

## Bhutan Vaccine Support

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

<b>1. Country:</b> Bhutan			
<b>2. Grant Number:</b> 1415-BTN-04a-X			
<b>3. Date of Decision Letter:</b> 23 September 2015			
<b>4. Date of the Partnership Framework Agreement:</b> 16 May 2014			
<b>5. Programme Title:</b> NVS, Pentavalent Routine			
<b>6. Vaccine type:</b> Pentavalent			
<b>7. Requested product presentation and formulation of vaccine:</b> DTP-HepB-Hib, 1 dose(s) per vial, LIQUID			
<b>8. Programme Duration<sup>1</sup>:</b> 2009 -2015			
<b>9. Programme Budget (indicative) (subject to the terms of the Partnership Framework Agreement):</b>			
	2009-2014	2015	Total <sup>2</sup>
Programme Budget (US\$)	US\$437,704 <sup>3</sup>	US\$33,500	US\$471,204
<b>10. Vaccine Introduction Grant:</b> Not applicable			
<b>11. Indicative Annual Amounts (subject to the terms of the Partnership Framework Agreement):<sup>4</sup></b>			
Type of supplies to be purchased with Gavi funds in each year	2009-2014	2015	
Number of Pentavalent vaccines doses		12,500	
Number of AD syringes		13,400	
Number of re-constitution syringes			
Number of safety boxes		175	
Annual Amounts (US\$)	US\$437,704 <sup>5</sup>	US\$33,500	
<b>12. Procurement agency:</b> UNICEF. The Country shall release its Co-Financing Payments each year to UNICEF.			
<b>13. Self-procurement:</b> Not applicable.			

<sup>1</sup> This is the entire duration of the programme.

<sup>2</sup> This is the total amount endorsed by Gavi for the entire duration of the programme.

<sup>3</sup> This is the consolidated amount for all previous years.

<sup>4</sup> This is the amount that Gavi has approved.

<sup>5</sup> This is the consolidated amount for all previously approved years.

**14. Co-financing obligations:** Reference code: 1415-BTN-04a-X-C

According to the Co-Financing Policy, the Country falls within the Accelerated Transition phase.

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	2015
Number of vaccine doses	39,200
Number of AD syringes	41,900
Number of re-constitution syringes	
Number of safety boxes	475
Value of vaccine doses (US\$)	US\$98,825
Total Co-Financing Payments (US\$) (including freight)	US\$104,000

**15. Operational support for campaigns:** Not applicable

**16. Additional documents to be delivered for future disbursements:**

Reports, documents and other deliverables	Due dates
<i>APR or equivalent</i>	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**

Hind Khatib-Othman

Managing Director, Country Programmes

23 September 2015

## Joint appraisal report

<b>Country</b>	Bhutan
<b>Reporting period</b>	2014. JA conducted in June/July 2015
<b>cMYP period</b>	2014-2018
<b>Fiscal period</b>	1 <sup>st</sup> July to 30 <sup>th</sup> June
<b>Graduation date</b>	Commenced 2011 Completed 2015

### 1. EXECUTIVE SUMMARY

#### 1.1. Gavi grant portfolio overview

**The GAVI Investment in Bhutan:** The GAVI investment in Bhutan (2002-2014 valued overall at a commitment of \$1.68 million) has consisted of support for tetravalent vaccine, pentavalent vaccine, IPV vaccine (introduction July 2015), injections safety support and a health system strengthening grant (\$194,000), of which the last tranche was disbursed in 2014. Bhutan is in 2015 in the final year of co-financing of pentavalent vaccine, after which the country will transition from GAVI support (except IPV).

**Grant Progress in Bhutan:** The GAVI investment in Bhutan has assisted the country to achieve its health and immunization objectives. Bhutan is a high coverage country which has sustained coverage over 95% and achieved important equity outcomes in recent years. The most recent JRF data indicates that all districts have achieved higher than 90% coverage in 2014. This is despite the challenge of mountainous topography, dispersed populations, and challenging transport and communications conditions. Although the HSS grant is very small, it is nonetheless focused on a main health system bottleneck, which is training of PHC staff to work in more remote health centers in the country. HSS reporting was limited in the APR, and therefore it is recommended that a completion report be developed at the end of 2015.

#### **Implementation and Graduation Challenges**

- Despite the significant equity outcomes, it still remains the case that special accelerated routine EPI activities are required in high risk and remote areas of the country.
- Limitations in surveillance systems of Adverse Events Following Immunization (AEFI) and information on the efficacy and costs of vaccines have slowed progress towards evidence based decision making and introduction of newer vaccines including pneumococcal, rotavirus and JE vaccines (see to NCIP (NTAGI equivalent) minutes submitted with the APR). Bhutan will therefore transition from GAVI support without having introduced these vaccines.

- In 2014, APR data still indicates that outside sources are financing traditional vaccines (JCV) as well as HPV vaccine (Australian cervical cancer foundation).
- Despite reliance on external financing, the recent Graduation Assessment indicates that the Bhutan Health Trust Fund (BHTF) has adequate income to fully fund the vaccines for the EPI programme in the coming years. This factor, in combination with steady rates of economic growth, provides good prospects for financial sustainability.

## 1.2. Summary of grant performance, challenges and key recommendations

### Grant performance (programmatic and financial management of NVS and HSS grants)

#### Achievements

- Maintenance of high coverage over the last 9 years
- Improving equity outcomes, with 90% coverage (DPT3) achieved for all Districts in 2014
- Introduction of new vaccines (pentavalent, hepatitis b Birth dose, HPV vaccines and IPV)

#### Challenges

- Improving surveillance systems for Adverse Events Following Immunization
- Establishing an evidence base for new vaccine introduction decision making
- Cold chain performance and implementation of EVM-IP
- Sustainability of vaccine financing
- Maintaining accessibility to services in remote areas

### Key recommended actions to achieve sustained coverage and equity (list the most important 3-5 actions)

- Equity interventions for higher risk groups to sustain coverage at > 95% (migrants, mountain populations)
- The graduation plan recommends to improve the performance of the Bhutan Health Trust Fund (BHTF) in order to sustain financing of vaccines in the post-graduation period from GAVI and other sources of international support through 1) governance and organizational re-structuring (e.g. de-link the BHTF from MoH, implement new organogram), 2) development of a 5 year operational plan and 3) develop and implement a resource mobilisation strategy.
- The graduation analysis identified the need to further strengthen the immunization supply chain to protect the potency of vaccines through improved vaccine management. The EVM Improvement Plan (IP) specifically defined remaining investments and activities related to the introduction of new technologies, cold chain equipment management and training of logisticians.
- Improving surveillance and developing the analysis to provide the evidence base for new vaccine introductions decision (e.g. rotavirus, PCV and JE vaccines).
- Developing systems and HR capacities for reporting and responding to AEFI events (e.g. finalize updated national AEFI guidelines, increase capacity to investigate AEFI cases timely, crisis communication, training of operational health workers).

## 1.3. Requests to Gavi's High Level Review Panel

### Grant Renewals

### New and underused vaccine support

- Renewal of the grant for the pentavalent programme (residual funds of 19.000 USD in the final year of graduation for the 20% of doses financed by Gavi)

#### **Health systems strengthening support**

- No renewal necessary. Expected completion of the grant in 2015. Request HSS progress and completion report (not submitted with APR as of May 25<sup>th</sup>, 2015) after the end of the FY in June.
- Support through UNICEF for further improvement of immunization supply chain based on the planned EVM follow up assessment report and recommendation in September 2015 (Business Plan).

#### **1.4. Brief description of joint appraisal process**

A consultant utilized the APR, cMYP 2014-2018 and the graduation analysis and plan (in addition to other documentation submitted with the APR) to make a draft Joint Appraisal document. This was then reviewed and updated by the MoH/ EPI programme in collaboration with the GAVI Secretariat and partners (WHO CO and SEARO, UNICEF CO and ROSA).

## 2. COUNTRY CONTEXT

### 2.1. Comment on the key contextual factors that directly affect the performance of Gavi grants.

#### ***Political and Socio Economic Context***

The economy in Bhutan is based on agriculture, forestry and increasingly hydropower. Economic growth in recent times has been strong, and GDP growth of 4.5% was estimated in 2013, and a GNI of \$2,460 for the same year. In 2014-2015, 8% of the national budget was allocated for health, and between 2002 and 2012, total health expenditure has been on average 4.46% of GDP (Graduation Report). In line with this growth, the poverty rate has fallen from 36% in 2000 to 12% in 2013. In terms of political reforms, the country is a constitutional monarchy, and recently democratized in 2006. Prior to this time, the governance model of administration also became increasingly decentralized, with each Dzongkhag (District) being responsible for development planning and all other socio economic activities (Graduation Situation Analysis 2013). 30% of all health expenditure is allocated to Dzongkhags. Generally speaking, these broader socio economic developments augur well for international health investments, as they in principle expand the fiscal space for health and move decision making and planning closer to populations.

#### ***The Development of the Bhutan Health System***

The high standard of EPI performance in Bhutan can be attributed in large part to the political commitment by the Royal Government of Bhutan (RGoB) to invest in the development of the primary health care system. In accordance with the national Health Policy, health care services are tax financed and are accessible free of charge to the population. The country over the last 20-30 years has been networked by a wide complex of district hospitals, basic health units and outreach clinics. Services are becoming progressively accessible to the population also through the recent expansion of road and communications networks. The main health system contextual challenge relates to shortages of human resources. Although there are 4 health personnel per 1000 population (there are 1,314 PHC workers), the recently completed Graduation Assessment (2014) points out a lack of human resources in more remote areas.

The second major contributing factor to the EPI program performance has been the degree to which the EPI program has been integrated into the decentralized management and PHC health care delivery system. Although there still remains strong vertical program financial and technical support from the Ministry of Health, the decentralized planning system, in combination with the network of PHC centers (including domiciliary visits and outreach clinics by PHC workers) means that there is wide reach and accessibility of PHC services in Bhutan.

The cMYP indicates that services are accessible to 90% of the population. Both of the above mentioned factors have ensured that GAVI investments (pentavalent vaccine in particular and IPV in the near future) are being delivered through a very sound health system platform.

#### ***Equity and Geographic Terrain***

Services are not equally accessible to all primarily due to the demographic picture of Bhutan. The population of 776,000 (with an under 1 year age cohort of below 15,000) is widely dispersed across northern alpine regions, central Himalayan valleys, and southern hotter and forested hilly areas and plains. This diversity in

terrain and accessibility accounts in large part for historical inequities in coverage by Dzongkhag (District). However, the most recent JRF data demonstrates that all districts (20) have now achieved coverage that is greater than 90% in 2014. This data is illustrative of a high level of both health program and GAVI grant performance.

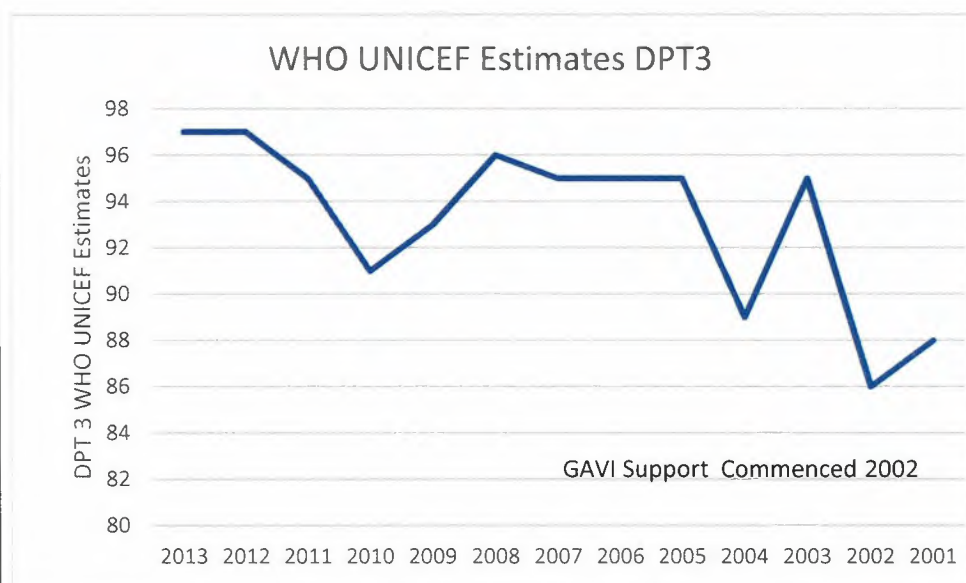
### 3. GRANT PERFORMANCE, CHALLENGES AND RENEWAL REQUESTS

#### 3.1. New and underused vaccine support

##### 3.1.1. Grant performance and challenges

###### **Overall Immunization Performance**

Official estimates indicate that coverage has been maintained at greater than or equal to 95% for DPT3 since 1995. Between 2011 and 2013, WHO UNICEF estimates for DPT3 have ranged between 91% and 97%. In the 1990s, the coverage was mostly in the 80s range, and in the 1980s the coverage was significantly lower than this. What this evidence demonstrates is a steady increase in the immunization coverage rates, which provides a strong basis for sustained high coverage in Bhutan.



Other important coverage data includes the following:

- Pentavalent vaccine (Gavi supported) was introduced in 2009 and since 2011 high coverage has been sustained as illustrated by the above mentioned WHO UNICEF estimates for DPT3
- The hepatitis B Birth dose (financed by government/ JCV<sup>6</sup>) was introduced in 2011, with coverage climbing from 29% in the introduction year to 78% in 2014 (Country Estimate, with WHO UNICEF estimate of 64% in 2013).
- Measles second dose (financed by government/ JCV) was introduced in 2008, and coverage has climbed from the baseline result in 2008 of 72% to 92% in 2014 (Country Estimate, with WHO UNICEF estimate of 89% in 2013). The drop out from measles 1 to measles second dose was only 5% in 2013. The last measles case was in 2012 (1 case).
- HPV Vaccine (support from Australian Cancer Foundation) for a cohort of 12 – 18 year old girls was introduced in 2011 through school based catch up

<sup>6</sup> Japan Committee “Vaccines for the World's Children”



campaigns. HPV Coverage is not reported either through the APR or Joint Report Form (as reported in the WHO Vaccine Preventable Disease Data base). However, the cMYP reports that in the initial phase of 3 rounds of vaccination, 90% coverage was achieved. In 2011, the HPV vaccine was introduced into the routine program for 12 year old girls.

- 4 tetanus cases were recorded in 2014 but the last neonatal case was in 2006. It is planned to confirm neo natal tetanus elimination status through the support of UNICEF in the current cMYP Planning cycle.

The cMYP states the intention of introducing new vaccines including rotavirus, PCV and JE. However, due to both lack of sufficient disease burden evidence and financial sustainability considerations, no decisions have been made on introduction as yet. The JRF reports 27 Japanese encephalitis cases in 2012, and 2 in 2014. In the next planning cycle, it is also proposed to switch MR for MMR, which will assist to reduce the large numbers of mumps cases being reported through the JRF system (206 cases in 2014).

The last National EPI Coverage Survey was conducted in 2009 and confirmed the reported high coverage rates. The survey indicated that coverage for DPT3 by card was 97%, and by card and history was 100%. More discussion may be required at country level to update these coverage survey results and confirm the success of the EPI program in Bhutan.

### ***The Equity Challenge***

The main reason provided by the graduation situation analysis and plan for inequities in coverage is “difficult to access health centers” in the northern plateau district of Gasa and in the southern forested district of Samste. These issues are addressed programmatically through intensification of routine immunization for migrant/hard to reach populations and high risk areas. Due to recent investment in road and communications in Bhutan, the proportion of rural population living within 6 hours walking distance of a road has increased from 84% to 90% between 2000 and 2008. It is the programmatic interventions in combination with wider socio-economic developments that have in all probability contributed to the improvements in equity of access to immunization. There is no system of sex disaggregated data collection for immunization, and the APR states that there is equal access for boys and girls. Despite very high coverage rates, it still remains the cases that in some very remote areas there are not adequate human resources for immunization services (Graduation Assessment, 2014).

### ***Adverse Events Following Immunization and Surveillance Challenges***

In the Annual Progress Report, the country is reporting “Yes” to all critical questions regarding presence of the relevant safety committees and risk communication strategies. Elsewhere however, some concern is expressed (both in the cMYP and Graduation Plan) regarding the country’s current capacity to report and respond to AEFI. **The AEFI surveillance system still needs to be strengthened** through establishing standard operative procedures for investigating AEFI, building technical capacities and advocating for reporting. For instance, it seems that more severe forms of AEFI that need hospitalization or medical attention are being reported, as well as some deaths associated with such events, but without investigation to validate these assumptions. Consequently, different training-related activities have been identified during the Graduation Assessment mission, such as the

dissemination of national guidelines and a manual on field investigations of AEFI, a training of trainers on AEFI monitoring, training workshops on AEFI with district and BHU EPI staff and on AEFI filed investigation.

Two major reasons are provided in various documents why rotavirus and PCV vaccines have not been introduced. These are due to financial sustainability concerns and to lack of clarity regarding disease burden and adequate AEFI surveillance systems (e.g. rotavirus vaccine intussusception). The APR states that the National Public Health Laboratory is conducting the surveillance and studies on prevalence of rotavirus disease in the country. No information is available on Pneumococcal disease burden assessment and surveillance. The cMYP indicates systems that will be put in place in order to assess the immunogenicity and reactogenicity of the vaccine in the Bhutan setting. No data is reported in the APR or supporting documentation. The NCIP will assess vaccine introduction based on availability of relevant clinical and epidemiological data produced in Bhutan.

No evidence is provided of the public health impact of pentavalent vaccine (in terms of reduction of meningitis or pneumonia cases). However, the cMYP indicates that a WHO study conducted in 2002 demonstrated that the incidence of Hib meningitis was estimated at 16-54 cases per year/ 100.000 population, while the incidence of Hib pneumonia cases was estimated at 80-270 cases per year/ 100.000.

#### ***Cold Chain and Logistics Challenges***

The last EVSM was conducted in September 2012. Only 1 of the nine criteria scored greater than the recommended 80% score for performance (storage capacity). Major issues identified in this assessment included temperature monitoring (41%), vaccine management (63%) and distribution (56%). The study recommended major actions in such areas as temperature monitoring and development of standard operational procedures for vaccine management.

The country has reported on the implementation status of this plan, and provides details on procurement of cold chain monitoring equipment and replacement of refrigerators updating of a cold chain inventory and training of EPI managers on vaccine management. The graduation plan includes funding to implement the EVM Improvement Plan and addresses the above mentioned challenges of the supply chain.

#### ***New Vaccine Introduction and Financial Sustainability Challenges***

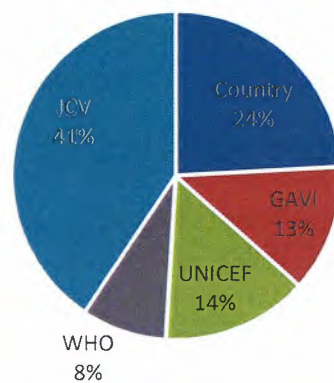
According to the most recent JRF data from 2014, 31% of the national EPI budget is funded by the Government of Bhutan (WHO Monitoring Database 2015). The APR states that total expenditures for immunization in 2014 was \$416,712, of which \$100,600 was sourced from government (24%). The country successfully co-financed pentavalent vaccine through the Bhutan Health Trust Fund, which will assume full financing of pentavalent vaccine in 2016.

The country still relied in 2014 on external financing to cover traditional vaccine costs through JCV. HPV vaccine is also financed through an external partner (Australian Cancer Foundation), and this financing is secured for 2016/17.

The graduation assessment concluded that the BHTF has adequate resources (revenue of US\$ 1.5m in FY 2013/14, US\$ 1m in FY 2012/13) to finance the vaccine programs (approximately US\$ 400.000). Financing of operational services is made more secure through the tax based financing of the regular budget of the primary health care system (with additional support from UNICEF and WHO).

There are two main challenges in relation to financial sustainability. The first is that the resources from the BHTF will be allocated starting in 2014 for essential medicines (up to US\$ 2 million p.a.) as well as for the vaccine program. The total cost of these supplies exceeds the investment revenues of the BHTF and requires a prioritization of vaccines. The second challenge is the hesitancy for new vaccine introductions as a result of financial sustainability risks. Although Bhutan is a country graduating from GAVI support, no decision has been reached on rotavirus or PCV vaccine introductions, and so the country, if it does decide to introduce these vaccines, will need to do so through the support of the BHTF or from other development partners. The section on the graduation assessment and plan includes further details.

Financing of the EPI Program in Bhutan in 2014 (APR 2014)



### ***Governance and Institutional Challenges***

The MoH has an established NCIP committee (NITAG equivalent) that convenes quarterly. The stated purpose of the NCIP is to review immunization activities and make technical recommendations. The role of this committee is discussed elsewhere in the submitted documentation with regards to its role in reviewing disease burden data in order to facilitate new vaccine decision making. Minutes have been submitted with the APR and which document discussion by stakeholders regarding the planning for IPV introduction in July 2015. This provides detailed discussions on the NCIPs deliberations on evidence to date on rotavirus disease epidemiology and genotypes. The findings in the minutes here makes note of the complex epidemiology, and diversity of genotype of rotavirus, and on the basis of these findings, recommends enhancing surveillance and AEFI surveillance systems. These minutes also highlights the NCIPs role in review of epidemiological evidence in order to support a high risk campaign strategy for hepatitis B prevention. The NCIP in Bhutan provides an interesting case study for the GAVI Alliance on the critical role of NCIPs in relation to informed new vaccine decision making at country level.

A major institutional challenge for the country relates to vaccine procurement mechanisms and economies of scale. As a small country, it is difficult to put in place the institutional means by which to procure vaccines and essential drugs at competitive prices. The country currently responds to these challenges through procurement by UNICEF and donor support for procurement of other vaccines (including HPV). An activity of the graduation plan supports the assessment of MoH and MoF of the procurement arrangement and whether to continue with UNICEF as

procurement agency. This assessment should compare different options.

Given the countries emphasis on self-reliance, more emphasis will be required in the future on use of the BHTF to finance vaccines, including financing for newer vaccines not yet included in the immunization schedule (including RV, PCV and JE vaccines).

There are also issues related to the Drug Regulatory Authority (DRA) with system development for regulation (in particular the absence of a quality management system) and acquiring the staff with the necessary skills to manage and direct the DRA (Graduation Assessment 2014).

### **3.1.2. NVS renewal request / Future plans and priorities**

#### ***NVS Renewal Request***

The graduation period for Bhutan is 2011-2015. GAVI support for co-financing of pentavalent vaccines ends in 2015, and the country will fully finance the vaccine in 2016. IPV vaccine introduction took place in July 2015.

The pentavalent programme requires a renewal decision for procurements in Q4 2015 (20% Gavi share in the final year of graduation).

#### ***Future Plan and Priorities***

The APR indicates the following set of priorities for 2015 and 2016:

In the Vaccine Management area, it is proposed to conduct an Effective Vaccine Management (EVM) assessment in the next two years, train EPI Technicians for refrigerator repair and cold chain maintenance and conduct a temperature monitoring study. This study aims to illustrate the extent to which the current immunization supply chain exposes vaccines to unnecessary temperature deviation, and can help target where better equipment and better staff practices are needed. These activities are supported by the graduation grant (UNICEF).

The APR also highlights the need for program management initiatives, including training for health workers on AEFI investigation & reporting (supported by graduation grant), supervision & monitoring at Health Centers and conducting assessments of immunization coverage in hard to reach populations.

Emphasis is placed on resource mobilization for vaccine financing, and review of the role and functions of the BHTF in order to sustain the financing of the existing immunization schedule. This has been included in the graduation plan.

The NCIP and related documentation also highlights the importance of improving sentinel surveillance in order to more accurately assess the disease burden and epidemiology of rotavirus, pneumococcal disease and JE.

In July 2015 IPV was introduced and subsequently a post introduction evaluation should be conducted. The inclusion of MMR vaccine is also planned in the next cMYP period. It is also proposed that in the coming planning cycle (2014-2018), maternal and neonatal tetanus elimination is validated, and measles elimination status is achieved by 2016.

### 3.2. Health systems strengthening (HSS) support

#### 3.2.1. Grant performance and challenges

##### ***Grant Design***

The objective of the GAVI HSS funding in Bhutan is to build human resource capacity to improve the quality of, demand for and access to maternal and child health services. This objective is being achieved through curriculum revision, cascading of training of health professionals and training of village health workers. The GAVI HSS funding to Bhutan \$194,000 for five years. The final disbursement of funds was made in 2014.

##### ***Grant performance and Challenges***

An incomplete HSS report has been submitted, and it is also stated in the APR that a more complete HSS report will be submitted later this year (after the end of the FY2014/15 in June). Data provided illustrates that 100% of planned activities in 2014 were achieved, which included the following:

- Training of Village Health workers in selected districts
- Providing in-service training programs in 20 districts
- Procurement of cold chain equipment

#### 3.2.2. Strategic focus of HSS grant

##### ***Contribution of HSS grant to Improving and Sustaining coverage and equity in access to immunisation.***

The APR indicates the HSS program will be completed in 2015. Limited data is provided in the APR or in supporting documentation on HSS strategic focus or impacts. A desk review of the HSS grant (GAVI 2009) suggest potential impacts on equity nationally through improved training of nursing staff in five of the poorest performing regions, through improving access to and demand for assisted deliveries.

A more detailed narrative in the APR or in a project closing report (project ends in 2015) would be required in order to assess the contribution of HSS to immunization coverage or outcomes.

#### 3.2.3. Request for a new tranche, no-cost extension, re-allocation or reprogramming of HSS funding / Future HSS application plans

Not applicable.

### 3.3. Graduation plan implementation (*if relevant*)

### ***Graduation Plan Situation Analysis***

The graduation period was used to identify the key activities to be implemented before the end of Gavi support in the country, and to ensure the capacity to financially and technically sustain access to vaccines. A first transition plan was identified in 2012 and a review of the Bhutan Health Trust Fund (BHTF) was conducted in 2013. In September 2014, a final graduation plan for 2015/16 was developed.

The twelve-month graduation plan requests supplementary financial support from Gavi of US\$ 245,930 (incl. WHO and UNICEF PSC overheads). The graduation plan activities are financed by 58% through the Gavi grant and the remaining support is shared by government, WHO and UNICEF.

The plan documents country context, immunization performance and challenges, immunization financing trends and issues and institutional capacities. In terms of immunization financing and trends, the assessment makes note of increasing health expenditure per capita and a significant allocation of government budget to health. The macroeconomic context also reinforces sustainability prospects, with steady rates of growth founded on agriculture, forestry and an expanding hydro-electric energy production.

Historically, the country has relied on development partners to finance the traditional vaccine budget. The Bhutan Health Trust Fund has taken over the responsibility to finance all vaccines in 2014, although the traditional vaccines (JCV) and HPV vaccines (Australian Cervical cancer Foundation) are still being financed through other partners.

The BHTF was launched in 1998 by the Royal Government of Bhutan (RGoB). The objective of the BHTF is to contribute to the provision of primary health care services by self-sustainably financing vaccines and essential medicines. The capitalization of the BHTF reached its target of US\$ 24 million in 2014 which is composed of various donor contributions and one-to-one matching funds from RGoB. Investments and income are in local currency (Ngultrum, Nu). In the FY 2013/14 (2012/13) the investment income of the Fund was equivalent to US\$ 1.5m (1.0m).

The BHTF has an adequate annual income to finance the procurement of vaccines in Bhutan. However, the funds are most likely not be adequate to cover both vaccines and essential medicines (up to US\$ 2m p.a.) which are also the responsibility of the BHTF.

The graduation assessment points out that, given economic growth rates in Bhutan, there is a progressive withdrawal of partners from the country. This factor, in combination with Gavi Graduation status from 2016, means that the financing situation for vaccines will inevitably effect the decision of the country to introduce new vaccines such as PCV, RV and JE.

### ***Graduation Plan***

The graduation grant 2015/16 will be implemented with the support of WHO and

UNICEF. The key activities in six strategic areas include the following:

- 1) Financing of Immunization (strengthening Bhutan Health Trust Fund)
  - The graduation plan recommends to improve the performance and sustainability of the BHTF through 1) governance and organizational restructuring (e.g. de-link the BHTF from MoH, implement new organogram), 2) development of a 5 year operational plan and 3) develop and implement a resource mobilisation strategy.
- 2) Supply chain and procurement of vaccines (implementation of EVM-IP)
  - The graduation analysis identified the need to further strengthen the immunization supply chain. The EVM Improvement Plan (IP) specifically defined remaining investments and activities related to the introduction of new technologies, cold chain equipment (CCE) management and training of logisticians. The capital investment component absorbs the largest portion of the graduation grant (approximately US\$ 100.000).
- 3) Crisis communication and health systems information (strengthening AEFI systems)
  - A standard national system to monitor adverse events following immunization is implemented in Bhutan and routine immunization reporting has been gradually strengthened following the suspension of the pentavalent vaccine in 2009 and its re-introduction in 2011. Although health staff regularly receives in-service training on AEFI surveillance, reporting and investigation, the AEFI surveillance system still needs to be strengthened through the development of a crisis communication plan, related operational procedures and promotion of health worker knowledge in the safety of vaccines and key messages for the target group.
- 4) National Regulatory Authorization strengthening
  - The Graduation mission assessed the capacity of the Drug Regulatory Authority (DRA) in the areas of market authorization and licensing. It identified the needs for an improved QMS and building the staff capacity regarding vaccine knowledge (quality, safety, efficacy), vaccine registration, GMP and national AEFI guidelines and investigation. For the implementation of some of the activities the cooperation with the Thai FDA will be established ('south-south cooperation').
- 5) Capacity building and training for EPI staff
  - This includes in-service training to increase the quality of immunization knowledge of operational level health staff (EPI technicians, Village Health Workers).
- 6) National immunization policy guidance/ NCIP
  - The NCIP is formally well established and functional. However, it requires access to updated and frequent information on the benefits of vaccines and immunization to improve its decision making process (e.g. economic analysis for the introduction of new vaccines like Rota, PCV, JE).

### 3.4. Financial management of all cash grants

**New Vaccine Grants** – A sum of \$100,000 has been received for activities to support implementation of IPV introduction in 2015. No expenditures were reported in the 2014 APR f

**ISS Grants** – Not applicable

**HSS Grants** – A total grant sum of \$194,000 was approved in 2008, and the final tranche of funding of \$41,000 was disbursed to the country in 2014. No detailed reporting of HSS expenditures is detailed in the APR.

### 3.5. Recommended actions

Actions	Responsibility	Timeline	Potential financial resources needed and source(s) of funding
Follow up Implementation of Graduation Plan	Gavi Secretariat and Alliance Partners	2016	Internal resources of GAVI
Conduct EPI Coverage Survey	Gavi Alliance Partners	2015-2016	Will require resource mobilization
Conduct EVM Assessment (as recommended in APR and cMYP)	MoH/EPI program	Planned for September 2015	Will require resource mobilization (UNICEF through BP/ PEF)
Project Completion Report HSS	MoH with technical support from in country partners	End 2015	NA
Establish/expand AEFI surveillance systems, as well as Sentinel Surveillance Systems for rotavirus and pneumococcal and JE diseases (as recommended by NCIP)	MoH with technical support from WHO and other partners	Ongoing from 2014	Will require resource mobilization (AEFI surveillance system included in graduation grant)

## 4. TECHNICAL ASSISTANCE

### 4.1 Current areas of activities and agency responsibilities

The GAVI Secretariat provided technical support for conducting the graduation assessment in 2014 (in collaboration with WHO and UNICEF). WHO has been providing technical assistance recently for the development of an IPV introduction plan, and UNICEF supported the last EVM assessment.



Future needs for technical support are not clearly specified in the APR. However, the NCIP minutes and the graduation situation analysis indicate that strengthening of VPD surveillance including new vaccine related diseases and AEFI surveillance are important considerations. More discussion may be required at country level in order to specify the TA needs in these areas and avoid overlaps with the graduation grant activities.

UNICEF supported the last *EVM assessment*, and similar support may be required for the next assessment in 2015/16. Given that it is over 6 years since the last *EPI coverage survey*, technical assistance may be required to support the development of the next survey.

*Financial Sustainability*: The APR states that no technical assistance is currently required for financial sustainability. This is covered by the graduation grant.

## 5. ENDORSEMENT BY ICC, HSCC OR EQUIVALENT & ADDITIONAL COMMENTS

Brief description of how the joint appraisal was endorsed by the relevant national coordination mechanism:

JA report was provided to MoH and partners for comments. No additional NCC/ICC endorsement was requested.

Issues raised during debrief of joint appraisal findings to national coordination mechanism:

n/a

Any additional comments from

- Ministry of Health: none
- Partners: none
- Gavi Senior Country Manager: none

## 6. ANNEXES

- **Annex A. Key data** (this will be provided by the Gavi Secretariat)
- **Annex B. Status of implementation of the key actions from the last joint appraisal and any additional High Level Review Panel (HLRP) recommendations**

Not applicable in this context. This is the first time Bhutan has undertaken a Joint Appraisal or has been reviewed by the HLRP.

- **Annex C. Description of joint appraisal process** (e.g. team composition, how information was gathered, how discussions were held)

1. A consultant reviewed all of the relevant documentation for the JA including the APR, cMYP, Transition Situation Analysis and Plan, the most recent EVM, NCIP minutes and relevant financial management information submitted with the APR.
2. The draft was then reviewed by GAVI, MoH, WHO and UNICEF in Bhutan and regional offices (SEARO, ROSA).

- **Annex D. HSS grant overview**

General information on the HSS grant							
1.1 HSS grant approval date		2008 - 2012					
1.2 Date of reprogramming approved by IRC, if any		In 2013 the IRC recommended reprogramming of funds to cold chain procurement.					
1.3 Total grant amount (US\$)		\$194,000					
1.4 Grant duration		2008					
1.5 Implementation year		month/year – month/year					
(US\$ in million)	<b>2008</b>	<b>2009</b>	<b>2010</b>	<b>2011</b>	<b>2012</b>	<b>2013</b>	<b>2014</b>
1.6 Grant approved as per Decision Letter	\$194,000						
1.7 Disbursement of tranches	37,500	38,500		40,000			\$41,000
1.8 Annual expenditure	Not reported in APR						
1.9 Delays in implementation (yes/no), with reasons		Yes. Reasons not provided as yet awaiting HSS Completion report					
1.10 Previous HSS grants (duration and amount approved)		Nil					
1.11 List HSS grant objectives		To ensure sufficient capacity to supply adequate numbers of competent and motivated health care provider, who can provide the high quality primary health services needed to reduce maternal and child mortality.					
1.12 Amount and scope of reprogramming (if relevant)		The original grant proposal was for 2008-2012. In 2013, the IRC recommended the reprogramming of funds, with a refocussing of funds on cold chain and logistics procurement.					

- **Annex E. Best practices**

1. Bhutan is one of the highest coverage countries in Asia. Sustained high coverage has been achieved through implementation of a National Health

Policy and constitutional mandate to provide health services to all free of charge (universal health coverage strategy). Bhutan may illustrate a best practice case for sustaining of EPI through state tax based financing in a low income setting of an integrated PHC delivery system (health system platform for EPI).

2. The Bhutan Health Trust Fund provides an innovative and rare case to establish an alternative financing mechanisms to sustain immunization financing beyond the period of GAVI support. Although shortcomings have been identified with the approach in the Graduation Assessment, it may provide a valuable case study for potential replication in other graduating country settings. This is a compelling reason for the Gavi Alliance and Secretariat to track the initiative post-graduation status.