

Gavi-2015-159

His Excellency David Sergeenko
The Minister of Labour, Health and Social Affairs
Ministry of Labour, Health and Social Affairs
144, Ak. Tsereteli Ave.
0119 Tbilisi
Georgia

1 July 2015

Georgia's introduction of Hexavalent vaccine in 2015 and revision of targets for Pentavalent vaccine

Your Excellency,

We are writing to confirm that Gavi support for pentavalent vaccine and related injection safety materials for the year 2015 has been revised downward in line with the request submitted to Gavi on 15 April 2015 by the National Center for Disease Control and Public Health of Georgia. The original approval of support for pentavalent vaccine was based on the information provided in the 2013 Annual Progress Report (APR) submitted by Georgia (the "Country") in May 2014. A Decision Letter was sent to the Country on 15 October 2014 informing the country of the approved Gavi support for pentavalent vaccine (the "2014 Pentavalent Vaccine Decision Letter").

Subsequently, the country informed Gavi of its decision to introduce six component vaccine (DTP+Hepb+Hib+IPV) to the national immunisation program. As a result of this decision, Georgia requested the procurement of 55,040 doses of pentavalent vaccine through Gavi support in 2015 (instead of 139,500 doses according to the 2014 Pentavalent Vaccine Decision Letter).

The previous approval for 2015 was for a total of US\$ 55,500. The revised approval is for US\$ 32,943. The attached Appendix B, the Pentavalent Vaccine Decision Letter, replaces the Appendix B-2 provided to the Country on 15 October 2014, and provides the financial and programmatic information for this approval. The Decision Letters dated 15 October 2014 for rotavirus and pneumococcal vaccines remain unchanged. We have attached them here for ease of reference.

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 Gavi support to Georgia

Appendix B: Financial and programmatic information for pentavalent vaccine

Appendix C: The terms and conditions of Gavi support

The following table summarises the outcome for each type of Gavi support applicable to Georgia in 2015, effective as of the date of this letter.



Type of Gavi support		Approved for 2015
New Vaccines Support	Pentavalent vaccines and related injection safety materials	US\$ 32,943
	Pneumococcal vaccines and related injection safety materials	US\$ 253,000
	Rotavirus vaccines and related injection safety materials	US\$ 19,500

Finally, Georgia has received a draft of the Partnership Framework Agreement (PFA) which has been revised at the request of the MoH. Please be advised that the Gavi Secretariat will closely follow up with Georgia on the PFA. Gavi will need to receive a signed PFA before any funding and support to Georgia can be continued.

Please do not hesitate to contact my colleague Ekaterina Rykovanova, Senior Country Manager (erykovanova@gavi.org) if you have any questions or concerns.

Yours sincerely,

Hind Khatib-Othman

Managing Director, Country Programmes

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cc: Th

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 Georgia (the "Country")

New Vaccines Support (NVS)

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

- Gavi Guidelines governing Georgia'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 can not 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

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 Gavi. 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.gavi.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).

<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.

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. Gavi 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 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 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 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.



NEW VACCINES SUPPORT - Pentavalent DECISION LETTER FOR VACCINE SUPPORT

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

Country: Georgia
 Grant Number: 1115-GEO-04b-X
 Date of Decision Letter: 1 July 2015
 Date of the Partnership Framework Agreement:
 Not applicable
 Programme Title: NVS, Pentavalent Routine
 Vaccine type: Pentavalent
 Requested product presentation and formulation of vaccine: DTP-HepB-Hib, 2 dose(s) per vial, LYOPHILISED
 Programme Duration¹: 2009 -2015
 Programme Budget (indicative) (subject to the terms of the Partnership Framework Agreement):

	2009-2014	2015	Total ²
Programme Budget (US\$)	US\$2,075,253 ³	US\$32,943	US\$2,108,196

- 10. Vaccine Introduction Grant: Not applicable
- 11. Indicative Annual Amounts: The Annual Amount for 2015 has been amended.

Type of supplies to be purchased with Gavi funds in each year	2009-2014	2015
Number of Pentavalent vaccines doses		10,260
Number of AD syringes		28,400
Number of re-constitution syringes		14,400
Number of safety boxes		475
Annual Amounts (US\$)	US\$2,075,253 ⁵	US\$32,943

- 12. Procurement agency: UNICEF
- 13. 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 amount that Gavi has approved.

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



14. Co-financing obligations: Reference code: 1115-GEO-04b-X-C

According to the Co-Financing Policy, the Country falls within the group Graduating.

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 in each year	2015	
Number of vaccine doses	43,800	
Number of AD syringes	30,000	
Number of re-constitution syringes	15,400	
Number of safety boxes	500	
Value of vaccine doses (US\$)	US\$85,374	
Total Co-Financing Payments (US\$) (including freight)	US\$92,000	

- 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 or equivalent	To be agreed with Gavi Secretariat

- 17. Financial Clarifications: Not applicable
- 18. Other conditions: Not applicable

Signed by On behalf of Gavi

Date: 1 July 2015

Hind Khatib-Othman Managing Director, Country Programmes

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Gavi Terms and Conditions

Countries will be expected to sign and agree to the following GAVI Alliance ("Gavi") 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 Gavi 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 Gavi. All funding decisions for this application are made at the discretion of Gavi Board and are subject to IRC processes and the availability of funds.

AMENDMENT TO THIS PROPOSAL

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

RETURN OF FUNDS

The Country agrees to reimburse to Gavi, 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 Gavi, within sixty (60) days after the Country receives Gavi's request for a reimbursement and be paid to the account or accounts as directed by Gavi.

SUSPENSION/ TERMINATION

Gavi 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-approved amendment to this application. Gavi retains the right to terminate its support to the Country for the programmes described in this application if a misuse of Gavi funds is confirmed.

ANTICORRUPTION

The Country confirms that funds provided by Gavi 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 Gavi, as requested. Gavi 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 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 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 Gavi 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 GAVI TRANSPARANCY AND ACCOUNTABILITY POLICY

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

ARBITRATION

Any dispute between the Country and Gavi 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 Gavi 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 Gavi. For any dispute for which the amount at issue is greater than US \$100,000 there will be three arbitrators appointed as follows: Gavi 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.

Gavi 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.

