GAVI/14/369/lm/dg/rk

Dr. Harsh Vardhan
The Minister of Health
Ministry of Health
155 - A, Nirman Bhavan
New Delhi – 110108
India

31 July 2014

Dear Minister,

Supplementary Annual Progress Report 2012 submitted by India

I am writing in relation to India's proposal to the GAVI Alliance for New Vaccines Support (NVS) for national scale up of pentavalent vaccines, submitted to GAVI in January 2014. This proposal was reviewed by the GAVI Independent Review Committee (IRC) in March 2014 and recommended for 'Approval with Clarifications'. We have since received a satisfactory response to these clarifications. I am pleased to inform you that consequently the GAVI Executive Committee (EC) on 12 May 2014 approved India's request for pentavalent vaccines as specified in the Appendices to this letter.

I would like to take this opportunity to re-iterate the provisions of GAVI support for pentavalent vaccines in India, previously communicated in our letter dated June 27, 2013 (GAVI/13/394/mk/rk) and also in the Information Letter dated March 25, 2014 (GAVI/14/181/ap/dg) following the IRC review in March 2014.

The terms and conditions of our financial support in 2015 are:

- GAVI agrees to support two thirds of the vaccine costs for continued implementation of the programme in 2015, up to a maximum of additional US$100 million.
- India agrees to provide additional financing for the remaining one third of birth cohort in 2015 and fully finance from 2016 onwards.

The GAVI Alliance approved in 2009 US$ 165 million for the support of the pentavalent programme in India. From this amount until the end of 2013 US$ 62.6 million were disbursed. The Indian programme will thus be supported by the GAVI Alliance with up to US$ 202.4 million (US$ 102.4 million + up to US$ 100 million) in 2014 and 2015 subject to the above mentioned terms and conditions (see Appendix B, Table 9 and 11 for the details).

The full cost of national scale up of pentavalent vaccines until April 2016 is approximately US $ 292.2 million (138.5 million doses as per the nation-wide scale-up plan. US$ 2.11 per dose – current GAVI price). The Government of India has made the commitment to fully self-finance the pentavalent programme from financial year 2016 onwards.

To ensure that we comply with the above terms and conditions related to GAVI's financing I kindly ask you to inform the GAVI Alliance on how the additional financial resources will be mobilized to ensure the implementation of the penta roll-out as planned until the end of

GAVI Alliance
2 chemin des Mines
1202 Geneva
Switzerland
Tel. +41 22 909 6500
Fax +41 22 909 6555
www.gavialliance.org
info@gavialliance.org

financial year 2015. It is important for us to know of any challenges you may face in this respect.

The Appendices of this letter include the following important information:

Appendix A: Description of approved GAVI support to India.
Appendix B: Financial and programmatic information per type of support
Appendix C: A summary of the IRC Report
Appendix D: The terms and conditions of GAVI Alliance support.

The following table summarises the outcome of GAVI support for the pentavalent programme in India:

Type of support	Appendix	Endorsed for 2015	Approved for 2015
NVS Pentavalent	B	US$ 136,871,623	US$ 96,871,623

Partnership Framework Agreement between India and the GAVI Alliance

India received a Partnership Framework Agreement (PFA) in February 2013. I would like to underline that to date the signatures of the Ministry of Health and Ministry of Finance on the PFA are still pending. The constructive discussions of the GAVI Secretariat with MoF/DEA and MoHFW to resolve a few outstanding issues are currently ongoing. However, please be advised that any GAVI funding to India in future will be subject to signing of the PFA.

Please do not hesitate to contact my colleague dgehl@gavialliance.org if you have any questions or concerns.

Yours sincerely,

Hind K. Khatib

Hind Khatib-Othman
Managing Director, Country Programmes

cc (via Email):

PS, The Minister of Health and Family Welfare
PS, The Minister of Finance
Secretary, Ministry of Health and Family Welfare
Additional Secretary, MD NHM, Ministry of Health and Family Welfare
Joint Secretary, Ministry of Health and Family Welfare
Deputy Commissioner (MCH), Immunization and HSS, MoHFW
Deputy Commissioner (Immunization); MoHFW
Deputy Commissioner (UIP), MoHFW
WHO Country Representative
UNICEF Country Representative
WHO HQ
UNICEF Programme Division
UNICEF Supply Division

Appendix A

Description of GAVI support to *India* (the "Country")

New Vaccines Support (NVS)

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

- The GAVI Alliance Guidelines governing Country's proposal application; and
- The final proposal as approved by the Independent Review Committee (IRC), including any subsequent clarifications.

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

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

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

The Country shall be solely responsible for any liability that may arise in connection with: (i) the implementation of any programmes in the Country; and (ii) the use or distribution of vaccines and related supplies after title to such supplies has passed to the Country. GAVI shall not be responsible for providing any additional funding to replace any vaccines and related supplies that are, or became, defective or disqualified for whatever reason.

Country Co-financing

The following section on country co-financing does not apply to the current GAVI support for India as the country is not required to co-finance vaccines. The standardized stipulations (in square brackets below) remain in the document for information purposes only:

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

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

If the purchase of the co-financed supply is carried out through UNICEF or PAHO, the payment is to be made to UNICEF or PAHO (whichever is applicable) as agreed in the Procurement Services Memorandum of Understanding between UNICEF or agreements

between PAHO (whichever is applicable) and the country, and not to the GAVI Alliance. Please keep in contact with UNICEF or PAHO (whichever is applicable) to understand the availability of the relevant vaccine(s) and to prepare the schedule of deliveries.

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

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

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

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

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

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

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

Not applicable to India: [Country Co-financing: GAVI must receive proof of country co-payment from the Country such as invoices or shipment receipts if neither UNICEF nor PAHO is the procurement agent for country co-financed vaccine for the prior calendar year.]

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

Country will report on the achievements and request support for the following year in the Annual Progress Report (APR) or equivalent. The APR or equivalent must contain information on the number of children reported to have been vaccinated with DTP3 and pentavalent vaccine dose 1 & 3 by age 12 months, based on district monthly reports reviewed by the Immunisation Coordination Committee (ICC), and as reported to WHO and UNICEF in the annual Joint Reporting Form (JRF). [Not applicable to India: The APRs or equivalent will also contain information on country's compliance with the co-financing arrangements outlined in this letter.] APRs or equivalent endorsed by the ICC (India: Immunization Action Group, IAG), should be sent to the GAVI Secretariat no later than 15 May every year. Continued funding beyond what is being approved in this letter is conditional upon receipt of satisfactory Annual Progress Reports or equivalent and availability of funds.

Appendix B

India
VACCINE SUPPORT

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

1. **Country:** India
2. **Grant Number:** 1014-IND-04c-X / 15-IND-04c-X
3. **Date of Decision Letter: 30 July 2014**
4. **Date of the Partnership Framework Agreement:** Not yet signed
5. **Programme Title:** NVS
6. **Vaccine type:** Pentavalent
7. **Requested product presentation and formulation of vaccine:** DTP-HepB-Hib, 10 dose(s) per vial, LIQUID
8. **Programme Duration**[1]**:** 2011 - 2015
9. **Programme Budget (indicative) (subject to the terms of the Partnership Framework Agreement):**

	2011-2012	2013	2014	2015	Total[2]
Programme Budget (US$)	38,144,719[3]	24,441,746	65,541,912	136,871,623	265,000,000

10. **Vaccine Introduction Grant:** Not applicable

[1] This is the entire duration of the programme.
[2] This is the total amount endorsed by GAVI for the entire duration of the programme. This should be equal to the total of all sums in the table.
[3] This is the consolidated amount for all previous years.

11. Indicative Annual Amounts (subject to the terms of the Partnership Framework Agreement):[4] In reference to the Decision Letter dated 21 October 2013, the Annual Amounts for years 2011 to 2014 have been amended as follows:.

Type of supplies to be purchased with GAVI funds in each year	2011-2012	2013	2014	2015
Number of Pentavalent vaccines doses		11,602,470[5]	31,136,500	46,141,000
Number of AD syringes				
Number of re-constitution syringes				
Number of safety boxes				
Annual Amounts (US$)	US$38,144,719[6]	US$24,441,746	US$65,541,912	US$96,871,623

12. Procurement agency: UNICEF.

13. Self-procurement: Not applicable.

14. Co-financing obligations: Reference code: Not Applicable

15. Operational support for campaigns: Not applicable

16. Additional documents to be delivered for future disbursements: Not applicable

Reports, documents and other deliverables	Due dates

17. Financial Clarifications: Not Applicable

[4] This is the amount that GAVI has approved. Please amend the indicative Annual Amounts from previous years if that changes subsequently.
[5] This amount includes 3.93 million doses that were not used in 2013 and which will be used in 2014. The total number of doses available for 2014 amounts to 35.1 million which is equal to the dose requirements as per the application which India submitted and which was reviewed by the IRC in March 2014.
[6] This is the consolidated amount for all previously approved years.

18. Other conditions: Not Applicable.

Signed by,

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

30 July 2014

Independent Review Committee (IRC) Country Report
GAVI Secretariat, Geneva • 27 February – 7 March 2014
Country: India

1. Type of support requested

Type of support requested	Planned start date *(Month, Year)*	Duration of support	Vaccine presentation(s) *(1st and 2nd choice, if applicable)*
Pentavalent for 11 states	Oct 2014	Up to March 31st 2016	DTP-HepB-Hib, 10 dose(s) per vial, LIQUID
Pentavalent for 16 remaining states	April 2015		

Background:
GAVI is currently funding pentavalent vaccine in eight Indian states. Tamil Nadu and Kerala introduced in December 2011, and Karnataka, Puducherry, Goa, Gujarat, Jammu and Kashmir and Haryana during 2012 – 2013. India applied for pentavalent vaccine in September 2008 and was approved in June 2009. India is now asking for nation-wide expansion until Q1 2016: 11 states plan to introduce in October 2014 and 16 states in April 2015.

India is a country subject to a tailored approach within the GAVI portfolio. According to strategic directions from the GAVI Board, the Secretariat applies a certain degree of flexibility and provides technical support to the country on how to apply for and implement vaccine and health systems support. In a letter from Seth Berkley to India in June 2013, the following funding limits are given by GAVI:

- GAVI agrees to India's request to utilize the unspent balance of approximately $100 million (from previously approved $165 million) to cover an additional birth cohort of 12.89 million children in 2014.
- GAVI agrees to provide additional GAVI support to enable pentavalent introduction in all states in 2014, covering the remaining birth cohort of 8.84 million children up to a maximum of $30 million (any unspent funds from the previously approved balance of $165 million will be offset against this cost).
- GAVI agrees to support two thirds of the cost for continued implementation of the programme in 2015, up to a maximum of $100 million.
- GAVI agrees that India will provide additional financing for the remaining one third of birth cohort in 2015 and fully finance from 2016 onwards.

This amounts to a limit of approx. $211 million[7] for additional pentavalent vaccine support under the above defined conditions.

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

The NTAGI was established in 2001. However, the committee has not functioned optimally all the time. It was reconstituted twice in 2008 and again in June 2013. According to the cMYP, there is a need for a well-defined NTAGI secretariat, regular meetings and clear scope of work. An objective in the cMYP is to "institutionalize mechanisms to guide the introduction of newer and underutilized vaccines".

On September 23, 2013 NTAGI endorsed scale-up of pentavalent vaccine in the remaining 27 states in a phased manner with simultaneous strengthening of the AEFI and sentinel surveillance systems.

Minutes are enclosed from an India Immunization Partner's meeting on 17th January 2014. This was convened to discuss plans for a Post Introduction Evaluation for pentavalent vaccine introduction in the six states that introduced during 2012-2013. There were 13 meeting participants from MOHFW, WHO and UNICEF. They are aiming to complete the PIE before the next APR is due in May.

Minutes of the 1st meeting of the Mission Steering Group of the National Rural Health Mission were also enclosed. Pentavalent vaccine scale up was among the agenda items discussed (Agenda Item #11).

3. Situation analysis – Status of the National Immunisation Programme

National vaccination coverage is believed to be around 72%. However, there are major differences in coverage among the states, ranging from below 30% to above 90% in some states. The private health sector provides an estimated 15–20% of immunization services.

Measles 2nd dose vaccine introduction

In 2010, 21 states with measles 1st dose coverage > 80%, introduced MCV2 in routine and 14 states did measles campaigns, followed by routine MCV2 introduction.

Delhi, Sikkim, Goa and Puducherry financed introduction of a 2nd measles dose (MMR) from their state budgets.

In September 2013, India committed to eliminating measles and controlling rubella/congenital rubella syndrome (CRS) by 2020, as part of SEARO's 66th regional committee.

---

[7] This amount has been updated by the GAVI Secretariat to be consistent with financial information as of July 2014.

Other new vaccines considered:
The Indian Government is considering introducing IPV and MR nationally. It is likely that PCV and rotavirus will be piloted in a selected state, but there are currently no concrete recommendations and plans for these vaccines.

Immunization Technical Support Unit (ITSU)
The Immunization Division at MoHFW has set up an Immunization Technical Support Unit (ITSU) staffed with technical officers. The unit will support various functions of the Universal Immunization Programme (UIP) in six areas:

- Strategic planning and system design;
- Monitoring and evaluation;
- Vaccine logistics and cold chain management;
- Adverse events following immunization (AEFI) management;
- Vaccine quality and safety; and
- Translation of evidence to policy, and strategic communication.

National Rural Health Mission:
The Mission has had a major positive impact on vaccination services in recent years. Districts have been provided with more human and financial resources. A community link worker has brought about a major improvement in community mobilization. Districts have strengthened their delivery systems and developed micro-plans for improved efficiency. The numbers of vaccine delivery and cold chain points have increased.

AEFI:
A target in the new cMYP is to "Institutionalize and strengthen surveillance mechanisms for AEFIs". An AEFI secretariat for the National AEFI Committee has been set up at ITSU-MoHFW to coordinate all AEFI related activities, with technical support and oversight from a leading medical college. Zonal AEFI consultants are planned to be in place to provide technical support and oversight to the AEFI Secretariat in the 4 zones of the country and enable timely reporting, investigation and support to the states. National AEFI Operational Guidelines which were revised in 2010 are again being revised and will be published in 2014.

GAVI Health System Support:
A HSS proposal has recently been approved by GAVI. The project will be implemented by the WHO, UNICEF and UNDP during 2014-16.

Aims:

1) Strengthen vaccine logistics and cold chain management in poor performing states through public-private partnerships and through improved human resources capacity, institutional strengthening and supportive supervision;
2) Design and implement an electronic vaccine intelligence network (eVIN) that will enable real-time information on cold chain temperatures and vaccine stocks and flows;

3) Increase in demand for routine immunization (RI) through innovations in behaviour change communication (BCC) Strategies;
4) Strengthen the evidence base for improved policymaking (at all levels) on programmatic areas like procurement and vaccine delivery and on sequencing and adoption of new antigens; and
5) Leverage the success of the National Polio Surveillance Project (NPSP) to strengthen routine immunization service delivery in 8 priority states.

4. Overview of national health documents

The first cMYP was for 2005-2010. The new cMYP is for 2013-2017. A cMYP supplement was prepared in the gap years that lasted until 2012.

cMYP preparation consultations with stakeholders were held in New Delhi and Kolkata. A core committee worked on the document, which was sent to NTAGI for comments before finalization.

Impressive, detailed strategies are given for all the cMYP objectives. The pentavalent vaccine is included in the schedule in the new cMYP and "number of states showing Pentavlent3 coverage of >80%" is a performance indicator for new vaccine objective of the plan. There is a section on pentavalent introduction as part of the activities.

Eleven sentinel sites for Hib meningitis in six different states have started in 2013 to measure impact trends of vaccination.

5. Gender and Equity

The new cMYP notes that "there are significant inequities in vaccination coverage in different states based on various factors related to individual (gender, birth order), family (area of residence, wealth, parental education), demography (religion, caste) and the society (access to health care, community literacy level) characteristics", and "there is a clear gender coverage differential as reported by different surveys. Boys generally have higher vaccination coverage than girls as reported by most surveys conducted across the country."

The cMYP key objectives include:

- Improve program service delivery for equitable and efficient immunization services by all districts
- Increase demand and reduce barriers for people to access immunization services through improved advocacy at all levels and social mobilization

The Introduction Plan for the nation-wide scale-up of pentavalent vaccine contains details on cold chain improvements and on developing a more robust approach to AEFI, but there is nothing specific in the document related to addressing gender and equity gaps.

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

The 11 states scheduled to introduce pentavalent vaccine in October 2014 collectively have the highest burden of disease, and have requested the Government for pentavalent vaccine. The remaining states consist of two groups: UP, Maharashtra and Odisha have high disease burdens and diverse health system challenges while the other states have small, scattered populations on hilly terrains. For a smoother implementation, these states are proposed for introduction in April 2015.

The number of doses requested is outlined in Table 3 of the introduction plan:

Year	**2014**	**2015**	**2016**
Target infant cohort			
Cohort already being covered as on Jan 01 of the year (a)	5,037,000	18,300,000	27,394,000
Additional targeted cohort to start in the year (b)	13,053,000	9,094,000	0
Vaccine doses requirement			
For the cohort already being covered for entire year (= a*3 doses*15% Wastage) (c)	17,830,980	64,782,000	96,974,760
For the additional cohort starting in the year (d)	11,551,905	24,144,570	0
Buffer stock needed for the cohort starting in the year (equal to 25% of annual cohort being targeted or =(b*25%*3*1.18) (e)	11,551,905	8,048,190	0
Total vaccine doses requirement in the year (=c+d+e)	**40,934,790**	**96,974,760**	**96,974,760**
US$ (US$ 2.1 per dose)*	**85,963,059**	**203,646,996**	**203,646,996**

*This row has been calculated by the IRC using the price per dose quoted in the introduction plan

The IRC calculates the total funding required for pentavalent vaccine over the period as approximately US$ 493,257,051. When excluding the 2014 doses for the eight states where pentavalent vaccine has already been introduced, the amount required comes to US$ 455,811,993. As stated in the introduction of this document, the funding limit from GAVI is US$ 211 million with certain conditions (see p. 1).

In Table 1, the birth cohort is used as the target population and 100% coverage has been assumed. Moreover, even though the vaccine is only scheduled to be introduced in October 2014 and April 2015, the full birth cohorts of the respective states have been used. This is not the usual practice for GAVI vaccine applications. The standard procedure is to multiply the number of surviving infants by either the most recent or the target coverage rate and by the vaccine wastage factor. Since the real coverage rates in the various states are considerably less than 100% and since only a fraction of the birth cohort will be covered in the introduction years, the number of doses needed have been overestimated in the introduction plan.

India has recently introduced an open vial policy, which has led to projections for pentavalent vaccine wastage in a 10 dose liquid presentation at 15% at the time of introduction. The introduction plan indicates wastage of 25% in 2013, reducing to 10% in 2017. However, while it is commendable to have such a goal and while it might be feasible in the longer term, especially in light of the current implementation of the open vial policy, the IRC is concerned that this target is not based on evidence of current wastage rates on a state-by-state basis. In a 2010 UNICEF study on vaccine wastage rates in India, it was concluded the national average wastage rates for DTP in a 10-dose vial was 38%. In the five studied states, this wastage rate varied between 19% and 58% (source: UNICEF, Vaccine Wastage Assessment, Field assessment and observations from National stores and five selected states of India, April 2010). It should be noted that these data were collected before the open vial policy was implemented. However, without another formal evaluation of the current DTP wastage rates, it is not possible to say whether the 15% target is realistic or not. Pentavalent vaccine wastage was documented in the Post Introduction Evaluation for Tamil Nadu and Kerala as around 8%, but these are high performing states.

cMYP cost and financing analysis:

The report on costing and financial sustainability of the India Immunization Program was developed during June to December 2013, under the auspices of the Immunization Technical Support Unit (ITSU) in India and assisted by the immunization partners WHO and UNICEF. Total UIP costs in 2012 were $718 million, including shared health systems costs. Expenditures on the routine program were $261 million and campaign activities $182 million.

The 2012 UIP costs were used to project resource requirements for the 2013-2017 cMYP ($5,282 million). The resource requirement will increase due to the new vaccine introduction and other program improvements.

The Government of India paid for most of the program expenditures (90%) in 2012. Other sources of financing were WHO (4%), UNICEF (3%) and GAVI (3%). Partners provided funding support for activities such as training, disease surveillance, IEC/social mobilization. The government health budget is expected to increase in the coming years to meet the growing resource requirements of the UIP.

The GoI will fund vaccination with pentavalent vaccine once GAVI Alliance support has ended.

7. Specific comments related to requested support

New vaccine introduction plan

Lessons learned from the PIE in Tamil Nadu and Kerala are emphasised in the introduction plan.

State-wise implementation will follow program implementation plans (PIPs) that all states submit to the National Health Mission.

Very detailed plans for AEFI are included in the introduction plan.

Training of staff will be cascaded from the state down to the block level. Training of trainers will be conducted at state and district level with the support of partner organizations. The trainers will conduct a half day intensified and focused training of the front line workers at the block level before the introduction of the vaccine. The quality of trainings and their progress will be monitored with the support of partners.

Pentavalent vaccine will be procured through UNICEF as is the case for the eight states using it now. The reason to procure through UNICEF for a vaccine produced in India is explained as: "*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*".

Vaccine management and cold chain capacity

India has one of the largest UIPs in the world, targeting over 26 million new-borns through over 28,696 health facilities in 640 districts of 28 states and seven Union Territories with five levels to the supply chain system.

India is deliberating on the options of introducing the Inactivated Polio Vaccine as a part of the polio end-game strategy and the combined Measles and Rubella vaccine as a part of its goal of eliminating measles and controlling rubella by 2020. The country is also looking at the possibility of a pilot introduction of PCV and rotavirus vaccine in selected states. The introduction plan proposes to support the introduction of pentavalent vaccine and also facilitate the process for future introduction of other newer vaccines.

A HSS proposal, approved for GAVI funding also aims to strengthen cold chain capacity in 12 states of India, where pentavalent vaccine is proposed to be introduced. The EVMA's have already been done in the majority of states proposed in this scale up.

A National Cold chain and Vaccine logistics Action plan (NCCVLAP) will be developed which shall provide directions, strategies, guidelines and standards for Immunization Supply Chain strengthening. The timeline calls for this to be in place by August 2014

National Supply Chain Snapshot (2013):

EVM's have been conducted in a number of states in order to develop a national portrait of the vaccine management situation. A National performance summary is shown below.

Summary of consolidated EVM indicator score

#	Indicator	Consolidated Scores					
		4 GMSD	18 State / RVS	14 Divisions	28 Districts	52 HF	National Average
1	Vaccine Arrival Process	52%	34%	NA	NA	NA	43%
2	Vaccine Storage Temperature	37%	43%	46%	71%	70%	54%
3	Storage Capacity	71%	66%	46%	57%	76%	63%
4	Building, CC Equip. & Transport	65%	64%	69%	70%	75%	69%
5	Maintenance & Repair	59%	61%	59%	58%	49%	57%
6	Stock Management	57%	56%	49%	46%	45%	51%
7	Distribution	24%	41%	39%	42%	77%	45%
8	Vaccine Management Practices	29%	50%	35%	47%	67%	46%
9	MIS & Supportive Functions	50%	65%	52%	58%	0%	56%

No criteria at any level of the 5 tier supply chain meets the WHO minimum recommended norm of 80%. Central store standards are the weakest of any assessment criteria and should be addressed as a high priority to avoid major risk to large volumes of supplied vaccines.

The following paragraphs summarise the key findings of the national assessment and measures required to strengthen the supply chain.

1. Pentavalent vaccine arriving from manufacturers will be registered and stored in the 4 GMSD stores and/or the state stores dependent upon the manufacturing source. National guidelines for vaccine arrivals are required. Substantially better monitoring and supervision is required at the regional and state headquarters locations. An average performance rating of only 43% is achieved. Also the national MIS needs to be revised to include provision for generating and reporting vaccine arrivals.

2. Monitoring of storage temperatures of Penta is important as it is freeze sensitive and somewhat heat sensitive (VVM 7-14) dependent upon source). Most vaccine storage equipment is not fitted with adequate temperature monitoring devices or devices are not working. Appropriately 75,000 temperature monitoring devices need to be procured and installed and personnel trained. Better monitoring and supervision and data management are also required.

3. 40,340 vaccine storage points are required, of which 27,000 are currently available but equipment needs to be replaced at 50% of the existing locations. An estimated 56,476 vaccine storage refrigerators/freezers. (>5,000 refrigerators will be solar and >5,000 hybrid) and approximately 430

cold/freezer rooms are required in the coming 3 years to accommodate the shortfall. Many newly supplied cold/freezer rooms need to be installed/made functional. Dry good storage space also needs to be addressed.

4. An estimated 85% of vaccine storage buildings (34,290 storage points) need physical improvement and more than 50% provided with data communication systems. More than 50% of districts and divisional stores need functioning generators and fuel supply. Forty four per cent of locations have poor transport systems and 24% have no transport.

5. Maintenance of equipment and facilities is a major issue. Maintenance standards of facilities were only 19% adequate and equipment maintenance standards 34% adequate over a sample of 116 locations

6. Max/min stock levels and vaccine wastage rates are not defined at any location. Stock outs of several vaccines are not uncommon. Stock monitoring, supervision and record keeping standards are less than adequate. Major improvements in vaccine stock management practices and systems, monitoring and supervision are required.

7. Vaccine distribution schedules are not respected and conducted in a timely manner at 75% locations. Vaccine transports practices are inappropriate for freeze sensitive vaccines and freeze indicators are not used and supply movements poorly documented.

8. Health worker knowledge of safe practices is good, but vaccine wastage reporting poor in 90% locations and waste management and disposal practices need improvement.

9. The quality of training on cold chain and vaccine management is good, but evidence based needs forecasting and vaccine wastage recording is low.

Conclusions:

The cold chain as a whole needs to be revitalized in order to improve the current standards, capacity and quality. Costs of doing this are estimated below at $342m over a 5-year period (2013 – 2017) and represent 6.5% of total scale up cost. KFW is providing US$30m for cold chain equipment in 2014-15. The HSS equipment budget is approximately US$25m for cold chain logistics including equipment and US$21m for data management including cold chain stock, temperature management etc. There are major financial and operational barriers to achieving the required improvements. India will prepare a National Cold Chain and Vaccine Logistics Action plan (NCCVLAP) as the focal mechanism to address these barriers. This is scheduled for completion by August 2014.

Cost Category (US$ Millions)	2013	2014	2015	2016	2017	Total
Cold chain equipment	20.2	30.5	41.4	52.9	64.6	209.6
Cold chain and other capital equipment maintenance	17.9	23.0	27.1	31.8	34.0	133.8
Direct Cold Chain related costs	**38.1**	**53.5**	**68.5**	**84.7**	**98.6**	**342.4**

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

The cMYP is a good, detailed document that outlines important action points. The introduction plan is adequate. It must be remembered that it is difficult to write a very detailed introduction plan for such a large country as each state will be responsible for the activities.

9. Overview of the proposal

Strengths:

- The expansion plans have been discussed extensively within the country and there is now overall support.
- Broad implementation plans for the expansion are in place.
- The new cMYP is of good quality and so is the separate financial analysis that accompanies the cMYP.

Weaknesses:

- The vaccine doses calculations need to be reviewed. It is necessary to estimate the number of doses using surviving infants instead of the birth cohort and to take state-wise coverage and realistic wastage rates into account.
- Vaccine supply, distribution, storage and reporting chains require major improvements to ensure the safe management of pentavalent vaccine.
- A budget is lacking for the pentavalent scale-up. However, the IRC recognises that the individual states will be responsible for the introduction.

Risks: Delays in introduction due to the autonomy of the states

Mitigating strategies: Improved technical expertise within the UIP.

10. Conclusions

The IRC commends India for moving forward with pentavalent vaccine introduction and for preparing a high quality introduction plan.

11. Recommendations

NVS:

Recommendation: Approval with clarification

Clarifications:

To the GoI:

1. Estimate vaccine doses needs on a state-by-state level, using state-specific target populations (surviving infants), coverage rates and wastage rates. The requested number of doses needs to be justified in this way.
2. Estimate the exact number of doses being requested from GAVI and the number of doses that will be procured by the Indian Government during the period 2014-2016. This should be shown for each state.
3. The weaknesses in the vaccine cold chain are of major concern to the IRC. The GoI has plans to address this as a priority action. The MoH is requested to:
   - Prepare an implementation plan to improve vaccine storage standards at GMSD and State Central Stores where pentavalent vaccine will be stocked. This plan should be submitted with the forthcoming APR.
   - Submit to the GAVI Secretariat the National Cold Chain and Vaccine Logistics Action Plan (NCCVLAP) due to be completed in August 2014.

To the GAVI Secretariat:

1. Closely monitor implementation of the supply chain improvement plan;
2. Closely monitor that the WHO recommended practice of submission of completed Vaccine Arrival Reports (VARs) to UNICEF within 72 hours of receipt of vaccines at central facilities is established and observed.

Appendix D

GAVI Alliance Terms and Conditions

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

FUNDING USED SOLELY FOR APPROVED PROGRAMMES

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

AMENDMENT TO THIS PROPOSAL

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

RETURN OF FUNDS

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

SUSPENSION/ TERMINATION

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

ANTICORRUPTION

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

AUDITS AND RECORDS

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

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

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

CONFIRMATION OF LEGAL VALIDITY

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

CONFIRMATION OF COMPLIANCE WITH THE GAVI ALLIANCE TRANSPARANCY AND ACCOUNTABILITY POLICY

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

ARBITRATION

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

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

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

USE OF COMMERCIAL BANK ACCOUNTS

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