GAVI/12/331

Honourable Dr Alexandre Manguele
Minister of Health
Ministry of Health
Maputo
Mozambique

18 December 2012

Dear Minister,

***Mozambique's 2012 application to GAVI* for the HPV Vaccine Demonstration Programme**

Thank you for your proposal to the GAVI Alliance for new vaccines support (NVS) for the HPV Vaccine Demonstration Programme, which was submitted in October 2012.

The GAVI Independent Review Committee (IRC) has reviewed all the proposals received and recommended to the GAVI Secretariat that Mozambique's application for HPV Vaccine Demonstration Programme needs **to be resubmitted**. Their report is attached, and sets out their primary concern at the capacity of the Ministry of Health to deliver this ambitious proposal. This concern is exacerbated by the fact that you are also preparing an application for Health System Strengthening (HSS) support, a resubmission for rotavirus vaccine support, and the national launch of pneumococcal vaccine.

I strongly believe that Mozambique's current priority must be health system strengthening and I very much hope that GAVI will receive a strong application for HSS support in January. I know that WHO and UNICEF are closely involved in this. Please do let any GAVI Alliance members know if we can do more to help with this vital process.

When you do resubmit your HPV Demonstration Programme proposal, it will be important to respond to the IRC's concerns, for example, by establishing a programme management group to take advantage of the Manhica Health Research Centre's project management capacity, to reduce the onus on government; and by reducing the number of districts involved in the demonstration. Exceptionally, I have agreed that a forthcoming IRC in February could consider your HPV resubmission, if you are able to resubmit it by 24 January. The next opportunity would probably be in late summer 2013.

Please do not hesitate to contact Charlie Whetham, Country Responsible Officer, if you have any questions or concerns, at cwhetham@gavialliance.org

Yours sincerely,

Seth Berkley M.D.
Chief Executive Officer

Attachment: Appendix A: Report from the Independent Review Committee

GAVI Alliance | 2 Chemin des Mines 1202 Geneva Switzerland | Tel. +41 22 909 6500 Fax +41 22 909 6555 | www.gavialliance.org

Appendix A

Application for HPV Demonstration Project by Mozambique
Report from the Independent Review Committee

Country:	**Mozambique**
Type of support requested:	**HPV Demonstration**
Reviewed:	**Geneva, 19th – 23rd November 2012**

Country profile/Basic data

Population - IRC report - GAVI-country hub	 23,391,000 24,475,186
Birth cohort	896,325
Surviving infants	898,731
DTP3 coverage (admin) DTP3 coverage (WHO/UNICEF)	76% 76%
Infant mortality rate	71.6

Govt. Health expenditure as % of General Govt. Expenditure	12.2%
GNI/capita	470
Cervical Cancer Incidence (Globocan 2008)	51
Cervical Cancer Mortality (Globocan 2008)	35

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

The first HPV vaccine choice is Cervarix and no second choice is indicated. The chosen vaccination strategy is school-based for school going girls, with two days for each school, and community-based campaigns (facility-based and outreach) for out of school girls. For out of school girls, a single year of age was selected (10 year olds) and for in school girls a single grade (5th grade).

There is a selection of districts to be vaccinated. The three districts are of varied settings and none of them meet the ≥80% of girls enrolled in schools. All have an urban-rural mix, with a maximum of 38% urban and 62% rural composition. The number of girls to be vaccinated is 3,991 in Manhica, 6,483 in Manica and 1,401 in Macimboa da Praia. The total number of girls to be vaccinated will be 11,875 for year 1 and 12,297 for year 2. Notably, all districts selected for the demonstration have school enrolment for eligible girls (9-13 years) well below the 80% desirable target for GAVI for consideration of a school-based strategy. Enrolment ranges from 41 to 66% across all three districts; furthermore, the range of school girls in the 5th grade, out of the enrolled school going girls, is 27-56%. It is noted that there are inconsistencies in the numbers of girls in 5th grade in the different districts presented in the proposal (Q5 page 7, Q13 page 12, and the cold chain forecasting tool).

The total cost for the vaccine requested to be funded by GAVI is US$ 1,195,239 and the total cash grant requested is US$ 206,818, while the cold chain cost to be covered by the government is US$ 9,400. The total value of the request is US$ 1,402,057, including the cost of vaccines. The implementation period will be from 2013 to 2015.

2. History of GAVI support

Table 1 - NVS and INS support

NVS and INS support	Approval Period
DTP-HepB	2001-2008
DTP-HepB-Hib	2009-2013
INS	2003-2005
Pneumococcal (PCV13)	2012-2016 (NB: introduction postponed)

Table 2 - Cash support

Cash support	Approval Period
ISS	2001-2012
ISS Bridging Support	2010 - until the country has access to Health System Funding Platform

3. Disease burden and eligibility

Mozambique has one of the highest age standardised incidence and mortality rates for Cervical Cancer globally. The Globocan 2008 data indicates cervical cancer incidence to be 51 and the mortality rate was estimated to be 35. HPV introduction, as part of a comprehensive cervical cancer control plan, is therefore a necessity. A demonstration project is ideal, as the country has no prior experience in HPV vaccination and a mixed approach is justified to allow access to the selected cohort. The country is eligible to apply as its DTP3 coverage for 2011 JRF (WHO/UNICEF) is 76%.

4. Role of ICC in application

The ICC, comprising members from the MOH, UNICEF, WHO, FDC, Village Reach and Manhica Foundation, met on the 29th October 2012 and discussed the introduction of PCV vaccine and the rotavirus application outcome from GAVI and endorsed the HPV proposal for the demonstration project. The proposal was endorsed by representatives from MOH and MOE, as well as the ICC.

5. Gender & Equity

Three districts, representing distinct cultural, social and economic ecologies to account for the large heterogeneity in Mozambique, have been selected. One in the south, with very strong patriarchal social structures; one in the central region, with a matriarchal structure; and one in the north, predominantly Islamic, should provide a good backdrop to a demo on a vaccine such as HPV.

In general, all districts have a school-based health program, which consists of provision of immunization services (TT vaccine to 1st and 2nd grade scholars in primary schools), de-worming, health education and promotion (sexual and reproductive health, oral health), screening for sight and ear ailments and referral for follow up if necessary.

There are existing interventions in the context of health school-based program targeting boys and girls. There are also adolescent friendly health services in health facilities, which deal with sexual and reproductive health, oral health, hand washing, screening for sight and ear ailments, targeted at girls and boys from 6 to 16 years (inclusive of the target group of girls aged 9-13 years).

It is proposed to involve a CSO - the Foundation for Community Development (FDC) – a champion in the fight against increasing the opportunities of girls to education and health. This CSO will lead the development of the communication and community engagement components of the demonstration project. The gender issues will be important aspects of the communication and mobilization strategy. Particular emphasis will be given to the explanation of why girls are the target of this vaccination.

In schools, all children will participate in the health talks so that grade five girls do not suffer negative impact for the gender specific aspect of being the recipients of this vaccine. When addressing other groups of children, namely boys and younger and older girls, health communicators will emphasize the benefits of targeting the 5th grade to everybody, including messages about the protection of the cohort of girls translating into future protection of their partners.

In the community, influential groups, such as the elderly, will receive messages on the advantages of having 10 year old girls vaccinated, as 10 years from the time of vaccination a full generation of women of reproductive age "would be free from cervical cancer".

6. District choice

The country has selected three districts - Manhica, Manica and Mocimboa da Praia – which have an urban composition ranging from 25% (Manhica and Manica) to 38% (Mocimboa de Praia). The total population estimates from the National Institute of Statistics for the districts for 2013 are 229,539, 265,518 and 103, 740, respectively. EPI Performance indicators for the three districts for the Penta3, OPV3 and MCV1 are all at least 70%-100% for the period 2011, while TT2+ for pregnant women is at least 52% to 70% (source quoted in JRF 2011). The districts are appropriate as they have both urban and rural mix, however, the country would benefit from scaling down to one or two districts, as the management of the demonstration with its ambitious goals might be compromised given the intention to submit a national proposal at the end of year 1 of implementation.

7. Target Group & Delivery Strategy

The target group in schools will be girls in the 5th grade, while the out of school target group will be 10 year old girls. The demonstration project has a mixed strategy, with school-based and community-based (through health facilities and outreach). Both strategies will employ a campaign-based approach of vaccination days, with intensive community mobilization prior to conducting the vaccination days. This appears to be a reasonable approach considering that there is significant proportion of girls who are out of school.

Although the total number of girls to be vaccinated is indicated, the targets are unclear – inconsistencies in figures provided in the different sections of the proposal as indicated in section 1. Mozambique has elaborated well the proportion of girls enrolled in schools and further a sub-set of these which is the proportion of girls who are in the fifth grade. The observation is that girls in 5th grade who are 9-13 years are 30% of the eligible school going girls (66% in district Manhica), 56% of the 41% school going girls in Manica and 27% of the 68% school going girls in Macimboa da Praia. It is unclear as to how the in school girls, who are 10 years old but not in the 5th grade will be treated. Will they be eligible to receive the vaccine with the out of school 10 yo girls, or left out of the demonstration as they are not accounted for in the numerator?

The strategy proposed appears to be appropriate, particularly in that part of the time for the vaccination days are targeted to reach those girls who may have missed vaccinations on the first day. However, the catch up provision would benefit from an extended time schedule, beyond the proposed two days per month for the vaccination days, for each school and community. It would be interesting to know the geographical location and relation to each of the other districts for the purposes of effective and feasible program management and monitoring. Widely spread out districts could pose a challenge in the management of such an ambitious demonstration.

8. Supply

The vaccine is appropriate in presentation and relevant to the country. There is a 5% wastage factored and 25% buffer estimates. GAVI is allowing 10% buffer for the demonstration. However, the vaccine is not yet licensed for use in Mozambique.

9. Effective Vaccine Management

District cold chain capacity for two of the districts indicates that there are gaps of about 27 and 59 liters. Notably, the HPV district-specific targets used in the forecasting of the cold chain needs for the three districts differ from what is presented in the proposal. Clarity on the target would provide a clear cold chain gap in the demonstration districts.

Cold chain technicians are only available at national and provincial levels. The provincial level technicians provide technical support to district levels and there are plans to train district level cold chain technicians. Districts are requested to provide analysis of temperature readings. Transportation of vaccines to lower levels is done through the use of cold boxes and ice packs and vaccine carriers to health centers and outreach points.

Disposal of injection waste is through incineration where these exist, while burn and bury are used when incineration is not possible. All selected districts have an incinerator at the district hospital. AEFI monitoring has been identified as a weak link. Through the pharmacovigilance unit, district focal point persons have been identified for training for AEFIs and other drug adverse events prior to the introduction of PCV and HPV vaccines.

10. Training, Community Sensitization & Mobilization Plans, Evaluation

Training materials will be adapted by the EPI unit at the central level. Training of provincial and district supervisors will be conducted and these in turn will train facility health staff. Health and education professional will be engaged from nearby health facilities to schools. The training will consist of various modules.

The project has planned to commence communication plans a month prior to vaccination, through the involvement of various community and civic structures, with the use of standardized communication messages on the vaccine using various forums. At community level, stakeholders in the education sector, parents/guardians and school health focal points will be the targets. Efforts to engage community media as well as radio stations will be utilized.

Potential barriers and risks have been identified to include cultural norms, low awareness to benefits of vaccines to older children, the fact that the vaccine targets only girls, as well as political turmoil. Measures to address these include preparation of Frequently Asked Questions for sharing with all mobilizers, use of local key champions in school health, press releases, engagement of media in the training for mobilizers.

The lead agency for the evaluation of the first vaccination round will be the Manhica Foundation, an independent agency which is reported to have experience in conducting monitoring and evaluation research. The components to be evaluated will include the feasibility and acceptability, the costs, and the coverage. The tools to be used will be WHO tools and methods (annex C).

11. Assessment of adolescent health interventions

The Foundation for Community Development will lead this assessment, as it has experience in the implementation of ADH. It is anticipated that its work shall start in the second quarter of 2013 through the listing of initial potential interventions, which will be reviewed by a group of stakeholders engaged in the provision of ADH services to build consensus on the package of interventions that will target both boys and girls.

12. Development of Cervical Cancer Prevention and Control Strategy

In 2008 Mozambique developed an Integrated Strategic National Plan for Prevention and Control of Non Communicable Diseases, of which cervical and breast cancers were a priority. Through this current strategy (which ends in 2012), the Visual Inspection assessment is implemented at primary health facilities under the coordination of the NCD Department. The updating of the National strategy, which shall include the national cervical cancer prevention and control, will be conducted in 2013 taking into consideration the HPV Vaccination Program. The TAG, which includes experts from various specialties, will review the current prevention and control program identifying gaps/ interventions to be addressed in the subsequent strategy. It is anticipated that the strategy will be finalized by the end of the first quarter of 2013.

13. Technical Advisory Group

The composition of the TAG includes the EPI group, Health Communication, Monitoring and evaluation, School health, NCD specialists, and education sector. There is room for further strengthening the group through involvement of other key stakeholders for the Reproductive and adolescent groups, pharmacovigilance or NITAG membership to mention a few.

14. Timeline

All activities are appropriate, comprehensive and in sequential order of implementation. The challenge that is apparent is the absence of the project management aspect, except for the mention of the EPI conducting the adaptations and trainings. Given the intensity of the project and the requirements to be fulfilled, Mozambique would benefit from EPI conducting this demonstration project along other national EPI priorities. However, the risk that is notable in the proposal is the capacity for program management to run this ambitious demonstration. The proposed project coordinator responsible for the day-to-day activities, the EPI program, has inadequate capacity and many other routine responsibilities, including the expected resubmissions of New Vaccine and Health Systems Strengthening proposals.

The submission of a national application assuming minimum coverage is reached would be feasible if a project management arm was considered to ensure timely implementation of all planned activities. In addition to this, the distance between the three might affect the implementation; the country could consider scaling down the number of districts and critically review the targets of girls in one or two of the selected district to address the gaps identified in arriving at the targets in the districts as described in section 1 above.

15. Financial Analysis

The budget costs by components have been adequately identified. However, the budget presented is a summary of the budget lines. It is difficult to comment on the adequacy of the budget without unit costs and quantities. The level of GAVI support requested appears realistic. There is no funding gap identified (there are multiple funders for the demonstration including UNICEF, WHO etc).

The cash grant request exceeds the maximum entitlement from GAVI. However, this will not significantly impact on the demonstration project implementation, particularly if additional resources are mobilized locally. The total requested from GAVI for the 1st year is US$ 152,010 (within GAVI limit of $152,600) and for the 2nd year is US$ 54,808 (about $1,108 more than the US$ 53,800 GAVI maximum for the 2nd year). Because an FMA is yet to be carried out, and given the fact that the country proposes a manual system of bookkeeping, TAP recommends that funds for HPV demo be sent through WHO or UNICEF.

16. Overview of the proposal: Strengths & weaknesses

Strengths:
- The proposal is well thought through;
- There is a TAG and NITAG;
- The planned activities appear to be in chronological order;
- Funds appear to be adequate for implementation with no major funding gap;
- Communication plan available;
- Identified evaluators for the various aspects of the project, and
- Locally available research institution with experience is conducting assessment.

Weaknesses:
- It is not clear whether school going girls eligible by age that are not in the fifth grade are part of the denominator, and
- The fact that the country proposes a manual system of bookkeeping and outstanding FMA yet to be conducted.

Risks
- Delay in Cervical Cancer Prevention and Control Strategy development given the short time available for extensive consultation and ambitious timeframe;
- Number of Districts selected are too many to be effectively managed;

- Lack of dedicated project management organ/arm identified;
- Two day-long vaccination days may not provide adequate time for girls with missed doses to be reached at the right time, but this can be addressed by learning, and
- Qualification of Organization conducting M&E activities not stated.

17. IRC Recommendation

Recommendation: Resubmission

Rationale: The proposal is well though through and clear in its intentions. However, the IRC notes with very serious concerns the capacity to implement this very ambitious project for the following reasons:

- It is stated in the proposal that the project coordinator responsible for the day-to-day running of the project will be the EPI. It is clear that this program has, in addition to this project, to resubmit the new vaccine support proposal and the health systems strengthening proposal, and currently has inadequate capacity within the EPI program to fulfill all these obligations and responsibilities. The IRC seeks assurance of adequate program management reassurance to ensure the success of this ambitious project.
- Country to clarify how they will manage school going girls eligible by age in schools who are not in the fifth grade and as to whether they will be part of the denominator.
-