GAVI/13/174/sc/cw

The Minister of Health
Ministry of Health
P.O. Box 212
Asmara
Eritrea

09 April 2013

Dear Minister,

Eritrea's Proposal to the GAVI Alliance for Rotavirus vaccine

I am writing in relation to Eritrea's proposal to the GAVI Alliance for New Vaccines Support for Rotavirus vaccine, which you submitted to the GAVI Secretariat in August 2012.

Following a meeting of the GAVI Executive Committee (EC) on 15 February 2013 to consider the recommendations of the Independent Review Committee (IRC), I am pleased to inform you that Eritrea has been approved with clarifications for rotavirus vaccine as specified in the Appendices to this letter.

In relation to your proposal for rotavirus vaccine, I can also confirm that Eritrea has provided a satisfactory response to GAVI to the clarifications required by the IRC.

You will need to co-finance the procurement of rotavirus vaccine in accordance with the GAVI co-financing policy, and the terms and conditions of this letter and its Appendices.

As noted in GAVI's letter dated 23 November 2012, the global supply of Rotarix will not meet all country requirements in the short term. UNICEF Supply Division, via its Country Office, will be in further contact throughout 2013 to plan the timing of the first vaccine shipment, expected for the fourth quarter of 2013. A GAVI Decision Letter will then be issued with the number of doses to be funded by GAVI as well as the co-financing requirements.

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

Appendix A: A summary of the IRC Report
Appendix B: The terms and conditions of GAVI Alliance support

The GAVI Alliance has recently sent to you a new Partnership Framework Agreement (PFA) designed to improve the ease and efficiency for countries to understand the GAVI requirements, in one clear and standardised document.

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Please do not hesitate to contact my colleague Charlie Whetham - cwhetham@gavialliance.org if you have any questions or concerns.

Yours sincerely,

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

Appendix A

IRC NVS COUNTRY REPORT

Geneva, 8th – 19th October 2012

Country: Eritrea
Type of support requested: NVS
Vaccines requested: Rotavirus

Country profile/Basic data (2012)

Population	5,580,862	infant mortality rate (2012)	48/1000
Birth cohort	194,285	Govt. Health expenditure (as a % of GDP)	13%
Surviving infants	184,950**	GNI/capita (2011)	$430***
DTP3 coverage (WHO/UNICEF estimate 2011)	99%	Co-financing country group*	Low income

*low income, intermediate or graduating Source: http://www.gavialliance.org/country/eritrea
** According to proposal section 5.1 surviving infants for 2012 is 106,452.
*** It was US$ 676 in 2007 (IMF source) as reported in the NVS proposal.

The figures used in the proposal differ significantly from those GAVI has on record, shown above. For example, for total population the NVS application has 3,715,618 (HMIS 2012), and GAVI has 5,580,862 or for Infant Mortality, where the NVS application has 42/1000, GAVI has 48/1000, both 2012. These data disparities are apparently an effect of uncertainty arising from the on-going conflict with Ethiopia. The country, however, acknowledges denominator problems and this is exacerbated by no census data.

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

The country is requesting Rotavirus vaccine, single dose, for use in a 2-dose schedule at national level. The implementation period is 2013-2016. The total amount of budget for 2013 is expected to be US$ 757,500, including the grant budget (US$ 100,000) for the introduction of the vaccine. This includes US$ 49,500 corresponding to the co-financed contribution by the Government of Eritrea. The vaccine amount requested to GAVI to cover the total vaccine period is US$ 2,268,000, which includes the introduction grant. Eritrea will contribute US$ 176,000 for the co-financing commitment. The number of surviving infants that are eligible for Rotavirus Vaccine in 2013 is estimated to be 109,819, with 81% routine immunisation coverage for the second dose.

2. History of GAVI support

Table 1. NVS and INS support

NVS and INS support	Approval Period
DTP-HepB	2002-2012
DTP-HepB-Hib	2008-2015
Measles	2012-2016
INS	2004-2006

Table 2. Cash support

Cash support	Approval Period
ISS	2002-2013
HSS	2008-2013

3. Composition & Functioning of the ICC

The ICC met on 24th August 2012 to endorse the Rota resubmission NVS application. MOH, WHO, UNICEF, MOE and JICA were all present during the meeting. There was representation from an organization, PL, which presumably is a CSO. The function of the ICC included oversight of implementation of EPI activities, programme coordination, endorsement of key decisions related to new vaccine introduction and SIAs, GAVI Annual Progress Report (APR) and Joint Format Report (JRF). Resources mobilization for immunisation is also a role of the ICC. The level of membership of the meeting that deliberated the proposal appeared to be technical staff, with the exception of JICA. This meeting was chaired by the EPI manager. The NITAG is yet to be established and the EPI Technical Committee currently undertakes this role.

The proposal resubmission considered comments from the IRC on MSD and Rota vaccine introduction. Given that the budget for introduction of vaccines by GAVI is limited, the ICC suggested that 'CBO' should contribute with operational support for transport. The Government provides a fuel subsidy of US$ 0.75 per litre for EPI operations, which should continue.

4. Status of the National Immunisation Programme

The country immunisation programme has recorded high performance, as evidenced in the Demographic Health Survey, as well as the coverage survey. Although the country estimates modest immunisation coverage, surveys have indicated much higher rates, with WHO/UNICEF estimates being in line with coverage findings. The targets set for rotavirus vaccines are in line with previous DTP3 achievements. There is no reference to previous lessons learnt on the introduction of new vaccines in the proposal.

The country provides justification for the requirement of the vaccine by stating that rotavirus is a leading cause of diarrhoea deaths in early childhood in Eritrea and diarrhoeal disease is among one of the top 5 child morbidity and mortality diseases in Eritrea (HMIS 2011). Its introduction in 2013 will help the country to continue being on track on the achievement of the MDG4 and the child survival goals of its multi-year plan (2012-2016) for immunisation systems strengthening.

Eritrea has successfully introduced a number of vaccines with GAVI support - hepatitis (2002), pentavalent (2008), measles second dose (2012) - and received a grant fund for Immunisation Service Support (ISS). To date, Eritrea delivers immunisation for children against eight preventable diseases: tuberculosis, diphtheria, whooping cough, tetanus, polio, measles, hepatitis B & haemophilus influenza type B.

Funding is now being requested to support the introduction of one dose vial for two-dose immunisation schedule of Rota Vaccine in 2013. Referring to the population growth projection of 2013, births are estimated to be 114,395 and surviving infants that are eligible for Rota vaccine will be 109,819, with 81% routine immunisation coverage for the second dose.

Neither gender nor equity have been addressed as part of the application. The proposal indicates no gender problems in Eritrea and that there is no gender disaggregation of immunisation data. The proposal acknowledges sub-optimal immunisation coverage associated with nomadic populations, as well as populations living in less accessible areas to the immunisation programme, based on findings through regular feedback of routine immunisation coverage. These challenges, however, were not addressed in the introduction plan.

5. Comprehensive Multi Year Plan (cMYP) overview

The 2012--2016 cMYP is based on data from a situational analysis conducted in 2006, the methodology of which is not provided in the document. Its duration is in line with the proposal and covers Rota introduction and plans the pneumococcal vaccine introduction by 2015. Appropriate analysis of the immunisation programme is provided, identifying government funding for immunisation, communication, transportation for immunisation services, availability of vaccinators and stock management as critical challenges. Although not specifically mentioned, data quality vis-a-vis denominator issues remain a major challenge, as evidenced by discrepancies in data through the various documents.

The national objectives reflected in the multi-year plan are appropriately defined, taking into consideration the introduction of new vaccines, which include rotavirus, pneumococcal, and measles second dose. The vaccines are costed and committed government funding is allotted for new vaccines, with partner funding procuring the traditional vaccines throughout the requested period.

The EPI operates under a general macroeconomic environment of low income per capita, where a large portion of the country's social and physical infrastructures were badly affected by the recent war and need significant investment for reconstruction. Due to competing demands by various sectors for resources, the health sector budget, and in particular the EPI budget, is low. The Eritrean EPI programme is heavily reliant on donor support and identifies the Government of Eritrea as the only source of funding by increasing its financial allocation and/or broaden funding resources for EPI to continue to achieve its objectives.

6. New vaccine introduction plan

A national introduction of rotavirus vaccine is planned, with GAVI being the sole contributor to the introduction. JICA provided significant financial resources to strengthen the cold chain and the Government subsidized fuel costs for EPI activities. The Government is looking into increasing the contribution to the EPI, as stated in the proposal narrative, with no deadline for an expected increase. However, the ICC requests GAVI to consider increasing operational resources in order for the Eritrea to better meet their EPI operational costs. There is no indication of what roles partners shall play in the immunisation schedule.

The procurement and delivery process of vaccines and injection safety materials will be through UNICEF. The co-financing amount will be made on an annual basis through UNICEF. Appropriate vaccine wastage rates have been used as guided by WHO. Wastage reduction strategies have been articulated and include increasing awareness of the community, create demand and proper planning of static and outreach services, emergency plan and accountability for vaccine wastage, effective transportation of vaccines as well as training of health workers and regular monitoring of vaccine stock at all levels.

7. Improvement plan

Eritrea has taken measures to address the Cold Chain and Logistics (CCL) weaknesses identified in the 2009 EVSM/VMA and a comprehensive national cold chain assessment was conducted in 2010 to address cold chain issues for the introduction of new vaccines including Rotavirus and MSD. The assessment revealed that 5 of 6 regional vaccine stores have sufficient capacity to accommodate new vaccines. Eritrea is also scheduled to conduct an EVM assessment in Q4 of 2012.

8. Cold chain capacity

An estimate of vaccine storage capacity requirement for routine and Rota vaccine was done for 2012 and 2014. An agreement with JICA will finance cold chain equipment for a 5 year period. Deliveries are expected to begin in Q4 of 2012. As a result of JICA support and a planned new cold room installation, vaccine storage capacity at the national level will be adequate for the routine programme inclusive of Rota vaccine.

In response to the IRC recommendation in 2011, the country has taken adequate measures to identify capacity needs required to introduce Rota in 2013, and provision for equipment supply. The country is in a position to store Rota at all levels of the cold chain in 2013. 30% of the introduction grant will support the strengthening of CCL. Measures to address waste management are planned, but the IRC is concerned about the likely environmental emissions from the single chamber incinerator technology being introduced. fVaccine storage temperature is monitored. Transportation constraints are, however, apparent.

The National cold chain equipment assessment showed that there was still much non-functional cold chain equipment in the health facilities in all the six regions. This was acted upon by the country and is shown in the UNICEF pre-assessment sheet.

Vaccine storage capacity at the districts and health facilities is sufficient to accommodate the new vaccines. However, shortage due to the increasing number of obsolete cold chain equipment at the facility levels has to be addressed accordingly.

9. Financial Analysis

Eritrea requested US$ 100,000 as an introduction grant from GAVI, out of the total financial requirement of US$ 187,000 for the new vaccine introduction. The country plans to spend more than half of the requested funding in Training (US$ 34,000) and Vehicles and Transportation (US$ 20,000). However, the country does not provide a narrative for the allocation of costs to the budget lines and projected costs.

It would have been useful for the country to have submitted more detailed information on the nature of the costs, unit costs and their resource allocation rationale. Given that the proposal states challenges in reaching nomads and hard to reach areas, compounded with high transport costs, the IRC is concerned that less than half of the expected budget has been allocated to transportation costs. The country has asked GAVI to increase operational costs to meet some of these challenges even if the Government subsidizes petrol costs. The proposal does not provide details as to how the MOH will address the US$ 87,000 shortfall to successfully introduce rotavirus in the country.

Further analysis of the cMYP costing tool shows that there is on average a 30% funding gap if only secured funds are considered. There is no funding gap with both secured and probable funding, though there are US$ 3.5 million from WHO and JICA and some portion of funding from UNICEF (US$ 4.7 million) considered as probable. Measures necessary to reduce the funding gap in case probable funds are not secure was not discussed. According to the cMYP, the country "survived" a 7% funding gap for the period of 2007-2011. There is no reference in any form to financial sustainability.

According to the cMYP costing tool, traditional vaccines were fully financed by UNICEF (US$ 206,000) in 2011 and Underused vaccines by GAVI (US$ 792,000). No other information is available about routine vaccine financing patterns in the past. The government intends to allocate some funds to vaccines from 2011 because of co-financing obligations in front of GAVI. The rest is expected to be fully financed by partners.

10. Co-financing arrangements

The committed level of co-financing in 2013 onwards is in line with the country classification of US$ 0.20 per dose. The country stated in the proposal (section 8.1e) that the GoE is responsible to allocate funds for co-financing. The information on country immunisation financing trend is very limited. Overall, the country EPI is heavily dependent on partner funding. The government only covers personnel, transportation, maintenance and overhead, as well as programmatic/operational costs, while routine vaccine costs and capital costs are supposed to be almost fully financed by partners.

11. Consistency across proposal documents

Priorities are clearly linked in the proposal and in the cMYP and in line with available evidence. The proposal is harmonised with the cMYP timeframe (2012-2016), the improvement plan and the national health plan (2012-2016). Requested vaccine volumes can be accommodated in the current cold chain and are in line with the data provided by the country but not with GAVI data. Calculations, however, seem correct, using 25% for stock and 5% for wastage as recommended. There is indication of vaccine co-financing by government though at the expense of traditional vaccines. Data quality is an area that requires attention in order for monitoring to be reliable.

12. Overview of the proposal: Strengths & weaknesses

Strengths: The proposal contains evidence of disease burden; cold chain issues addressed; clear introduction plans identifying critical areas essential for new vaccine introduction and completeness of the cMYP as per weaknesses identified by the IRC. The submission is clear, harmonised with the cMYP and other documents timeframes and in line with stated priorities.

Weaknesses: The vaccine introduction plan requires almost twice the resources provided by GAVI, with no identified source of finance for the gap identified in the introduction activities. Of particular concern is the transport cost gap, which could jeopardize a successful vaccine introduction. Eritrea solely relies on GAVI and a limited range of donors for the EPI programme. There are data discrepancies between routine reporting and survey, lack of census data creating uncertainties in denominator figures and different population figures in various documents might result in challenges in ascertaining the real coverage through routine systems as well as forecasting accurately the country's vaccine requirements.

Risks: Not able to undertake all of the activities planned for the vaccine introduction due to lack of financial resources to meet all of the envisaged expenses.

Mitigating factors: Identification of other sources of funding or streamlining their requirements to undertake the vaccine introduction within the available resources.

Note to the ICC: The proposal states challenges of vaccine access due to the underfunding of the EPI programme, particularly within the nomadic populations and remote areas. The vaccine introduction budget has apportioned US$ 20,000 from GAVI, out of the stated US$ 50,000 for transport costs with no identified financial resource to meet the gap. The IRC is concerned about the limited success the introduction may have if all of the transport costs required are not met and requests the ICC to identify other resources to meet this gap.

13. Recommendations

Vaccine: **Rotavirus**
Recommendation: **Approval with clarifications**

Clarifications:

1. The country is requested to resolve the discrepancies in population figures and targets across documents to be used for implementation of the rotavirus vaccine.
2. Provide clarity on financial sustainability strategy that will contribute to filling the funding gap.

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.