program has an injection safety policy in place and all standard protocols will be applied. The IPV introduction trainings include these elements.

Training, Community Sensitisation & Mobilisation Plans

Lessons learned from previous vaccine introductions will inform the design of training for IPV introduction. Training will involve Regional Surveillance Officers (RSOs) and trainers from regional level or central level, to ensure quality of training. In weak areas additional support will be provided at the level of townships.

Immunization services seem to be well accepted. A comprehensive "Communication for Development" (C4D) plan will address routine immunization in general and IPV as well. Operational research will look into the parents', health professionals' and media's perception of vaccines. The country plans to hold a national launching ceremony for IPV introduction with emphasis on polio eradication.

Monitoring and evaluation plans

According to the proposal, the monitoring and evaluation system is in place at all levels, even if the overall health information system seems weak. Monitoring of IPV introduction will be conducted through the existing system for immunization. A Post Introduction Evaluation (PIE) is planned, 9-12 months after IPV introduction. Supportive supervision is planned at all levels.

The National Committee for Immunization Practices (NCIP) and the National Certification Committee for Polio Eradication (NCCPE) will also monitor the IPV introduction at various levels and periodically report to Ministry of Health.

According to the proposal, and AEFI surveillance system is in place in all 330 districts. New AEFI guidelines have been revised and published in 2014. It is planned that all health staffs will be re-trained on AEFI reporting, recording and investigation.

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

The application documents are sufficiently well compiled and there is good consistency between the introduction plan and other documents. The IPV Introduction Plan is comprehensive and complete and includes synergies with other EPI activities. It is consistent with global guidance.

9. Overview of the proposal

Strengths:

- The country has a history of reasonably good immunization coverage, despite the decrease in the past few years.
- The country has experience in new vaccine introduction and seems to be using lessons learned.
- A comprehensive review of the cold chain system has been conducted. It appears that the government is seriously taking steps to strengthen its cold chain system at all levels.
- High donor commitment and support, both financial and technical.
- No anti vaccination lobby; vaccination is generally well accepted by the community

Weaknesses:

- Limited reliability of population data.
- Recent drops in immunization coverage.
- Geographical discrepancies in coverage, with pockets of non/under immunized communities (70 townships). A more complete gender and equity analysis may be needed to design appropriate measures.
- Some challenges in financial management, human resource availability and quality at peripheral level. Limited health workforce motivation.
- No recent EVM assessment or EPI review.
- Possible concerns about multiple injections.

Risks:

- The weaknesses and the problems that caused the recent decrease in coverage are likely to also affect the introduction of IPV.
- Limited accessibility to immunization services for hard to reach populations, access to conflict areas and the trend of increasing population displacement

Mitigating strategies:

- Preparation of a special micro-plan for implementation of the Reach Every Community (REC) strategy and Intensification of Routine Immunization interventions in high priority Townships
- HSS programme planned to expand to 180 townships in 2014-15.

10. Conclusions

The Republic of the Union of Myanmar has requested support to introduce IPV into their routine immunization system in-line with the GPEI Endgame Strategic Plan and recent WHO SAGE recommendations. The country has good experience with previous vaccine introductions and is attempting to utilize the lessons learnt, and to cope with current challenges in service provision and coverage. The proposal submitted by the country is well justified, complete and in line with Gavi's IPV guidelines. Technical partners are consistently supporting the country in EPI and new immunization activities. The government seems committed to carry on this new endeavour and improve EPI coverage to the previous level or higher.

11. Recommendation

Approval with Recommendations

Recommendations to the Country:

1. Conduct an EVM assessment in 2015, followed by the development and implementation of an Improvement Plan.
2. Review target population estimates as soon as the new census data become available.
3. Ensure implementation of special strategies to reach the non/under immunized children in the priority townships and capitalize on IPV introduction to penetrate the difficult areas.
4. Ensure implementation of a communication strategy and community awareness measures.
5. Consider private sector involvement in EPI activities and information sharing on IPV.

Recommendations to the Gavi Secretariat

1. Confirm that cold chain storage capacity is adequate before the vaccine is shipped to the country.
2. Consider updating the estimates of the birth cohort based upon census data that may soon become available.