GAVI/13/115/sc/md

The Minister of Health
Ministry of Health
P.O. Box 1234
Addis Ababa
Ethiopia

27 March 2013

Dear Minister,

Ethiopia's proposal to the GAVI Alliance
Measles SIA Support

I am writting in relation to Ethiopia's proposal to the GAVI Alliance for Measles SIA and Meningitis A support which were submitted to the GAVI Secretariat in October 2012.

As discussed with representatives of your Ministry, GAVI support to measles SIAs is for a target population of below five years of age. The GAVI Alliance Executive Committee recently confirmed this (see attachment). Accordingly, we would like to inform you that GAVI has approved support for the Ethiopia measles campaign for a target group of children from 9 months up to 5 years of age. GAVI has called on donors and partners to assist countries like Ethiopia with identifying resources to support the costs for target populatons of five years and above and we encourage Ethiopia to reach out to donors and partners for this purpose.

Following a meeting of the GAVI Independent Review Committee from 1 to 8 March 2013 to consider your final application for Menigitis A campaigns and the responses to conditions recently submitted, I am pleased to inform you that the GAVI Alliance has approved Ethiopia for GAVI support.

Description of the proposed support for both vaccines is provided in the Appendices to this letter, listed below:
Appendix A: Description of approved GAVI support to Ethiopia
Appendix B: Financial and programmatic information for measles and Men A vaccines
Appendix C: A summary of the IRC Reports
Appendix D: The terms and conditions of GAVI Alliance support

Men A and Measles catch-up / preventive campaigns are exempt from co-financing, however the country will cover the cost of the vaccines when the GAVI-supported campaigns have reached their completion.

The following table summarises the outcome for each type of GAVI support applicable to Ethiopia:

New Vaccines Support *Type of vaccine*	**Approved for 2013**	**Approved for 2014**
Measles SIA	US$ 4,477,000	
Measles SIA Operational support	US$ 7,606,000	
MenA Preventive Campaign	US$ 13,398,500	US$ 17,293,500
MenA Preventive Campaign Operational support	US$ 12,302,500	US$ 15,879,500

Please note that funds to procure injection and safety devices for the measles campaign (for a target group of nine months to 14 years) have already been disbursed in December 2012 to allow timely procurement and shipment. The excess devices procured for measles (i.e. for a target group of five years and older) shall be utilized for meningitis A campaigns and a corresponding amount will be deducted from the approved amount for meningitis A campaigns stated in this decision letter. In addition, the already disbursed amount for injection and safety devices for the measles campaign (for the target group up to five years) will be set off against the total approved amount mentioned in this letter.

Please do not hesitate to contact my colleague Maryse Dugué mdugue@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
The GAVI Finance Unit

Attachment

GAVI Executive Committee Meeting, 20 March 2013

Decision on support for measles SIAs in measles high risk countries

Noted that in June 2012 the Board, on an exceptional basis, decided to provide support for measles vaccines and operational costs ("SIAs") for six large countries at high risk of measles outbreaks (Afghanistan, Chad, DR Congo, Ethiopia, Nigeria, and Pakistan) (measles high risk countries) as a bridge until the implementation of a measles-rubella campaign, or by no later than 2017. This decision was taken in the context of insufficient available resources to countries for SIAs, such as through the Measles & Rubella Initiative.

Clarified that GAVI's support for SIAs in measles high risk countries shall be limited to a target population of below 5 years of age. The Executive Committee noted that WHO SAGE is expected to make recommendations on age targets for SIAs later in 2013. The Committee also noted the implications of the different assumptions for SIAs in the measles high risk countries.

Recognised the difficult and changing environment of measles epidemiology and called on donors and partners to assist the measles high risk countries to respond to the evolving measles situation including by identifying resources to support the costs for target populations of 5 years and above where appropriate. The Executive Committee noted that while the need for SIAs remains, it is critical for partners and countries to also invest in and strengthen routine immunisation services to prevent measles deaths sustainably.

Appendix A

Description of GAVI support to Ethiopia (the "Country")

Measles SIA and Men A support

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, 2014 and 2015 immunization programmes as set out in Appendix B. Financing provided by GAVI for vaccines will be in accordance with:

- The GAVI Alliance Guidelines governing Ethiopia's proposal applications; 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 immunisation provided with these vaccines.

Item number 11 of Appendices B-1 and B-2 summarise the details of the approved GAVI support for vaccines in 2013, 2014 and 2015.

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.

GAVI support will only be provided if the Country complies with the following requirements:

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

Financial Statements & External Audits: Compliance with the then-current GAVI requirements relating to financial statements and external audits.

Grant Terms and Conditions: Compliance with GAVI's standard grant terms and conditions (attached in Appendix D).

Monitoring and Annual Progress Reports: Ethiopia 's use of financial support 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 immunization coverage estimates. As part of this process, National Authorities will be requested to monitor and report on the numbers of children (and young adults in the case of Men A) immunised.

Ethiopia will report on the achievements and request support for the following year in the Annual Progress Report (APR due in 2014). The APR 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 ICC, and as reported to WHO and UNICEF in the annual Joint Reporting Form (JRF). APRs 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 and availability of funds.

Appendix B1

MEASLES SIA VACCINE SUPPORT

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

1. **Country:** Ethiopia
2. **Grant Number:** 12-ETH-09a-X / 13-ETH-23a-Y
3. **Decision Letter no:** 1
4. **Date of the Partnership Framework Agreement:** N/A
5. **Programme Title:** New Vaccine Support
6. **Vaccine type:** Measles
7. **Requested product presentation and formulation of vaccine:** Measles, 10 dose(s) per vial, LYOPHILISED
8. **Programme Duration**[1]**:** 2013
9. **Programme Budget (indicative): (subject to the terms of the Partnership Framework Agreement)**

	2013	**Total**[2]
Programme Budget (US$)	US$4,477,000	US$4,477,000

10. **Vaccine Introduction Grant:** N/A
11. **Indicative Annual Amounts (subject to the terms of the Partnership Framework Agreement):**[3]

Type of supplies to be purchased with GAVI funds in each year	**2013**
Number of Measles vaccines doses	12,988,100
Number of AD syringes	12,988,100
Number of re-constitution syringes	1,441,700
Number of safety boxes	160,175
Annual Amounts (US$)	US$4,477,000

12. **Procurement agency:** UNICEF
13. **Self-procurement:** N/A

[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 amount that GAVI has approved. Please amend the indicative Annual Amounts from previous years if that changes subsequently.

14. Co-financing obligations: N/A

15. Operational support for campaigns: The support for operational costs for campaign will be disbursed in cash

	2013
Grant amount (US$)	**US$7,606,000**

16. Additional documents to be delivered for future disbursements: N/A

17. Clarifications: N/A

18. Other conditions: N/A

Signed by
On behalf of the GAVI Alliance

Hind Khatib-Othman
Managing Director, Country Programmes
27 March 2013

Appendix B 2

MENINGITIS A VACCINE SUPPORT

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

1. **Country:** Ethiopia
2. **Grant Number:** 1315-ETH-16a-X / 1315-ETH-17a-Y
3. **Decision Letter no:** 2
4. **Date of the Partnership Framework Agreement:** N/A
5. **Programme Title:** New Vaccine Support
6. **Vaccine type:** Meningitis A
7. **Requested product presentation and formulation of vaccine:** Meninigitis A, 10 dose(s) per vial, LYO
8. **Programme Duration**[4]**:** 2013 - 2015
9. **Programme Budget (indicative):**

	2013	2014	2015	Total[5]
Programme Budget (US$)	US$13,398,500	US$17,293,500	US$10,669,000	US$41,361,000

10. **Vaccine Introduction Grant:** Not applicable
11. **Indicative Annual Amounts (subject to the terms of the Partnership Framework Agreement):**[6]

Type of supplies to be purchased with GAVI funds in each year	2013	2014
Number of Meningitis A vaccines doses	21,009,000	27,117,000
Number of AD syringes	21,008,900	27,117,000
Number of re-constitution syringes	2,332,000	3,010,000
Number of safety boxes	259,100	334,425
Annual Amounts (US$)	US$13,398,500	US$17,293,500

12. **Procurement agency:** UNICEF
13. **Self-procurement:** N/A

[4] This is the entire duration of the programme.
[5] 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.
[6] This is the amount that GAVI has approved. Please amend the indicative Annual Amounts from previous years if that changes subsequently.

14. Co-financing obligations: N/A

15. Operational support for campaigns: The support for operational costs for campaign will be disbursed in cash

	2013	2014
Grant amount (US$)	**US$12,302,500**	**US$15,879,500**

16. Additional documents to be delivered for future disbursements: Not applicable

Reports, documents and other deliverables	Due dates

17. Clarifications: N/A

18. Other conditions: N/A

Signed by
On behalf of the GAVI Alliance

Hind Khatib-Othman
Managing Director, Country Programmes
27 March 2013

Appendix C 1

IRC MEASLES SIA REPORT: 2nd RESPONSE TO CONDITIONS

Country name: Ethiopia
Type of support requested: Measles SIA Support
Vaccines requested: Measles, 10 dose/vial, Lyophilized

Country Profile/Basic Data

Population (GAVI -2012)	86,538,534	Infant mortality rate (GAVI-2012)	63.58/1000
Birth cohort (GAVI-2012)	2,616,032	Co-financing country group (2012)	Low Income
Surviving Infants (GAVI-2012)	2,449,704	GNI/capita (2011)	$400
DTP3 coverage (2011) * WHO/UNICEF Estimate JRF Country Estimate JRF Administrative	 51% 87% 87%	Government Health Expenditure, % Total Gov Expenditure (2010) Total Health Expenditure, % GDP (2010)	13.5% 4.9%

Source: GAVI Country Hub Data, JRF forms, WHO, World Bank, Country Application
*2011 DHS Survey conducted: DTP3 coverage =36.5% (2010)

1. Overview of IRC Review Process

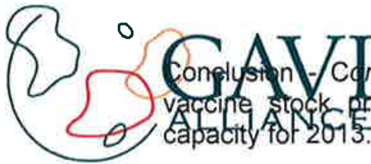
The initial IRC report (Nov 2012) approved support for the Ethiopia Measles SIA contingent on seven conditions. The country provided a first round of responses to these seven conditions and the IRC came to the below conclusions in its second report (Dec 2012). This current and third report (Jan 2013) represents the IRC review of the country responses to these below IRC conclusions.

Condition 1: Submit the results of the 2013 EVM and the 2012 cold chain inventory.
Conclusion - *Condition 1 not met.* Ethiopia is requested to reschedule the EVM for Jan/Feb 2013 and to revisit the methodology proposed including reducing both the number of sites to assess and the number of assessor teams and drawing upon the expertise of WHO/UNICEF experienced lead assessors.

Condition 2: Provide the PFSA equipment plan including installation timeline, budget and funding sources along with a copy of the government agreement with PFSA.
Conclusion - *Condition 2 met.* Ethiopia should advise the GAVI secretariat on progress towards completion of 2012 planned activities.

Condition 3: Provide a waste management plan for the 2013 measles SIA that is incorporated into the Measles SIA POA and includes costs, funding sources and obligations.
Conclusion - *Condition 3 partially met.* Ethiopia should provide a waste management plan, specific to the measles SIA, along with the timeline for implementation. The plan should demonstrate that waste equipment construction, inventory, maintenance, and training are completed with sufficient capacity to dispose of the over 100 tons of waste generated by the SIA.

Condition 4: Submit central and regional monthly vaccine stock projections (routine and campaign) for 2013.



Conclusion - *Condition 4 not met.* The country should submit central and regional monthly vaccine stock projections (routine and campaign) correlated with available vaccine storage capacity for 2013.

Condition 5: Clarify the discrepancy between the reported vaccine wastage rate of 10% for previous measles SIAs in the AF and the estimated 25% vaccine wastage for the 2013 measles SIA.
Conclusion - *Condition 5 not met.* The IRC has concerns with the country artificially increasing the estimated wastage rate to create a buffer stock for the campaign. The IRC concurs with the CRO recommendation that the country submit to the IRC an improved quantification of the target population in order to avoid stock-outs as opposed to requesting an artificial increase in the wastage rate (see Nov 2012 trip report). Buffer stocks are not required for campaigns if the target population has been quantified correctly. The country should also ensure there are no inconsistencies in the final wastage rate submitted in all documents (i.e. projected vaccine distribution spreadsheet, Measles SIA POA, Measles SIA AF) and that the ICC has approved this wastage rate.

Condition 6: Demonstrate how operational costs will be shared & attributed for the measles and OPV campaigns.
Conclusion – Condition 6 met.

Condition 7: Submit an updated cMYP and cMYP costing tool that includes the pertinent details of the planned 2013 measles SIA.
Conclusion - *Condition 7 partially met.* The country should clarify the discrepancies in the AF and the updated cMYP document regarding the cost of vaccine and supplies and the plans for deferring the measles SIA in 4 regions until 2014. Table 25 in the cMYP should be updated to include the costs for the 2013 measles SIA and the cMYP costing tool should include the government funding commitment for the 2013 Measles SIA in the "Government Funding & Co-Financing Indicators" spreadsheet.

2. *IRC Comments on Country 2nd Responses to Partially & Unmet Conditions*

Response to Condition 1: Submit results of the 2013 EVM and the 2012 cold chain inventory
IRC Observations:

Ethiopia has declined the IRC recommendation to reschedule the EVM to Jan/Feb 2013. Delaying the EVM until July/August 2013 violates by a significant margin the GAVI requirement that an EVM or equivalent must have been conducted within 36 months prior to the application date (Measles SIA Support Guidelines, pg 8). In addition, the absence of a recent EVM makes accurate assessment of the cold chain situation in the country extremely difficult. This issue is further compounded by IRC concerns with the following supporting cold chain information:

- Regional monthly vaccine stock projections were not provided as requested and the reasons put forward for the interruption of the stock management data do not justify the absence of this data (See Condition 4).
- The performance of the PFSA in vaccine management and distribution is unknown and the transfer of responsibility to PFSA will be in transition during the campaign.
- The country has not provided an update on the status of the cold chain inventory that should be underway according to previous information received from the country.

Conclusion
Condition 1 not met. Ethiopia is requested to reschedule the EVM to Jan/Feb 2013 as requested in the previous IRC reports. The absence of information in numerous domains relating to cold chain management and storage capacity presents an unacceptably high risk of inappropriate storage standards for the measles SIA vaccines.

Note to the GAVI Secretariat: The GAVI secretariat may choose to make an executive decision to lift the requirement for an EVM or equivalent within the past 36 months prior to the application date. However, GAVI should consider both the inequity and inconsistency issues this raises with other reviews and the IRC concerns with the risk to large stocks of vaccines if further information

is not provided on stock levels, stock management, storage capacity, and stock projections for 2013.

Response to Condition 3: Provide a waste management plan for the 2013 measles SIA that is incorporated into the Measles SIA POA and includes costs, funding sources and obligations.

The response adds very little to information previously provided. The country has indicated that disposal will occur at health facilities but does not indicate the status of the inventory, construction plans or schedules. The national regulatory framework on healthcare waste management (HCWM) is not well formulated, presenting a risk to health workers, waste handlers, the community and the environment.
Increasing the capacity and readiness of health facilities to properly handle and manage medical wastes has been identified as a priority by the MOH due to planned massive campaigns and increased number of antigens integrated in the routine immunization program. Progress towards this priority should be encouraged and monitored by the GAVI Secretariat

Conclusion
Condition 3 met. The GAVI secretariat should encourage the country to apply good injection safety and environmental practices relating to healthcare waste management and disposal.

Response to Condition 4: Submit central and regional monthly vaccine stock projections (routine and campaign) for 2013.

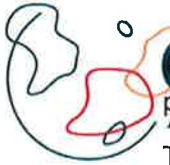
Ethiopia has not provided the requested information. Vaccine stock management data from the country has been published previously and personnel have recently been trained in country, therefore monthly stock management data should be available. Without the vaccine stock projection data the IRC is unable to assess whether cold chain storage capacity is adequate to accommodate the large volume of vaccine required for the Measles SIA along with storage requirements for routine, campaign and new vaccines.

Conclusion
Condition 4 not met. The country is requested to submit central and regional monthly vaccine stock projections (routine and campaign) correlated with available vaccine storage capacity for 2013.

Response to Condition 5: Clarify the discrepancy between the reported vaccine wastage rate of 10% for previous measles SIAs in the application form and the estimated 25% vaccine wastage for the 2013 measles SIA.

The country has reduced the wastage rate to 10%, in line with the approximate wastage experienced during previous measles SIAs. To deal with the issue of vaccine shortages during previous campaigns due to inaccurate population estimates, the country has revised the target population figures for the SIA in consultation with the Policy and Planning Directorate and a region-by-region table with the adjusted target population data was provided.
As a result of the change in the target population, the operating budget requested from GAVI has increased from the original $22,586,652 dollars to $24,085,673. However, the country has also decreased the cost for the vaccines and supplies from $0.55/person to $0.422/person, therefore decreasing the request for GAVI vaccine and supply funding from $19,111,783 to $15,648,574.
As a result of these changes the total budget request to GAVI has decreased by approximately $2,000,000.
The country has not indicated whether the ICC has approved the revised figures for the wastage rate, population estimates and budget request. Given the significant changes that have occurred as a result of these changes the IRC recommends that the ICC be briefed of the changes and provide endorsement of the updated application.

Conclusion
Condition 5 partially met. Provide ICC endorsement of the revised population figures, wastage rate and requested budget in the updated application form to the GAVI secretariat. In addition, Section 8 of the application form requires updating with the new budget information; the remainder of the application form has been updated appropriately.



Response to Condition 7: Submit an updated cMYP and cMYP costing tool that includes the pertinent details of the planned 2013 measles SIA.

The country has clarified in the written response that the SIA will be nationwide in 2013 and no regions will be deferred until 2014. The cMYP tool has been appropriately updated and includes revised measles campaign costs using the adjusted targets and costs. In Table 25, the campaign costs column for 2013 has been updated to include the Measles campaign but does not include the planned Men A campaign, and the grand totals for the table have not been updated.

Conclusion
Condition 7 met. Table 25 of the cMYP should be amended to reflect revisions made to the cMYP costing tool.

4. Recommendations

Vaccine: Measles SIA Support
Recommendation: ***Conditions Not Met***

Comments: The IRC remains concerned regarding the lack of knowledge of the cold chain situation in the country (Condition 1 and Condition 4) and the resulting risk this poses to the large volume of measles vaccine required for the campaign.

Note to the GAVI Secretariat: The IRC has no further inputs on the current application unless data become available on the cold chain situation. The GAVI secretariat will need to determine if they are prepared to waive requirements for information on the cold chain situation (Condition 1 and Condition 4). The issue of ICC endorsement of the revised application (Condition 5) can be treated as a clarification that the country can submit directly to the GAVI secretariat for verification. The GAVI secretariat and future IRC sessions should also continue to monitor the progress of the country towards strengthening injection safety and environmental practices relating to healthcare waste management and disposal.

Appendix C 2

IRC NVS Country Report

Country: Ethiopia
Type of support requested: NVS
Vaccines requested: Meningococcal A Preventive Campaign
Reviewed: Geneva, 8th – 19th October 2012

Country profile/Basic data

Population (2012, proposal)	86,841,347
Birth cohort (2011, JRF)	2,924,225
Surviving infants (2012, proposal) (2011, JRF)	 2,953,628 2,784,364
Target for Men A campaign (1 to 29 years; 2013, proposal) (1 to 29 years; 2015, UNPD)	 58,427,373 60,128,372
DTP3 coverage (2011, administrative) (2011, WHO/UNICEF) (2010, survey)	 87% 51% 36%

Infant mortality rate (2010, proposal)	59/1,000
GHE as % of GGE (2012, proposal)	10%
GNI/capita (2011, World Bank)	US$ 400
Co-financing country group	Low

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

The country is requesting 64.3 million doses of Meningogoccal serogroup A vaccine (10 doses per vial, liquid) for a total of USD 78,390,434* (US$ 40,412,657* vaccine and supplies + US$ 37,977,777 (US$ 0.65 per target) for operational cost). The implementation period is phased over 2013, 2014 and 2015.

Note(*): Estimates of vaccines and supplies are based on the assumption that a buffer stock of 25% will be provided for the first year of the campaign and a 5.6% buffer stock will be provided for the second year of the campaign.

2. History of GAVI support

Total value of GAVI support from 2002 to 2012: US$ 353,496,130.

Table 1. NVS and INS support

NVS and INS support	Approval Period
DTP-HepB-Hib	2007-2015
Pneumococcal (PCV10)	2011-2014
Rotavirus	2012-2015
INS	2002-2004

Table 2. Cash support

Cash support	Approval Period
ISS2	2002-2012
HSS	2007-2009
HSFP	2012-2015
CSO Type B	2009-2011

3. Composition & Functioning of the ICC

The report of GAVI's 2012 APR Monitoring IRC notes that the minutes of meetings provide adequate evidence of the functioning of the ICC. Members of the ICC signed the present proposal at the meeting of 27 August, 2012. It is worth noting that the only bilateral or multi-lateral donor representative at this meeting was the director of a USAID-funded project.

4. Status of the National Immunization Program

Review of data on routine coverage shows significant problems with data quality and inadequate coverage with routine immunization services. WHO/UNICEF estimates that DPT3 coverage in Ethiopia has been 51% or less from 2000 to 2011 (the last year for which a WHO/UNICEF estimate is available).

The report of GAVI's 2012 APR Monitoring IRC notes that: "The WHO revised DTP3 targets raise major concerns regarding how a (very) underperforming country consistently received ISS awards based on reported coverage that was substantially higher than WHO/UNICEF estimates (2011 coverage rate of just 51% when the country is reporting 86%).... Given that Ethiopia has received substantial resources from GAVI cash grants (HSS and ISS) of over US$ 90 million and in light of the new HSFP approved, the IRC requests Ethiopia to report on how the US$ 90 million have contributed to immunization outcomes.... it is unclear how the GAVI cash grants have been spent for this purpose."

As the proposal notes, however, the country has successfully conducted polio and measles SIAs, which achieved high levels of coverage. Reported coverage during measles SIAs is shown in the following table:

Table 3. Reported coverage during measles SIAs in Ethiopia, 2002 to 2011

Campaign	Age group	Target population	Children immunized	Coverage	
				Administrative	Survey
Catch-Up, 2002-2006	6 months – 14 years	31,059,572	28,426,546	92%	
Follow-Up, 2005-2006	6 to 59 months	12,816,380	11,289,287	88%	
Follow-Up, 2007-2008	6 to 59 months	12,922,920	11,935,607	92%	
Follow-Up, 2010-2011	9 to 47 months	8,500,000		106%	90%

These data suggest several things:

- the Ethiopian NIP <u>can</u> estimate with some precision the target population for campaigns;
- the NIP has a good deal of experience implementing large campaigns (though none as large as the one proposed); and
- it may be realistic for the NIP to plan for (close to) 100% coverage.

Of concern is the report from GAVI's CRO that "Ethiopia will apply for Measles SIA by end 2012".

Concerning prior experience with new vaccines introduction, the report of GAVI's 2012 APR Monitoring IRC notes the following issues:

- The country is considering the introduction of Rotarix RCV beginning late 2013;

- Over-estimation of requirements for Penta vaccine led to an over-stocking of 1.4 million doses; and
- Under-estimation of requirements for PCV led to a shortage of this vaccine and the need to advance by 3 months one of the scheduled shipments.

5. Comprehensive Multi Year Plan (cMYP) overview

The current cMYP (2011-2015) is aligned with the health sector strategic plan (HSDP IV) in both timing and content. The cMYP document was updated in July 2012 and includes references to all planned new vaccines and to the Men A campaign and its target population. The cMYP acknowledges the coverage survey of 2006, which appeared to validate the reported coverage at the time. However, the cMYP fails to acknowledge the immunization coverage findings of the 2010 survey (DPT3 = 36%), which formed the basis of WHO/UNICEF's revised estimates (DPT3 = 50% in 2010). The document reports that DPT3 coverage was 86% in 2010 as well as in 2011. The proposal notes that a National EPI coverage survey implementation is currently being carried out.

6. New vaccine introduction plan

Ethiopia lies in the meningitis belt of sub-saharan Africa. The proposal provides data on the number of meningitis cases and deaths during major epidemics in 1981 (50,000 cases and nearly 1,000 deaths), 1989 (46,000 cases and 1,700 deaths) and 2001 (6,964 cases reported with 330 deaths). Serogroup A of Neisseria meningitidis was in each case determined to be the responsible agent. The proposal notes that there have been "only few other serotypes isolated". Given the regularity of major epidemics (each 8 to 12 years), another significant outbreak can be expected soon.

The plans call for the campaign to be phased over three years and covering 19 million persons in 2013, 24.5 million in 2014 and 15 million in 2015 respectively. The phased approach is consistent with the global availability of vaccine for Ethiopia and a quantitative risk assessment, which identified a greater risk of meningitis in the Western part of Ethiopia. According to the vaccine introduction plan, a campaign in western Ethiopia will respond to a need to "expand the front of immunity against Nm A by the North Sudanese border, [and] the need to protect populations in areas where outbreak aggravating factors exist by the South Sudanese border..."

The vaccine introduction plan includes appropriate sub-activities, including developing training materials; logistics and data management tools; organizing national and sub-national trainings; conducting advocacy and social mobilization activities; and AEFI monitoring and case-based surveillance.

Estimates of funds, vaccines and supplies are based on the assumption of 100% coverage of the target age group. Given the apparent success with previous large campaigns, this target may be realistic. A 10% wastage rate and a 1.11 wastage factor are proposed for the campaign. These are within the norms for a campaign.

The proposal includes no discussion of plans to introduce Men A into routine immunization, but GAVI guidelines and GAVI's application template are largely silent on this issue, which is important for assuring the sustainment of the epidemiological impact of a Men A campaign and GAVI's considerable investment in it.

Meningitis is one of the weekly reportable diseases for which cases are reported through the Integrated Disease Surveillance and Response system. The report of GAVI's APR Monitoring IRC noted that: "Ethiopia does not have a functional Adverse Events Following Immunization (AEFI) Systems in place." However, the proposal notes efforts are already underway and others that are planned to strengthen this system.

Gender and equity issues have been addressed as part of the application. Both the proposal and the introduction plan refer to the special attention that will be given to the role of women's associations and the women's development army in the campaign to mobilize women to get their children vaccinated. The introduction plan has a specific section entitled 'Gender equality in the MenA campaign'. In addition to mentioning the daily analysis of sex data, the plan goes on to say that at the end of each phase of the campaign there will also be an analysis of lessons learned in terms of gender difference in vaccine utilization.

The cMYP hints that a barrier to successful immunization is increasing immunization coverage in all populations, particularly in hard to reach areas. However, the introduction plan does not go into any detail as to how this barrier will be addressed. The 2010 DHS found that 52% of children in the highest quintiles are fully immunized compared to 17% in the lowest quintiles. The same survey found no significant difference in immunization service utilization between males and females.

7. Improvement plan

A VMA was conducted in 2009 and an EVM assessment is planned for February 2013. This is 6 months beyond the 36 month condition stipulated by GAVI to conduct EVM's. An EVM conducted within the 36 month period would have provided information that is required to adequately review this proposal.

Cold chain management in Ethiopia will be transferred to a parastatal (PFSA) in late 2012. PFSA will take over all existing cold rooms in the regions and will deliver supplies to districts. PFSA is planning numerous activities for 2012 and beyond:

- Construction of dry and cold stores in 17 selected sites of the country;
- Establishment of cold chain maintenance workshops in major cities of the country;
- Conducting a nationwide cold chain equipment inventory by 2012 so that there will be updated data on cold chain status in the country;
- Completing an EVMA by early 2013; and
- Procuring and distributing to lower levels more than 1000 refrigerators each year.

Ethiopia is currently approved for introduction of RCV and will receive first supplies during Q3 2013 in support of a planned introduction in October 2013. Ethiopia proposes to conduct the 2013 MenA campaign prior to the introduction of RCV. There is a high risk of overstocking at the central and regional stores unless the supply sequence of vaccines is closely monitored. Additionally, there are no clear timelines as to when PFSA will undertake the planned procurement and installations, though the transfer is expected to occur by the end of 2012. In the absence of key documentation (the results of an equipment inventory planned for 2012 by PFSA and partners; the results of the EVM rescheduled for February 2013; and a schedule of PFSA activity for 2013) makes any assessment of the country's capacity highly uncertain.

8. Cold chain capacity

Numerous flags are raised as to whether adequate vaccine storage capacity will be in place to accommodate the MenA vaccine and other new vaccines planned for 2013. This situation is further compounded by the possibility that RCV will be supplied in the Rotateq presentation, which is more voluminous than Rotarix.

Packed volumes of vaccines for the MenA campaign are $53m^3$, $61m^3$ and $42m^3$ for each of the three phases from October 2013 to October 2015, respectively. The cold chain requirement and cold chain capacity for the national and sub national levels was analyzed using the EPI logistic forecasting tool. Results indicate that there is adequate storage capacity at central level ($284m^3$ gross capacity) but some gaps in certain regions. There is excess capacity at health centers; hence supplies can be routed directly to health centers.

The option exists to ship MenA vaccines to the Central and Regional stores in refrigerated containers. This approach would eliminate risk at central and regional storage locations and provide a strong foundation for further distribution of vaccines to zones and health facilities.

MenA is a relatively stable vaccine (VVM 30) and with good logistics management can be distributed at peripheral levels using cold boxes and icepacks.

9. Financial Analysis

The GAVI introduction grant (US$ 0.65/target) funds 100% of the operational costs of all three years/phases of the Men A campaign. The proposal notes that "The government contributes through social mobilization and human resources which is not costed in the application." The operational budget asks GAVI to provide US$ 8.6 million for human resources, so it is unclear what the government contribution will be.

The country estimated total operational costs (for 3 years) at US$ 37,977,776. Social mobilization, training and cold chain are the largest cost categories, absorbing almost half of the budget. The Plan of Introduction provides no details about the operational budget line items. It is noteworthy that "Other costs" (US$ 437,170) were not specified by the country in the application form.

Campaign-related resource requirements were reflected in the cMYP costing tool, however, projections in this tool differ from those in given on the Application Form. Also, the financing data were entered into the costing tool without indicating the financing sources. As a result, the tool shows that there is a 100% funding gap. The cMYP document is silent about financing in the future, hence there is no discussion of a possible funding gap and corresponding remedial actions.

10. Co-financing arrangements

GAVI guidelines stipulate that no co-financing is required for vaccines for Men A preventive campaigns.

11. Consistency across proposal documents

There is reasonable consistency between the narrative parts of the proposal, the Men A vaccine introduction POA and the cMYP document. The cost estimates from the cMYP costing tool do not agree with the cost estimates in the proposal itself.

Of greater concern, the recent WHO/UNICEF estimates and the 2010 DHS on which they are based are not reflected in any of the estimates of routine immunization coverage that appear in the updated CMYP or the proposal itself. Given the importance of routine immunization to the health of Ethiopia's children, as well as to future GAVI support of Ethiopia's national immunization program, the cMYP and other key documents need to be further updated to reflect best estimates of routine immunization coverage.

12. Overview of the proposal: Strengths & weaknesses

Strengths:

- The proposed Men A campaign is an important component of regional plans for control of meningitis due to Meningococcus serogroup A. Data from Ethiopia document that Men A disease imposes a significant national burden;
- According to the proposal, the phased approach to the campaign is consistent with global supply of Men A vaccine. A phased approach will also reduce the cold chain capacity needed for the campaign; and
- The Ethiopian National Expanded Programme on Immunization (ENEPI) has repeatedly succeeded with large measles SIAs, although the target populations have been smaller.

Weaknesses:

- The adequacy of cold chain and programmatic capacity may depend upon the sequencing of multiple supplemental/new activities: a measles SIA that may begin in 2013, introduction of rotavirus vaccine into routine immunization beginning in 2013 and a three year Men A campaign beginning in 2013;
- The proposal lacks some of the documentation required to adequately assess vaccine management and cold chain capacity;
- In spite of significant HSS and ISS support over the last decade, the National Immunization Program has not been able to lift routine coverage with conventional vaccines over 60%;
- A plan for incorporation of Men A vaccine into routine immunization is not provided; and
- Potential disruption in current supply chain management activities given the transition of functions to PFSA.

Risks:

- Inadequate vaccine management and/or cold chain capacity;
- Insufficient capacity of the ENEPI to manage multiple supplementary/new activities concurrently; and
- Reduced focus on routine immunization and primary care.

13. Recommendations

Vaccine: **Meningococcal A Preventive Campaign**
Recommendation: **Approval with conditions**

Conditions:
Please provide the following:

1. For assessment of vaccine management and the cold chain:
    - Results of the cold chain inventory planned by PFSA in 2012;
    - An equipment installation timeline (PFSA).

2. Additional information about the schedules for various supplementary/new activities (Men A campaign, measles SIA, introduction of rotavirus vaccine into routine immunization) and explain how the NIP will meet the management requirements to successfully complete these activities during the same time period.

Rationale:
Further information is needed to assure that vaccines can be adequately stored and transported before the time that the infrastructure proposed by PFSA is put in place. For the MenA campaign vaccines could be stored in refrigerated containers, however, this will not address concerns about the safe storage of other vaccines.

Recommendation to GAVI:
The GAVI Secretariat and UNICEF/SD should closely monitor the vaccine supply sequence and stock situation in 2013 to avoid risks of overstocking and to determine if the MenA vaccines should be transported in refrigerated containers rather than shipped to the central store.

IRC NVS Country Report – Review of the Response to Conditions

Country:	**Ethiopia**
Type of support requested:	**NVS**
Vaccines requested:	**Meningococcal A Preventive Campaign**
Reviewed:	**Geneva, 1st – 8th March 2013**

14. Review of Country Response to Conditions

Condition 1: For assessment of vaccine management and the cold chain please provide results of the cold chain inventory planned by PFSA in 2012 and an equipment installation timeline (PFSA).

Comments: The country submitted a plan for a cold chain inventory currently underway and anticipated to soon be completed. The schedule for reporting of results or the resulting action plan for addressing the shortcomings is not indicated. It is not clear if PFSA will conduct the inventory or the MOH, hence the country is not in a position to respond to the first part of this condition.

The PFSA, together with MoH and partners, is installing several cold rooms and also plans to purchase additional cold chain equipment, spare parts and vehicles. Details and a timeline for acquisition/installation are provided along with a budget and funding sources.

The Application and Summary of Clarifications documents state: "*Currently the available cold chain space at National store is adequate to receive doses of meningitis for each phase in addition to routine vaccine supply with the assumption that all the available cold chain space at national level will be used for vaccine storage only. However there are constraints at regional level and the plan is to distribute supply directly from the centres for zones not far from the capital Addis Ababa. The result of cold chain capacity is as shown below and the detail is separately attached.*" No additional information is attached, however.

The country has also indicated that in order to have sufficient cold chain space for the Meningitis A vaccine, additional cold chain equipment will be put in place and actions will be taken to fill gaps seen in the recent rapid cold chain assessment done in 2011. The country also indicates that an additional 1000 refrigerators have already been ordered and will be distributed to health centres to alleviate the constraint in cold chain space observed at health facility level. The country states "Further cold chain capacity will be increased through cold room construction and procurement of additional refrigerators as indicated in document 3". Document 3 provides adequate details and an implementation schedule.

The estimations of available storage space at the central stores indicate sufficient storage space is available for MenA and routine vaccines; however, the estimations appear to be based upon a quarterly supply cycle for routine vaccines and no provision for reserve stocks rather than six monthly cycle as normally practiced by UNICEF. UNICEF confirms that vaccine supply frequency is already adjusted to accommodate the capacity limitations at the central stores and that this strategy will continue.

Note that a MenA campaign conducted in Benin in late 2012 successfully distributed MenA vaccine in a "controlled temperature" environment, without cold chain storage at peripheral levels. There are strong indications of cold chain capacity gaps at intermediate storage levels in Ethiopia; however, a well-managed distribution program could permit the country to implement the campaign without undue risk to vaccines from storage shortcomings. If Ethiopia elects to adopt a similar strategy for peripheral distribution, limitations of this approach must be fully understood by all concerned and included in micro-planning activities.

FPSA will assume logistical responsibility for vaccine and dry good distribution and storage. FPSA has already successfully performed this role in 2010/2011 for a measles campaign integrated with other immunisation/nutritional services. The experience is well documented and

although smaller in scale demonstrates its infrastructure and management capacity to undertake such tasks.

Although results of the cold chain inventory are not yet available, cold chain expansion plans are in place and resources available. In addition PFSA has demonstrated its capacity to manage similar initiatives. In the light of this new information, cold chain inventory data is no longer critical.

Conclusion: Condition 1 is met.

Condition 2: *Provide additional information about the schedules for various supplementary/new activities (Men A campaign, measles SIA, introduction of rotavirus vaccine into routine immunization) and explain how the NIP will meet the management requirements to successfully complete these activities during the same time period.*

Comments: The measles SIA is now scheduled to take place in April/May 2013 and to be completed before launch of an October 2013 MenA preventive campaign. Preparations are proceeding for the introduction of the Rota vaccine late in the 4th quarter of 2013. The response includes a brief explanation of the preparation schedule for MenA but not the concurrence with other schedules.

The main points made in the response:

- The country was able to demonstrate successful implementation of national SIAs and new vaccine introduction in the past;
- Funds are available and preparatory activities will be initiated in good time before the October 2013 Men A campaign;
- Extra technical and logistical support will be arranged to those regions and zones targeted for the campaign;
- Preparatory activities for Rota vaccine introduction activities were initiated in early 2012, and so far the training materials, IEC materials and DVD for training are almost finalized;
- An additional 1000 refrigerators are already ordered for procurement, which will be distributed to health centres to alleviate the constraint in cold chain space observed at health facility level. Further cold chain capacity will be increased through cold room construction and procurement of additional cold chain equipment and transport systems
- UNICEF has confirmed that vaccine supplies can be adjusted based upon demand and the availability of adequate storage capacity at the central stores.
- UNICEF has also confirmed that Rota vaccine will be supplied in a 17cc/dose presentation.
- GAVI, in coordination with local partners (UNICEF/WHO/CHAI) will conduct a readiness assessment prior to the launching of the campaign.

Conclusion: Condition 2 is met.

15. Updated Recommendations

Vaccine: **Meningococcal A preventive campaign**
Recommendation: **Approval**

Note to Ethiopia:
The IRC recommends that a vaccination coverage survey be conducted soon after the completion of each of the three yearly phases of the MenA campaign. These surveys should be in addition to any rapid convenience monitoring that takes place.

Note to the GAVI Secretariat:
The IRC requests a copy of the report from the readiness assessment immediately upon availability.

Appendix D

GAVI Alliance Terms and Conditions

Countries will be expected to sign and agree to the following GAVI Alliance terms and conditions in the application forms, which may also be included in a grant agreement to be agreed upon between GAVI and the country:

FUNDING USED SOLELY FOR APPROVED PROGRAMMES

The applicant country (Ethiopia) 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 described in this application. Any significant change from the approved programme 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 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.