Response to GAVI Conditionality

Background

In September 2008, the Government of India (GoI) first applied to GAVI funding for new vaccine support (NVS) for the pentavalent vaccine (DPT + Hep B + Hib). The application was reviewed by the Independent Review Committee (IRC) and received conditional approval in November 2008. This response is the second response to the GAVI IRC, following an earlier response by GoI in January 2009, which by an interim GAVI IRC in February 2009 received 'conditional approval' yet again. This response includes the specific responses by GoI to the conditions of the IRC including:

- the analysis of resource requirements reflecting financial burden in case of introduction of new vaccines;
- sources of financing (immunization system components); and
- description of funding gap and sustainability strategies.

Rationale

Classed as a "special country" by GAVI, given the large target immunization population, India has a special cap for support from GAVI which currently includes an approved funding cap of US$365 million. Of the cap, GoI is requesting catalytic vaccine commodity support of US$165 million from the GAVI Alliance for the first two years (2009-2010) for the *Haemophilus influnazae b* (Hib) vaccine as pentavalent (DPT-HepB-Hib) vaccine for the introduction in 10 States of the country, starting 2009. The GoI will fund the vaccine for the remaining beneficiaries that will not be covered under the GAVI support. The procurement of vaccines will be through UNICEF for the initial support period. Beyond the GAVI support, the vaccine will be procured through existing Universal Immunization program processes. The GoI will procure AD syringes and safety disposal equipment to support the introduction of the pentavalent vaccine through existing procurement mechanisms.

The decision to introduce the pentavalent vaccine has been based upon the recommendations of the National Technical Advisory Group on Immunization (NTAGI) to the GoI, in June 2008. The NTAGI noted that there was sufficient data to support the recommendation to implement the introduction of the pentavalent vaccine in Universal Immunization program (UIP) of India. The decision was based on the review of the burden of disease, cost, safety, efficacy and effectiveness of vaccine, supply issues, harmonization of a new vaccine into the UIP, human resource and infrastructural capacity. This decision also builds on the results of the successful implementation of the GAVI supported Hepatitis B program, initially in 14 cities and 33 districts in 2003, followed by further expansion to 10 states in 2007-08. Subsequently, GoI approved the recommendation to introduce the (DPT+HepB+Hib) as liquid pentavalent vaccine in the UIP. The Inter-Agency Health Sector Coordinating Committee (IHSCC) supported the GoI in making programmatic decisions regarding the implementation plan, the vaccine presentation and the approach to introducing the vaccine in 10 states.

As part of the commitment, Government of India has prepared a detailed new vaccine introduction plan (Annex X) which addresses the specific aspects of the Hib introduction into the immunization programme and the Multi Year Strategic Plan (MYP) 2005-2010 for the UIP (Annex X) has been revised with an addendum that now includes a new objective for the introduction of Hib as pentavalent vaccine in UIP in India (Annex X).

The Government of India is committed to utilize the opportunity of the pentavalent introduction to reduce mortality and morbidity associated with: a) chronic HBV infection, including cirrhosis and liver cancer; b) Hib related infections specifically Hib meningitis, Hib pneumonia and other complications; and c) Diphtheria, Pertussis and Tetanus. Additionally, the new vaccine in UIP will provide further opportunities for strengthening the immunization system performance, the AEFI reporting system, increasing the surveillance capacity for Hib disease and monitoring immunization related activities.

The GoI will assume all costs of the pentavalent vaccine once the GAVI support ends. Under the 11th Five Year Plan, GoI will provide provisions to fund and sustain the implementation of the pentavalent vaccine until March 2012 and beyond.

Analysis of Resource Requirement reflecting financial burden in case of new vaccines

In view of the GoI plans to introduce the pentavalent vaccine in the UIP, efforts have been focused on mobilizing appropriate resources, facilitating access to funds, improving reliability and improving the efficiency of the programme.

Prior to the planned introduction of the new vaccine in the UIP, the total resource requirement for the period 2007-2008 was approximately US$346 million, of which the requirement for new vaccines was US$5 million. With the introduction of the pentavalent vaccines in 10 states in 2009-2010, the overall resources requirements goes up to an estimated US$471 million, of which new vaccines represents US$109 million. The breakdown of current and future resource requirements with the new vaccine is shown in table 1 below.

Table 1: Summary of current and future immunization budget

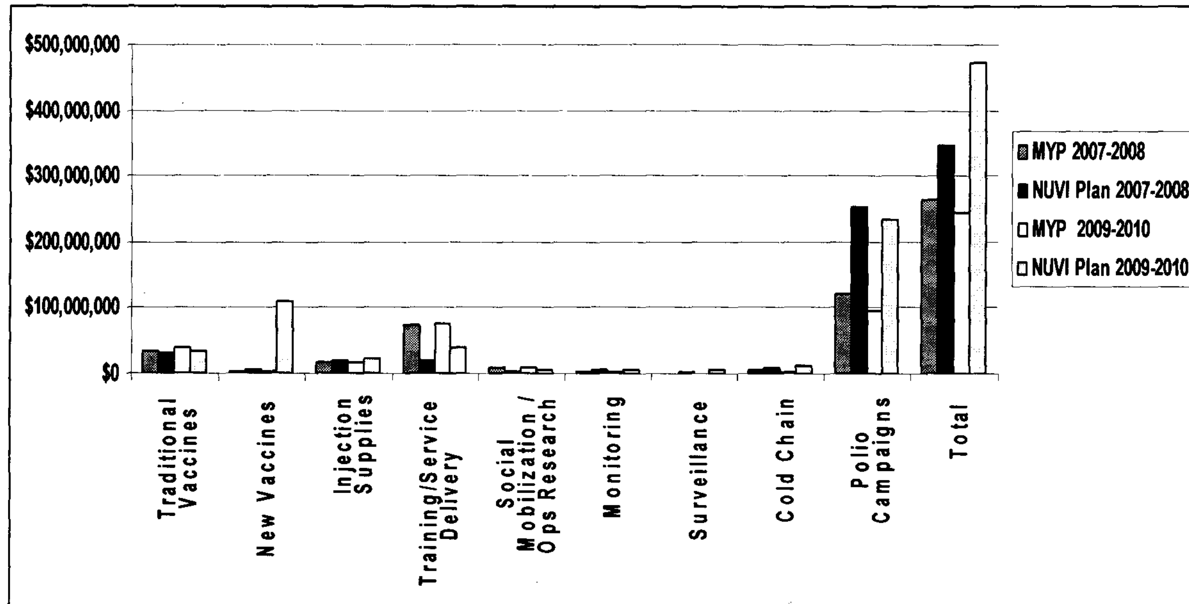
Cost Category	Estimated costs per annum in US$			
	Baseline	2009-2010	2010-2011	2011-2012
Traditional Vaccines	$30,400,000	$35,000,000	$37,000,000	$40,000,000
New Vaccines	$5,000,000	$108,900,000	$89,200,000	$84,800,000
Injection Supplies	$19,000,000	$22,000,000	$26,000,000	$21,000,000
Training	$20,500,000	$40,000,000	$44,000,000	$49,000,000
Social Mobilization	$2,500,000	$6,500,000	$5,400,000	$5,000,000
Monitoring	$4,500,000	$7,000,000	$8,500,000	$8,500,000
Surveillance	$2,500,000	$6,000,000	$12,000,000	$10,500,000
Subtotal Recurrent Costs	***$84,400,000***	***$225,400,000***	***$222,100,000***	***$218,800,000***
Cold Chain	$9,300,000	$12,500,000	$15,500,000	*$13,500,000*
Subtotal Routine Capital Costs	***$9,300,000***	***$12,500,000***	***$15,500,000***	***$13,500,000***
Polio Campaigns	$252,000,000	$233,000,000	$116,000,000	$116,000,000
Subtotal Campaigns	***$252,000,000***	***$233,000,000***	***$116,000,000***	***$116,000,000***
Grand Total	**$345,700,000**	**$470,900,000**	**$353,600,000**	**$348,300,000**

The projected cost in the original MYP 2005-2010) (Annex X) for the year 2009-10 is US$ 512.7 million including human resources, in comparison the revised costs in the new vaccine introduction plan shows a total resource requirement of US$ 471 million for the same period, excluding human resources. The major difference in comparable costs between the MYP 2005-2010 and the new vaccine introduction plan is attributed to the cost of the planned new vaccine introduction and the costing and financing (Annex X) replaces the budget given on page number 38 of the MYP 2005-2010 of India.

The original MYP 2005-2010 has an estimated cost for human resources and training for 2009-10 at US$ 268 million; which is not included in table 1 (as above) for new estimates and only training components have been mentioned, which will cost approximately US$ 6 million. If we deduct the cost of human resources (minus training) from the total of US$ 512 million the comparable figure becomes US$ 244 million in cMYP (2005-10) and US$ 470 million with new estimates in the introduction plan, which is much higher than the cost in the original MYP document. Secondly, the human resources for immunization are provided through the National Rural Health Mission (NRHM). Since the NRHM funded staff have a broader range of responsibilities in addition to immunization, it is not possible to calculate exact cost of the human resources for only immunization in the current scenario. However, the approximate annual cost of the human resources for immunization is estimated at US$ 300 million in India.

With the introduction of the pentavalent vaccine the cost profile of the UIP changes fairly significantly as per Graph 1 and the figures 1 and 2 below. The major change is related to the cost of the new *Haemophilus influenzae b* (Hib) vaccine and related injection safety materials.

Graph 1: Revised Immunization Budget Requirements

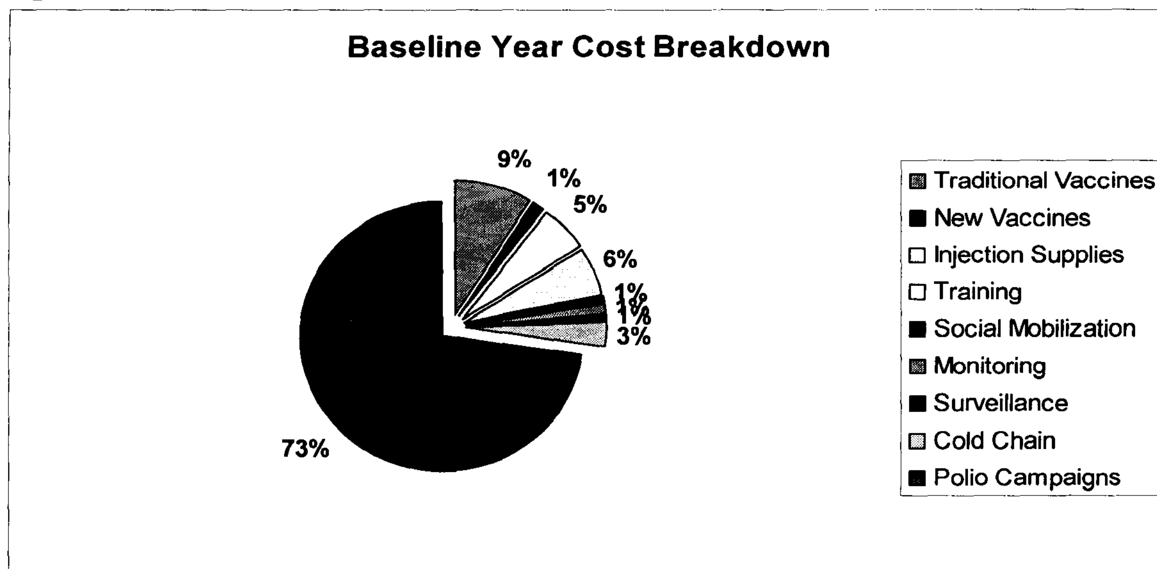


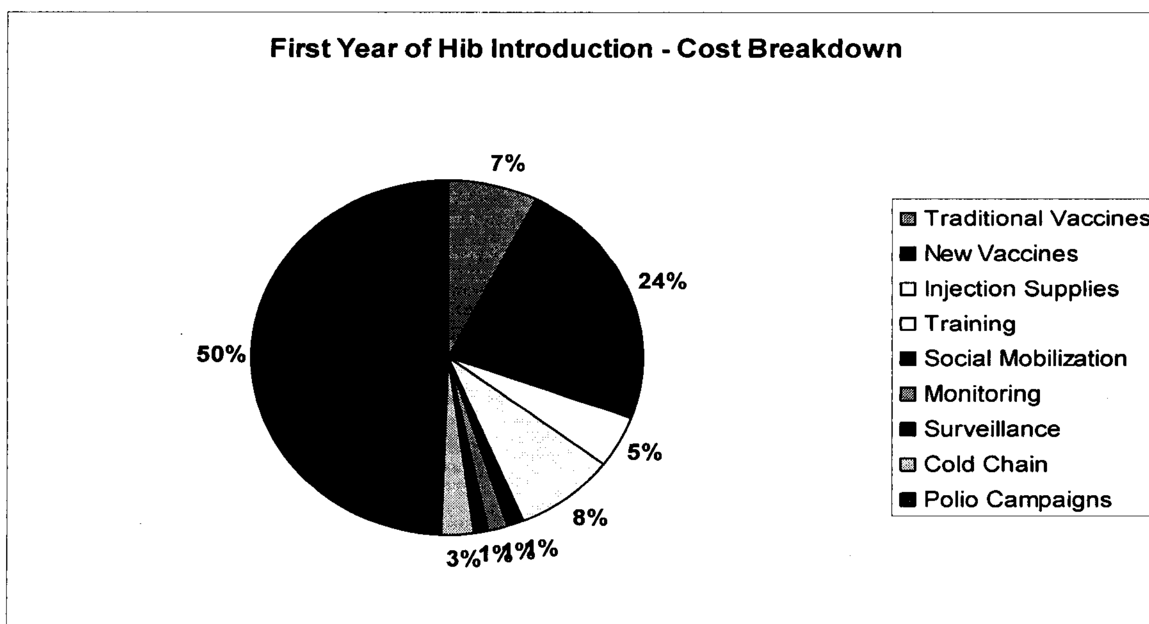
From Graph 1, we see that the costs of the immunization program doubles between the baseline year 2007-2008 to the first full year of new vaccine introduction in 2009-2010 and as compared to the costing table in annex 6 of the MYP (2005-2010) and the New Vaccine Introduction Plan

Evolution of costs with pentavalent introduction

In terms of the evolution of costs and program cost drivers, as per figures 1 and 2 below, we see that new vaccines account for 24% of the overall cost of the program in 2010-2011 as compared to 1% in the baseline year of 2007-2008. The majority of this increase in the budget for newer vaccines has been contributed by the increased budgetary allocation from the government of India and the relative contribution of the donor agencies has proportionately decreased.

Figures 1 and 2: Evolution of Costs





Sources of financing by cost component (Table 2)

The decision to introduce the newer vaccines (Hepatitis B and Hib) in UIP has led to the exercise to revise the budgetary allocation for UIP in India. This new estimated budget has higher investment in immunization program than planned and proposed in India's Multi Year Plan (MYP) 2005-2010 and Eleventh Five Year Plan of India (2007-12). The additional funding for the pentavalent vaccine is likely to be met from GAVI alliance support for new vaccines for India (Expected amount US$ 165 million), and from the savings of the ongoing schemes in the Reproductive and Child Health (RCH) program and The National Rural Health Mission (NRHM), within the Ministry of Health and Family Welfare, GoI.

Table 2: Sources of financing by cost component

Cost Category	Funding Source	Estimated costs per annum in US$			
		Baseline	2009-2010	2010-2011	2011-2012
Traditional Vaccines	GoI	$30,400,000	$35,000,000	$37,000,000	$40,000,000
New Vaccines	GOI/ GAVI	$5,000,000	$108,900,000	$89,200,000	$84,800,000
Injection Supplies	GoI	$19,000,000	$22,000,000	$26,000,000	$21,000,000
Training	GoI	$20,500,000	$40,000,000	$44,000,000	$49,000,000
Social Mobilization	GoI	$2,500,000	$6,500,000	$5,400,000	$5,000,000
Monitoring	GoI	$4,500,000	$7,000,000	$8,500,000	$8,500,000
Surveillance	GoI/WHO	$2,500,000	$6,000,000	$12,000,000	$10,500,000
Subtotal Recurrent Costs		***$84,400,000***	***$225,400,000***	***$222,100,000***	***$218,800,000***
Cold Chain	GoI/UNICEF	$9,300,000	$12,500,000	$15,500,000	*$13,500,000*
Subtotal Routine Capital Costs		***$9,300,000***	***$12,500,000***	***$15,500,000***	***$13,500,000***
Polio Campaigns	GoI/Polio Partners	$252,000,000	$233,000,000	$116,000,000	$116,000,000
Subtotal Campaigns		***$252,000,000***	***$233,000,000***	***$116,000,000***	***$116,000,000***
Grand Total		**$345,700,000**	**$470,900,000**	**$353,600,000**	**$348,300,000**

It is to be noted that the budgetary allocation for the UIP by GoI are made under the broad umbrella of Reproductive and Child Health (RCH) program, which itself is the part of NRHM in India.

In the last decade, there have been efforts to increase allocation for health programs in India. The National Rural Health Mission envisages increasing the proportionate allocation for health programs from the year 2000 baseline of 0.9% of GDP to 2-3% of GDP by 2012. This is also the goal in the National Health Policy of 2002. Furthermore, there has been a constant reduction in the proportion of donor funding, in anticipation of the increases in the government funding. The funding from the donor agencies has usually been used as a catalyst only.

Funding Gap and Financial Sustainability Strategies

The GoI has secured funding for the UIP in India for the 11th Five Year Plan period (2007-12), which is reflected in Table 3. With new vaccine introduction and considering probable and secure funding the financial gap is expected to increase gradually.

To bridge the funding gap, the GoI will also approach various development partners and donor agencies. The probable funding for the introduction of new vaccines from GAVI alliance is included in Table 3. The allocation for the procurement of the vaccines included in the UIP is always secured first as a priority to ensure sustainable availability of funds for vaccines. Any deficiency in the budget for UIP is always managed from unspent balances of other programs under the Ministry of Health and Family Welfare, including the NRHM.

Table 3: Resource Requirement, Financing and Gap Analysis

		2009-10	2010-11	2011-12
(A)	Total Resource Requirement	$470,900,000	$353,600,000	$348,300,000
(B)	Total Secured Funding from GOI			
	As per 11th 5 year plan	$ 348,013,953	$ 281,832,558	$ 288,288,372
	Others	Nil	Nil	Nil
	Total	$ 348,013,953	$ 281,832,558	$ 288,288,372
(C)	Probable Funding			
	GOI	As Above	As Above	As Above
	Others GAVI	$ 102,700,000	$ 62,300,000	Nil
(D)	Funding Gap with Secured and Probable Funding (A) – [(B)+(C)]	$ 20,186,047	$ 9,467,442	$ 60,011,628

Table 4: Break Up of Funding under 11th five year plan

(A)	Routine Immunization				
		2009-10	2010-11	2011-12	Total
	(i) Vaccines for Routine Immunization including JE	45,581,395	47,674,419	50,000,000	143,255,814
	(ii) Vaccine for Hepatitis B	33,153,488	33,820,930	36,788,372	103,762,791
	(iii) Needles and Syringes	9,302,326	9,302,326	9,302,326	27,906,977
	(iv) Cold Chain Equipment	27,906,977	27,906,977	27,906,977	83,720,930
	(v) Operation Research	465,116	465,116	465,116	1,395,349
	(vi) New Vaccines /	465,116	465,116	465,116	1,395,349
	Total	116,874,419	119,634,884	124,927,907	**361,437,209**
(B)	Pulse Polio Immunization				
	(i) Procurement of Vaccines	93,116,279	58,197,674	58,197,674	209,511,628
	(ii) Operating Cost including Corrective Surgery	96,162,791	60,976,744	60,976,744	218,116,279
	Total	189,279,070	119,174,419	119,174,419	**427,627,907**
(C)	Funds given to States for Immunization under NRHM	41,860,465	43,023,256	44,186,047	129,069,767
	Total				**129,069,767**
	Grand Total in US $	348,013,953	281,832,558	288,288,372	918,134,884

The table 3 and 4 above provides information on Five year plan funding and probable funding for Immunization Programme in India. There is a funding Gap in all three years for Immunization Programme. However, the detailed analysis of 11th Five year plan funding from GOI reflects that there is a sufficient funding allocation for the introduction of Pentavalent Vaccine in UIP in India. A major proportion of funding gap is in Routine Immunization during years 2009 to 2012 which is likely to be filled by funding from donors during this period. The second major gap appears due to cost of training, social mobilization and monitoring which are the parts of the broader umbrella of RCH/NRHM and funding for these activities are secured through different programmes and not included in the secured funding as described in Table 3 and 4.

Immunization financing sustainability

GoI is requesting GAVI to provide $165 million to support the introduction of pentavalent vaccine in 10 states as the initial catalytic funding needed to introduce the vaccine. The GoI will fully finance the vaccination of the children that are not covered under the GAVI support. The financing of the cost of AD syringes and waste management equipment has already become part of the planned immunization budget in India. Once GAVI funding is fully utilized, the GoI will assume all costs of pentavalent vaccine on a gradual basis starting in 2010-11 with transition to full GoI funding in 2011-12.

Improving Reliability

Procurement

The decision by GoI to procure the pentavalent vaccines through UNICEF for the medium term is to ensure a sustainable supply of reliable vaccines for the UIP and until the supply through direct procurement can be better assured.

Donor Support

GoI will continue to work with existing and new donors in improving the predictability and flow of funding to UIP and is committed to develop the next MYP as a platform for continued and new dialogue with donors for securing medium to longer term funding for the UIP.

Multi Year Funding:

The GoI has budgeted for the UIP in India for the 11th Five Year Plan period (2007-12), which is reflected in Table 2 above. This allocation is for all the activities in the immunization program including vaccine procurement. The GoI makes every effort to ensure that sufficient budget is allocated and available for the UIP, particularly, for the procurement of vaccines, as a priority. The multi year planning is one such mechanism to ensure the funding sustainability. Furthermore, in case of any unanticipated funding requirement, there is a provision of managing the unspent balance from the other schemes of health ministry including NRHM. The GoI may also approach various development partners and donor agencies for additional funds. The probable funding for the introduction of new vaccines from GAVI alliance is included in Table 3.

Improving Program Efficiency

Poor vaccine management practices and high vaccine wastage rates can lead to poor utilization of resources. There are a number of areas where UIP shall work to ensure improved efficiency of the programme.

The vaccine management assessments (VMA) have started in India and will continue. The assessment will help identify programme inefficiencies and more importantly lead to implementation of corrective strategies.

The overall objective for programme efficiency will focus on wastage reduction through better vaccine management practices, cold chain improvements in line with the recent cold chain assessment recommendations and enhanced monitoring and supervision. A pilot to assess the safety and efficiency of Open Vial Policy is being planned as part of the introduction of pentavalent vaccine.

The GoI will ensure that all activities related to the implementation of the pentavalent vaccine are monitored. A post introduction evaluation will be conducted 6-12 months after the introduction.