The Minister of Health
Ministry of Health
385 Wimalawansa Mawatha
Colombo 10
Sri Lanka

30 June 2014

Honorable Minister,

I am writing in relation to Sri Lanka'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 Sri Lanka's agreement with your Country Responsible Officer to provide the requested comments within the deadlines stated below, GAVI Alliance has approved Sri Lanka 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. Updating the current cMYP to include the IPV vaccine introduction including the date of revision	Country to inform GAVI Secretariat when revised cMYP or equivalent national immunization strategy incl. IPV will be available.	Country to inform GAVI about cMYP/ strategy revision 30 days after receipt of DL
2. Complete the table on table E1	Complete table	15 days after receipt of DL.
3. Prepare the community mobilization plans	To be submitted 30 days after receipt of the DL	30 days after receipt of the DL

Please be advised that if comments are not addressed in a manner satisfactory to GAVI within the agreed timeframe, Sri Lanka 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 Sri Lanka's initial allocation of IPV doses and associated supplies have been adjusted using UN population data[1] 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

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

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 Sri Lanka. Sri Lanka 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 progress.

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

Yours sincerely,

Mr. Dirk Gehl
Country Responsible Officer

Attachments: Decision Letter
IRC report

Appendix B

Sri Lanka
SUPPORT for
INACTIVATED POLIO VACCINE (IPV)

This Decision Letter sets out the Programme Terms of a Programme

1. **Country:** Sri Lanka
2. **Grant Number:** 1518-LKA-25c-X / 15-LKA-08h-Y
3. **Date of Decision Letter:** 30 June 2014
4. **Date of the Partnership Framework Agreement:** 03 April 2014
5. **Programme Title:** NVS, IPV Routine
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 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.

	2015	2016	Total[3]
Programme Budget (US$)	US$1,090,500	US$851,500	US$1,942,000

10. **Vaccine Introduction Grant:** US$297,000

[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 2015 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	2015
Number of IPV vaccines doses	910,900
Number of AD syringes	601,200
Number of re-constitution syringes	
Number of safety boxes	6,625
Annual Amounts (US$)	US$1,090,500

12. Procurement agency: UNICEF

13. Self-procurement: Not applicable

14. Co-financing obligations:
GAVI's usual co-financing requirements do not apply to IPV. However, The Government of the Democratic Republic of Sri Lanka 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 or equivalent	To be agreed with GAVI Secretariat for GAMR Joint or Internal Appraisal for support in 2014 and 2015.

17. Financial Clarifications: Not applicable.

18. **Other conditions**: If The Government of the Democratic Republic of Sri Lanka envisages a switch in product presentation, it is encouraged to incorporate elements for both IPV

[4] This is the amount that GAVI has approved.

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 the Democratic Republic of Sri Lanka.

Comment	Way forward	Deadline, agreed upon with the country
1. Updating the current cMYP to include the IPV vaccine introduction including the date of revision	Country to inform GAVI Secretariat when revised cMYP or equivalent national immunization strategy incl. IPV will be available.	Country to inform GAVI about cMYP/ strategy revision 30 days after receipt of DL
2. Complete table E1	Complete table	15 days after receipt of DL.
3. Prepare the community mobilization plans	To be submitted 30 days after receipt of the DL	30 days after receipt of the DL

Signed by,

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

Appendix C

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

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1. Type of support requested: IPV

Planned start date *(Month, Year)*	Duration of support	Vaccine presentation(s) *(1st, 2nd, and 3rd choice)*
January, 2015	2015-2018	1. 1-dose vials
		2. 5-dose vials
		3. 10-dose vials

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

- The Advisory Committee on Communicable Diseases convened in 03/03/2014 to review the proposal and endorsed the introduction of single dose of IPV into routine immunization schedule at 6 months of age in January 2015.
- IPV shall be given as an additional dose together with the 3rd dose of OPV. The shifting over to bivalent OPV from trivalent OPV will be introduced in 2016.
- The committee was represented by a wide range of independent experts and key stakeholders mainly government representatives, chaired by Director General of Health Affairs. No ICC meeting was convened
- The Advisory Committee on Communicable Diseases committee didn't discuss any issues related to introduction of IPV. The minutes were provided and approved by the committee
- The signature list of the members endorsing the initiative was provided. No civil society organizations were involved. The GAVI application was dully signed by both the Secretary Ministry of Health & MoF.
- The GAVI application for IPV support was prepared by the team of EPI with the support from other Ministry of health staff.
- Unfortunately, committee minutes do not refer to any NITAG decision on approval of introduction of IPV into EPI program and the replacement of tOPV with bOPV

3. Situation analysis – Status of the National Immunisation Programme

The Expanded Programme of Immunization (EPI) in Sri Lanka is an integral component of the public health system with the main objective of reducing mortality and morbidity associated with vaccine preventable diseases. Furthermore, EPI services are integrated with the other primary health care services at all levels.

All vaccines under National Immunization Programme are given free of cost including in the private sector. Furthermore, the immunization services are provided mainly through fixed and sometimes through outreach clinics.

The Expanded Programme on Immunization was launched 1978 and considered to be one of the government's highest priority programs. The immunization programme in Sri Lanka is self-funded, as nearly 98% of the cost is borne by the Government and the rest of the balance (2%) is covered by WHO, GAVI and UNICEF. This demonstrates good evidence of financial sustainability.

Furthermore, since then the country has successfully introduced a number of underutilized vaccines (HepB, Hib, JE and MMR vaccines) into routine immunization

The reported coverage of DTP3/penta3 coverage has been high (>95) for years. There is consistency between administrative and WUENIC estimates. (Official JRF and UNICEF/WHO estimates of DPT3 coverage are recorded at 99% over years). Results of the EPI Coverage Survey conducted recently in Kilinochchi and Mulativue districts (two districts that underwent hardships during conflict in the north and east of Sri Lanka) shows very good coverage.

No information on AFP surveillance was provided. However, the AFP surveillance is well established i.e. Non-polio rate >4/100,000 in children under 15 yrs of age, and no reporting of wPolio since 1993.

The AEFI surveillance system was an integral part of the EPI since 1995, covering all of the country. The reporting, monitoring, investigation and feedback guidelines are in place. An independent AEFI committee was formed to proper investigation of AEFI and monitoring of vaccine safety and all serious AEFI cases. In addition, health staff have been trained on AEFI reporting, recording and investigation. Serious AEFI cases are reported immediately and investigated and causality assessment is carried out.

4. Overview of national health documents

The cMYP adopted for 2012-2016 and IPV introduction isn't part of the current plan. Furthermore, the country has not provided any plans or dates for the revision of the cMYP. The annual EPI work plan are developed annually following review of past years achievements, constraints and recommendations.

5. Gender and Equity

Sri Lanka has a Gender Inequality Index (GII) value of 0.402, ranking it 75 out of 148 countries in the 2012 index. In Sri Lanka, 72.6% of adult women have reached a secondary or higher level of education almost at par with the value of 75.5 % in their male counterparts. The maternal mortality ratio is relatively low at 35 women per 100,000 live births. This is also portrayed in the almost 100% coverage for all antigens, reflecting the decent status of the women, the primary care givers. The application states that there are no specific geographical, economic, policy, cultural, gender and social barriers to immunization. Results of the EPI Coverage Survey conducted recently in Kilinochchi and Mulativue districts (two districts that underwent hardships during conflict in the north and east of Sri Lanka) shows very good coverage.

However, even in Sri Lanka, "vulnerable groups have been described. They are those marginalized from mainstream education and other services due to various barriers generated by economic, social, and geographic fault-lines and physical disabilities and other specific constraints.

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

Sri Lanka is a Graduating country. The country isn't planning to co-finance the IPV introduction. The country is financing the cost of all vaccines and injection safety logistics for the current EPI programme (11 antigens). Only a marginal proportion of the cost for Pentavalent vaccine was provided by GAVI in 2014. Furthermore, the country made the co-financing payments for Pentavalant vaccine since 2008 in time without defaulting, implemented until the end of 2014. The future resource requirements and financing gap analyses are detailed.

The target population numbers are the same as the birth cohort numbers, which is higher than the surviving infants. Further discussion is required with the country on target population

The country has requested a VIG grant request of $285,000 (357,000 x 0.80 = $ 285,000). The table E1 has not been completed

Details of operational costs of introduction of IPV eluded that 50% of the total funds financed by GAVI goes to vehicles and transportation followed by 25% goes for printing material. Other allocations sound reasonable. The requirement for IPV is estimated based on annual target of reaching almost 100% of children aged <1y plus 25% buffer stock.

The country indicated in the IPV application form that the one-time vaccine introduction grant should transferred to the government. The country confirmed that financial management assessment (FMA) is consistence with the current ones already agreed upon with GAVI i.e. the audit of the VIG is guaranteed

The country developed a comprehensive plan of action for the introduction of IPV to be initiated by March 2014

7. Specific comments related to requested support

a. New vaccine introduction plan

The IPV introduction is in line with the Polio Eradication and Endgame Strategic Plan as well as SAGE recommendations. The introduction will be nationwide in January 201 given at 6 months and co-administered intramuscularly with third dose of OPV3, DTP3-HepB-Hib 3 (PENTA) and PCV3, administered at the antero-lateral aspect of the mid left thigh. It has been estimated that the target is almost 100% of survival infants.

The monovalent IPV products are not registered in Sri Lanka. However, IPV containing polyvalent vaccine products have already been licensed and used in the country. All pharmaceutical products including vaccines imported into the country need to be registered with the Sri Lankan NRA by the manufacturer through a local agent. However, the NRA accepts the expedited procedure for national registration of WHO-prequalified vaccines. Currently there is no strict requirement for pre-delivery inspection of WHO pre-qualified vaccines.

There is no information on the synergies (relating to trainings, supervisions, advocacy, and communication packages etc) between the IPV introduction and the current on-going introduction activities for strengthening Immunization coverage.

The EPI Programme manager along with other stakeholders will lead and oversee the implementation of the different component of the plan.

b. Vaccine management and cold chain capacity
There are 32 cold rooms that are well maintained and the result of the EVM assessment conducted in May 2012 confirmed that there is no shortage of cold space throughout the supply chain even when HPV is introduced. Installation of an additional cold room at central level is underway to ensure there will be no issues regarding storage of IPV at central level. The new cold room is not funded from the VIG. Refrigerators used for vaccine storage at the lowest distribution level are supplied from the local market and managed quite well.
The EVM assessment recommended procurement of a refrigerated vehicle for distribution of vaccines to the 26 Regional Medical Supply Divisions. Procurement is in process 2 years later. The overall results of the EVM assessment showed that there is no major problem with supply chain and the performance of 4 out of 9 criteria of the EVM assessment is above 80%. Maintenance standards in particular require improvement. An improvement plan dated 2013 is provided. 40% of the 15 items listed are complete, 20% of the items are in process, 4 items relating to temperature monitoring are awaiting responses from WHO, and 1 item (a national inventory) is not done. The IRC is concerned that the use of domestic refrigerators and poor maintenance standards for vaccine storage may cause undue risk to vaccines (including IPV) if adequate continuous temperature monitoring systems are not used systematically throughout vaccine refrigerators.

c. Waste management
The country adopted appropriate planes on waste management and could be easily accommodate the IPV introduction.

d. Training, Community Sensitization & Mobilization Plans:
The country is equipped with well trained and experienced human resources at all levels in regards to introduction of new vaccines. In addition, the introduction of new vaccine (IPV) to the existing system will not demand extra human recourses, transport cost or any other logistical or implementation cost. There is no need to change or print new recording or reporting forms, as its already incorporated into the system.

Module based training package on risk communication and interpersonal communication for health care personnel and parents on immunization will be adopted. These activities will create formidable communication challenges to convince not only for parents but also the health care workers and medical practitioners. No community sensitization and mobilization plans were provided in the application.

e. Monitoring and evaluation plans:
Monitoring and supervision of health workers will be conducted within the existing system as the system has inbuilt supervisory staff and systems for regular supervision of all categories of staff in a cascade manner at all levels.

There is a well-established system for reporting and monitoring for the national immunization programme. EPI performance at divisional level is reviewed on a monthly basis, and at district level it is carried out quarterly. Annually, each district performance is

reviewed by the central EPI and MCH units. Quarterly EPI reports received from the divisions are compiled and analyzed by the central EPI unit and published and are available on web. Recording and reporting forms are developed to accommodate any new vaccine introductions. Country plans to conduct a Post Introduction Evaluation (PIE) after the vaccine introduction. Serious AEFI cases are reported immediately and investigated and causality assessment is carried out. Non serious AEFI cases are reported on monthly basis. These reports are reviewed by an independent AEFI committee.

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

The proposal and plans provided were almost complete, were of high quality and maintained a good consistency throughout.

9. Overview of the proposal

Strengths:

- The country had earlier demonstrated successful introduction of new vaccines
- Maintaining a high coverage over many years
- Currently there is no strict requirement for pre-delivery inspection of WHO pre-qualified vaccines
- Plans provided on the IPV introduction
- Adequate cold chain at the national, regional and provincial levels and overall vaccine & supply management and distribution

Weaknesses:

- Synergies are not well address between various introductory plan activities

Risks:

- Multi injection at the same session (receive 3 injections (Penta, Pneumococcal and IPV) and this might create some concern among the parents
- Past history AEFI events

Mitigating factors:

The country shows a high political commitment to immunization

10. Conclusions

The EPI program is a robust as evidenced by high political commitment and maintaining high vaccination coverage over many years. The EPI Programme also shows a strong will to build on previous lessons gained from introduction of new vaccines. This provides a sufficient justification for approval of IPV introduction

Recommendations:

Approval with comments

Comments:

Comments to the country

- Updating the current cMYP to include the IPV vaccine introduction including the date of revision
- Complete the table on table E1
- Prepare the community mobilization plans

Comments to the Secretariat

- follow-up with WHO to ensure a rapid response from WHO on temperature monitoring equipment, if this is not forthcoming immediately the request should be referred to UNICEF Regional Office (ROSA) or UNICEF supply division

- Confirm that the procurement of a refrigerated vehicle for vaccine distribution is not delayed further.