GAVI/ 13/613/ap/rk

H.E. Ghulam Nabi Azad
The Minister of Health
Ministry of Health
155 - A, Nirman Bhavan
New Delhi – 110108
India

21 October 2013

Dear Minister,

Annual Progress Report submitted by India

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

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

The Appendices includes 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 same appendices are also used in the Partnership Framework Agreement (PFA) – a new simplified arrangement that we are working to agree with your colleagues – that will replace this 'decision letter' format.

We would like to highlight that India received a Partnership Framework Agreement in February 2013. To date, we have not received the signatures of the Ministry of Health and Ministry of Finance on the Partnership Framework Agreement. Please be advised that the GAVI Alliance will no longer disburse subsequent tranches of HSS funds until the Partnership Framework Agreement has been signed between the GAVI Alliance and India

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

Type of support	**Appendix**	**Approved for 2014**
NVS Pentavalent	B	US$28,880,000

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

Yours sincerely,

Hind Khatib-Othman
Managing Director, Country Programmes

cc: PS, The Minister of Health
PS, The Minister of Finance
The DG Health Services
Additional Secretary, MD NRHM
Joint Secretary RCH, MoHFW
Assistant Commissioner Child Health
Deputy Commissioner (Child Health & Immunisation)
WHO Country Representative
UNICEF Country Representative
Regional Working Group
WHO HQ
UNICEF Programme Division
UNICEF Supply Division
The World Bank
The GAVI Finance Unit
The World Bank

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 Annual Progress Report (APR); and
- The APR 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 can not be paid for using GAVI funds.

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

Country Co-financing

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

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

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

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

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

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

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

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

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

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

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

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

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

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
3. **Decision Letter no:** 21 October 2013
4. **Date of the Partnership Framework Agreement:** Not applicable
5. **Programme Title:** New Vaccine Support
6. **Vaccine type:** Pentavalent
7. **Requested product presentation and formulation of vaccine:** DTP-HepB-Hib, 10 dose(s) per vial, LIQUID
8. **Programme Duration**[1]**:** 2011-2014
9. **Programme Budget (indicative) (subject to the terms of the Partnership Framework Agreement):**

	2011-2013	2014	Total[2]
Programme Budget (US$)	US$120,154,000[3]	US$28,880,000	US$149,034,000

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] The Annual Amount for 2014 has been amended.

Type of supplies to be purchased with GAVI funds in each year	2011-2013	2014
Number of Pentavalent vaccines doses		14,500,000
Number of AD syringes		
Number of re-constitution syringes		
Number of safety boxes		
Annual Amounts (US$)	US$120,154,000	US$28,880,000

12. Procurement agency: UNICEF. The Country shall release its Co-Financing Payments each year to UNICEF.

13. Self-procurement: Not applicable.

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

15. Operational support for campaigns: Not applicable

16. Additional documents to be delivered for future disbursements: Annual Progress Report 2013 is due by 15 May 2014

17. Financial Clarifications: Not applicable

18. Other conditions: Not applicable

Signed by, ,
On behalf of the GAVI Alliance

Hind Kh. Khatib

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

[4] This is the amount that GAVI has approved..

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

Appendix C

Type of report: Annual Progress Report
Country: India
Reporting period: 2012
Date reviewed: July 2013

1. Background Information

Surviving Infants (2012): JRF 24.201.403

DTP3 coverage (2012):

- JRF Official Country Estimate:85%
- WHO/UNICEF Estimate: 72%

Table 1. NVS and INS Support

NVS and INS support	Approval Period
HepBmonoval	2002-2011
DTP-HepB-Hib	2010-2014
INS	2005-2007

Table 2. Cash Support

Cash support	Approval Period
HSS	2013-2015

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

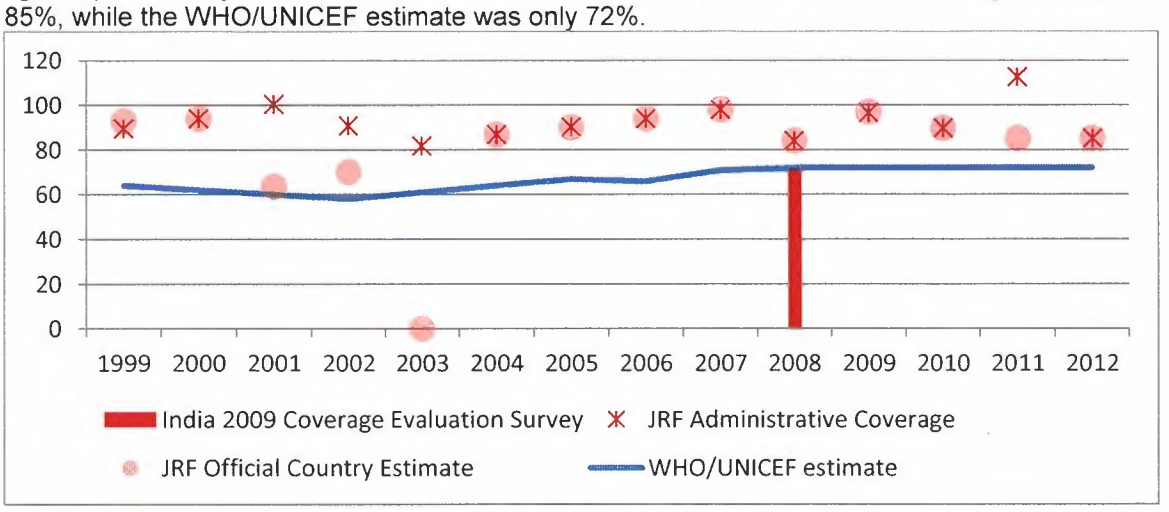
India Immunization Partner Forum acts as ICC/HSCC. Its membership consists of WHO, UNICEF, World Bank, UNOPS, USAID, DFID, and Ministry of Health and Family Welfare of India. CSOs included Indian Academy of Pediatrics and Indian Medical Association.

Based on the APR, the Forum met 8 times and discussed and agreed on a series of issues related to the NIPI and GAVI supported projects, including scaling up of Pentavalent vaccine implementation, Post Introduction Evaluation, implementation of Open Vial Policy, etc. In the meeting held in May 2013, the Forum has approved the 2012 APR. Based on the minutes of the Forum meetings and the 2012 IRC report, the Forum has been more active and providing an oversight role for the NIPI in India.

3. Programmeand Data Management

India is doing phased introduction of Pentavalent vaccine in the country. The target population with regards to Pentavalent is for two states (Tamil Nadu and Kerala) which started Pentavalent vaccination in 2011 and six additional states, (Jammu & Kashmir, Haryana, Goa, Gujarat, Karnataka and Puducherry) in December 2012- March 2013. The annual birth cohort in table 4 thus reflects the birth cohort for Tamil Nadu and Kerala as well as the 3 months period for the six other states.

The DTP3 coverage rate in India has been gradually increasing over the past decade, from some 60% in early 2000s to some 80% in recent years. There is inconsistency between the figures provided by JRF and the estimate from WHO/UNICEF. In 2012, the JRF figure was 85%, while the WHO/UNICEF estimate was only 72%.



India has made a fair progress in the improvement of traditional immunisation services. The coverage rates for BCG, Measles, OPV3 and TT+ have been achieved over 85%. Penta was introduced in 2011and the coverage rate was only 49% in 2012. It is expected to achieve a much higher coverage in 2013 and 2014. Based on the APR, the country has undertaken a series of activities related to social mobilisation, training of all cadres of health workers from different levels, strengthening supervision and M & E via HMIS, increased capacity for cold chain system and program management, etc. The country has been planning to scale up under-used and new vaccines in recent years.

The data from reported administrative system is not always consistent with the estimates from the surveys. The reported administrative coverage figures were often higher than the survey estimates. In order to improve the quality of immunisation service data, the government has introduced the electronic reporting system as part of the national health management information system (HMIS). Other reporting channels for immunisation data are no longer used. However, the operation of HMIS is still being improved and the process is likely to take some time to be more reliable and accurate. In addition, the government has also started an electronic name based mother and child tracking system nationwide which aims to help improve the quality of data reporting related to MCH services.

4. Gender and Equity Analysis

Gender

The country routinely collected sex-disaggregated data through Coverage Evaluation Surveys. The APR states: "The immunisation program in India aims to provide vaccines to all children irrespective of gender. The last Coverage Evaluation Survey of 2009 has reported that the differences in the coverage with various antigens were in the range of 1%." No recent DHS survey can corroborate this information. Data from 2005 DHS shows DTP3 coverage 57% boys 53% girls, Measles 61.4% for boys, 55.8% for girls, no vaccination 4.3% boys and 6% girls.

Equity

The IRC notes that based on the latest DHS survey 2005-06, DTP-3 coverage for the 8 selected states for Penta rollout ranged between 74-95.7% with the exception of Gujarat at 61.4%. This was in contrast to lower performing states with reported DTP-3 coverage of 28.7%in Nagaland, 30% in Uttar Pradesh, 39.3% in Arunachal Pradesh and 38.7% in Rajasthan. In view of GAVI's equity policy to placing an emphasis on reaching the unreached, this issue is being addressed as part of the GAVI funded HSS plan in India.

5. Immunisation Services Support (ISS)

N/A

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

Penta vaccine
In the Decision Letter sent by GAVI to the Government of India in 2012, the total number of 6,234,375 doses of Penta would be sent for the use of two states. However, there was an amendment agreed between the GAVI secretariat and the Government of India to expand the Penta vaccine to additional six states in the country. Therefore, the total amount of 10,505,040 doses was shipped to India in 2012. No overstock/under stock was reported in the APR. The late arrival of Penta vaccine resulted in a slightly later introduction to the new vaccine in some states of the country. PIE has been scheduled in August 2013.

According to Table 4 in the APR, a total of1,196,469 children were vaccinated for DTP3 and 1,207,356 for Penta 3 (totally 2,403,825) in 2012 and 5,037,000 children are targeted for 2014. Per APR, the reason for this jump is that the 2012 targets applied only to two provinces that were initially rolled out and this win 2015 applies to an additional 6 provinces where Penta is to be rolled out. In the proposal submitted, the target of 100% coverage is set up, in addition to the 25% buffer stock for the first year of introduction. There is a risk of over-procurement, which may lead to vaccines expiring and being wasted. Additionally, the country should consider the reduction of wastage level, which is currently set at the maximum of 25%.

Cold chain capacity including logistic management practices has been increased in recent years through a number of mechanisms. A number of field evaluations on cold chain system have been carried out, in collaboration with INCLEN and India Council of Medical Research. Findings from the evaluation are being used for developing policies and measures to strengthen vaccine management practices including storage.

Due to a large number of Indian states, EVM has been conducted in selected states. Between 2010 and 2012 five states have done EVM assessment (i.e. MP, Gujarat, MH, WB and TN).Each state has prepared an improvement plan which is an integral part of the state PIPs. Next EVM, which is to be undertaken in other states, is scheduled in early 2013.

The country is well positioned to reach Penta targets in the 8 states initially selected for roll out of this vaccine.

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

No co-financing group. The GAVI Alliance new vaccine introduction support to the Govt. of India has been agreed to be in the form of commodity assistance (providing vaccine only). The costs of AD syringes, Hub cutters & other injection safety & waste disposal material, and the cost of service delivery of immunisation program in India are borne by the Government of India and is considered the GoI's contribution for the new vaccine introduction (equivalent to the co-financing).

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

Sharp waste management: The Hub-cutters are provided to all UIP vaccinators in India; Red and Black plastic bags are provided for each session site for segregation and collection of immunization waste; safety pits for immunization waste are constructed under funding provided through NRHM.

AEFI surveillance

Efforts to strengthen AEFI surveillance in past years have resulted in higher reporting of cases. National AEFI committee met three times in 2012 and reviewed various surveillance aspects. State AEFI committees exist in all 35 States with regular trainings following introduction of new guidelines. India does have a national dedicated vaccine pharmaco-vigilance capacity and has a national development plan for vaccine safety.

9. Health Systems Strengthening (HSS): N/A

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

11. Risks and mitigating factors

There are several risks in Penta roll out. First, there is a small but vocal anti-vaccination lobby in India. Per CRO, a suspected AEFI following Pentavalent vaccine in 2013 in Kerala state caused the health secretary to threaten suspension of the program. There is a court case in process on this issue. Thus the vaccination climate remains very fragile and a robust AEFI system must be put into place in view of this. Effective strategies using public media and social mobilization to increase an awareness of public knowledge on immunisation may be developed and implemented to mitigate the potential risk.

12. Summary of 2012 APR Review

India has made a fairly good progress in the improvement of immunisation services over the past decade. The introduction of Penta vaccine has kicked off in eight states, albeit being a slightly delay. The IRC appreciates that India wants a rapid scaling up the delivery of the new vaccine to cover all the country. Given targets of 100%, challenges with monitoring distribution and wastage in the Indian context and high volume of vaccine going to that country, the IRC recommends GAVI and country to monitor vaccine management more closely. The IRC recommends that the country should develop a robust EVM improvement plan and submit regular progress reports that should focus on the states where the Penta vaccine has been introduced rather than the country as a whole.

13. IRC Review Recommendations

- **ISS N/A**
- **NVS**

  1) Approve 2014NVS support based on country request target

- **HSS N/A**

14. Clarification Required with Approved Funding

Short-term clarifications

(a) **Programmatic clarifications** (specify for each or indicate if not applicable, N/A)
   a. NVS – N/A
   b. ISS – N/A
   c. HSS – N/A
   d. CSO type A – N/A
   e. CSO type B – N/A

15. Request Re-submission of APR HSS Section

16. Other issues

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.