



The Minister of Health and Family Welfare
 Dhaka
 The Government of Bangladesh

30 June 2014

Honorable Minister,

I am writing to you in relation to the Government of Bangladesh's proposal to the GAVI Alliance for New Vaccine Support (NVS) for Inactivated Polio Vaccine (IPV) which was submitted to the GAVI Secretariat in March 2014.

In April 2014 your application was reviewed by the GAVI Independent Review Committee (IRC) which recommended "Approval with Comments" of your application. Based on The Government of Bangladesh's agreement with your Country Responsible Officer to provide the requested comments within the deadlines stated below, GAVI Alliance has approved Bangladesh for GAVI support for IPV, as specified in the Decision Letter and IRC report. This Decision Letter is part of the Partnership Framework Agreement (PFA) recently signed.

Comment	Way forward	Deadline, agreed upon with the country
1. Country to delineate activity plan timeline with specific months and years on the implementation plan and consider the timeline for introduction in line with vaccine availability and VIG release	The country shared the requested revised activity plan timeline	Complete
2. Country to provide a detailed budget for the revised VIG included in the DL (based on UN data) a. Provide cost drivers and/or assumptions for other elements in budget not currently included. b. Clarify the type of vehicle and if country plans to lease or buy the two vehicles proposed at a cost of USD 84,415 each	2. and 2a. The revised VIG budget will be submitted 30 days within the receipt of the decision letter 2b. Country plan to buy two vehicles (Truck)	30 days within receipt of decision letter To clarify as soon as possible after the receipt of the decision letter and well in advance to the procurement decision of actual vehicles.
3. Country to ensure implementation of coverage improvement plan in the low performing areas to ensure equity.	Country to provide information in the context of routine reporting to the GAVI Secretariat and during the GAMR Joint Appraisal mission in 2014.	This will be included in the GAMR Joint Appraisal ToRs.



4. Country to revise the PCV introduction timeline and ensure synergized activities	The revision has been submitted with the revised activity timeline.	Complete
---	---	----------

Please be advised that if comments are not addressed in a manner satisfactory to GAVI within the agreed timeframe, Bangladesh may be requested to reapply for IPV support.

In order to ensure sufficient funding for all GAVI countries applying for IPV support, please note that Bangladesh's initial allocation of IPV doses and associated supplies have been adjusted using UN population data¹ and WHO UNICEF estimates of DTP3 coverage in 2012, consistent with the calculation underlying the IPV budget approved by the GAVI Board in November 2013. Reflecting these adjustments, the Vaccine Introduction Grant (VIG) has been revised in line with UN population estimates of the birth cohort.

Following a country's introduction of IPV, in exceptional circumstances with clear supporting evidence of an additional need and in consultation with the country and partners, doses may be revised upwards to meet that need. Any such revision would be subject to GAVI's approval and reporting processes, and subject to sufficient GAVI funding for IPV being available.

Please note that there is not expected to be sufficient quantities of the single-dose vial available to support the introduction of IPV in Bangladesh. Your country has been initially allocated the 10-dose vial product presentation. However, the GAVI Alliance has noted your second preference for the 5-dose vial product and expects to be in a position to accommodate this request provided the vaccine achieves WHO pre-qualification of the vaccine in Q3 2014 as currently anticipated. UNICEF will keep you informed of the progress.

Please do not hesitate to contact me if you have any questions or concerns.

Yours sincerely,

A handwritten signature in black ink, appearing to read "Dirk Gehl".

Mr. Dirk Gehl
Country Responsible Officer

Attachments: Decision Letter
IRC report

¹ UN World Population Prospects, Revision 2012 (<http://esa.un.org/wpp/>)

**Bangladesh
SUPPORT for
INACTIVATED POLIO VACCINE (IPV)**

This Decision Letter sets out the Programme Terms of a Programme

1. Country: Bangladesh				
2. Grant Number: 1418-BGD-25c-X /1418-BGD-25c-Y/ 14-BGD-08h-Y				
3. Date of Decision Letter: 30 June 2014				
4. Date of the Partnership Framework Agreement: 24 June 2013				
5. Programme Title: NVS, IPV Routine				
6. Vaccine type: Inactivated Polio Vaccine (IPV)				
7. Requested product presentation and formulation of vaccine¹: Inactivated Polio Vaccine, 10 dose(s) per vial, LIQUID				
8. Programme Duration²: 2014 - 2018				
9. Programme Budget (indicative) (subject to the terms of the Partnership Framework Agreement): <i>Please note that endorsed or approved amounts for 2017 and 2018 will be communicated in due course, taking into account updated information on country requirements and following GAVI's review and approval processes.</i>				
	2014	2015	2016	Total ³
Programme Budget (US\$)	US\$2,176,500	US\$8,220,500	US\$6,846,500	US\$17,243,500
10. Vaccine Introduction Grant: US\$2,498,000				

¹ Please refer to section 18 for additional on IPV presentation.

² This is the entire duration of the programme.

³ This is the total amount endorsed by GAVI for 2014 to 2016.

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 (1418-BGD-25c-X)	2014	2015				
Vaccine Doses	1,817,800	6,875,300				
Annual Amounts (US\$)	US\$2,109,000	US\$7,975,500				
Type of supplies to be purchased with GAVI funds in each year (1418-BGD-25c-Y)	2014	2015				
AD Syringes	1,199,700	4,377,800				
Safety Boxes	13,200	48,175				
Annual Amounts (US\$)	US\$67,500	US\$245,000				
12. Procurement agency: UNICEF shall procure the vaccines while Bangladesh shall procure the syringes and safety boxes.						
13. Self-procurement: The amount corresponding to the value of syringes and safety boxes will be disbursed to the country in the form of cash.						
14. Co-financing obligations: GAVI's usual co-financing requirements do not apply to IPV. However, The Government of Bangladesh 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:						
<table border="1"> <thead> <tr> <th>Reports, documents and other deliverables</th> <th>Due dates</th> </tr> </thead> <tbody> <tr> <td>Annual Progress Report or equivalent</td> <td>To be agreed with GAVI Secretariat in the context of GAMR Joint Appraisal for support in 2014</td> </tr> </tbody> </table>			Reports, documents and other deliverables	Due dates	Annual Progress Report or equivalent	To be agreed with GAVI Secretariat in the context of GAMR Joint Appraisal for support in 2014
Reports, documents and other deliverables	Due dates					
Annual Progress Report or equivalent	To be agreed with GAVI Secretariat in the context of GAMR Joint Appraisal for support in 2014					
17. Financial Clarifications: N/A						

⁴ This is the amount that GAVI has approved.

18. Other conditions: If The Government of Bangladesh 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 The Government of Bangladesh.

Comment	Way forward	Deadline, agreed upon with the country
<p>2. Country to provide a detailed budget for the revised VIG included in the DL (based on UN data)</p> <p>a. Provide cost drivers and/or assumptions for other elements in budget not currently included.</p> <p>b. Clarify the type of vehicle and if country plans to lease or buy the two vehicles proposed at a cost of USD 84,415 each</p>	<p>2. and 2a. The revised VIG budget will be submitted 30 days within the receipt of the decision letter</p> <p>2b. Country plan to buy two vehicles (Truck)</p>	<p>30 days within receipt of decision letter</p> <p>To clarify as soon as possible after the receipt of the decision letter and well in advance to the procurement decision of actual vehicles.</p>
<p>3. Country to ensure implementation of coverage improvement plan in the low performing areas to ensure equity.</p>	<p>Country to provide information in the context of routine reporting to the GAVI Secretariat and during the GAMR Joint Appraisal mission in 2014.</p>	<p>This will be included in the GAMR Joint Appraisal ToRs.</p>

Signed by,



On behalf of the GAVI Alliance
Hind Khatib-Othman
Managing Director, Country Programmes
30 June 2014

Independent Review Committee (IRC) Country Report
GAVI Secretariat, Geneva • 28 April – 1 May 2014
Country: Bangladesh

1. Type of support requested: IPV

Planned start date (Month, Year)	Duration of support	Vaccine presentation(s) (1st, 2nd, and 3rd choice)
October 2014	2014 -2018	1 st choice: 1 dose vial
		2 nd Choice: 5 dose vial (to become the first choice as soon as it is available)
		3 rd Choice: NA*

*10 dose vial was not mentioned, not even as a third choice

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

Proposal development involved a National Consultative Workshop held in Feb 2014 with directors and managers of the Ministry of Health and Family Welfare and expert panels on immunization in Bangladesh including the National Committee on Immunization Practice, and National Regulatory Authority on the introduction of IPV in the routine immunization programme.

The ICC comprising of representatives of government, multilateral and bilateral agencies, international organizations and one civil society organization reviewed the application. Decisions taken at the meeting included the review and endorsement of the country's IPV application for submission and a June 2014 deadline set for the inclusion of the IPV introduction into the CMYP. While the list of attendees at this meeting was unclear, the application is fully endorsed by the Secretary and Additional Secretary of the Ministries of Health and Finance.

3. Situation analysis – Status of the National Immunisation Programme

Bangladesh is one of the few countries set to reach the MDG 4 and 5 goals, it has achieved remarkable success in reducing under-five and maternal mortality during the last decade.

The trend of immunization coverage shows that the immunization programme has a strong capacity to reach more than 100% of the children in the last two years with DPT-3/Penta-3, with very low DOR (2%), there is no significant difference in the coverage between urban and rural areas and all districts achieved Penta-3 coverage of 80% or more. However disparities exist across geographical locations as coverage of fully vaccinated children varies from 68% in the lowest performing districts to 91% in the highest performing districts. Despite the high coverage, there are data quality issues with difference between the administrative (96%) and WUENIC data (90%). No Data Quality assessment has been conducted recently nor planned.

An EPI, VPD surveillance review and a Post-Introduction Evaluation of Hib (pentavalent) vaccine was conducted in Bangladesh in March 2012, and findings reflected strong



programme components and highlighted some weaknesses. These weaknesses included low coverage in some urban areas compared to rural areas (~75% Penta3), vacant positions of field workers and supervisors in some areas, turnover of mid-level managers, high turnover rates of NGO workers, Inadequate supervision and under-reporting of AEFIs. Measures have been taken and are ongoing to address the above mentioned weaknesses.

The National EPI has successfully introduced HepB, Hib as Pentavalent, MR and MSD vaccines in 2003, 2009 and 2012 respectively, with many lessons learnt from the previous new vaccine introductions that will facilitate the IPV introduction.

4. Overview of national health documents

The application pointed out that the National Immunization Policy is presently under review to incorporate IPV in the policy documents. The cMYP spans 2011 to 2016 with a planned comprehensive update in June 2014. There is a section on introduction of new and underused vaccines but IPV introduction is yet to be specifically reflected. The cMYP highlights principles to guide new vaccine introduction efforts to focus on *Quality and safety, maximal coverage, equity and gender equality*.

5. Gender and Equity

Bangladesh has a Gender Inequality Index (GII) value of 0.518, ranking it 111 out of 148 countries in the 2012 index, signifying a low status of women, the primary care givers, and the attendant impeded health literacy and autonomy. Inequalities remain across the different socioeconomic groups and geographical locations. The coverage of fully vaccinated children at 12 months of age is 76.9% in the lowest socioeconomic quintile compared to 83.7% among the highest quintile population. Disparities also exist across geographical locations as coverage of fully vaccinated children varies from 68% in the lowest performing districts to 91% in the highest performing districts.

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

The country has provided a clear introduction activity plan with a logical flow, to be implemented in 5-6 months before the introduction date. The application proposes to use the grant to develop and roll out refresher trainings, implement a communication strategy, vaccine and other logistics support, supportive supervision, program management, monitoring and evaluation.

Bangladesh estimated an operational cost of IPV introduction at **USD 4,032,477** and is requesting GAVI to contribute to **USD 2, 699,248** while the remaining balance will be covered by Ministry of health and EPI partners. An overall budget plan clearly shows the planned GAVI support and the government funding elements. However the budget in some areas shows unit costs, it is largely unclear what the cost drivers and/or assumptions are for other elements included. The training budget constitutes about 43% of the VIG, Projected funds and sources have been defined for non-vaccine costs and are provided by the Government, HSS & partners. No funding gap is identified and no country co-financing for IPV is planned. The country has requested that current financial management modalities agreed with GAVI remain applicable.

7. Specific comments related to requested support

New vaccine introduction plan

Bangladesh proposes to introduce nationwide IPV in October 2014. The proposed implementation plan appears rather ambitious but feasible given the country's goal of



creating efficiency by a joint introduction with PCV. However, it will be highly dependent on how soon the funds and the vaccines can be made available. The country will go ahead with the planned PCV introduction if joint introduction is not possible. In line with SAGE recommendations, a single dose of IPV will be given at 14 weeks of age along with OPV3/ Penta3 vaccine. The site for injection is clearly stated.

IPV will be procured and delivered through existing mechanisms with UNICEF. All vaccines used in the national immunization programme are WHO pre-qualified and if procured through UNICEF are granted waivers by the NRA. There is no requirement for pre-delivery inspections. Having undergone an FMA, all financial arrangements remain the same. These will help to reduce bottlenecks and challenges to make the introduction date feasible.

Vaccine management and cold chain capacity

The IPV Introduction Plan states that there is mainly sufficient vaccine storage capacity in and at all levels of the supply chain. The country presented three scenarios highlighting minimum shortages at the district storage levels for the IPV (alone) or IPV+PCV introduction. Country expects to procure an additional 434 ILRS providing cold chain space of 65m³ will be available (procured by WHO, UNICEF and GoB) in 2014 to cover the deficit at the district level stores. USD98, 000 is expected from GAVI to support CC equipment. Given the critical role of this investment and the short planning time available, there is no clear identification of the time of completion of this procurement. Country states that there is provision for back-up power supply through generator rentals at district and Upzila levels and funded on a needs basis.

Waste management is based on the National Policy on Injection Safety and is premised on the "bundling" principle being followed for the procurement and distribution of vaccines with auto-Disable syringes and safety boxes for the collection of sharps. The final disposal of used syringes and sharps is being done by incineration (where an incinerator is available) or by pit burning. \$444,000 will be invested in supply chain upgrade relating to IPV of which 50% is funded from Govt, 25% from UNICEF and 22% from GAVI.

Waste management

The application pointed that there is a National Policy on Injection Safety, which address the "bundling" principle. The final disposal of used syringes and sharps is being done by incineration (where an incinerator is available) or by pit burning. The National EPI is procuring AD syringes from a local manufacturer which is WHO prequalified through the government funds. All existing waste management and injection safety activities will be followed for IPV in line with national guidelines.

Training, Community Sensitisation & Mobilisation Plans:

Country plans to maximize efficiencies through combined trainings for IPV and PCV introduction if approved. The National EPI guideline will be revised to include IPV, and training will be conducted in cascade manner. The training plan along with the estimated budget will be endorsed & approved by the ICC. The training funds will be covered from Government support as well as from VIG. There is a potential to combine the training plan



development geared to happen in month four with the training materials review and development process in months 2 to free up more time for implementation.

The application addressed development of a comprehensive communication, advocacy and social mobilization strategies targeting different audiences, service providers, communities, and parents before the beginning of the IPV introduction

Monitoring and evaluation plans

The recording and reporting system is planned to be revised and updated at all levels, and tools and materials will be updated printed and distributed. According to the timeline, two months is allocated for all revisions and productions/reproductions of documents. PIE is planned for after the introduction, with a budget line addressed in the IPV introduction plan. Other monitoring activities (supervision, review meetings, etc) were not mentioned clearly.

Adverse Event Following Immunisation (AEFI) monitoring and reporting.

AEFI surveillance system is in place in all districts. Health staff have been trained on AEFI reporting, recording and investigation. An independent AEFI committee has been formed at national level and all serious AEFI cases are investigated and causality assessment is done by AEFI committee members. Special focus on crises communication strategy training regarding AEFI is considered.

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

The proposal and its attachments are complete as per guidelines. There is no mention of IPV introduction in the revised cMYP although there is a well written section on the introduction of new and underused vaccines. The ICC has advised that the full revision of the CMYP be slated for June 2014. While budget in some areas show unit costs, it is largely unclear what the cost drivers and/or assumptions are for other elements included. It is not also clear from budget the type of vehicle nor if country plans to lease or buy the two vehicles proposed at a cost of USD84, 415 each.

9. Overview of the proposal

This is a clearly focused proposal, in which Bangladesh has demonstrated its readiness to address the SAGE recommendations by its plan to introduce IPV into its routine immunization. The proposal outlined a clear introduction plan including the main components and activity time line is provided. Budget break down is generally clear, cold chain capacity is sufficient. Country plans to build on previous lessons learned and use existing procurement and financial management structures to process this introduction. Country actually calculated doses for last quarter of first year of introduction. Country plans to utilize existing HSS grant and integrate the already approved PCV grant to maximize efficiencies. Risk and challenges were identified, mitigating strategies by country appear reasonable and feasible.

Strengths: Bangladesh has a robust immunization programme, with high DPt3 coverage with previous experience of successful introduction of new vaccines. Introduction plan is adequate and clear with no major cold chain issues. There is a high quality AFP surveillance system in place. **Weaknesses, risks and challenges** identified include the programmatic challenge of administering three injectable vaccines at the same visit at 14 weeks of age; filling up vacant



posts, increasing the demand & utilization of services, particularly by the hard-to-reach and high-risk populations and building community trust in case of occurrence of severe AEFI related to the new vaccines. **Mitigating strategies** by country appear reasonable and feasible. They include plans to fill up vacant position, use existing channels like the network community clinics, improve program monitoring and undertake communication interventions through different communication channels such as mass media, outdoor media and traditional folk media to disseminate key messages & addressing AEFI concerns. Country also plans to develop a risk communication plan to maintain the uniformity in addressing major AEFI and prevent unnecessary panic situations.

10. Conclusions

Bangladesh has demonstrated a strong capacity and highly commendable integrated approach to introduce IPV and PCV if feasible. The introduction decision is taken with participation of related stake holders. Full support from GAVI is required, no co-financing is planned. Country's EPI program is a robust program as evidenced by high coverage. There is a need to urgently focus on the pre-introductory activities which appear ambitious.

Recommendations

Approval with comments

Comments to country

1. Country to delineate activity plan timeline with specific months and years on the implementation plan and consider the timeline for introduction in line with vaccine availability and VIG release
2. Country to revise the VIG budget calculation based on birth cohort and :
 - a. Provide cost drivers and/or assumptions for other elements in budget not currently included.
 - b. Clarify the type of vehicle and if country plans to lease or buy the two vehicles proposed at a cost of USD 84,415 each
3. Country to ensure implementation of coverage improvement plan in the low performing areas to ensure equity.
4. Country to revise the PCV introduction timeline and ensure synergized activities

Comments to the secretariat:

1. Clarify the conflicting statement in the introductory plan and procurement plan in respect of passive carriers
2. CRO through UNICEF to ensure that IPV vaccine procurement process is expedited
3. CRO to support country to address above comments asap to enable it achieve its goal of a joint IPV/PCV roll out.