GAVI/11/227/sk/rh

The Minister of Labour, Health and Social Affairs
Ministry of Labour, Health and Social Affairs
Gamsakhurdia Ave. 30
380060 Tbilisi
Georgia

27 September 2011

Dear Minister,

Georgia's Proposal to the GAVI Alliance

This letter is in relation to Georgia's proposal to the GAVI Alliance for New Vaccines Support for **rotavirus and pneumococcal vaccines**, which was submitted to the GAVI Secretariat in May/June 2011.

In a letter of 19 July 2011, you were informed that the Independent Review Committee (IRC) made the following recommendation of:

- "**Approval**" of your proposal for rotavirus vaccine.
- "**Approval**" of your proposal for pneumococcal vaccine.

The IRC summary report is attached in Appendix B for your reference.

Subsequently, the GAVI Executive Committee (EC), at its meeting on 26 September 2011, endorsed Georgia's 2012-2015 proposal for the introduction of rotavirus vaccine (two-dose schedule), and Georgia's 2013-2016 proposal for the introduction of pneumococcal vaccine (PCV10).

The EC also approved a budget as stated in Appendix A, subject to the availability of supplies, funding and the terms and conditions of this letter.

The country will co-finance the procurement of rotavirus and pneumococcal vaccines in accordance with the GAVI co-financing policy, and the terms and conditions of this letter and its Appendices.

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

Yours sincerely,

Mercy Ahun
Managing Director, Programme Delivery Team

Attachments: Appendix A: GAVI Support to Georgia
Appendix B: IRC Review Report

cc: The Minister of Finance
The Director of Medical Services

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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

Appendix A

GAVI support to Georgia

New Vaccines Support (NVS)

The GAVI Alliance Board has endorsed Georgia's request for the support of the introduction of rotavirus vaccine for the period 2012-2015 and approved the budget for 2012.
Table 1 summarises the details of the approved GAVI support for rotavirus vaccine for 2012.

Table 1a: Details of GAVI support for Rotavirus for 2012 to Georgia (Ref N° 1215-GEO-13b-X)

Type of material to be supplied to the country	2012
Number of doses of Rotavirus vaccine in 2-dose schedule	87,400
Number of safety boxes	925
Total support in US$	**$253,000**

Table 1b: Details of Introduction grant support to Georgia

	Year of support	US$
Introduction grant to support the introduction of rotavirus vaccine (Ref N° 12-GEO-08a-Y)	2012	$100,000

The Board also endorsed the support of the introduction of pneumococcal vaccine for the period 2013-2016 and the respective budget.
Table 2 summarises the details of the endorsed GAVI support for pneumococcal vaccine for 2013.

Table 2a: Details of GAVI support for Pneumococcal vaccine for 2013 to Georgia (Ref N° 1316-GEO-12b-X)

Type of material to be supplied to the country	2013
Number of doses of PCV10	136,300
Number of AD syringes	145,500
Number of safety boxes	1,625
Total support in US$	**$975,784**

Table 2b: Details of Introduction grant support to Georgia

	Year of support	US$
Introduction grant to support the introduction of pneumococcal vaccine (Ref N° 13-GEO-08a-Y)	2013	$100,000

Note: Georgia is responsible for paying any required taxes, customs, toll or other duties imposed on the importation of vaccines and related supplies. Georgia is also responsible for any liability that may arise in connection with the distribution or use of vaccines after title to such vaccines has passed to the country, except the manufacturer of the vaccines shall remain responsible for any produce defect as a direct consequence of any acts committed by the said manufacturer.

Financing provided by GAVI for vaccines and safety equipment will be used by Georgia to increase access to immunisation services, including the new and under-used vaccines, for children in Georgia as specified:

- In the GAVI Alliance Guidelines governing Georgia's proposal application; and
- The final proposal as approved by the IRC, including any subsequent clarifications.

The principles of the WHO-UNICEF-UNFPA joint statement on safety of injections (WHO/V&B/99.25) shall apply to all immunisations provided with these vaccines.

Country Co-Financing

According to the current GAVI co-financing policy Georgia is categorised among the graduating countries and in its application for GAVI support the country has agreed to co-finance $0.55 per dose of all rotavirus vaccine doses needed in 2012, and $0.70 per dose of all pneumococcal vaccine doses needed in 2013. Table 3 summarises the budget and the quantity of supply that will be procured with country funds in 2012 and 2013.

Table 3a: Georgia's co-financing budget for Rotavirus vaccine for 2012
(Ref N° 1215-GEO-13b-X-C)

Type of material to be procured by the country	2012	US$ value
Number of doses of Rotavirus vaccine in 2-dose schedule	20,500	$56,322
Number of safety boxes	250	$3,178[1]
Total co-financed in US$		**$59,500[2]**

Table 3b: Georgia's co-financing budget for Pneumococcal vaccine for 2013
(Ref N° 1316-GEO-12b-X-C)

Type of material to be procured by the country	2013	US$ value
Number of doses of PCV10	31,400	$109,624
Number of AD syringes	33,500	$7,876[1]
Number of safety boxes	375	
Total co-financed in US$		**$117,500[2]**

[1] Includes total amount of shipment and insurance of supplies and vaccines
[2] Calculated as follows: [doses procured by the country + doses supplied by GAVI] * co-financed amount per dose

For the purchase of the supply detailed in this letter Georgia should pay UNICEF directly for the co-financed vaccines in accordance with the Procurement Services Memorandum of Understanding between UNICEF and the country. Georgia should keep in contact with UNICEF Supply Division to understand the availability of vaccine and eventually to prepare the schedule of deliveries.

The total co-financing amount expressed in table 3 indicates costs for the vaccines and related injection safety devices. It does not contain the cost for contingency buffer nor UNICEF's handling fee as per standard practice (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.

Requirements for Subsequent Support

All subsequent support is subject to the availability of GAVI funding as and when approved by the GAVI Alliance Board. For subsequent support Georgia must complete the following requirements:

(1) Transparency and Accountability. Georgia must comply with the TAP requirements and the requirements of the Aide Memoire.

(2) Financial Statements & External Audits. Georgia must comply with the then-current GAVI requirements relating to financial statements and external audits.

(3) Grant Terms and Conditions. Georgia must comply with GAVI's standard Grant Terms and Conditions, as amended from time to time.

(4) Country-Co-financing. GAVI must receive confirmation from UNICEF that Georgia made the country co-payment for the prior calendar year.

(5) Monitoring and Annual Progress Reports. Georgia's use of financial support for the introduction of new vaccinations with rotavirus and pneumococcal vaccines is subject to strict performance monitoring. The GAVI Alliance uses country systems for monitoring and auditing performance as well as other data sources including WHO/UNICEF estimates. As part of this process, National Authorities will be requested to monitor and report on the numbers of children immunised and the delivery of funds to co-finance the vaccine.

For 2013, GAVI support will be subject to submission of the 2011 Annual Progress Report (APR) which is satisfactory to GAVI. The 2011 APR, which is due by 15 May 2012, should include a report on activities undertaken to prepare for the introduction of the vaccines and on the roll-out of the vaccinations with rotavirus and pneumococcal vaccines. All subsequent support is subject to receipt of an APR for the prior calendar year, which is satisfactory to GAVI.

Georgia will report on the achievements and the required support for the following year in the APR. The APR must contain information on the number of children reported to have been vaccinated with DTP3, 2 doses of rotavirus vaccine and 3 doses of pneumococcal 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. The APRs will also contain information on country's compliance with the co-financing arrangements outlined in this letter. APRs endorsed by the ICC, should be sent to the GAVI Secretariat no later than 15 May.

Appendix B

IRC NVS COUNTRY REPORT
Geneva, June 24 – July 08 2011

Country name: Georgia
Type of support requested: NVS
Vaccines requested: Rota 2012 and **PCV** 2013

Country profile/Basic data (2010)

Population	4,410,900	Infant mortality rate (year)	15%
Birth cohort	64,244 63,758	Govt. Health expenditure GGHE	8% 22,4%
Surviving infants	62,80 63,287	GNI/capita (year)	2,587
DTP3 coverage (administrative)	86 %	Co-financing country group*	graduating

*low income, intermediate or graduating

1. Type of support requested/Total funding/Implementation period

Georgia is requesting introduction of Rota 2 dose schedule in 2012 and PCV (10) 2 dose/vial 3 dose schedule liquid in 2013. The PCV request was changed to PCV (13) in the introduction plan. The total cost of the vaccines is $6.613, 380

2. Georgia received the following GAVI support

ISS. 2002-2006
HepB 2002-2008
Penta 2008-2015
INS 2002-2004
HSS 2007-2010
CSOA 2009

3. Composition & Functioning of the ICC

The Interagency Coordinating Committee (ICC) was first created in September 2000 in order to optimize the support and coordination of the work of all agencies involved in the National Immunization Program. The ICC was re-established in 2010.

The ICC is composed of all major country-level partners, including the NCDC, WHO, UNICEF, USAID and it is currently chaired by the Deputy Minister. ICC meetings are held regularly, at minimum 4 times a year, with a good participation from the different members including non- governmental organizations. Members participated in ongoing review, strategic planning, coordination, resource leveraging and oversight of the immunization programme implementation. The decision to introduce a new vaccine, Rota and PCV and apply for donors assistance was made by the Minister of Health based on the resolution of

the inter-agency coordinating mechanism (ICC/HSCC). The ICC additionally provides support on evaluation and planning of short-term and long-term activities related to the NIP and the implementation of the NIP priorities; resource mobilization and advocacy. Minutes attached do not reflect the work of the ICC. There is no evidence of a functioning NITAG.

Status of the National Immunisation Programme

National Immunization Program is performing well and the program targets 10 infectious diseases viz: TB, hepatitis B, Polio, Diphtheria, Tetanus, Pertussis, Hib, Measles, Mumps and Rubella and has high coverage rates.

The program goals are to ensure 95% of coverage at OPV-3 by 2015; to decrease transmission of endemic measles virus by 2012 and prevent sustained transmission of imported measles viruses in Georgia beyond 2015; to achieve more then 90% coverage with DTP3, HepB3, TD and DT in every district by 2012; and to maintain the polio free status of the country;

The progam maintains an effective oriented surveillance system for all EPI diseases and has successfully achieved its disease reduction targets for Vaccine Preventable Diseases

There is a national policy to ensure vaccine safety. There are quality control systems at each step from procurement to the point of use.

Georgia introduced Hib containing pentavalent vaccine in January 2010. The well organized immunization programme allowed smooth introduction of the new vaccine. There were no significant problems reported and high coverage rates were achieved within a short period of time. The success of the programme was attributed to proper planning together with implementation of critical activities prior to introduction of vaccine that included advocacy and communication activities, training of personnel, revision of immunization programme guidelines and the immunization information system.

The drop-out rate is in the range of 10% in 2010. Vaccine wastage rates for the base year of 2010 is 25%

4. Comprehensive Multi Year Plan (cMYP) overview

- The National Plan of Action for Immunization covers the period 2012-2016 and is well written. The situational analysis outlines the disease burden and provides justification for the introduction of both rota and PCV new vaccines into the EPI schedules. However, no reason is given for the preferred choice is PCV 10.

Diarrheal diseases cause 15-17% of hospitalizations observed among 0-3 year old children and contribute to up to 20% of emergency cases that place significant demand on the health services. Hospital based sentinel surveillance of rotavirus gastroenteritis, which is carried out by the WHO support in Georgia has demonstrated that rotavirus infection is responsible for 40% of all gastroenteritis hospitalizations among children under 5 years.

Invasive pneumococcal diseases also place significant demand on the health system. The overall burden of invasive pneumococcal disease is difficult to measure directly, but methods are available to estimate it with reasonable accuracy. According to such estimates annually approximately 1,300 children less than 5 years age get ill and 75 (range 56-88) children of this age group die from a preventable invasive pneumococcal disease. Death toll contributes to 12% among all death cases in children age 1 month to 5 years. There are a number of measles and rubella cases reported.

This plan includes the following objectives and priorities:

- Improving the timely immunization coverage against all 8 antigens up to 95% at the national levels and at least to 80% at all district levels throughout the country;
- Sustaining Polio free status and continuing supplementary disease control activities for Measles/CRS and Diphtheria;
- Decreasing vaccine wastage rates;
- Introduction of new vaccines based on epidemiological and cost-benefit analysis;
- Improving immunization coverage and program management capacities in conflict affected zones;

5. New vaccine introduction plan

Both antigens will be implemented nationwide.
Rotavirus gastroenteritis is a significant public health problem in Georgia. In accordance to WHO estimate for 2006 there were more than 100 deaths in young children due to rotavirus diarrhoea. The rotavirus sentinel surveillance was established in the Republic of Georgia in 2006 with WHO support. The surveillance data showed that significant proportion of severe diarrhea (40-47%) in children under 5 years of age that required hospitalization was due to rotavirus.

During 2005-2009 the average number of suspected cases of septic meningitis was 112 representing an incidence rate of 2, 55. Bacteriological diagnosis of Streptococcus pneumonia pneumonia is still largely deficient in Georgia due to the lack of laboratory capacities.
In order to overcome the difficulty in assessing the burden of the invasive Streptococcus pneumonia diseases, Georgia is using estimated data produced by WHO studies.

WHO estimated that *Streptococcus pneumonia* caused severe illness including pneumonia and meningitis in more than 1600 Georgian children less than 5 years of age and was responsible for more than 160 deaths in 2000[1,2]. Results from bacterial meningitis surveillance at sentinel hospital in 2009 showed that *Streptococcus pneumonia* was detected in 15% of cases of bacterial meningitis occurring in children less than 5 years of age.

Several preparatory actions have already been carried out towards introducing the rotavirus and pneumococcal vaccines in Georgia. The cMYP for the period 2011- 2015 was

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[1] World Health Organization. *WHO estimates for the burden of Hib and pneumococcal disease.* Available at: http://www.who.int/immunization_monitoring/burden/GDB_Hib_Sp_Results_Database.xls Accessed 24 January 2011.

[2] O'Brien KL, Wolfson LJ, et al. *Burden of disease caused by Streptococcus pneumoniae in children younger than 5 years: global estimates.* Lancet **2009**; 374: 893–902

developed and approved. It includes actions on introduction of both Rota and PCV (13) vaccines.

Targets for Rota and PCV are 92% coverage with two doses of rotavirus vaccine and three dose PCV and an increase to 95% by 2015. Targets appear achievable given the success of the National Immunization program.

Rotavirus vaccine will be administered to children of 2 and 4 months of age together with the DTP-HepB-Hib and OPV vaccines. The pneumococcal vaccine will be administered at the age of two, four, and six months together with pentavalent vaccine and OPV

Choice of the vaccine formulation: A two-schedule vaccine is preferred for the rotavirus vaccine. For pneumococcal vaccine, a 13-valent formulation is preferred due to a higher coverage of serotypes, especially the inclusion of serotype 19A. (There is an error in the application form for PCV (10))

Previous experience in introduction of vaccines in Georgia is well documented

The Georgia NIP has a large past experience in the introduction of new antigens into the programme and extending its services to different target population groups. The Hepatitis B vaccine was implemented in 2001. In 2004 combined measles-mumps-rubella vaccine has replaced the monovalent measles at 12 months and the second dose was established at 5 years of age.

All activities were performed after detailed plans and activities were prepared and performed. Staffs at all levels of the health system were trained, communication and advocacy activities to raise awareness and create demand for vaccine in ere implemented and supportive supervision conducted after the introduction of the new antigen in the immunization schedule. Pentavalent Hib-containing vaccine was introduced in 2010 as a three-dose schedule and achieved 63% full immunization coverage (3 doses). Supportive supervision visits conducted at all levels after introduction of Hib containing vaccine did not reveal significant errors and showed positive impact of introduction on immunization programme in general.
The new vaccines will be added to the current routine childhood immunization schedule.

Costs of rotavirus and pneumococcal vaccine introduction:

The various scenarios of the costs of rotavirus and pneumococcal vaccine introduction were estimated and are part of the cMYP.

6. Improvement plan

An Effective Vaccine Management study in Georgia is planned in August 2011.
(EVSM) assessment of the national vaccine store at NCDC was conducted by a WHO consultant in September 2007. Various recommendations were made which have been fully implemented. Table of achievements provided to support implementations of the recommendations.

Recommendations on Immunization Quality and Safety

1. Reinforce and monitor Safe Immunization Practices and AEFI.
    - Improve AEFI surveillance guidelines and training for health staff, especially at district and health facility level.
    - Define, monitor and analyze AEFI system quality indicators.

- Ensure follow-up and decisions re: EVSM (2007, WHO EURO).

2. Strengthen vaccine management.
   - For Government vaccine procurement start contract process timely.
   - Make action plan for central cold store to adopt Model Quality Plan and SOP.
3. Ensuring uninterrupted supply of vaccines and immunization materials. These recommendations have been implemented.

Opportunity for the revised recommendations from the 2011 EVM will occur before the scheduled introduction of Rota in 2012 and PCV in 2013

7. Cold chain capacity

There is a sufficient cold store capacity in the country, even if the new vaccines planned for 2012-2013 are introduced in the NIP and total need of vaccines is stored in 2016.

8. Financial Analysis

The costing exercise was detailed and included all NIP program components:

The total program costs (without shared costs) are $20.3 million, of which 82% are for vaccines and logistics, followed by 10% for program management, 5% for service delivery, 3% for monitoring and surveillance, and 1% for advocacy and communication different scenarios.

The sources of financing for the program are the government, local governments, WHO, and GAVI. The government is paying for all of its basic vaccines and co-finances for the underserved and new vaccines. There is no financing gap with secure and probable financing.

9. Co-financing arrangements

The cMYP has indicated that co-financing payments will be made based on the required financing for the country.

10. Consistency across proposal documents

Things to consider: consistency between the proposal and

- cMYP is well written and there are no data inconsistencies.
- Improvement Plan outlines implementation of the 2007 assessment
- APR consistency with good performance

11. Overview of the proposal: Strengths & weaknesses

Strengths:
High coverage of antigens
Cold chain capacity
Introduction plan and cMYP
Costing analysis
Situation analysis

Weaknesses:
Minor error with PCV request

ICC meetings do not reflect the work of the committee.
Number of Rubella and measles cases suggests low coverage rates

12. Recommendations

Vaccine: Rota
Recommendation: Approval

Vaccine: PCV
Recommendation: Approval