GAVI ALLIANCE

GAVI/12/312/HK/aa

26 November 2012

Dear Minister,

Mozambique's 2012 application to the GAVI Alliance for New Vaccines Support

We are writing to update you on the status of Mozambique's application for New Vaccines Support for **Rotavirus vaccine,** which was submitted to the GAVI Secretariat in August 2012 and reviewed by the GAVI Independent Review Committee (IRC).

The Independent Review Committee (IRC) concluded that Mozambique's **application for introduction of Rotavirus vaccine is subject to "resubmission".** This means that the IRC considered the application as incomplete and a full application should be submitted in a future round. For your information, the next IRC will start on 28 February 2013 and the deadline for new submission is 24 January 2013.

The main findings of the IRC assessment are attached in Appendix A.

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

Yours sincerely,

Hind Khatib-Othman
Managing Director, Country Programmes

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 New Vaccines Support by Mozambique

Report from the Independent Review Committee

IRC NVS Country Report

Country:	Mozambique
Type of support requested:	NVS
Vaccines requested:	Rotavirus
Reviewed:	Geneva, 8th – 19th October 2012

Country Profile/Basic Data

Population (GAVI-2012) Population (INE-2011)	24,475,186 23,045,356	Infant mortality rate (GAVI-2012) Infant mortality rate (INE-2011)	78.8/1000 93/1000
Birth cohort (GAVI-2012) Birth cohort (INE-2011)	896,325 990,924	GNI/capita (2011)	$470
Surviving infants (GAVI-2012) Surviving Infants (INE-2011)	825,696 898,768	Co-financing country group	Low income
DTP3 coverage (2011) a) WHO/UNICEF b) JRF Official Country Estimate b) JRF Administrative	 76% 76% 85%	Gov Health Expenditure as % of total expenditure (2010) Total Health Expenditure % of GDP (2010)	12.2.% 5.2%

Source: GAVI Country Hub Data, JRF forms, WHO, World Bank, Country Application

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

Mozambique is applying for support for a nationwide introduction of rotavirus vaccine, with first preference for a 2-dose schedule (oral liquid, 1 dose/vial) and second preference for the 3-dose schedule (oral liquid, 1 dose/vial). The implementation period is 2014-2016 and the total value of the request over this period is 15,195,000 USD, plus a one-time vaccine introduction grant of 850,501 USD.

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

3. Composition & Functioning of the ICC

Mozambique appears to have a functional ICC that meets twice a year and has representation from the MOH, WHO, UNICEF, USAID, Ireland Embassy, and CSOs (Foundation for Community Development and Village Reach). The GAVI application for Rotavirus was discussed at an ICC meeting held on Aug 16, 2012 and the minutes indicate that support and commitment for the application and vaccine rollout was obtained from all members. The ICC also met on April 26, 2012 to endorse the 2011 APR submission to GAVI.

The application form indicates that a researcher at the Manhica Health Research Centre, WHO and UNICEF EPI focal points, and the EPI Manager prepared the proposal application. The signatures that were uploaded for the current application from the Minister of Health, Minister of Finance and the ICC members are from the previous NVS application made in May 2011 for PCV13; signatures specific to this application were not included in the application.

Mozambique has recently put into place a NITAG, referred to as the *Committee of Experts on Immunization* (CoPI), which convened its first meeting in April 2011. The NITAG has representation from clinicians, microbiologist, epidemiologists, logistician, researchers, health economist, public health specialists and an IEC specialist. Minutes from the meeting held in April 2011 indicate that the committee made a recommendation for the introduction of Rotavirus vaccine in the routine EPI schedule as soon as possible (ideally in 2013) and strongly urged the MoH to create the logistics conditions for its introduction by 2012. The application also indicates that the NITAG met on April 27, 2012 to review and endorse the proposal, however, no minutes or signatures were provided for this 2012 meeting.

4. Status of the National Immunisation Programme

a) Overview

The EPI program has offered vaccination with the six traditional vaccines since 1979. In 2001, Hepatitis B vaccine was introduced through use of a quadrivalent vaccine and in 2009 *Hib* was introduced using the pentavalent vaccine; both introductions were implemented using GAVI support. PCV13 was scheduled for introduction in 2012 but, due to global vaccine supply shortfalls, introduction has been delayed until the 1st or 2nd quarter of 2013. The country has also agreed to implement with their second presentation preference, PCV10 (2 doses/vial).

In 2011, both the JRF official country estimate and the WHO/UNICEF estimate for DTP3 are 76%, while the JRF administrative coverage rate is 85%. This discrepancy was explained in the 2011 APR as due to denominator (population under-estimate) and numerator issues (inclusion of children older than 1 year), as well as general data quality

and data management issues. To address this issue, the government plans to rollout a District Vaccine and Data Management Tool that will track the number of immunized children against quantity of vaccine delivered.

The target for RV coverage in the first year (2014) is 70%, and increases to 94% and 95% in 2015 and 2016 respectively. This is significantly higher than the coverage targets for DTP3 and PCV13 provided in the 2011 APR – 88% for 2015 and 90% for 2016. The DTP3 targets for 2015 and 2016 provided in the RV NVS application (Section 5.2) were updated to match the RV targets of 94% and 95% for 2015 and 2016. This increase in targets is not in keeping with country progress to date and raises feasibility concerns.

Key issues identified during previous introductions of new or under-used vaccines included: districts with high numbers of unimmunized children and drop-out rates up to 20%; vaccine wastage rates were not systematically recorded; shortage of cold chain capacity in some northern provinces resulting in the need for more shipments than normal; and a depleted cold chain in some districts with frequent breakdowns. A number of action points were provided to deal with these key lessons learned including: implementing a RED approach/microplanning processes; updating data collection tools to include wastage rate; providing training on vaccine management; appointing EPI logisticians at national and provincial levels; conducting an EVMA every two years; improving storage capacity at central, provincial and district level; and creating an inventory of cold chain equipment countrywide.

b) Gender and Equity Issues

The country reports sex-disaggregated data for the indicator 'children fully immunized'. According to results from various surveys, there is no difference in the utilization of immunization services between females and males. In the proposal it is stated that gender has been addressed as part of the application. The proposal goes on to say that 'This is because even though no differences are found among girls for the utilization of immunization services, differences are found in the level of education of the mother.' However, nothing was specifically found that addresses gender and education in the application.

The country narrowly interprets the term 'socio-economic barriers' - the proposal states 'There is no socio-economic barriers as immunization is provided free of charge in Mozambique.' A RED strategy was developed by the country but has not expanded according to plans due to limitations in available funds. The existing "health service delivery points" where immunization is provided reaches only half of the population; this results in significant differences in DTP3 coverage across provinces and individual districts. Although the 2012 cMYP does state that periodic SIAs and the mother and child health weeks are opportunities to increase access and coverage since 'The EPI program, operates from fixed health facilities and outreach sites, it is unable to adequately reach a significant proportion of the target population, despite the presence of an outreach service delivery strategy.'

5. Comprehensive Multi Year Plan (cMYP) overview

The cMYP period from 2012-2016 is in line with the application implementation period and covers the proposed request for rotavirus vaccine. An appropriate situation analysis was conducted looking at coverage, service delivery, vaccine supply and logistics, advocacy, surveillance, monitoring, program management, and securing sustainable funding. The national objectives and planning strategies are appropriately defined and take into

consideration the introduction of rotavirus vaccine. The only linkage identified with broader health sector planning was a mention of alignment of the cMYP with the achievement of MDG 4 and 5 and mention of aspects of the plan that focus on strengthening the health system for quality service delivery.

6. New Vaccine Introduction Plan

The New Vaccine Introduction Plan (VIP) makes numerous references to PCV introduction, as opposed to rotavirus vaccine (RV) introduction, due to use of the PCV introduction plan to create the RV introduction plan.

The country provided a general rationale for introduction of the rotavirus vaccine, including reduction in diarrhoeal disease morbidity and mortality among children, reduction of disease carriage, reduction of health care costs and indirect costs for families and indirect benefits to unvaccinated individuals due to herd immunity. National rotavirus disease burden data and/or economic evaluations of vaccine introduction were not provided to support the application (information does not appear to be available). No regional data was provided to support the application in the place of national data, as recommended in the application guidelines. Nevertheless, in a country where diarrhoeal deaths account for 9% of mortality among children <5 years (WHO) and rotavirus mortality in children less than five has been estimated to be in the range of 100-1000 deaths per 100,000 (WHO Global Rotavirus Surveillance Network), there is a clear and strong justification for introduction of the vaccine on the basis of disease burden.

Introduction of RV will be nationwide, with pre-implementation activities occurring in 2013 and initiation of routine vaccination targeted to start in April 2014. The procurement of the rotavirus vaccine will be 100% through the UNICEF supply division mechanism. Traditional vaccines in Mozambique are procured through the MOH Drug and Vaccine Procurement System using WHO pre-qualified suppliers. The target vaccine wastage figures are appropriate and an adequate vaccine wastage reduction plan is provided.

The vaccination schedule for RV was not provided; the schedule provided is for the three-dose PCV13 implementation. Therefore, it is not possible to know how the country plans to integrate RV into the current immunization schedule (i.e. at 6 and 10 weeks vs. 10 and 14 weeks). WHO recommends that the first and second doses of a two-dose RV should be administered with the first and second doses of DTP to ensure maximum disease protection and reduce potential for late administration beyond approved age window. The training section of the new VIP is also specific to PCV and does not address the specific training requirements for RV (i.e. oral vaccine, proper opening of twist cap tubes, importance of on-time vaccination/age constraints, recognizing early signs of intussusception, etc). The use of RV as part of a comprehensive strategy to control diarrhoeal diseases is not mentioned in the VIP or cMYP. The VIP discusses implementing an M&E system for the new vaccine introduction using indicators developed and agreed upon by the ICC.

Rotavirus sentinel surveillance has not been implemented in Mozambique, though the cMYP indicates plans to conduct a rotavirus disease burden assessment and to implement rotavirus sentinel surveillance starting in 2012. Information from sentinel surveillance is required to evaluate the impact of vaccination in reducing burden of disease. Baseline rates for intussusception are not provided and this surveillance need is not addressed in any documents (required for estimation of potential vaccine-attributable risks). In addition, tools for collecting, investigating and reporting AEFIs have not been developed and the issue of AEFI surveillance has not been addressed in the VIP. Due to the small risk for

intussusception, WHO recommends that rotavirus vaccines should be introduced into NIPs with careful post-marketing national surveillance. The 2012 annual work plan in the cMYP does include activities to introduce AEFI monitoring and reporting including; provision of adequate tools and training for AEFI reporting, monitoring, investigating, responding and reporting on AEFIs; inclusion of AEFIs in national data base for district monitoring and maintaining a register for AEFIs.

7. Improvement plan

An EVM was conducted in May 2012. The report is well written and highlights critical weaknesses. The central store currently has a storage capacity of $27m^3$ net for 2-8 vaccines, which is sufficient to accommodate traditional vaccines and Penta. PCV10 is being introduced in 2013 and RV in 2014, which will require additional storage capacity. The country plans to increase the frequency of incoming shipments of PCV to accommodate the shortfall of storage space at central level. The procurement of new cold rooms is planned for 2014 using HSS funds. If the HSS funding application is not approved there is no clear indication of alternative funding sources for cold chain expansion.

The NVS application and the 2012 EVM assessment indicate storage capacity constraints in 10 of the 11 provinces, as well as at the central level, and the need to procure eight new cold rooms and a number of refrigerators to address this problem. In contrast, the NVS introduction plan indicates that procurement of items including cold rooms and 700+ refrigerators has already taken place over the last three years. As previously noted, the NVS introduction plan for RV is adapted from an earlier introduction plan for PCV13 and many references to PCV remain. UNICEF/SD advise that no CC equipment has been purchased through UNICEF since 2007 but that the government has indicated a need to purchase cold rooms and some refrigerator equipment, which would be supplied in 2013 and installed in 2014.

Issues are also raised with respect to the availability of RV vaccines. The 2 dose oral liquid schedule is planned, which requires a storage space of 17cc/dose; however, a 3 dose oral liquid schedule is offered as a second choice, the space requirement being 46cc/dose (4 x the volume of 2 dose schedule). This would have a major impact on the required storage capacity. Estimations of storage capacity requirements indicated in the NVS application appear erroneous as no provision is made for buffer stock storage.

The Government reports that it will use different funding mechanisms, including HSS and internal donor support, to provide funds for purchasing these WICR and refrigerators. They also report that the introduction of RV will add an average of 28.4 million USD to the EPI costs, which includes 875,295 USD for cold chain investment at different levels. There is no clear statement as to funding sources, except reference to GAVI/HSS and a statement that the MOH and its partners intend to channel funds in an amount of approximately 2.7 million USD in the next 5 years (2012-2016) to cover the procurement of cold chain equipment for replacement of depleted equipment and expansion of fixed vaccination posts, and another 1.0 million USD to cover the need for spare parts.

As part of the improvement plan, the EVM assessment recommends an investment of approximately 0.5 million USD in cold rooms and other cold chain related equipment to establish two regional stores, and an investment of approximately 0.7 million USD for the procurement of vaccine refrigerators at peripheral levels. As in numerous other countries in the region, kerosene supply is becoming a serious issue. The EVM assessment results are generally good, with the notable exceptions on vaccine and stock management standards, and temperature monitoring. It should be noted that the EVM assessment method analyses

the preceding 12-month period, where neither PCV nor RV were introduced, hence storage capacity issues (particularly at the central store) were not identified as critical. The EVM assessment also proposes a need to conduct a nationwide equipment inventory and cold chain capacity assessment. This would provide clarity and should be a prerequisite to an approval to introduce RV.

8. Cold chain capacity

There are strong indications that Mozambique is currently not equipped to introduce RV, unless substantial procurement of cold chain equipment (approximately 1.2 million USD) occurs in 2013. PCV10 can, however, be supplied in 2013 with assurances of appropriate storage assuming a revised international shipment schedule.

The availability of funding appears linked to GAVI/HSS resources, though financial planning is not clearly defined. There are strong indications that the national cold chain is in poor condition, with large quantities of obsolete equipment at peripheral levels compounded by shortage of kerosene supply. Plans to make a transition to solar refrigerators are not specific. Storage of RV and PCV vaccines at central and provincial levels is also not assured without setting up regional depots proposed in the EVM assessment and equipping almost all provincial stores with cold rooms.

9. Financial Analysis

Mozambique estimated total financial needs for new vaccine introduction at 1,204,286 USD, out of which 71% (850,501 USD) are expected to be financed by GAVI. The country intends to finance the remaining 353,785 USD from the internal MoH budget and with the support of development partners. According to the VIP, 1,186,764 USD (or 98.5% of the total budget) is already secured. Table 7 of the document provides details of financing by sources and budget lines and shows that the government only finances 6.4% of the introduction budget, and that UNICEF and WHO are the major source of financing after GAVI. Social mobilization (21%), training (20%) and cold chain equipment (12%) constitute more than half of the new vaccine introduction budget. It is worth noting that the country allocated funds for "post introduction evaluation" (40,000 USD or 3% of the budget).

The cMYP provides a description of cost structure and financing of the NIP in the past (2011) – it shows that underused vaccines constituted half of the NIP budget and that GAVI bore 46% of NIP expenses. The country fully finances its own traditional vaccines and co-finances underused vaccines, while GAVI is the only source of non-governmental financing of routine vaccines. The cMYP Costing Tool does not allow validation of new vaccine related costs because the country used WHO Vaccine Forecasting Tool, which was not provided.

Future resource requirements increase six times due to the introduction of new vaccines (90 million USD in 2016 vs. 15 million USD in 2012). The country provided a thorough analysis of the funding gap; according to the cMYP Costing Tool there is no funding gap if both secure and probable financing is considered, and the funding gap constitutes only 13% of the total resource requirements (for 2012-2016) if only secure financing is counted.

10. Co-financing arrangements

Mozambique's committed co-financing exceeds the level of co-financing required for a low-income country; the country has committed to co-finance 0.25 USD/dose in the first year and 0.30 USD/ dose in the second and third years. To date, Mozambique has met its co-financing obligations.

11. Consistency across proposal documents

The RV coverage target for 2014 provided in the GAVI application form (70%) was inconsistent with the RV coverage target provided in the VIP (80%). There were also inconsistencies in the birth cohort data between the GAVI Country Hub figures and the national INE figures.

Mozambique is requesting that rotavirus vaccines be in the country by December 2013, to allow for distribution of vaccines to all the districts and during the 1st quarter of 2014. UNICEF noted in their pre-assessment that this request is unlikely to occur due to the current constrained supply situation.

12. Overview of the proposal: Strengths & weaknesses

Strengths:

- Implementation of a promising NITAG (CoPI).
- Thorough financial analysis provided; country fully finances routine vaccines; co-financing obligations to GAVI have been met.

Weaknesses:

- The cold chain and logistics information in the 2012 EVMA, VIP, and GAVI NVS application is contradictory and does not permit the CCL situation to be clearly assessed;
- Country or regional disease burden information to support application was not provided, rotavirus sentinel surveillance and an AEFI monitoring and reporting system has not been established, and no baseline rates for intussusception at sentinel sites;
- Targets for RV, PCV13 and DTP3 provided in the proposal are not in keeping with country performance; and
- PCV VIP submitted last year was used to create RV VIP, resulting in numerous references to PCV instead of RV throughout the document.

Risks:

- Rotavirus Vaccine Application has not been signed off by Minister of Health, Minister of Finance or the ICC – signatures submitted were from the PCV Application submitted in 2011;
- Information specific to RV implementation is not provided in the VIP (including basics such as the immunization schedule) and erroneous info has been provided applicable to PCV not RV;
- No AEFI system to monitor low but potential risk of intussusceptions, as recommended by WHO/SAGE;
- Possible lack of availability of rotavirus vaccine for a 2014 1st quarter roll-out due to global supply issues; and

- Given delay of PCV rollout, the RV rollout will occur only 1 year after PCV has been initiated, possibly overwhelming the immunization system.

Mitigating Factors:

- The 2012 annual work plan in the cMYP indicates plans for initiating RV disease burden assessment, RV sentinel surveillance, and an AEFI monitoring and reporting system. Models developed by PAHO to detect AEFI associated with RV to be disseminated to all implementing countries (WHO).

13. Recommendations

Vaccine: **Rotavirus**
Recommendation: **Resubmission**

Rationale: The mandatory requirement for signatures from the Minister of Health, Minister of Finance and ICC members on the submitted application was not met and a new vaccine introduction plan specific to rotavirus vaccine was not provided. The issues identified in this report should be used to strengthen the rotavirus vaccine introduction plan developed. In addition, before resubmission, a national cold chain inventory and storage capacity assessment should be conducted and a section should be created in the new vaccine introduction plan that defines a timeline of CCL financial needs matched to materials supply and a financial resource plan.