

GAVI/13/054/lm/dlc

The Minister of Health Ministry of Health Government Building No.3 375001 Yerevan Armenia

22 April 2013

Dear Minister,

Armenia's 2011 Annual Progress Report to the GAVI Alliance - revised targets for Rotavirus Vaccine

We are writing to inform you that the GAVI support for Rotavirus vaccines and related injection safety materials for the year 2013 has been revised downward in line with the request submitted by the Country to GAVI on 11 March 2013. The original approval was based on the 2011 Annual Progress Report (APR) submitted by Armenia (the "Country") in May 2012 on which the GAVI Executive Committee (EC) on 11 October 2012 approved funding for rotavirus vaccines as well as pentavalent and pneumococcal vaccines. A decision letter was sent to the Country on 26 November 2012 informing the country of the approved GAVI support for rotavirus vaccine (the "Original Rotavirus Vaccine Decision Letter").

The previous approval was for a total of US\$ 107,000. The revised approval is for US\$ 81,000. The attached Appendix B1-B, the Rotavirus Vaccine Decision Letter, replaces the one provided to the country on 26 November 2012. The decision letter dated 26 November 2012 for Pentavalent vaccine remains unchanged and is being provided here for information purposes only.

Please note the terms and conditions specified in the Appendices to this letter.

For your information, this document contains the following important attachments:

Appendix A: Summary of approved current GAVI support to Armenia

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 financial and programmatic information for the approvals are detailed in the attached Appendix B1 (for vaccine support) and B2 (for cash support), with additional Appendices per type of support, i.e. Appendix B1-A, B1-B and B2-A and B2-B, etc. The format of these appendices will be used in a partnership agreement that the GAVI Alliance aims to introduce to simplify information exchange between countries receiving GAVI support and the Secretariat. The Secretariat will be pleased to provide any clarifications on this process.

The following table summarises the current GAVI support applicable to Armenia.

Type of GAVI support		Approved for 2013	
New Vaccines Support	Pentavalent vaccines and related injection safety materials (remains unchanged - for reference)	US\$ 363,500	
	Rotavirus vaccines and related injection safety materials	US\$ 81,000	

Please do not hesitate to contact my colleague Nilgun Aydogan (naydogan@gavialliance.org) if you have any questions or concerns.

Yours sincerely,

Stad F. K brill

Hind Khatib-Othman Managing Director, Country Programmes

cc: The Minister of Finance

The Director of Medical Services Director Planning Unit, MoH

The EPI Manager

WHO Country Representative UNICEF Country Representative

Regional Working Group

WHO HQ

UNICEF Programme Division

UNICEF Supply Division

The World Bank

The GAVI Finance Unit

Description of GAVI support to Armenia (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 2013 immunization programme as set out in Appendix B. Financing provided by GAVI for vaccines will be in accordance with:

- The GAVI Alliance Guidelines notified to the Country with the APR format; and
- The APR, as recommended by the IRC for approval for funding, including any subsequent clarifications.

The vaccines provided will be used for routine immunisation of children under 12 months of age. 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 2013.

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

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 in 2013.

Item number 14 of Appendix B summarises the budget and the quantity of supply that will be procured with country's funds in 2013.

The total co-financing amount expressed in item number 14 of Appendix B indicates costs for the vaccines and related injection safety devices only. It does not contain the cost for contingency buffer nor UNICEF's handling fee as per standard practice as indicated in http://www.unicef.org/supply/index_faq.html#1. An estimation of the complete cost including contingency buffer and handling fee will be provided as part of the cost estimate to be requested by the country.

For the purchase of the co-financed supply detailed in item number 14 of Appendix B the payment is to be made to UNICEF as agreed in the Procurement Services Memorandum of Understanding between UNICEF and the country, and not to the GAVI Alliance. Please keep in contact with UNICEF Supply Division to understand the availability of the relevant vaccine(s) and to prepare the schedule of deliveries. UNICEF 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.

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 then-current 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).

<u>Country Co-financing</u> 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.

<u>Monitoring and Annual Progress Reports:</u> Use of financial support for the introduction of new vaccinations is subject to strict performance monitoring.

Achievements and the required support for the following year will be reported on in the APR. The APR must contain information on the number of children reported to have been vaccinated with DTP3 and with three doses of pentavalent vaccine by age 12 months, based on district monthly reports reviewed by the 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 arrangements outlined in this letter.

Please note the following conditions for future reporting:

- Signature of the APR by the Ministers of Health and Finance, and endorsement by members of the HSCC and/or ICC
- Attach minutes of all HSCC and ICC meetings held during the reporting year with the APR:
- Attach minutes of the HSCC/ICC meeting that explicitly discusses and endorses the APR submission;
- Attach financial statements with the APR as required for cash-based support, including HSS, CSO Type B and ISS. These statements should be prepared for the reporting year, and signed by the MOH chief accountant or the Permanent Secretary; and,
- Submit audit reports as required for cash-based windows of support, including HSS, CSO Type B and ISS. These audit reports are due to the GAVI Secretariat six to nine months after the close of your government's financial year.

GAVI encourages countries to continue working closely with their HSCC and/or ICC and local partners including Civil Society Organisations (CSOs). For the APR 2012 it is also recommended to share a draft report with the Regional Working Group for any technical input prior to final signatures and subsequent submission to GAVI before the 15 May 2013.

NEW VACCINES SUPPORT

DECISION LETTER FOR VACCINE SUPPORT- Pentavalent vaccine

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

2. Grant Number: 1115-ARM-04b-X	
3. Decision Letter no: 1	

4. Date of the Partnership Framework Agreement: Not applicable

5. Programme Title: NVS

1. Country: ARMENIA

6. Vaccine type: DTP-HepB-HIB

7. Product presentation and formulation of vaccine: 2-dose vial lyophilized

8. Programme Duration¹: 2009-2015

9. Programme Budget (indicative):

	2009 – 2012	2013	2014	2015	Total ²
Programme Budget (US\$)	1,328,043 ³	363,500	282,000	199,500	2,173,043

10. Indicative Annual Amounts:

Type of supplies to be purchased with	2009– 2012	2013	
GAVI funds in each year			
Number of pentavalent vaccines doses		97,300	
Number of AD syringes		97,400	
Number of re-constitution syringes		54,100	
Number of safety boxes		1,700	
Annual Amounts (US\$)	1,328,043 ⁴	363,500	

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

12. Self-procurement: 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.

⁴ This is the consolidated amount for all previously approved years.

13. Co-financing obligations:

According to the Co-Financing Policy, the Country falls within the Graduating group. The following table summarises the Co-Financing Payment(s) and quantity of supply that will be procured with such funds in the relevant year.

Type of supplies to be purchased with Country funds	2013	2014	2015
in each year			
Number of vaccines doses	49,400	71,900	94,700
Number of AD syringes	49,400		
Number of re-constitution syringes	27,400		
Number of safety boxes	875		
Dollar amount value of vaccine doses (US\$)	145,541		
Total Co-Financing Payments (US\$) (including freight)	184,500	268,500	353,500

14. Operational support for campaigns: Not applicable.

15. Additional documents to be delivered for future disbursements: The Country shall deliver the following documents by the specified due dates as part of the conditions to the approval and disbursements of the future Annual Amounts.

Reports, documents and other deliverables	Due dates
APR 2012	May 2013

- **16. Clarifications:** The Country shall provide the following clarifications prior to the disbursement of the Annual Amount in 2013. Please refer to Appendix C.
- 17. Other conditions: Not applicable.

Signed by **On behalf of the GAVI Alliance**

Wind F. Thath

Hind Khatib-Othman Managing Director, Country Programmes 22 April 2013

Rotavirus VACCINE SUPPORT

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

- Country: Armenia
 Grant Number: 1215-ARM-13b-X
 Decision Letter no: 2
 Date of the Partnership Framework Agreement: n/a
 Programme Title: NVS
 Vaccine type: Rotavirus
 - 7. Requested product presentation and formulation of vaccine: Rota, 2 dose(s)
 - 8. Programme Duration⁵: 2012-2015
 - 9. Programme Budget (indicative): (subject to the terms of the Partnership Framework Agreement)

	2012	2013	2014	2015	Total⁵
Programme Budget (US\$)	US\$ 270,000	US\$81,000	US\$59,500	US\$12,500	US\$423,000

- 10. Vaccine Introduction Grant: Not applicable
- 11. Indicative Annual Amounts (subject to the terms of the Partnership Framework Agreement):

Type of supplies to be purchased with GAVI funds in each year	2013
Number of Rotavirus vaccines doses	30,000
Number of AD syringes	
Number of re-constitution syringes	
Number of safety boxes	
Annual Amounts (US\$)	US\$81,000

- **12. Procurement agency:** : UNICEF. The Country shall release its Co-Financing Payments each year to UNICEF.
- 13. Self-procurement: Not applicable.

⁵ This is the entire duration of the programme.

⁶ 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

⁷ This is the amount that GAVI has approved. Please amend the indicative Annual Amounts from previous years if that changes subsequently. Ceci est le montant approuvé par GAVI. Prière de modifier les montants annuels indicatifs des années précédentes si cela change ultérieurement

14. Co-financing obligations: Reference code: 1215-ARM-13b-X-C According to the Co-Financing Policy, the Country falls within the Graduating group. The following table

summarises the Co-Financing Payment(s) and quantity of supply that will be procured with such funds in the relevant year.

runds in the relevant year.			
Type of supplies to be purchased with Country funds in each year	2013	2014	2015
Number of vaccines doses	40,500	72,000	91,500
Number of AD syringes			
Number of re-constitution syringes			
Number of safety boxes			
Value of vaccine doses (US\$)	US\$102,729		
Total Co-Financing Payments (US\$) (Including freight)	US\$108,000	US\$190,000	US\$245,000

15. Operational support for campaigns: Not applicable

16. Additional documents to be delivered for future disbursements:	 Not applicable
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Reports, documents and other deliverables	Due dates
Annual Progress Report	15 May 2013

- 17. Clarifications: The Country shall provide the following clarifications prior to the disbursement of the Annual Amount in 2013:
- 18. Other conditions: Not applicable.

Signed by

On behalf of the GAVI Alliance

Think A. Thath

Hind Khatib-Othman Managing Director, Country Programmes

22 April 2013

Country: Armenia

Type of report: Annual Progress Report

Reporting period: 2011
Date reviewed: July 2012

1. Background Information

Surviving Infants (2011): 55,561 (JRF)

DTP3 coverage (2011):

JRF Official Country Estimate: 95%WHO/UNICEF Estimate: 94%

History of GAVI support:

Table 1. NVS and INS Support

NVS and INS support	Approval Period
HepB monovalent	2002-2008
DTP-HepB-Hib	2009-2015
Rotavirus	2012-2015
Pneumococcal (PCV10)	2013-2016
INS	2002-2004

Table 2. Cash Support

Cash support	Approval Period	
ISS	2002-2006	
HSS	2007-2011	

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

The ICC/HSCC met seven times in 2011. The ICC has broad representation from government and representatives from some foundations and academic institutes. Topics discussed during meetings included the Annual Progress Report, corrections in the JRF to be sent to the WHO Regional office for Europe, introductions' of Rota virus vaccine in 2012 and PCV in 2013 and planning campaigns for polio. The minutes of ICC meetings endorse the extension of vaccine support and signatures of health and finance ministers (or delegates) are provided with the submission.

3. Program Management

Key activities noted by NIP for 2011 were active surveillance for AFP, an assessment of polio vaccination coverage, and catch-ups for oral polio vaccine (two rounds). Vaccination coverage has increased from 88% to 95% between 2008 and 2011.

The programme was presented with several challenges in 2011. The declaration of a polio outbreak in the region resulted in the need to implement polio campaigns. Also, there were stock outs of MMR and OPV at central level, which are reported to have had some impacts on the program. Some populations remain difficult to reach. Migration issues and poor performance of door-to-door census were identified as constraints. AEFI guidelines are not yet fully implemented

at many health facilities and there has been limited use of surveillance data for programme management and impact evaluation.

A comprehensive set of programme activities are described for the period 2011 – 2013 that include supplementary immunisation campaigns, social mobilisation campaigns, identification of high risk areas and strengthening of surveillance activities. A new cMYP has been developed for the period 2012-2016. The main objectives of the plan include raising coverage for all antigens and introduction of PCV vaccine in 2013 and rotavirus vaccine in 2012.

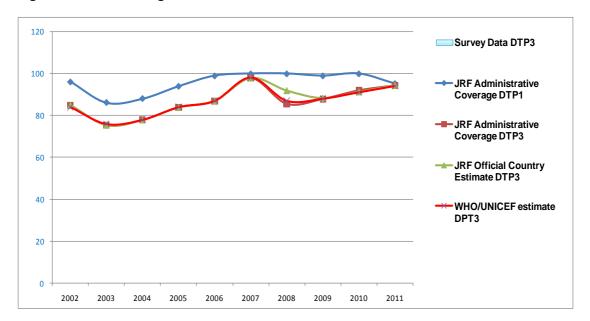


Figure 1. DTP3 coverage in Armenia

Data Quality: Different population figures have been used to the JRF. The civil registry reports the total number of surviving infants as being 57,328 in 2011, which is different to the number of births documented by the JRF. NIP state that the JRF data is sourced from health centres and primary health care, and the Ministry of Health considers that civil registry data are more reliable. There have been no reported coverage surveys in the last 10 years (the last one being a MICS survey in 2000).

4. Gender and Equity Analysis

Sex disaggregated data was not provided, therefore any discrepancy between the coverage rates for males and females cannot be determined. No plans are reported for future collection of this data. The APR does not address strategies for reaching marginalised or hard to reach populations. The APR states "Both males and females have equal access to the immunisation services in Armenia". The programme proposes to identify high risk and low performing areas at each level (regional and district) through the use of supplementary immunisation activity data. This analysis will also include analysis of finances and resources.

5. Immunisation Services Support (ISS)

Armenia is a graduating country according to GAVI classifications and is no longer eligible for further cash grants.

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

Vaccines: A total of 195,200 pentavalent vaccines DTP-HepB-Hib were received by 31 December 2011. This does not correspond with the UNICEF assessment, as UNICEF records show delivery of 160,300 doses. The vaccine stock on 1 January 2012 was estimated to be 75,900. A Comprehensive Multi-year Plan was produced in May 2011 outlining the implications of introducing rotavirus and pneumococcal vaccine into the Immunisation Programme in 2012 and

2013, respectively. Armenia does not require changes to any of the vaccine presentations for future years. A Post Introduction Evaluation is planned for May 2015. Coverage target doses (comparing the achievement in 2011 with the target in 2013) indicate an 11% increase in coverage between the target and the achievement in 2011. This is justified on the grounds of up dated birth cohort estimates provided through the Civil Registry as outlined above and as documented in the ICC minutes. The coverage targets are reasonable.

DTP3 doses – target 2013	59,014
DTP3 doses – achievement 2011	52,551
Difference	11%

Cold Chain Capacity or Issues: An EVM assessment was undertaken in July 2011, and an evidence-based plan to improve management, monitoring and supervision of the country immunisation supply chain was developed. The assessment found vaccines are exposed to relatively low risk of damage during handling and storage; however, identified procedures are not adequately documented. Quantity and quality of cold store equipment was found to be satisfactory at all levels. The preparation of the EVSM/VMA/EVM improvement plan is in progress and the next Effective Vaccine Management (EVM) assessment is planned for December 2015.

Surveillance and AEFI: The programme places a lot of emphasis on strengthening surveillance systems, particularly for AFP. The APR reports that there are no AEFI systems, and no national pharmacovigilance capacity. However, the cMYP documents that guidelines, policies and systems exist, including a national AEFI committee.

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

Co financing: Armenia is classified as a graduating country according to GAVI rules, and is cofinancing three vaccines (PCV, Pentavalent and Rotavirus vaccines). PCV is being co-financed at 70 cents per dose from 2013, and increasing thereafter until 2016. Pentavalent and rotavirus vaccines are being co financed at the recommended levels.

Financial Sustainability: The programme indicates that there are no significant financial gaps. The country is expecting to receive all budgeted funds for 2012. Very large increases in expenditure correspond with the years of introduction of new vaccines. Expenditures in 2012 were estimated at US\$ 4.8 million in 2012 and US\$ 5 million in 2013. The cMYP identifies that 81% of the funding has been secured. The National EPI program is reported to add up to 0.9% of the total government health budget and 0.2% of the total expenditures on health.

Financial Management: Fund flow and management is outlined in the APR. All financial expenditures are monitored by a governmental accounting agency. The ICC approves the APR with the information about financial expenditures, funding requests for the next calendar year and possible changes in planned activities to be discussed at the ICC. No external audit has been conducted, because HSS expenditure was minimal in 2011.

8. Health Systems Strengthening (HSS)

There are five objectives of the HSS proposal relating to motivation of personnel, skills upgrading, supportive supervision, and service delivery capacity. An original grant of US\$ 436,642 was awarded in 2007 and all funds have been disbursed. US\$ 15,118 was expended in 2011, leaving a balance of US\$ 124,500 for 2012. Late arrival of funds hindered implementation of HSS in 2011. The HSS pre-assessment states "There has been almost no progress in 2011. In most cases, no implementation of planned activities is reported [because] Implementation of activities was not possible, as HSS funds (124.500 USD) were received in December 27, 2011". Reports in M & E are made of progress in implementation of training programs and supervision visits. Similarly, a brief plan is presented for ongoing HSS activities in the areas of training and supervision for 2012.

It is recommended that a completion report for HSS be provided to GAVI with the next APR.

9. CSO support

Not applicable.

10. Summary of 2011 APR Review:

The government of Armenia is a major financial supporter of the NIP. Support of the programme, along with key partners, has resulted in DTP vaccination coverage increasing to 95%. This result is to be commended. The country has conducted the required preparatory action to introduce Rota and PCV vaccination, although the EVSM/VMA/EVM improvement implementation status report needs to be submitted. A completion report for HSS should also be completed in 2012, detailing the main activities and outputs achieved.

11. IRC Review Recommendations

NVS

Pentavalent, PCV-10 and Rotavirus

The IRC recommends the approval of NVS support for Pentavalent, PCV-10 and Rotavirus vaccines based on country request target.

The IRC endorse NVS based on new cMYP 2011 - 2015.

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.