

The Hon'ble Shri Jagat Prakash Nadda Union Minister Ministry of Health and Family Welfare Nirman Bhavan, New Delhi-110011 India

Via Email: hfwminister@gov.in

19 December 2014

Dear Minister,

Supplementary Annual Progress Report 2012 submitted by India

I am writing in relation to India's proposal to Gavi, The Vaccine Alliance, for New Vaccines Support (NVS) for national scale up of pentavalent vaccines, submitted to Gavi in January 2014. **This letter is a revision of the Decision sent to India on 31 July 2014**.

I am pleased to inform you that Gavi on 19 December 2014 <u>approved</u> India's request for pentavalent vaccines as specified in the Appendices to this letter.

Gavi agrees to support the vaccine costs for continued implementation of the programme in 2015 up to a maximum of additional US\$ 100 million.

The Gavi Alliance already approved in 2009 US\$ 165 million for the support of the pentavalent programme in India. The total funds for the programme until 2015 amount thus to US\$ 265 million. US\$ 119.5 million have been disbursed until November 2014.

The Government of India understands that Gavi support for pentavalent vaccines in India is conditional upon the Government of India providing full financial support for the pentavalent vaccination programme from 2016 onwards, as decided by the Mission Steering Group on 6 December 2013. To the extent that such commitment is not met by the Government of India, this may affect other support that Gavi provides to India.

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 GaviAlliance 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	В	US\$ 136,871,623	US\$ 136,871,623	

Please also see Table 9 (Programme Budget) and Table 11 (Indicative Annual Amounts) in Appendix B for further financial details.

The number of doses which this funding level equates to is dependent on the price obtained (see Table 11).

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 discussions of the GaviSecretariat with MoF/DEA and MoHFW to resolve an outstanding issue regarding the tax exemptions of goods financed with Gavi funds 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 <u>dgehl@gavialliance.org</u> if you have any questions or concerns.

Yours sincerely,

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





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 cofinanced 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:

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

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

<u>Grant Terms and Conditions:</u> 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.





India VACCINE SUPPORT

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

1. Country: Inc	dia					
2. Grant Numb	er: 15-IND-04c-X					
3. Date of Dec	ision Letter: 19 De	ecembe 2	2014			
4. Date of the	Partnership Frame	ework A	greement: N	lot yet sig	ned	
5. Programme	Title: NVS, Pentav	/alent Ro	outine			
6. Vaccine typ	e: Pentavalent					
7. Requested dose(s) per v	product presentati	ion and	formulation	of vaccii	ne: DTP-HepB-h	lib, 10
8. Programme	Duration ¹ : 2011 -	2015				
	Budget (indicative Agreement):	e) (subje	ect to the ter	rms of th	e Partnership	
	Agreement):		ect to the ter			tal ²
		14	US\$136,8	2015		tal²
Programme Budget (US\$)	Agreement): 2011-201	14 8,377 ³	US\$136,8	2015	То	
Programme Budget (US\$)	Agreement): 2011-202 US\$ 128,128 roduction Grant: Nonual Amounts (s	14 8,377 ³ lot applic	US\$136,8 cable	2015 71,623	To US\$265,000,0	000
Programme Budget (US\$) 10. Vaccine Into	Agreement): 2011-202 US\$ 128,128 roduction Grant: Nonnual Amounts (see purchased	14 8,377 ³ lot applic	US\$136,8 cable	2015 71,623	To US\$265,000,0	000

Type of supplies to be purchased with Gavi funds in each year	2011-2014	2015
Number of Pentavalent vaccines doses		65,143,000 ds minimum and dependent on final pricing. A reduced price (not yet determined) is being negotiated so for illustrative purposes, pricing of US\$1.50 / dose would mean supply of 91m doses.
Number of AD syringes		

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.

⁴ This is the amount that Gavi has approved. Please amend the indicative Annual Amounts from previous years if that changes subsequently.



Number of re-constitution syringes		
Number of safety boxes		
Annual Amounts (US\$)	US\$128,128,377 ⁵	US\$136,871,623

13. Self-procurement: Not applicable

14. Co-financing obligations: Not applicable

15. Operational support for campaigns: Not applicable

16. Additional documents to be delivered for future disbursements:

Reports, documents and other deliverables	Due dates	
Annual Progress Report 2014	May 2015	

17. Financial Clarifications: The Country shall provide the following clarifications to Gavi*: Not applicable

18. Other conditions:

The Government of India understands that Gavi support for pentavalent vaccines in India is conditional upon the Government of India providing full financial support for the pentavalent vaccination programme from 2016 onwards, as decided by the Mission Steering Group on 6 December 2013. To the extent that such commitment is not met by the Government of India, this may affect other support that Gavi provides to India.

Signed by,

On behalf of Gavi Hind Khatib-Othman

Managing Director, Country Programmes

19 December 2014

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^{*}Failure to provide the financial clarifications requested may result in Gavi withholding further disbursements

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



Appendix C

The IRC report of March 2014 has already been included in the Decision Letter dated July 31, 2014.



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.