



Bhutan

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

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

1. Country: Bhutan			
2. Grant Number: 1518-BTN-25d-X / 15-BTN-08h-Y			
3. Date of Decision Letter: 30 July 2014			
4. Date of the Partnership Framework Agreement: 16 May 2014			
5. Programme Title: NVS, IPV Routine			
6. Vaccine type: Inactivated Polio Vaccine (IPV)			
7. Requested product presentation and formulation of vaccine¹: Inactivated Polio Vaccine, 1 dose(s) per vial, LIQUID			
8. Programme Duration²: 2015 - 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>			
	2015	2016	Total ³
Programme Budget (US\$)	US\$27,000	US\$48,000	US\$75,000
10. Vaccine Introduction Grant: US\$100,000			

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	9,100
Number of AD syringes	9,600
Number of re-constitution syringes	
Number of safety boxes	125
Annual Amounts (US\$)	US\$27,000
12. Procurement agency: UNICEF	
13. Self-procurement: Not Applicable.	
14. Co-financing obligations: N/A GAVI's usual co-financing requirements do not apply to IPV. However, Bhutan 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
17. Financial Clarifications: Not Applicable	

⁴ This is the amount that GAVI has approved. Please amend the indicative Annual Amounts from previous years if that changes subsequently.



18. Other conditions: Not applicable.

If Bhutan 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 Bhutan.

Signed by,

A handwritten signature in black ink that reads "Hind Khatib-Othman".

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

1. Type of support requested: IPV

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

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

The National Coordination Committee (NCC), a body formed to monitor GAVI grants, approved the IPV introduction Plan at the meeting held on 15th of April 2014. Members of the committee included the MOH, Gross National Happiness Commission (GNHC), UNICEF, WHO and NGO. However, in the minutes of this meeting it is mentioned that the Committee asked the Vaccine Preventable Disease Programme (VPDP) to obtain technical clearance from the Essential Medicines & Technology Division (EMTD) for the use of IPV in routine immunisation services. Signatures of the Committee members, MoH Secretary and GNHC Secretary are submitted with the application. A standing technical advisory group on immunisation is available, referred to as the National Committee on Immunisation Practice. It has formal written terms of reference. The NCIP endorsed the proposal to introduce IPV into the routine schedule.

3. Situation analysis – Status of the National Immunisation Programme

The Expanded Programme on Immunisation (EPI) in Bhutan was launched in 1979, offering immunisation services against the 11 traditional vaccine-preventable diseases. In recent years, Bhutan has substantially strengthened the routine immunisation system through the successful introduction of the pentavalent and the Human Papillomavirus (HPV) vaccines, and has **robust capacity to absorb the introduction of IPV**. The feasibility of introducing Pneumococcal and Rotavirus vaccine is under discussion by the NCIP. The immunisation delivery system is robust and provides above 90% coverage for all EPI antigens, including coverage of above 80% in all districts. The EPI programme is fully integrated into the general health system. The services are provided throughout the country from the fixed centers at hospitals/BHUs and outreach clinics. The primary health care workers, namely the Health Assistants (HA), Auxiliary Nurse Midwives (ANM) and Basic Health Workers (BHW) are responsible for providing immunisation services to the children and pregnant women.

Administrative data and official country estimates of DTP3 coverage do not differ from WUENIC data. The estimation of DTP3 coverage was 97% in both 2012 and 2013. **No Coverage survey data was provided.**

DTP 3 / Penta 3	Coverage reported (JRF)		
	2013	2012	2011
	97%	97%	95%

An **EPI review was undertaken in 2011**, and the results revealed that the systems are in place and able to provide coverage >90% for all antigens. Other results were as follows: communities are well informed about the importance of childhood immunisation and location

of services; the immunisation delivery system is able to absorb new vaccines; the AEFI system is in place and has capacity to handle more cases; lack of standardisation of waste management with space is a critical issue in some places; cold chain system is intact but there were concerns about the age of some equipment; high risk migrant groups and nomads were not well enumerated and consequently not adequately targeted for both immunisation and surveillance activities. The reviews recommended conducting mid-level management training for existing health staff focusing on district health officers and assistant district health officers; ensuring that adequate training on AEFI management was provided before pentavalent reintroduction in June 2011; mapping high-risk areas and tracking migrant children; clarifying sharps/waste management and universal precaution issues; and conducting cold chain risk assessment.

One particular barrier exists for **high risk populations of people living and working in areas bordering the Indian states of West Bengal and Assam as well as nomadic populations**. The children from these groups are not adequately enumerated and consequently not adequately targeted for immunisation and surveillance activities. Efforts are ongoing to map these high-risk areas and groups, to enumerate and track these children for immunisation and surveillance activities.

The AFP surveillance is well established and shows robust surveillance indicators i.e. Non-polio rate >2/100,000 in children under 15 years of age, and no reporting of wPolio since 1986.

Justification and eligibility criteria for IPV introduction are in line with the SAGE recommendation and the Polio Eradication and Endgame Strategic plan.

4. Overview of national health documents

The comprehensive Multi Year Plan (cMYP) 2014-2018 is available and covers IPV Introduction.

5. Gender and Equity

Population	741,822
HDI rank	140/187
<5 mortality	45 (2012)
MMR	180
GII	0.46
GII Rank	92/148
Adolescent fertility rate	45/1,000 births

Bhutan is the least populated country in the South East Asian Region. The sources of data used are old (2005) and there is some discrepancy between stated data and UNICEF and WHO figures. The high coverage of vaccine is stated as the proof of gender equity. Bhutan is also one of the first developing countries globally to offer HPV vaccines to girls in Bhutan.

One particular barrier which was pointed out by the a review in 2011, was existence of high risk populations of people living and working in areas bordering the Indian states of West Bengal and Assam as well as nomadic populations throughout the country (see above). Although coverage is high, the data quality and sex disaggregated data is not provided and there is no analysis of gender and equity related barriers.

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

Bhutan is applying for the lump sum of US\$ 100,000 for the introduction grant. The country has requested that the one-time VIG to be transferred to the bank account provided earlier. Therefore, Bhutan has to provide Attachment 4, with a description of their proposed funding mechanism to manage the IPV introduction grant, specifically covering the following processes: a) Budget execution arrangements including internal controls; b) Procurement arrangements; c) Accounting and financial reporting.

More than 60% of the budget is for training and meetings. The target population and birth cohort figures are inconsistent between the different budget tables.

In terms of financial sustainability, Bhutan is a GAVI graduating country. By the end of 2015, the country will have to rely either on its own resources or look for alternative donor support for procuring new vaccines introduction. The Government is confident that all the recently introduced vaccines together with other routine vaccines can be sustained particularly with the Bhutan Health Trust Fund actively taking up support for immunisation. There is no co-financing requirement with this window.

7. Specific comments related to requested support

New vaccine introduction plan

Bhutan's National Committee for Immunisation Practice (NCIP) has opted to introduce IPV nationwide in July 2015. One dose of IPV would be administered at 14 weeks of age along with the third dose of oral polio vaccine (OPV) and the pentavalent vaccine, in line with the Polio Eradication and Endgame Strategic Plan.

The Injection site is the opposite thigh to the Pentavalant but the plan does not state injection position in relation to the DTP3 (i.e. 2 cm apart).

The time line is reasonable providing a clear delineation of activities.

In terms of vaccine presentation: 1st choice: 1 dose vial; 2nd choice: 5 dose vial; 3rd choice: 10 dose vial. This preference will limit wastage that is expected to be high in Bhutan with multi-dose vials because of the small birth cohort and high proportion of rural population resulting in a low number of infants vaccinated during each session.

The National EPI policy is currently under revision and will include introduction of a single dose of IPV.

Licensure status: Bhutan Drug Regulation Authority (DRA) was established in June 2004. Drugs Technical Advisory Committee provides advice to the board on all technical areas related to registration of medicinal products and other technical matters as and when required by the board. Pre-marketing control and post marketing control are major functions performed by the DRA. The Ministry of Health is in the process of ensuring that stand-alone IPV is registered for use in Bhutan. The DRA does follow WHO expedited procedures for registration by the manufacturer.

All vaccines for the country are procured through UNICEF.

Synergy with existing plans is noted. The country is still planning to introduce Rotavirus and Pneumococcal vaccines.

Vaccine management and cold chain capacity

Bhutan conducted an EVM assessment in Nov 2012. The aggregate performance was good (72%). Vaccine storage capacity was rated at 91% average and information management at 56% as the weakest of the 9 assessed criteria. Information management was weakest at peripheral levels of the supply chain. A complete cold chain assessment is planned for 2014. (However, this is NOT an EVM).

An improvement plan was provided along with a corresponding budget of US\$ 64,000. All recommended improvements are made with perhaps the exception of the addition of 1 regional cold room and replacement of some aging domestic refrigerators for WHO/PQS approved refrigerators. There has been HSS1 support to Bhutan until 2013, so some procurement may have been made within this cash support programme. The application is silent on this issue but an equipment inventory is maintained.

15 new refrigerators will be procured as part of the IPV introduction. UNICEF will fund US\$ 21,833 of the cost and US\$ 8,167 of support is requested from the GAVI VIG.

Bhutan maintains and updates its equipment inventory on a quarterly basis, and a computerised stock management system is now in place at the central store (2013). Personnel are trained and refresher training is planned.

The application clearly indicates adequate space to store IPV single dose presentation of vaccines and provides quantitative estimates of the required additional volume (6.4% additional capacity). It estimates FIC volumes of 240cc/FIC at national level and 279cc/FIC at peripheral levels. Net storage capacity with annual vaccine shipments is 3.99 m³ at the central store.

The country is sensitive to freeze risks of IPV and has introduced 30-DTR continuous temperature monitoring devices in refrigerators and will introduce electronic freeze indicators for transporting IPV vaccines in cold boxes and vaccine carriers. The activity will be supported by appropriate training.

Bhutan prefers a 1 dose presentation of IPV for good reasons although this would cost an additional US\$ 3,822/year as compared to a 5 dose presentation. Bhutan is a GAVI-graduating country in 2015 and has estimated resource requirements for longer term self-financing. There are no major supply chain challenges related to the introduction of IPV in Bhutan.

Waste management

No changes in current practices will occur.

Training, Community Sensitisation & Mobilisation Plans

The introduction of IPV is an important opportunity to re-train health workers and EPI staff on all aspects of immunisation practices, and to reinforce this training by supportive supervision and reporting requirements. The IPV introduction plan and timeline includes specific activities that will ensure successful development of training materials, IEC materials and messages, and an integrated training strategy that not only addresses IPV but also provides refresher training for HWs on immunisation practices such as injection safety, AEFI communications, cold chain management, data collection, analysis, and use for action. Training from national to health facility level will be conducted using cascade training through a series of workshops, beginning with training the trainer sessions at the national level. Specific emphasis will be placed on inter-personal communication as a key vaccinator skill.

The proposal states that there may be concerns on the acceptability of introducing a vaccine that poses risks of other new vaccine introductions (see Table 6 in introduction plan). Efforts

to mitigate risk will include development of effective communications and advocacy strategy along with a crisis communication plan is developed. The Ministry of Health will collaborate with WHOM, UNICEF and other global partners to leverage the use of existing tested messages and materials to develop a strategy appropriate for the needs of the Bhutanese population.

Monitoring and evaluation plans

The EPI programme in Bhutan is being monitored at four levels – impact, outcomes, outputs and inputs. Supportive supervision will be emphasised as a key component of successful training. Supportive supervision is ongoing but will be enhanced through IPV introduction. Each supervisory team will be expected to carry out a debriefing to facility staff at the end of each visit. It is recommended that the national level staff should undertake supervision at least once every year and districts once per quarter. The supervisory visits will include a review of the monitoring data, injection practices, social mobilisation, logistics, stock management, and vaccine handling practices at the healthcare center. The monitoring tools will be updated to include IPV vaccine. As well as the Health Information Management System updated accordingly. **No information is provided on independent DQS assessment.**

The AEFI system in Bhutan is functioning well. Definitions are available, reporting mechanisms are in place, and validation is standardized and documented. The review team observed that the system for reporting serious cases functions with an AEFI committee at the central level that meets to review serious cases for causality assessment. The AEFI system is capable of handling more cases (minor cases) and which was deemed to be important for additional new vaccine introduction such as IPV.

The introduction plan indicates that an evaluation of the IPV introduction will be carried out 6 months post-introduction.

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

Well-presented proposal; inconsistency noted in relation to the data on birth cohort and target population.

9. Overview of the proposal

Strengths:

- Government finances all traditional vaccines, indicating strong government commitment to the immunisation programme.
- Country has demonstrated successful ability to implement new vaccine introductions with very good coverage achieved.
- Adequate cold chain capacity is available for IPV introduction for all presentation options.

Weaknesses:

- Financial arrangement: Country is required to clarify whether the same arrangements as for the implementation of the HSS grant apply.

Risks:

- Future Financial Sustainability: Bhutan is a graduating country, and sustainability will depend on government and partners funding especially for introduction of other priority new vaccines that are crucially needed in Bhutan.

- The acceptability of introducing a vaccine for disease that has been eliminated in the country could be low with decision-makers, health workers, and parents.
- Community acceptability of a second injection.

Mitigating strategies:

- Formation of The Bhutan Health Trust Fund Initiative
- Lessons learned from previous new vaccine introduction are being seriously considered. A strong communications and advocacy strategy will take those issues into consideration.
- Focused efforts to strengthen the national AEFI system

10. Conclusions

Bhutan has requested support to introduce single dose of IPV into their routine immunisation system in accordance with Endgame Strategic Plan mandate. The country has provided adequate justification and documentation to support the introduction. The country also has adequate space to accommodate the vaccine. Furthermore, other activities for the new vaccine introduction are well described.

Recommendation:

Approval with Comments

Comments for Country:

- Ensure plans are in place for conducting immunisation activities, among displaced and refugee groups, and in areas with low immunisation coverage.
- To secure access to sufficient supply during the global roll out of IPV, consider licensing of all vaccine presentations for IPV.

Comments for Secretariat:

- Clarify / ensure that arrangements of the HSS grant financial management apply.