DECISION LETTER FOR CASH SUPPORT

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

1. **Country:** Bhutan
2. **Grant number:** 15-BTN-27a-Y
3. **Date of the Decision Letter:** 13 August 2015
4. **Date of the Partnership Framework Agreement:** 16 May 2014
5. **Programme Title:** Graduation Grant
6. **Monitoring and Reporting Requirements:** Gavi shall periodically review the challenges and assess the progress of implementing the Graduation Grant through established mechanisms such as annual joint appraisals. Bhutan shall cooperate with Gavi during these appraisals and provide the information necessary to assess its performance.
7. **Programme Duration:** 2015
8. **Programme Budget (indicative) (subject to the terms of the Partnership Framework Agreement):**

Programme Year	2015	**Total**[1]
Programme Budget (US$)	US$ 245,930	US$ 245,930

9. **Indicative Annual Amounts (indicative) (subject to the terms of the Partnership Framework Agreement):**

Programme Year	2015	Total
Annual Amount(s) (US$)	US$ 245,930	US$ 245,930

10. **Clarifications:** Not applicable.
11. **Other conditions:** Not applicable.

Signed by (on behalf of Gavi):

Hind Khatib-Othman
Managing Director, Country Programmes
13 August 2015

[1] This is the total amount endorsed by Gavi for the entire duration of the programme.

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Appendix A

Gavi-GRADUATION SITUATION ANALYSIS

BHUTAN 2014

Mission from the 10th to the 18th of September 2014

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List of Acronyms

AFP: Acute Flaccid Paralysis

ANM: Auxiliary Nurse Midwives

BHTF: Bhutan Health Trust Fund

BHU: Basic Health Units

BHW: Basic Health Workers

cMYP: comprehensive Multi-Year Plan

DTP: Diphtheria Tetanus Pertussis

EPI: Expanded Program in Immunization

FYP: Five-Year Plan

GIVS: Global Immunization Vision and Strategy

GNH: Gross National Happiness

GNI: Gross National Income

HA: Health Assistants

Hep B: Hepatitis B

Hib: Haemophilus Influenza type B

JCV: Japan Committee "Vaccines for the World's Children"

JE: Japanese Encephalitis

MDG: Millennium Development Goals

NCIP: National Committee on Immunization Practices

NID: National Immunization Day

ORC: Outreach Clinics

QMS: Quality Managements System

RGoB: Royal Government of Bhutan

SNID: Sub-National Immunization Day

TT: Tetanus toxoid

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VHW: Volunteer Health Workers

VPD: Vaccine Preventable Disease

VPDP: Vaccine Preventable Disease Program

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Executive summary

Bhutan received different kinds of support from GAVI since 2002 (Health System Strengthening, Injection Safety support, Tetravalent, Pentavalent and IPV support as well as Vaccine Introduction Grants). Currently, the remaining support from GAVI to the country is for the Pentavalent vaccine (received since 2011), which will be co-funded until the end of 2015.

The country entered Graduation in 2011, meaning that the country has been linearly increasing the Pentavalent vaccine co-financing since 2012 and until financing 100% of vaccines by 2016.

Consequently, the Graduation period was used to identify the key activities to implement before the end of Gavi support in the country, and to ensure the country capacity to financially and technically support access to vaccines. A first Transition plan was identified in 2012, and the review of the Bhutan Health Trust Fund (BHTF) was conducted in 2013. In September 2014 (10-18 / 09 / 2014), a "Graduation" mission was conducted to identify and cost a Graduation plan for 2015 (briefly presented below). The Graduation grant is mainly financed by Gavi, with some support from the government.

Table 1. Graduation process in Bhutan

	2011	2012	2013	2014	2015	2016
Pentavalent Vaccine support	1st year support	Graduation period: linear increase in the Pentavalent vaccine co-financing				The country finances 100% of the Pentavalent vaccine
Graduation process	1st year Graduation	Transition plan	BHTF Review	Costed Graduation Plan	Implemen-tation of the Graduation plan	

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Table 2. Summary of the Graduation plan in Bhutan

Main areas of intervention	Main challenges	Identified strategies	Total cost (in US$)
Financing of immunization	The BHTF is able to finance current traditional vaccines and Pentavalent (excluding HPV): what about **new vaccines** to introduce (JE, PCV, Rota, HepB adults) and **essential drugs** just added to the BHTF responsibilities.	- De-link BHFT from MoH with new governance and organization - Develop and approve 5 year plan that includes needs, costs and impact - Develop and implement Resource Mobilization Strategy	2,000
Procurement and supply chain of vaccines	Ensuring that the MoF approves the exception of **using UNICEF SD** after graduation Continuing investments and activities regarding the already identified **needs of the Cold Chain**	<u>Procurement:</u> - Provide a technical note presenting cost-benefits results for using UNICEF SD <u>Cold chain:</u> - Temperature monitoring study - Use of findings from Temperature Mapping study; - Staff training (i) computerized temperature recorder (ii) Pre-service training for 5 EPI-Medical technician/logisticians; - Procurement of cold chain equipment (fridges and walk-in cold room).	124,753
Crisis communication strengthening	Prepare for **communications "issues management"** in the event of AEFIs or rumours / misinformation AND **Promote health worker confidence** in the safety of vaccines	- Develop a crisis communication plan defining roles and responsibilities as well as standard operating procedures and build capacity in MOH to manage communications around suspected AEFIs. - Outreach to health workers / vaccinators and pediatricians to reinforce key messages, providing them with job aids to deliver	50,000

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		messages to mothers/caregivers.	
National Regulatory Strengthening	Absence of **Quality Management System**; need for **NRA staff capacity** building; and need for **AEFI system strengthening**	- Build QMS in DRA - Technical cooperation between Bhutan DRA and Thai FDA - Build vaccine specific knowledge in registration, and GMP for vaccines - Strengthen the AEFI system (update manuals, training, ...)	53,000
Capacity building and training	The **lack of in-service training** reduce quality of knowledge in the immunization area	- Develop facilitated in-service training such as e-learning activities for API technicians	20,000
Decision making	Lack of **access to update data** and difficulties to produce economic evaluation for decision-making process	Ensure that the NCIP have access to updated and frequent information and can benefit from comprehensive economic analyses in order to improve its decision making process	10,000
		TOTAL Graduation plan =	**259,753**

The present report details the different characteristics of the immunization program in Bhutan, the Graduation-related challenges and the activities identified during the Graduation mission to implement in 2015.

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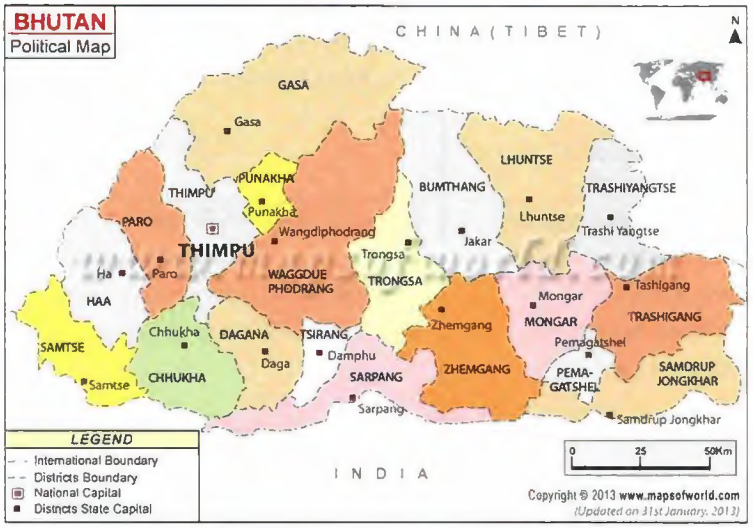
1. Country context and situation analysis

1.1. Geography, population and demographics

The Kingdom of Bhutan is a small landlocked country in South Asia, located in the eastern Himalayas and bordered by India and China. The Kingdom is home to an estimated population of 765,552 in 2014, spread between 20 Dzongkhags (districts), which are further divided into 205 Gewogs (blocks). Each Dzongkhag is headed by a Dzongda (governor) appointed by the central government. The Dzongda is responsible for overseeing the implementation of all socio-economic development activities in the Dzongkhag.

Figure 1. Map of Bhutan



1.2. Economic and financial trends and challenge

Bhutan's economy, one of the world's smallest and least developed, is based on agriculture and forestry, which constitutes the main source of livelihood for over 60% of the population**.** The economy is closely aligned with India's, through strong trade and monetary links. Education, social, and environment programs are underway with support from multilateral development organizations. Each economic program takes into account the government's desire to protect the country's environment and cultural traditions.

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New hydropower projects are the driving force behind Bhutan's ability to create employment and sustain growth in the coming years[2]. While the country's rapid economic expansion has been attributed to the hydropower sector, Bhutan's actual GDP growth has not followed projections based on the acceleration in hydropower-related construction. Thus, instead of a projected growth rate of 12.5% in 2013, GDP was estimated at 4.5%[3]. On the other hand, per capita Gross National Income (GNI) is one of the highest in South Asia and has consistently risen from $780 in 2000 to $2,460 in 2013. Inflation has also risen, reaching 13.5% in the second quarter of 2012, with both food and non-food components accelerating. Bhutan's medium-term outlook is favorable, as growth should remain strong at around 8%–9%, driven by hydropower, manufacturing, and domestic services.[4]

1.3. Political and institutional capacities and issues

The country has seen significant political changes and transitions in recent years, until the adoption of its first modern constitution in 2008. Bhutan's political system has evolved from an absolute monarchy to a constitutional monarchy, following a decade of planning and consultations. After 34 years on the throne, the Fourth King, Jigme Singye Wangchuck, stepped down on December 9, 2006, in favor of his son, Jigme Khesar Namgyel Wangchuck. The Constitution was prepared, following a process led by the Chief Justice, which involved widespread public consultations within Bhutan and the international community. The new democratic system comprises a National Council and a National Assembly, the latter based on political party affiliations. Elections for the National Council were held on December 31, 2007, while elections for the National Assembly were held on March 24, 2008.[5] Parliamentary elections were held again in July 2013, and the opposition People's Democratic Party won 32 seats in the lower house, against the incumbent Druk Phuensum Tshogpa party's 15 seats[6]. Today, Tshering Tobgay is the Prime Minister of the new government[7].

1.4. Social and health system development and outcomes

a. Development indicators in Bhutan

Overall, Bhutan's development has been rapid. Until the 1950s, Bhutan was largely isolated from the rest of the world. Since the 1960s, the country began to gradually open up and develop, based

[2] http://unohrlls.org/meetings-conferences-and-special-events/bhutan/
[3] Note that Bhutan exports most of its production of electricity. Because of a probable lack of forecasting capacities, it happened that Bhutan had to buy electricity back to India during winter.
[4] http://www.worldbank.org/en/country/bhutan/overview
[5] http://www.worldbank.org/en/country/bhutan/overview
[6] http://www.bbc.com/news/world-south-asia-12641778
[7] http://www.tourism.gov.bt/about-bhutan/political-system-of-bhutan

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on a series of five-year development plans. The Eleventh Five-Year Plan (FYP) (2014-2018) is currently under implementation and constitutes the basis for the country's Poverty Reduction Strategy Program.

Bhutan is characterized by good progress in human development, particularly in urban areas. The poverty rate has fallen from 36% in 2000 to 23% in 2007 and down to 12% in 2012[8]. However, progress has been slower to reach Bhutan's more remote areas. Poor road access isolates a large proportion of the rural population from markets and social services, and limits their livelihood to subsistence agriculture. To address this constraint, the Royal Government of Bhutan (RGoB) and development partners have built over 1,500 kilometers of farm roads and tracks since 2003. As a result, the proportion of rural population residing within one hour and within six hours walking distance of a road has increased from 40% to 53%, and from 84% to 90% respectively between 2000 and 2008.

Over the past decade, social indicators have largely improved. With a national 0.36 Gini index[9], and insignificant variance in equity between rural (0.34) and urban (0.35) areas, Bhutan shows good results in terms of equity. Health-related Millennium Development Goals (MDGs) have been achieved (as discussed in further detail in the following section), and life expectancy at birth has risen from 65 years in 2005 to 69 years in 2010. Literacy and education enrolment rates have also improved, with a net enrolment rate in primary schools of 89% in 2010. Unlike much of the rest of South Asia, primary school enrolment among girls is higher than among boys in many urban areas. Nationwide, almost half of primary school students are girls. However, unemployment among youth, which comprise almost 59% of the population, is growing. Adequate job creation among this group will depend on robust private sector development, combined with initiatives to increase skills and employability.[10]

[8] Bhutan Poverty Analysis report 2012
[9] The Gini coefficient is a commonly used indicator of inequality between quintiles of population (based on consumption), and ranges between 0 to 1 (with zero meaning perfect equality and one meaning perfect inequality).
[10] http://www.worldbank.org/en/country/bhutan/overview

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b. *National health system and policy*

Ensuring access to healthcare is one of the government's top priorities. The concept of health in Bhutan must be understood in the context of the country's overall development strategy that defines development as the preservation of spiritual and emotional as well as economic well-being. Therefore, the national health sector policy objectives reflect the national ones: equity, social justice, sustainability and efficiency, in the context of the preservation of national culture.

Bhutan adopted a Primary Health Care (PHC) approach for the delivery of healthcare services in 1979. Currently, healthcare is provided through a network of 32 hospitals, 205 Basic Health Units (BHUs), 23 sub-posts and 519 outreach clinics (ORCs) spread over 205 gewogs (blocks)[11]. These facilities are staffed by doctors, nurses, paramedics and technicians (with 3 health workers per BHU). At the community level, village-based Volunteer Health Workers (VHW) assist regular health staff in reaching out to the communities. Basic health care services and essential medicines are provided free of charge to all Bhutanese citizens and foreign nationals working or visiting Bhutan.

Healthcare is at the forefront of the decentralization policy, which was initiated by the RGoB in 1981. Today, the health system is fully decentralized to the dzongkhags, with all primary healthcare programs integrated into the dzongkhag healthcare delivery system. Today, over 90% of the population has access to healthcare services. The challenge remains in reliably covering sparsely populated districts. The Ministry of Health (MoH) has expressed full commitment to extend access to healthcare to these hard-to-reach populations.

c. *Health outcomes*

Bhutan has achieved (and sometimes over achieved) health-related MDGs. Many of the health-related MDGs have been met – several already by 2005. Infant mortality fell to 30 per thousand live births in 2013, and child mortality was down to 37 in 2013, against the MDG targets of 30 and 41, respectively. The proportion of the population with access to safe drinking water rose to 84% in 2005, again exceeding the MDG target a decade in advance. Three out of four pregnant women in Bhutan make the minimum four or more antenatal visits, and over 75% of pregnant women deliver with the assistance of health workers. Immunization coverage now extends to over 95% of all children.

[11] MoH. Annual Health Bulletin, 2014

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Table 3. Health-related MDG's progress review

Health MDG indicators	1990	2000	2012 /2013	Target 2015	Status
Under-five Mortality Rate (per 1,000 live births)	123	84	37.3	41	Over achieved
Infant Mortality Rate (per 1,000 live births)	90	60.5	30	30	Achieved
Proportion of one year old children covered under immunization program	84%	85%	95%	95%	Over achieved
Maternal Mortality Rate (per 100,000 live births)	560	255	86	140	Over achieved
Proportion of births attended by skilled health personnel	15%	24%	75%	100%	Over achieved

Source: Annual Health Bulletin 2014 and MDG's midway progress report 2008

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1.5. Current key challenges and opportunities

Box 1. Risks and challenges in the Health Sector identified in the cMYP 2014-2018

1. **Shortage of human resources**: "As the government's own fund is limited, the ministry relies much on collaborating partners to develop human resources for health. However, as many collaborating partners do not want to commit funds for long-term training, it will take a long time to achieve self-sufficiency in human resources for health and unless the gap in this key component is filled, the programs will continue to suffer"
2. **Geography and scattered settlement**: In order to overcome this problem, the Government, with support from WHO, initially started the solar-powered radio communication system to link the basic health units (BHUs) to the district hospitals. To complement this initiative, the government has then embarked upon the telemedicine program in collaboration with WHO and the Japanese government. Slow results also explained by the development of telecommunication at the same time, but motivating results.
3. **Dependency on imports for all products**: Even if the quality of drugs and vaccines can be assured by purchasing them from WHO authenticated suppliers in the region, hospital equipment and other supplies remain to be a problem.
4. **Shift from coverage to quality of services**: the whole of next five years will be devoted to setting and implementing standards of services and facilities and working towards fulfilling them.

2. Immunization performance and challenges

2.1. Immunization policy, priorities and challenges

The Expanded Program on Immunization (EPI) was first launched in the country in 1979 for seven Vaccine Preventable Diseases (VPD). The EPI's objective was to reduce morbidity and mortality from tuberculosis, diphtheria, pertussis, tetanus, polio, measles and hepatitis B. Tetanus Toxoid (TT) immunization of pregnant women was introduced in 1983 and a National Plan of Action for the acceleration of EPI was launched in 1987. Strong government commitment combined with community mobilization efforts supported the achievement of Universal Child Immunization (UCI) in 1991. During the 2008-2012 period, the country managed to improve the top ten disease morbidity trends and EPI coverage trends, with notable achievements in measles, rubella and tetanus

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morbidity and mortality. However, going forward, innovative measures will need to be developed to reach the remaining 5% of the population.

The national immunization policy was first formulated in 2004 and adequately updated thereafter. This policy was reviewed in 2011 in order to incorporate global policy recommendations such as Global Immunization Vision and Strategy (GIVS) and the comprehensive Multi-Year Plan (cMYP).[12] The main goal articulated in the policy document is to "reduce morbidity, disability and mortality related to VPD to a level where they cease to become a public health hazard". The guiding principles are to reach 100% immunization respecting global and local safety practices in an equitable and sustainable manner. The main objectives set for the next five years (2013-2018) are to enhance and sustain immunization DTP3 coverage over 95%, to eradicate polio and to eliminate measles, rubella and neonatal tetanus.[13]

The table below presents the history of the different vaccines introduced in the EPI:

Table 4. Chronology of the EPI in Bhutan

Date	Vaccines introduction
1983	Tetanus toxoid for pregnant women introduced
1986	The last clinically compatible polio case is reported - since then Bhutan maintained "zero" polio status.
1991	Universal Child Immunization (UCI) achieved in 1991.
1997	Hepatitis B introduced as monovalent vaccine
2004	HepB monovalent replaced by DTP-HepB3 (tetravalent)
2006	First case of Neonatal tetanus reported since the last one in 1994.
2006	Measles-Rubella (MR) vaccine introduced in early 2006, replacing monovalent measles.
2009-2011	DTP-Hepb3 replaced by DTP-HepB-Hib (Pentavalent)
2012	No cases of Diphtheria and Pertussis were registered in the country over the past twelve years from 2001 to 2012.

[12] Ministry of Health. National Immunization Policy and Strategic guideline, Department of Public Health, MoH, RGoB and UNICEF, 2011.
[13] RGoB. Eleventh Five year Plan Program Profile, Ministry of Health, department of Public Health, 2013.

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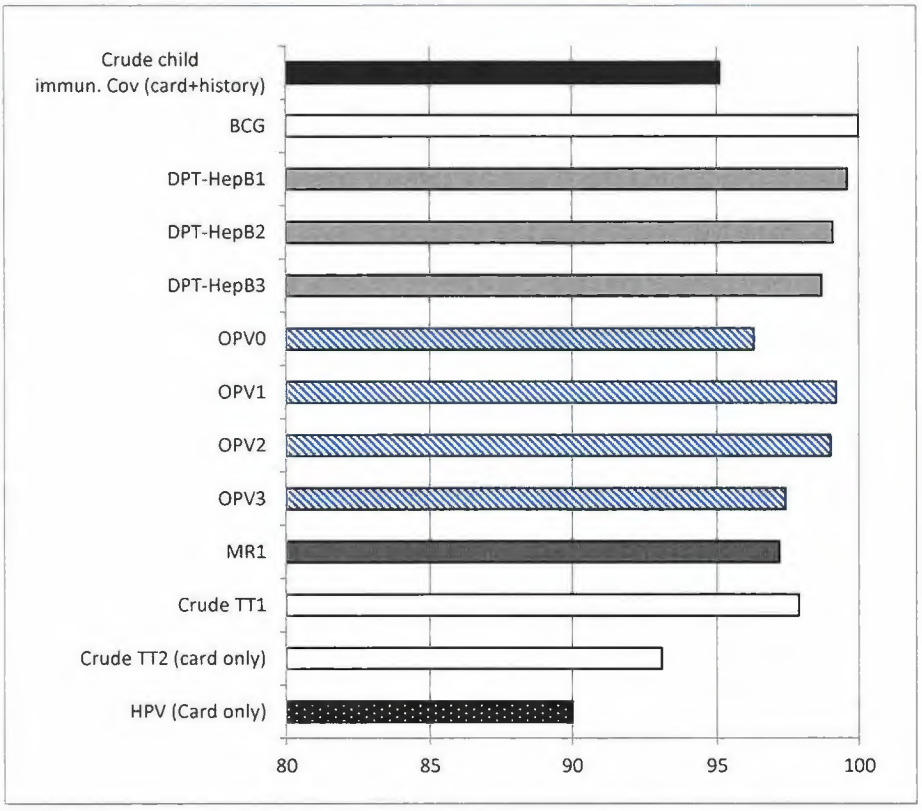
2008 2012	Unfortunately, Measles cases (clinical diagnosis) continued to be registered in 2008-2012 although in much smaller numbers than before. Currently, laboratory diagnosis for suspected cases of measles and rubella is being regularly provided.
2010	HPV vaccine started to be administered to 12-year old girls.
2011	HPV vaccine introduced into regular immunisation schedule.
2018-2022	The country is planning to switch to MMR vaccine during the next cMYP cycle.

2.2. Coverage trends and challenges

Coverage of all vaccines has been over 95%, except for Hepatitis B at birth and TT2. Out of 20 districts, 19 presented more than 80% coverage for a DTP-Hib-HepB3, 17 presented more than 90% coverage for MCV1 and 10 (50%) presented more than 80% coverage for TT2+ in pregnant women. Only one district in the country reported more than 10% drop-out rate for DTP-Hib-HepB1 to DTP-Hib-HepB3.[14]

Figure 2. Immunization coverage (2012)



[14] WHO. EPI fact sheet 2012

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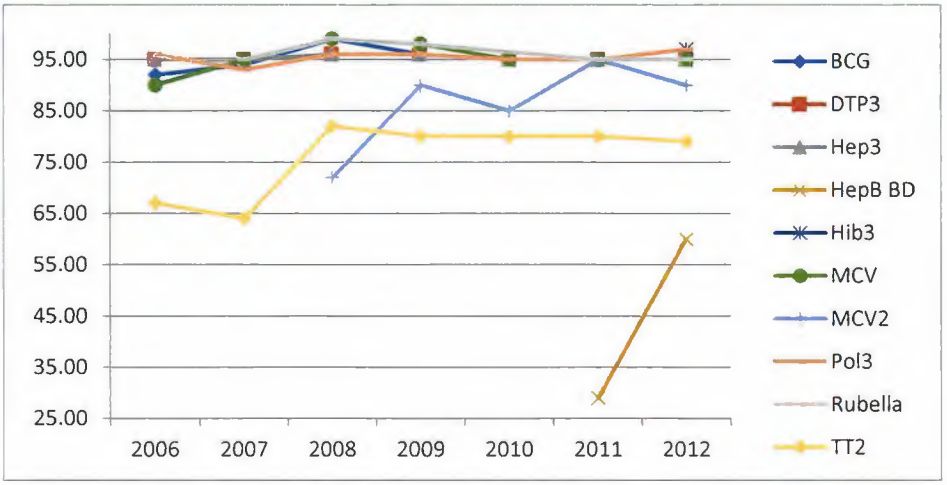
Source: annual health survey 2012[15]

Bhutan has succeeded in maintaining high immunization coverage rates since 2006. The graph below presents immunization coverage trends by antigen. Trends are around 95% for a majority of traditional vaccines (DTP3, HepB3 Hib3 and MCV) since 2006. MCV 2 coverage is up to 85% since 2009 and Hep B coverage doubled between 2011 and 2012.

Figure 3. Trends in immunization coverage per antigen between 2006 and 2012, Bhutan



Source: WHO immunization monitoring data

The 2009 EPI survey demonstrated that immunization coverage was equitable with high coverage in all three regions. However because of low card retention, confirmed immunization coverage[16] was lower in the western region (54.5%) compared to the eastern (73.5%) and central regions (78%).[17] Immunization rates are reportedly lower among vulnerable population groups, including migrant workers[18] and mobile populations. Nevertheless, no study has been carried out to confirm this.

Difficult access to health centres is the main factor explaining lower coverage in some regions. The key bottlenecks for the minority 3-5% of the population located in the two districts of Samtsi (one of the poorest districts) and Gasa (highlanders and migrant populations) are: remoteness, distance

[15] Data from the 2014 Annual Health Bulletin were not analyzed yet to present coverage rates.

[16] Valid immunization is defined as immunization given, and evidenced by card with the date of vaccination clearly marked for the vaccine on the card. Validity for the various antigens was defined as: BCG given within 0-367 days, OPV/DPT 1 between 41-367 days, OPV/DPT 2 given not less than 27 days after OPV/DPT 1 and within 367 days, OPV/DPT 3 given not less than 27 days after OPV/DPT 2 and within 367 days, and MR given between 267-367 days.

[17] Ministry of Health. National EPI survey, 2009.

[18] Migrants are those that move in search of work usually from rural to urban areas

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from health centres, lack of access to roads, lack of awareness of availability of services and are mainly

To address difficult access to health centres, the RGoB started to invest in improving roads and communications in the two high-risk districts of Samtsi and Gasa. Awareness needs to be strengthened and complemented with regular outreach services. In order to intensify routine immunization in 2012, activities were conducted to reach high-risk areas, migrant/hard to reach populations and low performing areas.[19]

2.3. ADC: polio, measles

The last case of wild poliovirus was reported in 1986 and Bhutan has maintained its polio free status since that date. Polio eradication activities started in 1976 with the introduction of DTP and OPV vaccines in selected sites. Following the 1988 World Health Assembly (WHA) resolution on the global eradication of poliomyelitis by the year 2000, Bhutan committed to eradicating the disease by 2005.

The measles vaccine was introduced in Bhutan in 1979, along with BCG, DTP and OPV. In 1993, the last measles death was reported in the country. Following the execution of the EPI acceleration plan starting in 1988, coverage had reached 89% by 1991. Bhutan conducted three nationwide measles vaccination catch–up campaigns in 1995, 2002 and 2006, allowing the country to sustain a 95% MCV1 coverage until now. Bhutan introduced MCV2 into routine immunization in 2006, and passive surveillance for measles is ongoing.

The implementation of targeted strategies for the eradication of poliomyelitis and measles explain Bhutan's good results: intensified regular vaccinations (accompanied by mass media campaigns, outreach clinics, complete immunization as a pre-requisite for primary school entry, etc.); national immunization days (NIDs) and sub-national immunization days (SNIDs) (7 SNIDs between 1996 and 2002); mop-up operations; and surveillance for acute flaccid paralysis (AFP).

[19] WHO. EPI factsheet Bhutan 2012

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2.4. Routine vaccines and Gavi vaccines

Bhutan's population is provided with the following traditional vaccines through the EPI.

Table 5. Current EPI schedule in Bhutan

Antigen	No of doses	Age of child for vaccination
BCG	1	At birth
HepB	1	At birth
OPV	4	At birth, 6 weeks, 10 weeks, 14 weeks
DPT-HepB-Hib	3	6 weeks, 10 weeks, 14 weeks
MR	2	9 months, 24 months
DTP	1	24 months
Td	2	6 years and 12 years
Td	2	1st contact of pregnancy, +1 month
HPV	3	12 years, + 2 months, +6 months (girls only)

2.5. New vaccine introduction

IPV

In line with the global polio eradication endgame strategic plan 2013-2018, the country plans to introduce IPV in 2015. Gavi will financially support the IPV introduction until 2018.

Rotavirus vaccine

The National Committee on Immunization Practices (NCIP) has recommended conducting a surveillance study on rotavirus based on the high burden of diarrheal disease and associated mortality among children in Bhutan. According to a burden of rotavirus and genotype study conducted in 2010-2011, the observed wide diversity of rotavirus strains and genotypes raised concerns around the efficacy of the currently available vaccine. The study also concluded that while rotavirus diarrhoea caused a high burden of disease, associated-mortality was low and that further surveillance was required to inform decision-making. It also recommended that a vaccine trial period be initiated prior to introducing the vaccine. The program has thus been advised by the NCIP to withhold any decision until further surveillance or vaccine trial data are available for consideration. An additional likely

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reason for withholding a decision is the country's graduation from Gavi support by 2017 as well as the possible withdrawal of other partners.

Pneumococcal vaccine

The NCIP considered introducing the pneumococcal vaccine in the immunization schedule and surveillance for pneumonia was initiated in order to collect clinical and epidemiological data with a target introduction set in 2015. However, no results or reports have been released to date and data collection is ongoing. No decision has been taken and it is likely that Bhutan's graduation from Gavi support as well as the progressive withdrawal of partners will influence the decision to introduce any new vaccine in Bhutan, including the pneumococcal vaccine.

Japanese Encephalitis

Since 2009, Bhutan began reporting Japanese Encephalitis (JE) cases – a standard case definition was developed and adopted in clinical settings. An especially high risk of JE outbreaks exists in the southern areas of the country bordering India. The threat of a JE outbreak looms large over all malaria endemic areas of the country. It is planned to upgrade the capacity of National Laboratory to support diagnosis and surveillance of JE and to strengthen links with regional laboratories to investigate any suspected meningitis/encephalitis outbreaks/syndromes to verify diagnoses as well as identify any possible JE cases.

3. Immunization financing, trends and issues

3.1. Financing of health and of immunization in Bhutan

Health and Immunization budget and expenditures in Bhutan

Health expenditure in Bhutan has remained constant over the last decade. The health expenditure per capita (PPP, US$) has increased from US$ 22 to US$ 90 between 2000 and 2012, but total health expenditure in terms of GDP has remained the same between 2003 and 2012 (4.46% on average).

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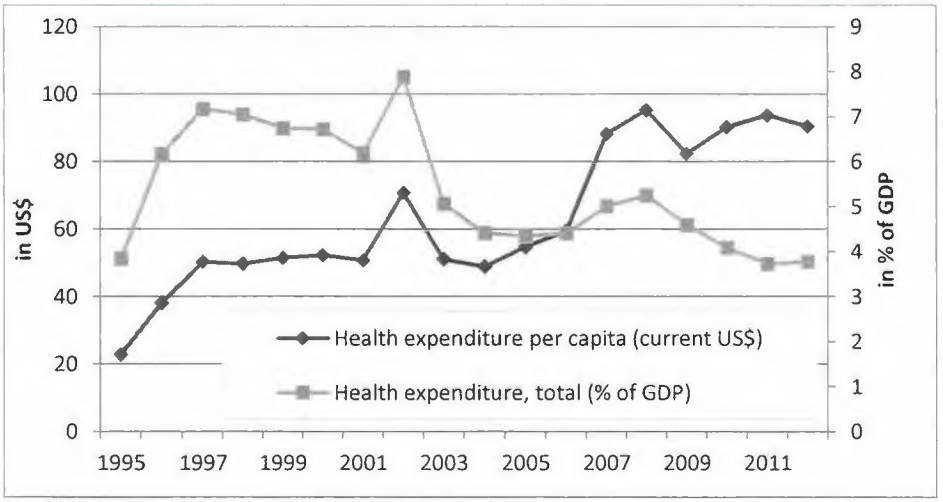
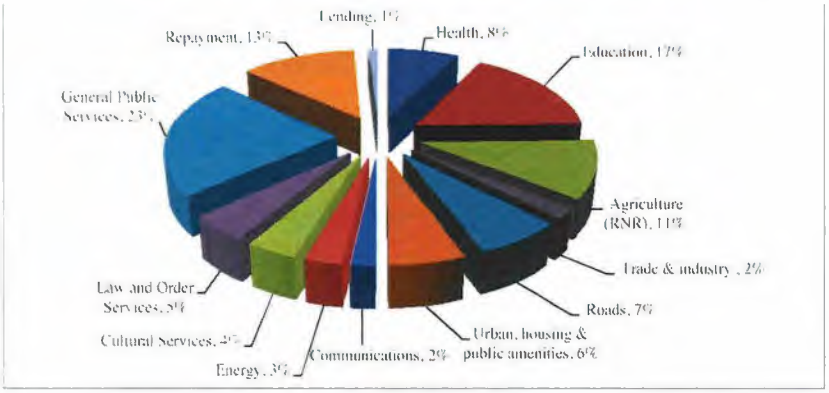
Figure 4. Health expenditure trends in Bhutan



Source: WHO repository

In 2014-2015, 8% of the national budget is allocated to health, that is to say Nu. 3,206.024 million or US$ 52.5 million. During that period, according to the approved budget for health, the budget allocated to the Vaccine Preventable Disease Program (VPDP) is Nu 8.482 million (or around US$ 138,900) and represents 1% of the total approved budget for the 2014-15 FY. The VPDP budget was Nu 8.559 million for 2013-14 FY, or 3% of the total budget allocated to health.

Figure 5. National budget breakdown 2015/15



National budget 2014-2015

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Sources of funding

The procurement of vaccines is currently funded through five different mechanisms in Bhutan:

1. **Traditional vaccines are purchased through UNICEF Supply Division (SD) with funding from the Japan Committee "Vaccines for the World's Children" (JCV)**[20]. Because JCV's agreement to finance is provided annually, this financing presents risks in terms of planning and accountability;
2. **Gavi supports the purchase of the pentavalent vaccine through UNICEF SD**. Between 2011 and 2015 (the graduation period), Bhutan will gradually increase its co-financing for this vaccine;
3. **The Bhutan Health Trust Fund (BHTF) funds the co-financing requirement for pentavalent vaccine.** Funds are transferred for procurement through UNICEF SD; co-financing amounts will increase by 20% per annum until the vaccine is fully financed by the RGOB (through the BHTF) in 2016;
4. **The Australian Cervical Cancer Foundation funds the HPV vaccine supply**. This agreement concludes in 2015 when the RGoB will be responsible for the overall financing of the program; and
5. **Operational costs for the VPDP are met by the RGoB annual budget** and have augmented through specific inputs from WHO and UNICEF country programs. The operational costs of the VPDP are being met by the RGoB under its normal health budget processes. These costs, however, are not easily discernible from other costs as they are mostly shared costs. The VPDP team has two program officers in the MoH but other regional and district level staff involved in immunization is not dedicated solely to the VPDP and so are funded under shared costs (transition plan 2012).

The RGOB has remained and will continue to be the major funding source of the EPI, covering more than 75% of its total cost, most of it through financing health care personnel and healthcare facilities, as well as current EPI-related costs. The Bhutan Heath Trust Fund (BHTF) is starting to play an increasingly important role in EPI financing. While currently financing the country's co-financing towards pentavalent Gavi support, the BHTF has fully taken over the financing of all the vaccines in 2014 and is expecting to also finance essential medicines from 2015.

The purpose of the BHTF is to ensure "sustainability of primary health care (PHC) services through provision of core PHC supplies of vaccines, essential drugs, needles, syringes, cold chain equipment and other related drugs/equipment".

[20] While the support from JCV is welcomed and commended, the lack of stability and predictability of this support could place the VPDP in jeopardy should the funds suddenly have to be mobilized from elsewhere. Nevertheless, during a telephone interview with JCV on the 25th of September, JCV confirmed their funding until 2017.

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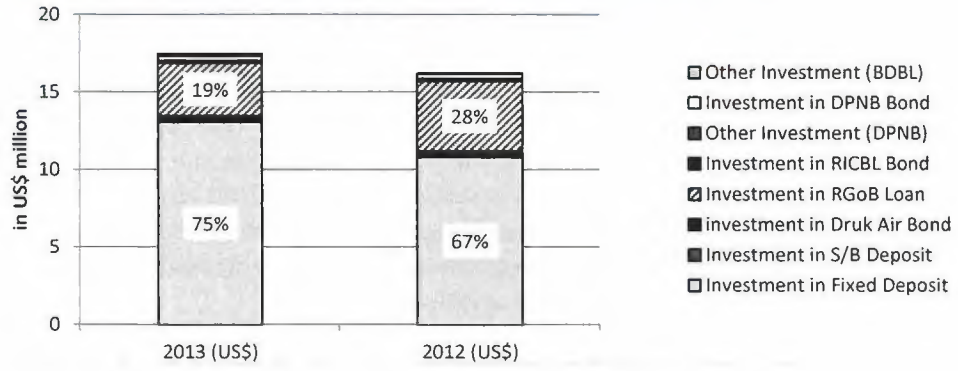
Main recommendations from the review of the BHTF carried out in 2013 were:

- Organizational and structural changes to optimize the efficiency and functionality of the BHTF; and
- Utilization of the interest accrued to fund the purchases of vaccines, related consumables and essential medicines.

The main source of revenues of the BHTF is from investment. The two larger types of investment are the investment in Fixed Deposit (75% of all investment in 2013) and the investment in RGoB Loan (19% in 2013) (see graph below).

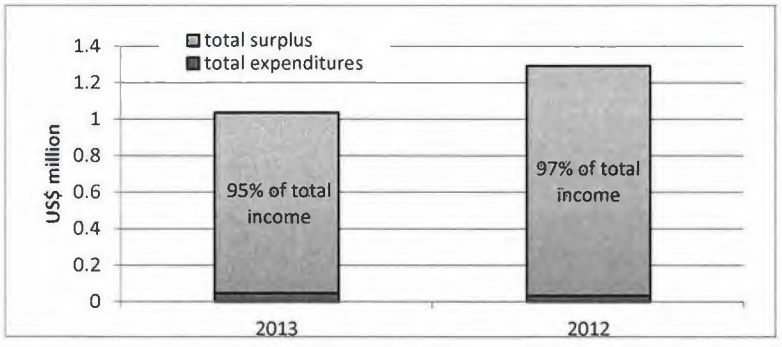
Figure 6. Investments of the BHTF in 2012 and 2013



source: BHTF booklet

In total in 2013, the BHTF raised more than US$ 1 million in income but used only 5% of the total income for vaccines. BHTF financing resulted in 66,139 children vaccinated in the last five years.

Figure 7. Total income of the BHTF in 2012 and 2013



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3.2. Implementation of immunization annual budgets

Central level

Similarly to other sectoral budgets, the health budget is allocated following the submission of sectoral proposals to the MoF and validation by Parliament. The new budget cycle begins when the Ministry of Finance (MoF) calls for proposed line ministry budgets in January (the fiscal year in Bhutan begins on the 1st of July). The EPI Unit submits its proposed annual budget through the Department of Public Health. Discussions with the ministries and external partners continue through February-April. During this period, a specific budget envelope is set for each ministry. The MoF checks the correspondence of indicative budgets with the five-year sectoral plans. During May-June, each ministry submits its final proposed budget to the MoF. Final directives are prepared and the full budget goes to the Cabinet of Ministers for final review. The MoF then presents the final budget to Parliament. In 2014-15, around 8% of the total budget was allocated to health. With the advent of democratic government in 2008, Parliament is given only the last five days of June to study, debate and approve the proposed budget.

Upon approval, the Department of Public Accounts releases funds on a quarterly basis. If needed, the Government may request supplementary funds from Parliament during its winter session (which has never happened).

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District level

Public finances are well devolved to the districts. In 2014-15, local governments are expected to manage about 7.5% of all public expenditures (Nu 2,795.4 million). Regarding health expenditure, nearly 30 % of the total government resources for health is allocated to Dzongkhags (districts) under the decentralized system. Each of the country's 20 autonomous agencies is represented at district level and prepares its own annual budget. Combined district budgets are sent directly to the MoF, which uses a population-based formula to allocate district budgets. Once approved, district budgets are managed by District Financial and District Accounting Officers, operating under the MoF. Notably, the national VPDP team never actually sees the district health budgets.

The Government budget for 2014-215 FY is supported by tax revenues (51%), non-tax revenues (22%) and grants (23%). Budgetary reallocations are possible but not between capital and recurrent budgets. Over the past 5 years, the capital budget has been US$ 11.3 million and the current budget US$ 18.3 million on average. In the 2014-15, capital and current budgets were Nu 630.6 million (US$10 million) and Nu 726.2 million (US$ 12 million) respectively. Expenditures are reported quarterly, through the primary health clinic level. The health budget execution rate is around 85 – 90% for 2013/2014, compared to 25% of non-executed budget the previous years.

3.3. Funding of non Gavi supported vaccines: trends, sources and issues

The Japan Committee "Vaccines for the World's Children" (JCV) has been funding traditional vaccines in Bhutan since 2008. There is little information about JCV's involvement in immunization program in the future. During the mission held in September 2014, it was unclear whether 's engagement would continue and for how long. Finally, following the mission, an interview with Christopher Takanori GANZU (25th of September 2014), International Affairs and Donor Relations Officer for JCV, confirmed the organization's involvement in the financing of traditional vaccines until 2017.

Estimates from the Transition Plan in 2012 indicated likely expenditures on traditional vaccines. According to these estimates, JCV funding for all traditional vaccines (BCG, DTP, MR, OPV, Td and HepB) would represent US$ 177,000 and US$ 183,000 in 2015 and in 2016 respectively.

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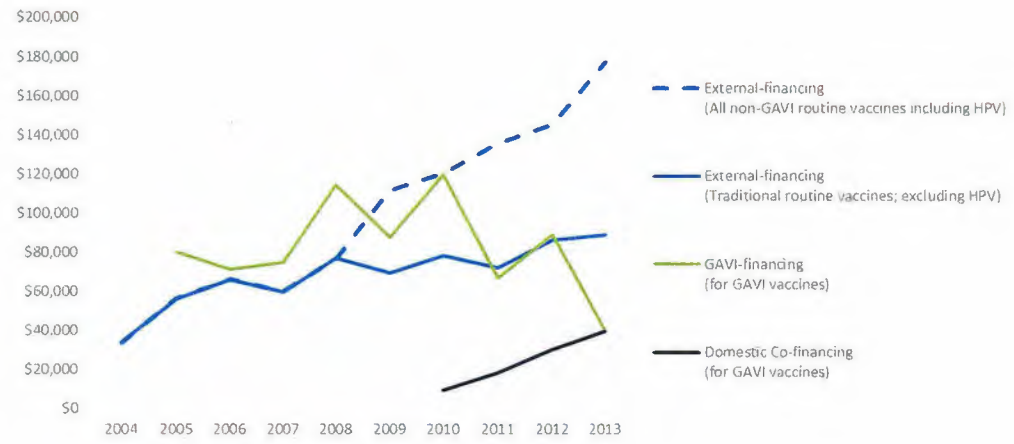
3.4. Funding of new vaccines

The Australian Cervical Cancer Foundation (ACCF) has been funding HPV since 2010. The first round of financing was to cover the introduction period until 2015. Although the information remains unconfirmed to date, funding is likely to be extended for an unlimited period. ACCF's HPV "access price" and funding is presented in Annex 2. HPV vaccine funding was estimated around US$ 125,000 and 126,000 in 2016 and 2017 respectively.

3.5. Immunization financial sustainability regarding graduation process

Over the last ten years, the RGoB has relied on donor financing to cover the costs of traditional and other routine vaccines (i.e. DT/DTP, BCG, OPV, TT/Td, M/MR, HepB) outside of tetra- and pentavalent. Donor financing has doubled over this period, thereby facilitating much of the aforementioned expansion in the immunization schedule. At the same time, the donor mix has shifted from a sovereign donor (JICA) to a non-governmental organization (JCV). It should be noted that over the last four years, government financing for vaccines has increased markedly. Since entering into the Gavi graduation phase, the RGoB has steadily and successfully reduced its reliance on Gavi financing. Nevertheless, as shown in the graph below, external financing of immunization remains much higher than the RGoB financing.



Source: UNICEF Programme Division (New York) and UNICEF Supply Division (Copenhagen)

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NB$_3$: Gavi vaccines = Tetravalent (DTP-HepB) and Pentavalent (DTP-HepB/Hib) vaccines

NB$_4$: Traditional vaccines = BCG, Measles, OPV, and TT/Td vaccines

NB$_5$: From looking at the quantities procured and actual products shipped, we can see that the peaks and troughs in Gavi financing is driven by the switch from tetravalent (DTP-HepB) to pentavalent (DTP-HepB/Hib), the building of buffer stocks for these vaccines, and changes in the specific products used (i.e. switching form one manufacturer to another).

Gavi started to provide support to the RGoB for the introduction of the pentavalent vaccine in 2009. The co-financing for pentavalent was initially on a fixed sum per dose basis, but from 2011, the co-financing has been based on a gradually increasing percentage of the total financing, starting at 20%.

The RGoB has committed to increasing its co-financing of the pentavalent vaccine with funds from the income generated from the BHTF. The following data was provided in the approval letter from Gavi for Bhutan to forecast and prepare for the increased funding requirements under graduation:

Table 6. Estimates of co-financing from the past Transition Plan

	2012	2013	2014	2015
Total Value	$140,500	$123,000	$110,500	$104,000
Gavi Value	$98,000	$73,000	$54,000	$31,000
Bhutan Value	**$42,500**	**$50,000**	**$56,500**	**$73,000**

Source: Bhutan Transition Plan 2012

The annual income of the BHTF can cover the procurement of vaccines in Bhutan. Indeed, the BHTF income is around US$ 1 million in 2013, compared to a total of around US$ 400,000 for vaccine procurement[21]. This shows that the RGoB is totally able to finance immunization procurement (through the BHTF) and immunization activities (through the national budget).

[21] Traditional vaccines from JCV for approx. US$ 183,000 in 2016, HPV vaccines for approx. US$ 125,000 in 2016 and pentavalent vaccine for approx.US$ 105,000 in 2015 (total of approx. US$ 413,000)

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Due to the importance of the BHTF revenues, it was decided that the BHTF will also cover the Essential Drugs' cost by 2014. In 2013/14, the procurement of essential drugs was estimated around US$ 2 million (Nu 140 million). Consequently, the BHTF revenues will not be sufficient anymore to cover the total of required resources for both vaccines and drugs. During the graduation mission in September 2014, a new financing strategy to be indentified was recommended for the BHTF in order to adapt to this new scenario. Some resource mobilization activities should be developed and implemented.

4. Institutional capacities

4.1. Priority setting mechanisms and processes

The national FYPs serve as the overall guide for national development efforts and include all sectors under the government. The 11th FYP, has adopted a log frame approach and lists an overall goal, outcome and output indictors, targets and lists of activities to be implemented over the next five years. Each activity is prioritized, and appropriate budget is allocated per funding source. Every 2.5 years, the Gross National Happiness (GNH) Commission carries out a mid-term review, during which each unit has to develop a progress report. The new FYP is produced one year before the end of the current FYP.

Immunization coverage targets are included in the 11th FYP and are all rated "high priority". A total amount of Nu 152.3 million (approx. US$ 2.5 million) has been budgeted for immunization related activities of the FYP, or approximately 11% of the total budget for the 11th FYP. Out of this budget, 90% (Nu 136 million, or approx. US$ 2.2 million) is allocated for the procurement of vaccines, syringes, refrigerators, EPI vans, cold boxes and autoclaves.[22]

The VPDP has been developing comprehensive multi-year plans for immunization (cMYP) in five-year cycles, closely aligned to the FYP. The current cMYP for the period 2014-2018 is in line with the 11th FYP for the period 2013-2017. The program is managed by two program officers responsible for implementing the program under the guidance of the chief of communicable disease division and Director General of the department of public health (see organogram).

The cMYP is comprehensive and sets out clear goals, objectives, strategies and activities for the program. It was developed by the program with the assistance of WHO and UNICEF through a

[22] GNHC. 11th Program plan for the Ministry of Health, Department of Public health, Public health Health Sector Plan, 11th FYP

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consultative process. The plan is then endorsed by the Ministry of Health and serves as an implementation guide for the program.

4.2. MOH and Immunization program: HR situation and organization

Availability of human health resources

With around 10 skilled health workers per 10,000 inhabitants, Bhutan's Human Resources for Health (HRH) situation needs to be improved. In 2012, Bhutan had 194 doctors (including expatriates), that is to say 2.7 doctors per 10,000 population. The total number of nurses was 736 (10.2 per 10,000 population). In 2012, 4,280 health personnel of different categories served in different health facilities, as presented in Table 6 below

Table 7. Healthcare workers in Bhutan

Category of health workers	2012
Doctors (MBBS / Specialists)	194
Assistant Clinical Officers (ACO)	39
Nurses (Assistant Nurse/GNM/B. Sc. Nurse)	736
Health Assistants (HA)	416
Basic Health Workers	162
Medical Lab Technologists	27
Drungtshos (Indigenous physicians)	35
Technicians	780
Administrative and support staff	1202
General Service Personnel	439
Others	250

Source: cMYP 2014-2018.

According to national estimates presented in the HRH master plan 2011-2023, Bhutan must dramatically increase its production of health workers. The HRH master plan provides an overall

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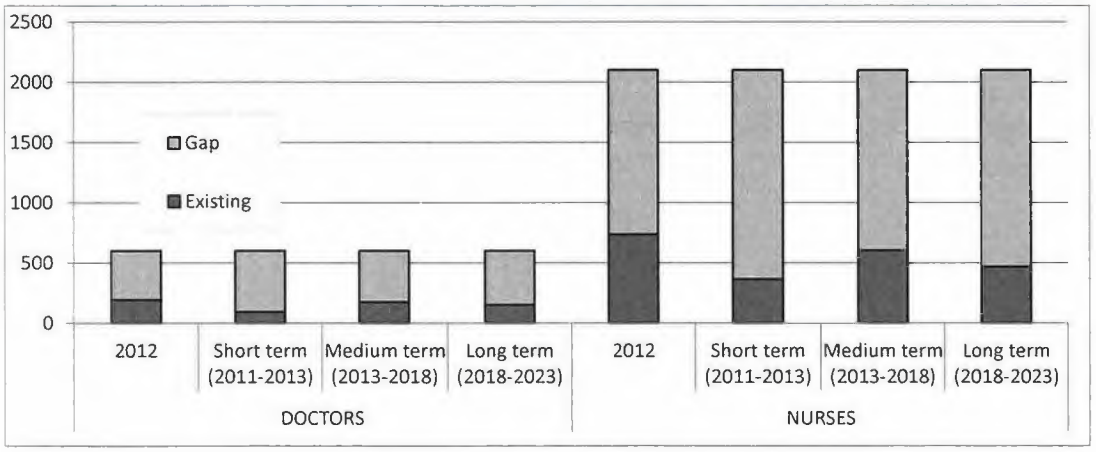
analysis of the situation of HRH and forecasts HRH needs. The number of doctors, specialists and dental surgeons needed was estimated to be around 602, that is to say more than 3 times the actual number of doctors. Additionally, the estimated number of nurses needed was 2100, almost three times more than the actual number of nurses in that year (736).

Figure 8. Existing and needed number of Health Workers in Bhutan



Source: HRH Master plan 2011-2023

Primary health care workers, namely the Health Assistants (HA), Auxiliary Nurse Midwives (ANM) and Basic Health Workers (BHW) are responsible for providing immunization services to children and pregnant women. A total of 1,314 primary health care workers were responsible for immunization activities in 2012, or more than 4 health personnel per 1,000 population. Nevertheless, there is a lack of HRH in remote areas, in spite of the government's implementation of a financing compensation system, through which health workers located in rural and remote areas are entitled to an additional 5% of salary.

Community level volunteers, called village health workers (VHW), have been a crucial link between the health system and the community in Bhutan. This scheme was introduced to supplement the work of rural health facilities in the early 1980s, after the introduction of the Primary Health Care program. Currently, about 1,200 VHWs are operational in the country and their contribution to improving rural health is recognized. The main roles of VHWs are: 1) to facilitate increased access to health care services; 2) to improve healthy lifestyle of the community; and 3) to provide first aid and treatment of minor ailments. VHWs play a specific role in immunization:

- To help mothers attend maternal and child health clinics regularly;
- To observe any disease outbreaks in the community; and

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- To notify the nearest health center immediately.

Capacities of Human Health Resources

Human resource capacities are one of the major issues in Bhutan. Inadequacy in numbers but also in technical capacities is visible at all levels and has been a major barrier to the country's EPI program. Currently, EPI comprises two officials at the central level, assisted by 9 cold chain technicians (4 at the central level, 3 in the central region and 2 in the eastern region). The lack of skills and knowledge of personnel at the central level contributes to weak program management and supervision of EPI activities at district level. Additional training needs were identified in the areas of maintenance at the central level, cold chain equipment and monitoring and in-service training on immunization basics.

4.3. Immunization system: stakeholders analysis

WHO and UNICEF are key partners in delivering immunization services to the mothers and children of Bhutan. Their support to the EPI program occurs mainly in the form of consultancies and short-term human resource development focusing on updating knowledge and skills in vaccine delivery and cold chain management.

Vaccines and injection equipment are funded by JCV, Gavi and ACCF. There are very few NGOs in Bhutan as they were forbidden by law prior to 2007. No NGO is currently registered as acting in the immunization domain.

Table 8. Partners' involvement in the EPI

Domain of intervention	Type of activities	Partners
Vaccine delivery and cold chain management	Consultancies and short term human resources development	WHO and UNICEF
Vaccine injections and equipment	Financial support	JCV, Gavi and ACCF

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4.4. NITAG structure and functioning

The NCIP is the institution in charge of guiding decision-makers and program managers in the formulation of immunization policy. It is comprised of eight members that provide technical guidance to the immunization program (see in Annex 4 the list of members and other committees in Bhutan).

The NCIP meets routinely twice a year and whenever required by the immunization program. The VPDP acts as the secretariat and prepares the agenda as well as minutes of the meeting. The decisions taken by the NCIP are submitted to the Ministry for final approval. In addition to the NCIP, there are several other **committees** that support the program in terms of providing guidance, monitoring and supervision in different areas of immunization (see Annex 3).

Decision-making should be strengthened at NCIP, in particular with regards to economic considerations related to new vaccine introductions. While Bhutan has the possibility to introduce new vaccines including the rotavirus, pneumococcal or Japanese Encephalitis vaccines, the NCIP's decision as to whether these introductions should proceed should be informed by rigorous cost-effectiveness analyses.

4.5. Regulation, NRA structure and functioning

Regulatory System functioning

Bhutan's Drug Regulation Authority (DRA) was established by the Royal Government in June 2004 with the mandate of ensuring safety, quality and efficacy of medicinal products in protection of consumer's health. The Drugs Technical Advisory Committee (DTAC) provides advice to the DRA 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 Registration of vaccines, new vaccines under pre marketing control and monitoring of adverse drug reaction are now major activities related to the immunization program, carried out by the DRA.

In general, the Medicines Act and the Medicines Rules and Regulations provide the DRA with sufficient independence for decision-making on tasks within its scope. The DRA is entirely government-funded. There is no direct revenue on fees collected, e.g. for product registration. The

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DRA regularly receives financial support from WHO, representing around USD 30,000. The DRA does not receive a training budget from the government, and estimates its funding situation to be stable and sufficient (able to accommodate projected increasing human resources for instance – see next paragraph).

Organizational Strategic Development plan

Although there is no detailed organizational strategic development plan, a yearly plan is generated including targeted achievements during the year. This plan is submitted to the Board for endorsement.

There is a lack of skilled heath personnel, and the current number of staff should be increased. The DRA currently has 25 staff, 17 of which are at scientific/professional level. This is not considered to be sufficient to address the DRA's current and projected workload. Three key positions (Chief Regulatory Officers planned as heads of divisions) are vacant because people with the desired profile are not available on the market[23]. One person was recruited as Regulatory officer (Gyen Tshering) in order to ease the situation.

The 11th Five Year Plan (FYP) for 2013-2018 includes request to hire 25 additional staff[24]. The GNHC approved this FYP (including the request to recruit 25 additional staff and the related training budget) and the Ministry of Finance must now validate the plan.

The main challenges identified in relation to the main functions of the DRA include the absence of a Quality Management System (QMS), and of **official standards for the inspection of premises** for manufacture, sale, import, export and distribution of medicinal products.

See Annex 4 for details on other functions of the DRA.

[23] Profile required is bachelor in pharmacy / pharmacology with training in relevant field, position level is P1 (professional level).
[24] Civil servants (8 regulatory officers (RO), 11 drug inspectors (DI), 1 Legal officer, 1 procurement assistant, 3 Office assistants), plus 1 dry sweeper.

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Marketing authorization and licensing activities

A legal framework for marketing authorization and licensing exists in Bhutan but would need a better design. The DRA regulates marketing authorization and licensing for manufacturing activities in accordance with the 2003 Medicines Act and the 2012 Medicines Rules and Regulations.The marketing authorization of medicinal products including vaccines manufactured, imported, exported and sold in Bhutan are to be registered under provision 16.2.1 of the Medicines Act.

The licensing for manufacturing activities is regulated by the Ministry of Trade and Industry[25], based on the approval of DRA. Once a premise or facility is ready for production, the applicant submits an application to the DRA for it to conduct an inspection of the facilities, to verify that construction and layout respect Good Manufacturing Practices (GMP). Based on the DRA's inspection report and the Drug Technical Advisory Committee (DTAC)'s recommendation, the Board approves or rejects the application. The DRA can then issue a provisional authorization with a two years validity following the date of issuance. Finally, the Ministry of Trade and Industry issues the license.

There is a dual evaluation process depending on whether products are already registered or not. Products may be considered for an *abridged evaluation* if WHO prequalified or registered in referenced NRAs. Products will otherwise be considered for *full evaluation* (see more details in Annex 4). The guidelines for the registration of medicinal products (2013) provide further details around these processes and were developed by the DRA for use by applicants. Technical assessments of the medicines and vaccines are done by the technical committee. The registration certificate of the medicinal product is valid for 3 years.

The Graduation assessment mission allowed for the capacity of the DRA to be assessed in the areas of market authorization and licensing. The different observations and respective recommendations mainly concern capacity building/training as well as the review and/or production of regulations and guidelines. They are summarized below and detailed in annex 6:

- Revision and update of the rules and regulations;
- Develop QMS (hire QMS Manager, training and policy development);
- Capacity building on full evaluation of vaccines with respect to Quality, Safety and Efficacy should be strengthened through Improved Development Plan (IDP)[26] for Bhutan DRA.

[25] to issue licenses for manufacture, import, export and sale of medicinal products by retail or wholesale

[26] The IDP is the plan produced after each NRA assessment to help the country implementing activities which will strengthen the NRA.

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Adverse Events Following Immunization (AEFI)

A standard national system to monitor adverse events following immunization is implemented in Bhutan, and routine immunization reporting has been gradually strengthened. Bhutan introduced Panacea's pentavalent vaccine in September 2009. Five cases of encephalopathy and/or meningoencephalitis were identified shortly after pentavalent vaccination and prompted the authorities to suspend vaccination on 23 October 2009[27]. All cases were reviewed by independent national and international experts, who concluded that none of the fatalities could be causally associated with the vaccine. The vaccine was subsequently reintroduced in 2011. In 2013 and 2014, 17 and 23 cases were reported respectively, with 3 and 9 deaths temporally associated to an AEFI. However, causality assessment had not been conducted by the national experts group at the time of the mission and without a thorough review of these AEFIs cases no conclusion can be finalized (see Annex 1 for the reported AEFIs and supposedly associated deaths).

Although health staff regularly receives in-service training on AEFI surveillance, reporting and investigation, 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.

See details in Annex 4

[27] WHO. Pentavalent vaccine in Asian countries. Available at http://www.who.int/vaccine_safety/committee/topics/pentavalent_vaccine/Jul_2013/en/

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4.6. Procurement and management capacities and issues

Procurement mechanism in Bhutan

Current procurement of vaccines and related consumables for the VPDP is conducted through UNICEF SD based in Copenhagen. The capacities at the level of the VDPD are limited and the assessment conducted in 2012 concluded that "the experience and resources required to conduct self-procurement of vaccines for the VPDP are not available within the procurement unit".

However, the Drugs, Vaccines and Equipment Division (DVED) of the MoH is also in charge of procurement for two vaccines. The DVED manages and maintains the central vaccine storage facility and is also involved in the release of vaccines delivered to Paro airport. The DVED is also responsible for the procurement of two vaccines: the anti-rabies and the Hepatitis B vaccines, at respectively Nu 196 per dose (US$ 3.19) and 191 Nu per 10 doses (US$ 3.1). A global tender is shared with registered suppliers and principal companies[28] (to avoid multiple bidders) through the media ("Kuensel" – Bhutan daily news). Since these two vaccines are already on the essential medicines list, there is no need to tender separately. If a product is not registered with the DRA, a separate note is processed, which will need to get approval from the Chairperson of the Board, in which the DRA is also involved member, as well as the Minister. Once bids are received, there are separate tender opening, evaluation and selection committees. Based on their recommendations, winning bidders are notified and purchase orders can then be placed. For instance, , procurement of the two above mentioned vaccines is made through the Serum Institute of India (Pune, India), which is a principal company.

In light of the size of Bhutan (birth cohort of less than 15,000 children in 2014), the country should continue using UNICEF SD procurement mechanisms to procure vaccines, including the pentavalent vaccines that Bhutan will fully finance (through the BHTF). It should be noted that JCV could use the BHTF as well, and the latter would be in charge of pooling available financing for the procurement of vaccines. This would ensure BHTF accountability in financing all vaccines for the RGoB.

Regarding procurement process itself, it is worth noting that using UNICED SD channel is considered as an exception, that will require relevant justification to be maintained. Indeed, the Public Procurement Policy Division – PPPD, at the Ministry of Finance, reminded the mission that using UNICEF SD after graduation might not be possible anymore, unless there is a strong rationale shared with the MoF. Consequently, the MoH should prepare, with support from partners, a

[28] No dealer in between

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technical note showing the economical and cost-saving impact of using UNICEF SD. This note will be used as an advocacy tool to ensure the continuity of using UNICEF SD mechanisms.

Cold chain and supply chain

An assessment of the cold chain system was carried out in 2012 (see main results in the table below). The cold chain system was studied at four levels: central stores, regional stores, district hospitals and basic health units. During the assessment period, no freezing of vaccines or the cold chain failure was observed. However, there were still lots of problems that required appropriate intervention, such as:

- Supply for new or replenishment CC equipment;
- Cold chain preventive/replacement maintenance plan;
- Training the vaccine handlers in cold chain equipment maintenance (CCEM) & vaccine logistics (VL);
- Weak supervision of health workers.

According to EVM initiative, vaccine management is considered effective when scores exceed 80% by each of the nine criteria.

Table 9. Mean EVM criteria scores (%) by facility levels

	Criteria								
	E1	**E2**	**E3**	**E4**	**E5**	**E6**	**E7**	**E8**	**E9**
	Vaccine arrival	Tem pera ture	Storage capacity	Building, equip., transport	Maintena nce	Stock mangt.	Distribution	Vaccine mangt	MIS, supportiv e functions
Central Store	68	41	94	77	75	74	56	63	69
Regional Stores	N/A	79	78	91	79	80	64	58	55
District Stores	N/A	74	92	73	76	71	48	55	45
BHUs	N/A	76	100	86	72	72	88	77	N/A

Source: EVM 2012

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According to the EVM improvement plan and its implementation progress assessment carried out during the mission, the following activities were identified as "completed" or "in-process":

- E5. Maintenance: Maintenance plan;
- E6. Stock Management: stock management forms updated and staff trained to these tools;
- E7. Distribution: freeze tags used to monitor freeze-sensitive vaccines during distribution and test of cool water packs use;
- E9. MIS and supportive functions: SOP Manual (Standard Operating Procedures) and trial for the use of a Cold Chain inventory software, to use to update respective documents.

Consequently, the remaining activities from the EVM improvement plan were reviewed during the graduation analysis mission (see section below).

Immunization Supply Chain

During the graduation analysis mission, Ministry of Health officials and Gavi partners identified a need to **further strengthen the immunization supply chain** and specifically to undertake several remaining activities that were codified in the EVM Improvement Plan (IP) related to the introduction of new technologies, cold chain equipment (CCE) management, and training of logisticians. In particular, the assessment highlighted that some regional cold rooms, and all cold chain equipment at facility levels needed upgrading; e.g. most facilities in Bhutan rely on domestic refrigeration units rather than WHO pre-qualified units. As such, drawing upon agreed activities that had yet to be implemented from the EVM IP, the following were prioritized for remediation during the remainder of Bhutan's graduation:

- Conduct of a temperature monitoring study[29] to monitor temperatures continuously as vaccine shipments travel through the cold chain from primary stores, to intermediate stores, to health centres and, to the outreach delivery sites. 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;
- Procurement and installation of the necessary CCE: (i) 100L Compression refrigerators; (ii) Sibr refrigerators; and (iii) a walk-in cooler room; and
- Staff training (i) for effective use of computerized temperature recorder (Multilog) covering all cold chain units, future equipment additions and ambient temperature measurement (ii) and pre-service training for 5 EPI-Medical technicians (CCE maintenance).

The CCE procurement and installation will upgrade the 'hardware' of the immunization supply chain while the training should commensurately upgrade the 'software' of the supply chain, and ready the next generation of logisticians to manage Bhutan's immunization supply chain. UNICEF and the

[29] WHO/IVB/05.01 study protocol

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Department of Medical Supplies and Health will lead all identified activities, with support from Department of Public Health.

4.7. Information, communication and advocacy capacities and performance

The Health promotion division (Information and Communication Bureau - ICB) assists the VPDP in advocating and communicating to the public on immunization practices. There is a high degree of awareness on immunization among the general population which is well accepted. Information, education and communication (IEC) materials on immunization have been developed and disseminated widely across the country. There have been challenges, especially with AEFI being reported for pentavalent vaccines, however the public's confidence in immunization has been regained, mostly thanks to efficient information and mass media campaigns.

There is a lack of capacities to analyze collected data. The Bhutan Health Information Management System (HMIS) has been collecting, compiling and reporting health data for the Ministry of Health since 1983. It produces an Annual Health Bulletin (AHB) that reports on compiled health data collected routinely from every health centre in the country. Routine health data was collected on a quarterly basis until 2013, however after upgrading to a web based system, the data is now collected on a monthly basis. The latest issue is the AHB 2014 which is a collection of data for the year 2013. Although the data is informative and comprehensive, it is a collection of reported data without any analysis. The data on immunization for example provides absolute numbers of children immunized, district wise for BCG, OPV zero dose, OPV 3 and DPT-Hep B. Without any data on the denominator, the coverage for example cannot be calculated.

In terms of immunization coverage, the program has been conducting national EPI coverage surveys periodically every 5-7 years. The last survey was done in 2009. Another source of data is the national health survey which is conducted every 10 years. The last such survey was conducted in 2012.

The BHMIS needs to be strengthened so that the data can be analyzed, reported and used to inform programming. Additional data such as AEFIshould also be collected and reported through this system. Similarly, data collected vertically need to be integrated into the common health information system. The challenges are mainly in providing reliable internet connectivity in the districts and building the capacity of data managers. A well planned system of monitoring and validating the data will assist in producing more reliable data.

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5. Graduation plan

Following discussions, collection of data and analyses of previous assessments and updated data, the following graduation plan was identified by the government with support from the mission, and validated during its presentation to the MoH and other partners.

Financing of immunization	
Achievements	
• The RGoB presents a certain ability to pay for vaccines, especially thanks to the BHTF • The BHTF is now fully in charge of the financing of vaccines in Bhutan • The BHTF will also be in charge of the Essential Drugs List financing	
Challenges	**Lines of action under the Graduation Plan**
• Strengthen to ensure the sustainability of the BHFT to finance all vaccine requirements	• De-link BHFT from MoH with new governance and organization • Develop and approve 5 year plan that includes needs, costs and impact • Develop Resource Mobilization Strategy • Implement RM Strategy

Procurement, storage and supply chain	
Achievements	
• Procurement of vaccines through UNICEF SD is an exception to the national procurement regulation. • An EVM has been carried out and many actions are already in process regarding Maintenance, Stock Management, distribution and MIS and supportive actions.	
Challenges	**Lines of action under the Graduation Plan**
• To keep on benefiting from the exception which allows using UNICEF SD to procure vaccines, a technical note to prove that the mechanism is cost-saving is required • Strengthen immunization supply chain by supporting cold chain equipment management, and the	**Procurement** • Provide a technical note showing economic and helath results of different scenarios (with or without using UNICEF SD) to present how cost-benefit this option is. **Supply Chain** • Temperature monitoring study to monitor temperatures continuously as vaccine shipments travel through the cold chain from primary stores, to intermediate stores, to health centres and, to the outreach delivery sites. • Staff training (i) to learn computerized temperature recorder (Multilog) (ii) Pre-service training for 5 EPI-Medical technician/logisticians

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• introduction of new technologies as appropriate	• Use of findings from Temperature Mapping study to inform where to switch from domestic (non-PQ'd) refrigerators at the block/health facility level to WHO PQ refrigerators. • Procurement of the necessary (i) 100L Compression refrigerators and (ii) Sibr refrigerators • Procurement walk-in cooler room

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Crisis communication and health system information	
Achievements	
• The health system information regularly collect and report data but there is a lack in terms of analysis of data • Mass media campaigns are effectively and regularly carried out • The crisis communication activities have to be strengthened to avoid potential reluctance from the population with regards to the increasing number of AEFE reported (thanks to a better system and not an increase in the real number of AEFI)	
Challenges	**Lines of action under the Graduation Plan**
• Prepare for communications "issues management" in the event of AEFIs or rumors/misinformation • Promote health worker confidence in the safety of vaccines	• Develop a crisis communication plan defining roles and responsibilities as well as standard operating procedures and build capacity in MOH to manage communications around suspected AEFIs. • Outreach to health workers / vaccinators and paedatricians to reinforce key messages, providing them with job aids to deliver messages to mothers/caregivers.

National Regulatory Authorization	
Achievements	
• The legal framework for marketing authorization and licensing exist in Bhutan but would need better design • The licensing for manufacturing activities is regulated by the Ministry of Trade and Industry, based on the approval of DRA • There is a dual evaluation process depending on whether products are already registered or not. • AEFI are more and more reported but without adequate following investigation	
Challenges	**Lines of action under the Graduation Plan**
• There is no Quality Management System designed and implemented • There is a need in capacity building for the NRA staff on registration and Good Manufacturing Practice (GMP) • Strengthening AEFI causality assessment through better quality data and dissemination of AEFI training to BHU and hospital Health assistant	• Build QMS in DRA • Technical cooperation between Bhutan DRA and Thai FDA for regulatory capacity building for vaccines and exchange of information • Build vaccine specific knowledge in registration • Build vaccine specific knowledge in GMP for vaccines • Revise and update national AEFI guideline • Develop manual for field investigation of AEFI • Training workshop to implement AEFI guideline and manual on AEFI field investigation

Additional capacity building for EPI staff

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Achievements	
• There is not a critical shortage of Human resources for health in Bhutan regarding immunization delivery service (there is a lack of specialist doctors though) • It is also due to the implementation of the volunteer Village Health Workers but who might need improved refreshing training	
Challenges	**Lines of action under the Graduation Plan**
• The lack of in-training service reduce quality of knowledge in the immunization area, which is a critical issue to maintain good results in terms of immunization coverage	• The EPI technicians should benefit from facilitated in-service training such as e-learning activities

National immunization policy guidance	
Achievements	
• The national immunization policy is designed through a rigorous and participative system • The National Committee for Immunization Program regularly meets and is in charge of high level decisions	
Challenges	**Lines of action under the Graduation Plan**
• The NCIP does not have access to comprehensive information in terms of vaccine prices, product procurement. This implies difficulties to use economic evaluation for decision-making process	• Ensure that the NCIP have access to updated and frequent information and can benefit from comprehensive economic analyses in order to improve its decision making process

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ANNEXES

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Annex 1. Reported AEFI between 2009 and 2014, and supposedly associated deaths

Table 10. Report AEFI between 2009 and 2014

Type of AEFI	2009	2010	2011	2012	2013	2014
Abscess	1					
Encephalitis	1					
swelling	1	1	1	2		
seizure		2				4
sudden pallor		1				
Fever and Pain			1		8	
Death				1	3	9
excessive crying/vomiting				1	4	2
anaphylaxis					1	1
hypotonic hypo-responsive					1	
severe bronchopneumonia						2
sepsis						4
breath holding spell						1
Total	3	4	2	4	17	23

Table 11. Reported deaths supposedly from AEFI

Mortality	2009	2010	2011	2012	2013	2014
Unknown				1		2
Pneumonia					1	
Bronchopneumonia/ARDS					1	1
Vomiting					1	
Sepsis						4
Encephalopathy						2

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Total	9			1	3	9

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Annex 2. Financing of new vaccines: HPV and the Australian Cervical Cancer Foundation

HPV Merck and the ACCF – Transition plan 2012

In April 2010 a Memorandum of Understanding was signed between Merck Sharp & Dohme Corp (Merck), the RGoB and The Australian Cervical Cancer Foundation (ACCF). Essentially the MOU indicates that Merck would provide vaccines for the 2010 introduction campaign of all Bhutanese females between the ages of 12 and 18 from 1 May to the conclusion at the end of 2010. From 2011 to the end of 2015 funding for the purchase of vaccines would be provided by the ACCF, if Bhutan were able to gain subsidy through the Gavi approval of HPV then the ACCF agreed to pay the co-financing portion or if not the entire funding requirement. However, as a graduating country Bhutan is not eligible to apply for HPV funding when Gavi opens this window in 2012.

The price ACCF is to pay is termed the "Access price" and is defined as "a price consistent with the price offered to the public sector of the countries which meet the criteria set forth for Gavi alliance support". Shipping, Insurance and delivery is also covered under this support. Other than as specified in the MOU the RGoB agreed to undertake at its expense all the technical and related activities in connection with the administration of the HPV vaccine program.

At the conclusion of 2015 Merck agree to provide doses of HPV to the RGoB at the Access price and provide support to AEFI and pharmacovigilance.

Change of ownership and responsibility for the vaccines takes place at the point of delivery. Any failure or losses incurred after that point are the responsibility of the RGoB in order to maintain the agreed project. For example if a break in the cold chain requires replacement of the vaccines in order to maintain coverage, the RGoB will be required to purchase the vaccines at the Access Price and cover other related costs.

The eligible population is anticipated to increase by 1% per annum with the number of vaccines required in 2015 anticipated to be 22,151 based on 3 immunizations for 7032 girls and a 5% wastage rate. Maintenance of a 20% buffer established in 2010 is required.

To attempt to gauge the funds required to maintain the HPV programme the following assumptions have been made:

1. The Access Price is USD 5 per dose[30]
2. Population Increases at 1% per year
3. Wastage Rate maintained at 5%

[30] http://www.cervicalcanceraction.org/newsletters/2011-06/CCA_news_June11.htm

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Year	Total Doses Required (Incl 3 Dose Schedule, 5% Wastage & 1% annual Increase)	Price for Vaccine at 5USD per dose	Total Including 12% Freight and Insurance
2016	22373	$111,863	$125,286
2017	22596	$112,981	$126,539
2018	22822	$114,111	$127,804
2019	23050	$115,252	$129,082
2020	23281	$116,405	$130,373

TRANSITION PLAN 2012

[31] Based broadly on the MR as the price is similar to that of HPV (UNICEF SD Bhutan Provisional Plan for pentavalent 2012)

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Annex 3. List of the NCIP members

1. Dr. K.P Tshering, Interim President, UMSB (Chairman)
2. Dr. T. B Rai, Sr. Medical Specialist, RBA Hospital, Lungtenphu (Vice Chairman)
3. Dr. Mimi Lhamu Mynak, HoD, Pediatric Dept. JDWNRH
4. Dr. Tshokey, HoD, Pathology Dept, JDWNRH
5. Mr. Sonam Dorji, Drug Controller, DRA
6. Mr. Sonam Wangchuk, Chief Laboratory Officer, PHL, DoPH
7. Mr. Dorji Chhewang, Sr. DHO, Thimphu
8. Mr. Thinley, Pharmacist, JDWNRH

Table 12. Other health committees in Bhutan

Sl.No	Committee/Commission	Date estb.	Chairman	Members:
1	National Commission for Certification of Polio Eradication (NCCPE)	**1998**	Dr. Tandi Dorji, Pediatrician	Mr. Tshering Wangchuk, Retired DHO
2	National Committee of Immunization Practices (NCIP)	**2009**	Dr. K.P Tshering, Pediatrician	Drug Controller, Microbiologist, District Health Officer, Pediatrician, Pharmacist, Medical Specialist
3	National Polio Expert Committee	**1998**	Dr. K.P Tshering, Pediatrician	Medical Specialist, Pediatrician
4	National Adverse Events Following Immunization (AEFI)	**2009**	Dr. K.P Tshering, Pediatrician	Drug Controller, Microbiologist, District Health Officer, Pediatrician, Pharmacist, Medical Specialist
5	National Laboratory Task Force Members for Laboratory containment activities for polio	**2003**	DG, DoPH	Microbiologist, National Centre for Animal Health& ThimphuThomdey
6	National Coordination Committee (NCC) for Global Alliance for Vaccine Immunization (Gavi)	**2004**	CPO,CDD	Tarayana, GNHC, MoH, WHO, UNICEF
7?	Child Health Advisory Committee (CHAC)	**Reco**	Was a recommendation from the Short Programme Review of the child health programme	

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		2010	

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Annex 4. Drugs and Regulatory Authorities analysis

Table 13. List of Bhutan DRA Members met

Division	Name	Position
1. Administration	a. Mr. Sonam Dorji b. Mrs. Kuenzang Wangmo c. Mr. Pema Gyeltshen	-Drug Controller -Assistant Administrative Officer -Accountant
2. Registration Division	a. Mr. Kunzang Dorji b. Mr. Gyem Tshering	-Senior Regulatory Officer (Head of Registration Division) -Regulatory Officer (Head of Product Registration Section)
3. Inspection Division	a. Mrs. Ngawang Dema	-Senior Regulatory Officer (Head of Inspection Division)
4. Post Marketing Control Division	a. Mr. Jigme Tenzin,	Regulatory Officer

DRA main functions status

Conflict of Interest (COI):

DRA staff has to comply with Civil Servant rules that include provisions for COI. For DTAC, provisions are made under section 8 e. COI has to be declared on form I-CI of the regulation which is only used when committee members declare it by themselves. It has not been used by any member of the committee in the past. There is no active control that there is no COI.

Quality Management System (QMS)

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Recalls

A recall procedure is in place (due to the deaths associated with Penta, import of Penta was stopped, but not recalled). Legal bases are present for DRA to be responsible for recalls in Rules and Regulation 176 – 179. No vaccines have been recalled in the past.

Disposals

A guideline exists, which is in draft form.

Lot release and lab access

(these functions were not assessed in detail, as it is not in the main scope of the mission)

Lot release is performed following an SOP. The summary lot protocol is assessed, visual tests and freeze tests are performed on the vaccines, presence of import authorization is checked. There are no analytical tests performed on the vaccines, neither in Bhutan nor externally. There is no formal provision in the Medicines Act or in the Rules and Regulation that DRA is responsible for lot release. For surveillance purposes, mainly for pharmaceutical drugs, DRA wishes to use the Drug Testing Laboratory. For economic reasons, there is a tendency to only establish one lab under the Ministry of Health which would include the service as a DTL.

Clinical Trials

(this function was not assessed in detail, as it is not in the main scope of the mission)

No clinical trials are performed in Bhutan. DRA has no assigned responsibilities and no structures for Clinical trials.

Good Distribution Practice – Good storage practice

(this function was not assessed in detail, as it is not in the main scope of the mission)

DRA, according to the Rules and Regulation, is responsible for inspections of premises for manufacture, sale, import, export and distribution of medicinal products. However, no official standards for these inspections are defined.

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Abridge vs full evaluation of new medical products

The medicinal products can be considered for *abridged evaluation* route if it is WHO prequalified or registered in referenced NRAs; if not, it will be considered for *full evaluation* (see more details in Annex). The Guideline for Registration of the Medicinal Products (2013) was developed by DRA as administrative instructions available for applicants. The technical assessments of the medicines and vaccines are done by the technical committee. The registration certificate of the medicinal product is valid for 3 years.

Abridge evaluation with minimal documents will be applied for medicinal products approved by at least one of the reference DRAs namely: Therapeutic Goods Administration of Australia, Health Canada, US Food and Drug Administration, European Medicines Agency, UK Medicines and Health Regulatory Agency, Japan DRA, Health Science Authority of Singapore, Drug Control Authority of Malaysia and Thai Food and Drug Administration as per chapter IV section 35 of the Bhutan Medicines Rules and Regulation 2012.

However, marketing authorization is exempted if falls under the following cases:

a. Importation of any medicinal product for the purpose of research as approved by the relevant agency or board set up for the purpose.

b. Product Samples for the purpose of registration as specified in the guideline for product registration.

c. Medicinal products which are meant for personal use, in the quantity not exceeding the amount stated in the prescription unless justified by a registered medical practitioner.

d. List of quantified products intended for treatment of a serious life-threatening situations with strict time-bound treatment regime verified by the Chairman, National Drug / Veterinary Drug Committee and as approved by the Chairman of the Board.

e. In Public Health Emergencies as defined by the Board.

f. List of Orphan drugs verified by the Chairman, National Drug/ Veterinary Drug Committee and as approved by the Chairman of the board.

g. Medicinal products imported for named patients as sanctioned by the registered medical practitioners in a government Health and Veterinary centres.

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h. List of medicines for temporary medical camps for a duration not more than one month.

i. All the raw materials which are required for manufacture of the medicinal products by the pharmaceutical manufacturers.

j. List of Products not registered or not available in the local market at the time of application but required in a government initiated or approved projects for duration not more than one year.

k. Medicinal Products which are supplied to government approved agencies in kind by an external government agency as approved by the Chairman of the Board.

In addition to above exemption clauses the Bhutan Medicines Board approves the import of medicines through approval of Note sheet for those products which are non-registered but are required in the country.

According to chapter XV section 249 of the Bhutan Medicines Rules and Regulation 2012 the medicines are classified into 6 schedules whereby vaccines fall under schedule F.

Lot release of vaccines is required regardless of origin with the following documents;

a. Batch quality control certificate from the manufacturer

b. Summary Lot Protocol and

c. Shipping documents received

The main challenges and respective recommendations are presented in the table below:

Table 14. Observation and recommendation on the Market Authorization and Licensing mechanisms

OBSERVATIONS	RECOMMENDATIONS
Discrepancies between in the Bhutan Medicines Rules and Regulation 2012 and the Medicines Act of the Kingdom of Bhutan 2003	Bhutan DRA should revise the Rules and Regulation 2012 by: i) Adhering to section 5.1 and 5.11 of the Medicines Act 2003 as the Board may constitute Drug Technical Advisory Committee (DTAC) and technical sub-committees. Therefore, all technical committees under the Rules and Regulation 2012 should be

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	reclassified as technical sub-committees. ii) Identifying other case of registration exemption under section 34 to reflect the registration exemption to the importation of medicinal products through "Note Sheet". iii) Adding complete set of forms (application forms and certificates) as annexes to the Rules and Regulation for public access.
No Quality Management System (QMS) in place	Bhutan DRA should promptly develop QMS (hire QMS Manager, training and policy development)
The "Guideline for Registration of the Medicinal Products, 2013" is not aligned to international standards	Capacity building on full evaluation of vaccines with respect to Quality, Safety and Efficacy should be strengthened through Improved Development Plan (IDP) for Bhutan DRA. Moreover Bhutan DRA shall: i) Establish system to monitor skill after training of each individual staff; ii) Have written criteria for recognition of other NRAs under section 35 of RR 2012; iii) Train GMP inspectors dedicated to vaccines; iv) Develop specific Guideline for assessment of variation of vaccines with clear definition of major and minor variation; v) Publish Summary of Product Characteristic like information of approved vaccines available for public.
No specific guideline on assessment of vaccines with respect to Quality, Safety and Efficacy.	
Training course received on registration of medicinal products but not on vaccine and lack of capacities in terms of full evaluation regulatory pathway for vaccine or GMP inspection as all registered vaccines are WHO-prequalified (no need for full evaluation etc.)	
No policy, guidance and procedures for Good Manufacturing Practice (GMP) standard of non-domestic manufacturers (on the contrary, GMP Pharmaceutical Inspection Cooperation Scheme (PICS) is required for local manufactures while there is no local manufacturers in Bhutan).	
No SPC like information of authorized vaccines are available	

Adverse Event Following Immunization (AEFI) and public confidence in vaccine

Background and findings

In recent years Bhutan experienced a sharp increase of the number of AEFI reports. In 2014, for the first 9 months of the year 17 AEFI cases were reported representing 6-fold increase compared to 2009 figures with 3 cases reported. See figure 3 AEFI cases 2009-2014 Bhutan.

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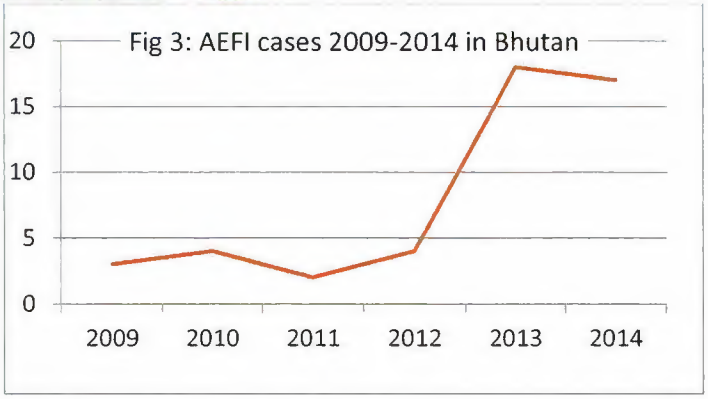
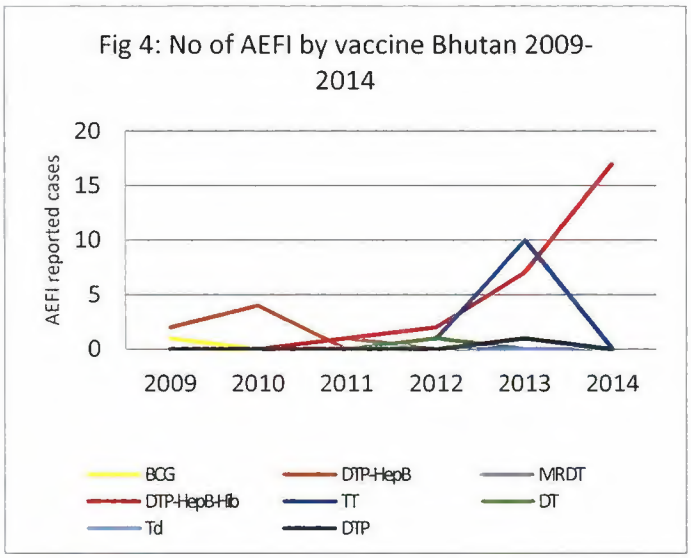


The training workshop on AEFI monitoring and causality assessment conducted in September 2010 with 21 participants[32] contributed to improve capacity of the surveillance system to detect and report AEFI cases. However, in 2013 and during the first 9 months of 2014, Bhutan has experienced an unusual number of serious AEFI and deaths associated to the pentavalent DTP-Hep-Hib vaccine. Fig 4 displays the number of AEFI by vaccine 2009-2014.



The national immunization program target population is small with 13,500 children under less than 1 year old. AEFI are expected but mostly non serious. Serious AEFI cases are extremely rare events. For example anaphylaxis occurs within the range of 1-3.5 per millions doses depending on the type of vaccines[33]. The type of AEFI reported in Bhutan in 2013-2014 shows an abnormal high number of very rare events. Anaphylaxis, sepsis and seizure which are very rare AEFI represents 36% of all cases

[32] The List of Participants included senior pediatricians and medical specialists from Jigmi Dorji Wangchuk national referral hospital inThimphu and Lungtenphu Hospital Royal Bhutan Army, Thimpu; Medical officers from District hospitals including Mangar, Damphu, Riserboo, Trongsa, Samtse, Lhuntshi; Head research and Epidemiological and Chief Program Officer Communicable Disease Division and EPI Program Officer in the Ministry of Health; Director and professors from the Royal Institute of Health Science in Thimpu; Chief Procurement Officer, Pharmacists and representative of the DRA.

[33] http://www.who.int/vaccine_safety/initiative/tools/vaccinfosheets/en/

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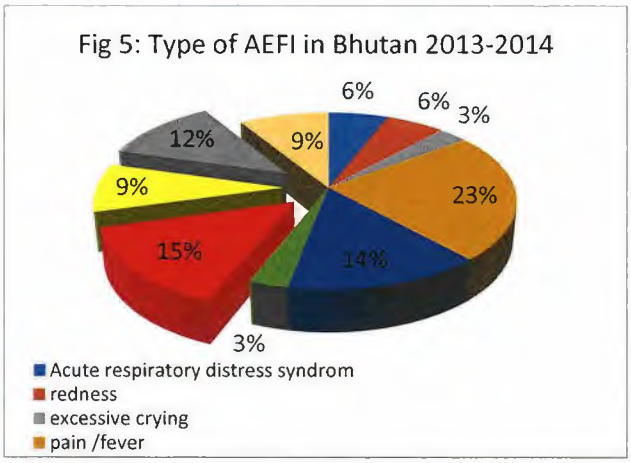
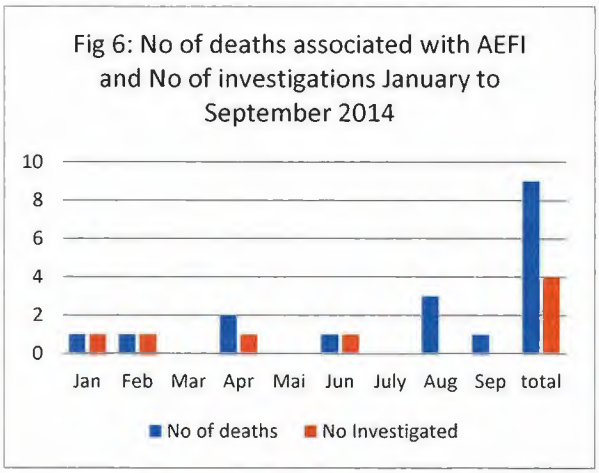
in Bhutan which highlights an over reporting. See figure 5 displaying type of AEFI cases in Bhutan 2013-2014.



The MOH is also concern with the backlog of deaths associated to pentavalent vaccine which have not yet been investigated. In 2012 and 2013 all cases were investigated but in 2014, for the first 9 months of the year, only 4 out of nine AEFI cases were assessed for causality assessment by the national AEFI committee. See Fig 6 No 0f AEFI cases and No of cases investigated in Bhutan in 2014. It is critical to improve the response system when serious AEFI occurred to avoid a crisis situation and loss of public confidence in immunization programme. A core team of investigators including, EPI managers, Epidemiologists, pediatricians and Drug Regulatory Authority representatives should be constituted to respond to notification of serious AEFI with a field investigation conducted within 48 hours. Collecting quality data to enable the causality assessment committee to verify hypothesis of vaccine safety issues is challenging in Bhutan. Cultural barriers to proceed post-mortem autopsy, limited laboratory capacity and geographical access to reach some part of the country within 48 hours are some of challenges that could be addressed with a team well trained that can be deployed rapidly to reinforce Rapid Response Team (RRT) at district level.



In 2014, the national AEFI guideline is to be updated and represent a good opportunity to discuss and finalize a manual for AEFI field investigation to standardize approach to collect quality data with vaccine safety stakeholders including, immunization service providers, family, parents and

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community, hospital pediatricians, NIP programme managers, cold chain manager, the regulator the manufacturer and to enhance access to international expertise on vaccine safety through WHO network when needed.

The NIP and DRA in Bhutan have submitted request to WHO to visit a country with well performing vaccine pharmacovigillence system in the SEA region. Discussions are on-going with Sri-Lanka which has established vaccine safety surveillance system that monitors serious and non-serious AEFI cases.

In 2015, the NIP and DRA propose to conduct training of trainers who in turn will conduct AEFI training workshops with BHU Health Assistant and all immunization providers. Those activities were identified with WHO and are included in country office and regional office workplan 2014-2015. There are funded with existing Gavi contributions to the region for vaccine safety I 2014-2015.

Recommendations and follow-up activities

- The EPI with the collaboration of RDA has developed a draft national AEFI guideline. This draft was shared with WHO for comments. Comments and suggestions will be provided by WHO SEARO Regional Advisor on Vaccine Safety and Quality by mid October 2014.
- WHO SEARO will follow up with DRA request to visit a country in the region to study and share experience to establish vaccine pharmacovigillence system. Sri-Lanka with well-established vaccine pharmacovigillence system with monitoring of serious and non-serious AEFI would be suitable to host a study tour but other countries like Thailand, Indonesia could be other choice to host a study tour of a team of Bhutan DRA/NIP representatives, pediatricians and epidemiologists. WHO will facilitate and support this activity has part of SEARO regional workplan for 2914-2015.
- It is urgent to address AEFI especially serious cases to build EPI and DRA capacity to investigate AEFI within 48 hours. In this connection, it is propose to support a workshop to prepare a manual for AEFI filed investigation to be in annex of the updated national AEFI guideline to be finalized by end of 2014. The objective of this workshop is to review and finalize national AEFI guideline, to enable core team of national AEFI investigators who will be identified by MOH prior to the workshop to plan, coordinate and conduct AEFI field investigation among national vaccine safety stakeholders to collect quality AEFI data to enable national AEFI committee to conduct timely and conclusive causality assessment, the NIP/DRA to provide appropriate responses if programmatic, regulatory and/or case management issues are involved and the MOH to maintain the public informed about vaccine safety and benefits of immunization.
- The 2015 training plan prepared by the DRA with the NIP includes 3 workshops for the training of trainers (TOT) on AEFI monitoring who will in turn provide orientation and refresher trainings to BHU Health Assistants and other immunization service providers. Budget will be funded with MOH funds and SEARO existing Gavi funds for vaccine safety and NRA capacity building.
- There is also need to revise curriculum of medical institutes and training centers that provide pre-service training to medical assistants and other immunization providers. Budget and funding sources were not discussed in depth with DRA and EPI but more long term plan need to be developed to address pre-service training of future immunization providers, hospital pediatricians and nurses about vaccine safety and AEFI case management. To bridge the gap until curriculum are revised and implemented, DRA and NIP with the MoH could encourage the use of

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- WHO Elearning material on AEFI monitoring[34] available on Internet for those involved in providing immunization services.

Activity timeframe, estimated budget and funding sources to implement recommendations

The activities and budgets in Table 1 were discussed with DRA, NIP and Gavi graduation mission to be included into the overall Bhutan graduation plan but is not an additional financial need because they are part of the SEARO workplan for 2014-2015 and were funded by Gavi through grants to WHO region to support vaccine safety and NRA strengthening.

Table 15. Recommendations to strengthen the AEFI monitoring system in Bhutan

Strategy	Activity	Detailed activities
To strengthen AEFI causality assessment through better quality data and dissemination of AEFI training to BHU and hospital Health assistant	Revise and update national AEFI guideline Develop manual for field investigation of AEFI Training workshop to implement AEFI guideline and manual on AEFI field investigation	Printing and dissemination of national AEFI guideline
		3 Training of Trainers (TOT) workshops on AEFI monitoring at provincial level
		3 Training workshops on AEFI with District and BHU EPI staff and vaccinators on AEFI detection and reporting
		Workshop to develop manual on field investigation of AEFI
		Training workshop on AEFI field investigation to train team of DMO and RRT involved in AEFI investigation

[34] http://vaccine-safety-training.org

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Annex 5. List of persons met during the Graduation mission

Name	Designation	Agency	Organization
Ms Kinley Zam	APO	Planning and Policy Division	MoH
Mr Tshewang Tamang	Senior Program Officer	Vaccine preventable disease control program	MoH
Mr Dorji Phub	Deputy Chief	Health Promotion Division	MoH
Mr Khampa Tshering	Deputy HRO	Human resource Division	MoH
Mr Sonam Tobgay	Asst HRO	Human resource Division	MoH
Mr Tshering Jamtsho	Head	Bhutan Medical Health Information Division	MoH
Mr Dopo		Bhutan Medical Health Information Division	MoH
Mr Bhim Thara	Senior Medical technitian	Central Cold store, DMSHI	MoH
Mr Kuenga Jampel	Officiating Director	Department of Medical Supply and health infrastructure	MoH
Dr Dorji Wangchuk	Director General	Department of Public Health	MoH
Mr Pema Wangchuk	Procurement Officer	Medical Supplies and procurement division, DMSHI	MoH
Mr Jangchub	Procurement Officer	Medical Supplies and procurement division, DMSHI	MoH
Mr Choiten Wangchuk	Director General	Department of Public Accounts	MoF
Dr Karma Lhazeen	Chief	Communicable Disease Division, DoPH	MoH
Mr Rudra	Chief	Finance	MoH
Dr Shaheen Nilofer	Representative	UNICEF	UNICEF Bhutan

Dr Isabel	*Health and Nutriton specilaist*	*UNICEF*	UNICEF Bhutan
Mr Kinley		*UNICEF*	
Mr Sho Takano	*Deputy Representative*	*Japanese International Corporation Agency*	JICA, Bhutan Office
Mr Karma Wangdi	*Chief Procurement Officer*	*Public Procurement Policy Division*	MoF
Mr Choizang	*Director*	*Bhutan Health Trust Fund*	
Mr Nado Dukpa	*Chief*	*Planning and Policy Division*	MoH