



GAVI/13/565/ap/rk
The Minister of Health
Ministry of Health
Bhutan

21 October 2013

Dear Minister,

Annual Progress Report submitted by Bhutan

I am writing in relation to Bhutan's Annual Progress Report (APR) which was submitted to the GAVI Secretariat in May 2013.

Following a meeting of the GAVI Independent Review Committee (IRC) from 15 to 26 July 2013 to consider your APR, I am pleased to inform you that the GAVI Alliance has approved Bhutan for GAVI support as specified in the Appendices to this letter.

The following table summarises the outcome for each type of GAVI support for Bhutan:

Type of support	Appendix	Approved for 2014
NVS Pentavalent	B	US\$57,500

The Appendices includes the following important information:

Appendix A: Description of approved GAVI support to Bhutan

Appendix B: Financial and programmatic information per type of support

Appendix C: A summary of the IRC Report

Appendix D: The terms and conditions of GAVI Alliance support

Please do not hesitate to contact my colleague Ranjana Kumar at rkumar@gavialliance.org or email gavihss@gavialliance.org if you have any questions or concerns.

Yours sincerely,

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

Hind Khatib-Othman
Managing Director, Country Programmes



cc: The Minister of Finance
 The Director of Medical Services
 Director Planning Unit, MoH
 The EPI Manager
 WHO Country Representative
 UNICEF Country Representative
 Regional Working Group
 WHO HQ
 UNICEF Programme Division
 UNICEF Supply Division
 The World Bank



Appendix A

Description of GAVI support to *Bhutan* (the “Country”)

New Vaccines Support (NVS)

The GAVI Alliance has approved the Country’s request for supply of vaccine doses and related injection safety material which are estimated to be required for the immunization programme as set out in Appendix B. Financing provided by GAVI for vaccines will be in accordance with:

- The GAVI Alliance Guidelines governing Country’s Annual Progress Report (APR); and
- The APR as approved by the the Independent Review Committee (IRC), including any subsequent clarifications.

The vaccines provided will be used as the country has proposed. The principles of the WHO-UNICEF-UNFPA joint statement on safety of injections (WHO/V&B/99.25) shall apply to all immunisation provided with these vaccines.

Item number 11 of Appendix B summarises the details of the approved GAVI support for vaccines in the years indicated.

Any required taxes, customs, toll or other duties imposed on the importation of vaccines and related supplies can not be paid for using GAVI funds.

GAVI is not responsible for any liability that may arise in connection with the distribution or use of vaccines and related supplies after title to such vaccines and related supplies has passed to the country, excluding liability for any defect in vaccines and related supplies, which remain the responsibility of the applicable manufacturer.

Country Co-financing

In accordance with the GAVI Co-financing Policy, the Country has agreed to make the required contribution to co-financing vaccine doses as indicated in Appendix B. Item number 14 of Appendix B summarises the budget and the quantity of supply that will be procured with country’s funds in the corresponding timeframe. The total co-financing amount indicates costs for the vaccines, related injection safety devices (only applicable to intermediate and graduating countries) and freight.

Countries may select to co-finance through UNICEF Supply Division, PAHO’s Revolving Fund, or self-procure their co-financing requirement following their own procedures, except for the Pneumococcal vaccine that needs to be procured through UNICEF.

If the purchase of the co-financed supply is carried out through UNICEF or PAHO, the payment is to be made to UNICEF or PAHO (whichever is applicable) as agreed in the Procurement Services Memorandum of Understanding between UNICEF or PAHO (whichever is applicable) and the country, and not to the GAVI Alliance. Please keep in contact with UNICEF or PAHO (whichever is applicable) to understand the availability of the relevant vaccine(s) and to prepare the schedule of deliveries.



The total co-financing amount expressed in item number 14 of Appendix B does not contain costs and fees of the relevant Procurement Agency, such as contingency buffer and handling fees.

Information on these extra costs and fees will be provided by the relevant Procurement Agency as part of the cost estimate to be requested by the country. UNICEF/PAHO will share information with GAVI on the status of purchase of the co-financed supply. In accordance with the GAVI Co-financing Policy (<http://www.gavialliance.org/about/governance/programme-policies/co-financing/>), the co-financing contribution is payable annually to UNICEF/PAHO.

If the purchase of the co-financed supply is carried out by the Government, following its own procurement procedures and not procuring from UNICEF Supply Division or PAHO's Revolving Fund, the Government must submit to GAVI satisfactory evidence that it has purchased its co-financed portion of the vaccines and related supplies, including by submitting purchase orders, invoices, and receipts to GAVI. GAVI encourages that countries self-procuring co-financed products (i.e. auto-disable syringes and syringe and needle disposal boxes) ensure that products appear on the applicable WHO list of pre-qualified products or, for syringe and needle disposal boxes, that they have obtained a certificate of quality issued by a relevant national authority.

GAVI support will only be provided if the Country complies with the following requirements:

Transparency and Accountability Policy (TAP): Compliance with any TAP requirements pursuant to the GAVI TAP Policy and the requirements under any Aide Memoire concluded between GAVI and the country.

Financial Statements & External Audits: Compliance with the GAVI requirements relating to financial statements and external audits.

Grant Terms and Conditions: Compliance with GAVI's standard grant terms and conditions (attached in Appendix D).

Country Co-financing: GAVI must receive proof of country co-payment from the Country such as invoices or shipment receipts if neither UNICEF nor PAHO is the procurement agent for country co-financed vaccine for the prior calendar year.

Monitoring and Annual Progress Reports: «Country's» use of financial support for the introduction of new vaccinations with the vaccine(s) specified in Appendix B is subject to strict performance monitoring. The GAVI Alliance uses country systems for monitoring and auditing performance and other data sources including WHO/UNICEF immunization coverage estimates. As part of this process, National Authorities will be requested to monitor and report on the numbers of children immunised and on co-financing of the vaccine.

Country will report on the achievements and request support for the following year in the Annual Progress Report (APR). The APR must contain information on the number of children reported to have been vaccinated with DTP3 and 3 doses of pentavalent vaccine by age 12 months, based on district monthly reports reviewed by the Immunisation Coordination Committee (ICC), and as reported to WHO and UNICEF in the annual Joint Reporting Form (JRF). The APRs will also contain information on country's compliance with the co-financing



arrangements outlined in this letter. APRs endorsed by the ICC, should be sent to the GAVI Secretariat no later than 15 May every year. Continued funding beyond what is being approved in this letter is conditional upon receipt of satisfactory Annual Progress Reports and availability of funds.

Bhutan VACCINE SUPPORT

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

1. Country: Bhutan				
2. Grant Number: 1415-BTN-04a-X				
3. Date of Decision Letter: 21 October 2013				
4. Date of the Partnership Framework Agreement: Not applicable				
5. Programme Title: New Vaccine Support				
6. Vaccine type: Pentavalent				
7. Requested product presentation and formulation of vaccine: DTP-HepB-Hib, 1 dose(s) per vial, LIQUID				
8. Programme Duration¹: 2009-2015				
9. Programme Budget (indicative) (subject to the terms of the Partnership Framework Agreement):				
	2009-2013	2014	2015	Total ²
Programme Budget (US\$)	US\$402,776 ³	US\$57,500	US\$38,500	US\$498,776
10. Vaccine Introduction Grant: Not applicable				

¹ This is the entire duration of the programme.

² This is the total amount endorsed by GAVI for the entire duration of the programme. This should be equal to the total of all sums in the table.

³ This is the consolidated amount for all previous years.

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	2009-2013	2014
Number of Pentavalent vaccines doses		20,100
Number of AD syringes		21,300
Number of re-constitution syringes		
Number of safety boxes		250
Annual Amounts (US\$)	US\$402,776 ⁵	US\$57,500
12. Procurement agency: UNICEF. The Country shall release its Co-Financing Payments each year to UNICEF.		
13. Self-procurement: Not applicable		
14. Co-financing obligations: Reference code: 1415-BTN-04a-X-C According to the Co-Financing Policy, the Country falls within the group Graduating. 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	2014	2015
Number of vaccine doses	25,000	32,900
Number of AD syringes	26,500	
Number of re-constitution syringes		
Number of safety boxes	325	
Value of vaccine doses (US\$)	US\$63,192	
Total Co-Financing Payments (US\$) (including freight)	US\$71,500	US\$93,000
15. Operational support for campaigns: Not applicable		
16. Additional documents to be delivered for future disbursements: The Annual Progress Report 2013 is due by 15 May 2014		
17. Financial Clarifications: Not applicable		

⁴ This is the amount that GAVI has approved.

⁵ This is the consolidated amount for all previously approved years.



18. Other conditions: Not applicable

Signed by,
On behalf of the GAVI Alliance

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

Hind Khatib-Othman
Managing Director, Country Programmes
21 October 2013

IRC NVS COUNTRY REPORT

Geneva, 19 July 2013

Type of report: Annual Progress Report

Country: Bhutan

Reporting period: 2012

Date reviewed: 19 July 2013

1. Background Information

Surviving Infants (2012): UNDP: 14,293; JRF: 13,628

DTP3 coverage (2012):

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-

JRF Official Country Estimate: 97%

WHO/UNICEF Estimate: 97%

Table 1. NVS and INS Support

NVS and INS support	Approval Period
DTP-HepB (Tetra)	2003 – 2010
DTP-HepB-Hib (Penta)	2009 – 2013
HSS	2008 – 2014
INS	2003 - 2005

Table 2. Cash Support

Cash support	Approval Period
HSS	2008 – 2012
Vaccine introduction grant	2002 and 2004
CSO Type A	N/A
CSO Type B	N/A

2. Composition and Functioning of Inter-agency Coordinating Committee (ICC) / Health Sector Coordinating Committee (HSCC)

ICC held 2 meetings in 2012, with minutes available from the September meeting. In lieu of the ICC the NCIP (National Committee for Immunisation Practice) conducted 2 meetings and minutes were provided. The members are mainly the Directorate General of Public Health, relevant division members and representatives from WHO and UNICEF. The key recommendations made by the ICC was to appropriate some funds from HSS support for the procurement of refrigerators and training of vaccine inspectors from the Drug Regulatory Authority of Bhutan. Around US\$ 18,000 will be needed for this purpose. Also discussed was the possibility of vaccine introduction (rotavirus and pneumococcal) into the routine immunization program. The introduction of the flu vaccine in response to the annual burden of seasonal occurring flu is also being discussed. An immunization coverage survey will be conducted with the National Health Survey in Nov 2012. CSO involvement is stated, but no

names of Tarayana Foundation members were visible on signature sheets. The APR 2012 was signed by both ministries of health and finance.

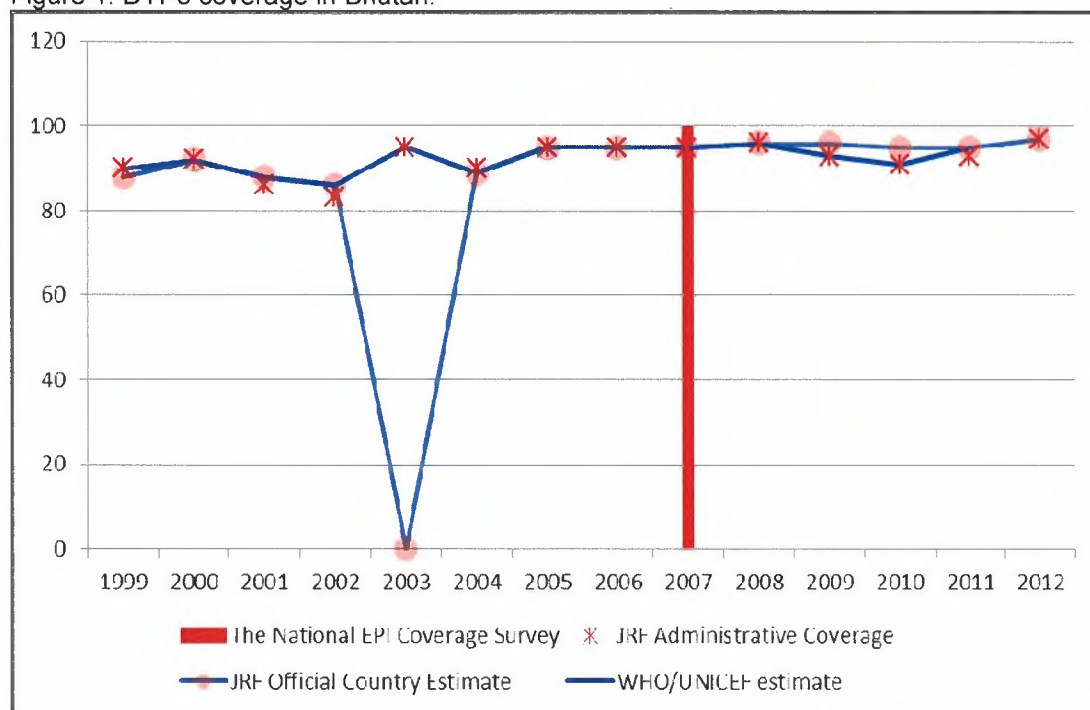
3. Programme and Data Management

Bhutan conducted in 2012 a catch-up campaign for all floating population. BHUs and CHUs in hospitals were reviewed monthly by the unit heads on immunisation related to issues of coverage, dropout rate and any existing discrepancy data for the activity. A quarterly review was conducted by the DHO. Half yearly a review is performed by the National Immunisation Program and Health Information Management System and HIMs and feedback is generated for improvement. The APR states the constant and consistent dialogue with the stakeholders. Also, CSOs are strategically involved (NGO/INGOs) for acceleration in campaigns and support.

There was no assessment of the administrative data and no major activities or plans to be undertaken to improve the administrative data systems from 2010 to present.

DTP3 coverage for both JRF and WHO/UNICEF estimate is consistently high, in 2012 at 97% [see Figure 1]. Differences in reported estimates result from discrepancies between HMIS and Districts level data and mobile population for immunization services. Wastage is kept at a minimum standard (<5%); and no cold chain issues were reported.

Figure 1: DTP3 coverage in Bhutan:



Challenges to program performance stated in the 2011 APR included shortage of human resources, remote populations, donor dependence, and financial sustainability (despite the launch of Health Trust Fund and an Adverse Event Following Immunization (AEFI) observed after the initial introduction of pentavalent vaccine). Though most of the issues were obviously tackled effectively, others may remain, suggesting some country-tailored approach to support Bhutan in its graduating process.

4. Gender and Equity Analysis



Bhutan implemented district wise mapping of hard to reach population areas which are underserved by the immunisation program. In addition, a catch up campaign was conducted to ensure all floating population is reached. Gasa is the only district that reports immunisation coverage below 80%. This is due to sparse population living in the mountains and consistent migrating population for economic reasons. There is no sex-disaggregated data collection and no plan to do so in the future because the country's immunisation program provides access to immunisation services irrespective of sex.

5. Immunisation Services Support (ISS)

Not applicable

6. New and under-utilised Vaccines Support (NVS)

Pentavalent vaccines (DTP-HepB-Hib) 1 dose vials presentation, liquid

The total doses for 2012 as per the DL (33,600) does not correspond with the 48,127 the country reports on in the APR. The country reported 45,600 doses were delivered in 2012, as well 12,000 co-financing doses (the balance of 2,600 co-financing doses will be procured in 2013 as was noted on the APR as quantity postponed). According to UNICEF's record, 33,600 doses were delivered in 2012, as well as 12,000 co-financed doses. The secretariat is following up data correction/adjustment. There were no stock-outs and over-stocks in 2012; no introduction of new vaccines in 2012. Bhutan does not require changing any of the vaccine presentation for the future years.

Year 2013 is the last year of GAVI support for Penta and the country is requesting for extension of GAVI support from 2014 to 2015. An addendum to cMYP 2009-2013 was submitted to GAVI. New funding requirement for Penta from 2014 to 2015 is US\$ 56,500 and US\$ 73,000 respectively. A new cMYP for 2014-2018 will be prepared on 16 July 2013 with WHO support which will be submitted to GAVI. PIE was not conducted and is planned in October 2016.

EVM assessment was conducted from 15 October to 06 November 2012. Storage capacity for all the four levels of the cold chain system is very impressive particularly at the BHU level. Major improvement activities are as follows: a) temperature monitoring study; b) continuous temperature monitors; c) sop and maintenance plan preparation workshop; d) temperature mapping of current domestic refrigerators and updating guidelines; e) freeze tag procurement for all vaccine transports; f) additional cold room procurement; and g) solar refrigerator equipment testing. Other EVM criteria that need improvement will be addressed in the Improvement Plan.

2014 vaccine request:

Pentavalent vaccines (DTP-HepB-Hib) 1 dose vials presentation, liquid

No stock-outs and over-stocks in 2012. Bhutan does not require changing any of the vaccine presentation for the future years.

The cMYP ends in 2015; whereby the country requests for an extension of GAVI support for Pentavalent vaccines, 1 dose per vial, liquid for 2014 and 2015 with the commitment of co-financing.

Year 2013 is the last year of GAVI support for Penta and the country is requesting for extension of GAVI support from 2014 to 2015.

7. Vaccine Co-financing, Financial Sustainability and Financial Management



Bhutan falls into the graduating country co-financing group. The co-financing amount for pentavalent vaccine doses, AD syringes and Safety Boxes increases from USD\$ 0.30 in 2011, to USD\$ 0.88 in 2012 which was higher than the required level of co-financing. The level of co financing in 2013 is in line with the minimum requirement. The country is considered a strong performer and has not defaulted on its co-financing obligations since 2009.

New and underused vaccines are funded by GAVI and Country, whereas vaccines for routine EPI are funded by Japan Committee of Vaccines for World Children (JCV). In future cost of these vaccines will be funded by Bhutan Health Trust Fund (BHTF). GAVI, WHO and Sabin Institute in 2012 developed an action plan from an Aide Memoire.

8. Injection Safety Support (INS) and Adverse Events Following Immunisation Systems

Bhutan has an injection safety plan. Some issues of AD syringes re-capping of needles were reported; whereby the standard guideline states that the re-capping of used syringes is not to be practiced.

The country has also a waste management system implemented, in which sharp waste is incinerated, burned and buried. There is a functional AEFI system in place, which is closely followed by the NCIP.

As per APR 2012, no sentinel surveillance exists for rotavirus diarrhoea or for paediatric bacterial meningitis. However, the NITAG (National Immunisation Technical Advisory Group) or ICC regularly reviews the sentinel surveillance and additional activities in surveillance and further training is planned for 2013. These sentinel surveillance are also utilised for monitoring and evaluating the impact of common vaccine introduction.

9. Health Systems Strengthening (HSS)

Not applicable.

10. Civil Society Organization Type A/Type B (CSO)

Not applicable

11. Risks and mitigating factors

Some risks in the light of information gaps. Mitigating factors in all actions and activities seemed to be well discussed and planned for in advance with the relevant stakeholders.

12. Summary of 2012 APR Review

The IRC acknowledges the country's overall efforts on routine immunisation and the re-introduction of the pentavalent vaccine, as we recognise the challenge for the staff from EPI and Ministry of Health to regain the people's confidence in the vaccine following its suspension due to AEFI. Implementation of the improvement plan will result Bhutan being cold chain compliant.

13. IRC Review Recommendations

- ISS

Not applicable, country is not eligible for a reward.

- NVS

Pentavalent (DTP-HepB-Hib) 1 dose per vial, liquid:



Approve 2014 NVS support based on country request target.
Approve for the extension of Penta from 2014-2015.

- **HSS**
Not applicable.

14. Clarification Required with Approved Funding

Short-term clarifications

N/A

15. Request Re-submission of APR HSS Section (if applicable)

The country is requested to submit the HSS section and duly report on 2012 HSS fund use and activities.

16. Other issues

Not applicable



Appendix D

GAVI Alliance Terms and Conditions

Countries will be expected to sign and agree to the following GAVI Alliance terms and conditions in the application forms, which may also be included in a grant agreement to be agreed upon between GAVI and the country:

FUNDING USED SOLELY FOR APPROVED PROGRAMMES

The applicant country ("Country") confirms that all funding provided by the GAVI Alliance for this application will be used and applied for the sole purpose of fulfilling the programme(s) described in this application. Any significant change from the approved programme(s) must be reviewed and approved in advance by the GAVI Alliance. All funding decisions for this application are made at the discretion of the GAVI Alliance Board and are subject to IRC processes and the availability of funds.

AMENDMENT TO THIS PROPOSAL

The Country will notify the GAVI Alliance in its Annual Progress Report if it wishes to propose any change to the programme(s) description in this application. The GAVI Alliance will document any change approved by the GAVI Alliance, and this application will be amended.

RETURN OF FUNDS

The Country agrees to reimburse to the GAVI Alliance, all funding amounts that are not used for the programme(s) described in this application. The country's reimbursement must be in US dollars and be provided, unless otherwise decided by the GAVI Alliance, within sixty (60) days after the Country receives the GAVI Alliance's request for a reimbursement and be paid to the account or accounts as directed by the GAVI Alliance.

SUSPENSION/ TERMINATION

The GAVI Alliance may suspend all or part of its funding to the Country if it has reason to suspect that funds have been used for purpose other than for the programmes described in this application, or any GAVI Alliance-approved amendment to this application. The GAVI Alliance retains the right to terminate its support to the Country for the programmes described in this application if a misuse of GAVI Alliance funds is confirmed.

ANTICORRUPTION

The Country confirms that funds provided by the GAVI Alliance shall not be offered by the Country to any third person, nor will the Country seek in connection with this application any gift, payment or benefit directly or indirectly that could be construed as an illegal or corrupt practice.

AUDITS AND RECORDS

The Country will conduct annual financial audits, and share these with the GAVI Alliance, as requested. The GAVI Alliance reserves the right, on its own or through an agent, to perform audits or other financial management assessment to ensure the accountability of funds disbursed to the Country.

The Country will maintain accurate accounting records documenting how GAVI Alliance funds are used. The Country will maintain its accounting records in accordance with its government-approved accounting standards for at least three years after the date of last disbursement of GAVI Alliance funds. If there is any claims of misuse of funds, Country



will maintain such records until the audit findings are final. The Country agrees not to assert any documentary privilege against the GAVI Alliance in connection with any audit.

CONFIRMATION OF LEGAL VALIDITY

The Country and the signatories for the government confirm that this application is accurate and correct and forms a legally binding obligation on the Country, under the Country's law, to perform the programmes described in this application.

CONFIRMATION OF COMPLIANCE WITH THE GAVI ALLIANCE TRANSPARENCY AND ACCOUNTABILITY POLICY

The Country confirms that it is familiar with the GAVI Alliance Transparency and Accountability Policy (TAP) and will comply with its requirements.

ARBITRATION

Any dispute between the Country and the GAVI Alliance arising out of or relating to this application that is not settled amicably within a reasonable period of time, will be submitted to arbitration at the request of either the GAVI Alliance or the Country. The arbitration will be conducted in accordance with the then-current UNCITRAL Arbitration Rules. The parties agree to be bound by the arbitration award, as the final adjudication of any such dispute. The place of arbitration will be Geneva, Switzerland. The language of the arbitration will be English.

For any dispute for which the amount at issue is US\$ 100,000 or less, there will be one arbitrator appointed by the GAVI Alliance. For any dispute for which the amount at issue is greater than US \$100,000 there will be three arbitrators appointed as follows: The GAVI Alliance and the Country will each appoint one arbitrator, and the two arbitrators so appointed will jointly appoint a third arbitrator who shall be the chairperson.

The GAVI Alliance will not be liable to the country for any claim or loss relating to the programmes described in this application, including without limitation, any financial loss, reliance claims, any harm to property, or personal injury or death. Country is solely responsible for all aspects of managing and implementing the programmes described in this application.

USE OF COMMERCIAL BANK ACCOUNTS

The eligible country government is responsible for undertaking the necessary due diligence on all commercial banks used to manage GAVI cash-based support, including HSS, ISS, CSO and vaccine introduction grants. The undersigned representative of the government confirms that the government will take all responsibility for replenishing GAVI cash support lost due to bank insolvency, fraud or any other unforeseen event.