GAVI/13/174/sc/cw

The Minister of Health
Ministry of Health
PO Box 84
Kigali
Rwanda

09 April 2013

Dear Minister,

Rwanda's Proposal to the GAVI Alliance for HPV vaccine

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

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

I confirm that in relation to your proposal for HPV vaccine, Rwanda has provided a satisfactory response to the clarifications that were required by the IRC.

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

A tender process for HPV vaccines is on-going. The outcome of this process will determine the allocation of specific product presentations and timing of supply. UNICEF will reach out to you once the tendering process is completed with information on timing and product availability.

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

Appendix A: Description of approved GAVI support to Rwanda
Appendix B: Financial and programmatic information for HPV vaccine
Appendix C: A summary of the IRC Report
Appendix D: The terms and conditions of GAVI Alliance support

The GAVI Alliance has recently sent you a new Partnership Framework Agreement (PFA) designed to improve the ease and efficiency for countries to understand the GAVI requirements, all in one clear and standardised document. For ease of reference, the PFA will include appendices in the same format as Appendix B.

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

New Vaccines Support *Type of vaccine*	**Approved for the first year**	**Approved for the second year**
HPV	US$ 2,128,000	n/a

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

Yours sincerely,

Hind Khatib-Othman
Managing Director, Country Programmes

cc: The Minister of Finance
The Director of Medical Services
Director Planning Unit, MoH
The EPI Manager
WHO Country Representative
UNICEF Country Representative
Regional Working Group
WHO HQ
UNICEF Programme Division
UNICEF Supply Division
The World Bank

Appendix A

Description of GAVI support to *Rwanda* (the "Country")

New Vaccines Support (NVS)

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

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

The HPV vaccines provided will be used for adolescent girls in the appropriate age group as in the proposal. 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 Appendix B summarises the details of the approved GAVI support for vaccines in 2014 and 2015.

Any required taxes, customs, toll or other duties imposed on the importation of vaccines and related supplies cannot 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.

Country Co-financing

In accordance with the GAVI Co-financing Policy, the Country has agreed to make the required contribution to co-financing vaccine doses in 2014.
Item number 14 of Appendix B summarises the budget and the quantity of supply that will be procured with country's funds in 2014. The total co-financing amount indicates costs for the vaccines, related injection safety devices and freight.

Countries may select to co-finance through UNICEF Supply Division, PAHO's Revolving Fund, or self-procure their co-financing requirement following their own procedures, except for the Pneumococcal vaccine that needs to be procured through UNICEF.

If the purchase of the co-financed supply is carried out through UNICEF or PAHO, the payment is to be made to UNICEF or PAHO (whichever is applicable) as agreed in the Procurement Services Memorandum of Understanding between UNICEF or PAHO (whichever is applicable) and the country, and not to the GAVI Alliance. Please keep in contact with UNICEF or PAHO (whichever is applicable) to understand the availability of the relevant vaccine(s) and to prepare the schedule of deliveries.

The total co-financing amount expressed in item number 14 of Appendix B does not contain costs and fees of the relevant Procurement Agency, such as contingency buffer and handling fees.

Information on these extra costs and fees will be provided by the relevant Procurement Agency as part of the cost estimate to be requested by the country.

UNICEF/PAHO will share information with GAVI on the status of purchase of the co-financed supply. In accordance with the GAVI Co-financing Policy (http://www.gavialliance.org/about/governance/programme-policies/co-financing/), the co-financing contribution is payable annually to UNICEF/PAHO.

If the purchase of the co-financed supply is carried out by the Government, following its own procurement procedures and not procuring from UNICEF Supply Division or PAHO, the Government must submit to GAVI satisfactory evidence that it has purchased its co-financed portion of the vaccines and related supplies, including by submitting purchase orders, invoices, and receipts to GAVI. GAVI strongly encourages that countries self-procuring co-financed products (i.e.auto-disable syringes and syringe and needle disposal boxes) ensure that products appear on the applicable WHO list of pre-qualified products or, for syringe and needle disposal boxes, that they have obtained a certificate of quality issued by a relevant national authority.

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).

Country Co-financing: GAVI must receive proof of country co-payment from the Country such as invoices or shipment receipts if neither UNICEF nor PAHO is the procurement agent for country co-financed vaccine for the prior calendar year.

Monitoring and Annual Progress Reports: Rwanda's use of financial support for the introduction of new vaccinations with HPV vaccine 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 immunised and the delivery of funds to co-finance the vaccine.

Rwanda will report on the achievements and request support for the following year in the Annual Progress Report (APR). 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). The APRs will also contain information on country's compliance with the co-financing arrangements outlined in this letter. APRs endorsed by the ICC, should be sent to the GAVI Secretariat no later than 15 May 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.

GAVI ALLIANCE

Appendix B

HPV VACCINE SUPPORT

This Decision Letter sets out the Programme Terms

1. **Country:** Rwanda
2. **Grant Number:** 1417-RWA-19b-X
3. **Decision Letter no:** 1
4. **Date of the Partnership Framework Agreement:** N/A
5. **Programme Title:** New Vaccine Support
6. **Vaccine type:** HPV
7. **Requested product presentation and formulation of vaccine:** HPV QUADRIVALENT
8. **Programme Duration[1]:** 2014 - 2017
9. **Programme Budget (indicative): (subject to the terms of the Partnership Framework Agreement)**

	2014	2015	2016	2017	Total[2]
Programme Budget (US$)	US$2,128,000	US$1,757,500	US$1,803,500	US$1,874,000	US$7,563,000

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	2014
Number of HPV vaccines doses	406,200
Number of AD syringes	451,100
Number of safety boxes	5,025
Annual Amounts (US$)	US$2,128,000

12. **Procurement agency:** UNICEF. The Country shall release its Co-Financing Payments each year to 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. *Ceci est le montant approuvé par GAVI. Prière de modifier les montants annuels indicatifs des années précédentes si cela change ultérieurement*

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14. Co-financing obligations: Reference code: 1417-RWA-19b-X-C

According to the Co-Financing Policy, the Country falls within the Low Income group. The following table summarises the Co-Financing Payment(s) and quantity of supply that will be procured with such funds in the relevant year.

Type of supplies to be purchased with Country funds in each year	**2014**	**2015**	**2016**	**2017**
Number of vaccines doses	16,400	13,500	13,900	TBC
Value of vaccine doses (US$)	US$81,634	TBC	TBC	TBC
Total Co-Financing Payments (US$) (Including freight)	US$84,500	US$70,000	US$72,000	TBC

15. Operational support for campaigns: N/A

	2014	2015
Grant amount (US$)		

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
09 April 2013

Appendix C

IRC NVS COUNTRY REPORT
Geneva, 8th – 19th October 2012

Type of support requested: NVS
Vaccines requested: HPV

Country profile/Basic data (2012)

Population	11,271,786
Birth cohort	459,709
Surviving infants	416,688
DTP3 coverage (administrative)	82% (JRF 2011) 97% (WHO/UNICEF)

Infant mortality rate	93.58/1000
Govt. Health expenditure (World Bank)	20.1%
GNI/capita	$570
Co-financing country group*	Low-income

*low income, intermediate or graduating

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

The country is requesting new vaccine support for HPV vaccine (1 dose per via, liquid). The period of implementation is 2014-2017. The vaccine costs are US$ 2.40/child, with co-financing at US$ 0.20. The total requested from GAVI is US$7,551,500.

2. History of GAVI support

Table 1. NVS and INS Support

NVS and INS support	Approval Period
Pentavalent	2007-2015
PCV13	2009-2012
Rotavirus	2012-2015
INS	2003-2005

Table 2. Cash Support

Cash support	Approval Period
ISS 1	2001-2012
HSS	2007-2009

3. Composition & Functioning of the ICC

An ICC has been in place since 1996 and meets quarterly for its technical and advocacy role in support of the immunization program. Representatives include MOH, WHO, UNICEF, USAID, International Rotary Club, SPIU and two CSO, BUFMAR and URUNANA Development Corporation. Minutes of one ICC meeting from 15 August 2012 are provided. This was attended by representatives from the MOH, USAID, WHO, UNICEF and Rotary International. The potential GAVI request was discussed and endorsed at this meeting. The Ministry of Education (MOE) has signed the proposal but no representative from the MOE currently sits on the ICC. The proposal states that NITAG endorsed the proposal but the minutes attached are the minutes referred to above from the ICC.

4. Status of the National Immunization Programme

EPI conducts routine vaccination, supplemental immunization activities, and surveillance for target diseases. Pentavalent vaccine (PCV) was introduced in 2002 and pneumococcal vaccine in 2009. HPV vaccination was introduced using a school-based approach in 2011 and rotavirus vaccine in 2012. Rwanda has experienced dips in vaccine coverage over the

past 10 years. PCV dose 3 coverage fell between 2004 and 2008, but is now at 82% (JRF Admin coverage) / 97% (official country estimate). Problems with denominators have been highlighted for a number of coverage estimates, with an overestimate of the denominator figure in some districts. The IRC monitoring report (July 2012) documents concern over recent declines in administrative coverage of DTP3. There have been some problems with over-stocking of PCV vaccines and an IRC recommendation was for the country to work with UNICEF to adjust shipments of PCV in 2011.

The country received a three year donation of the quadrivalent 16/18/6/11 HPV vaccine from Merck & Co., which ends in 2013. The government covered costs of vaccine consumables and delivery. The programme has vaccinated 9-14 year old girls in schools and adolescent girls at health centres. The proposal mentions some school-based health interventions (e.g. deworming, nutrition etc.). Table 4 in the cMYP relating to HPV vaccine delivery in 2011 had no coverage estimates, but the document stated that coverage was 97% (it is unclear which dose this applied to). Coverage estimates from a recently published paper on the first year of the HPV vaccination programme have different denominators and coverage was 95% for dose 1; 94% for dose 2; and 92% for dose 3.

Disease burden

There is a good case for routine provision of HPV vaccine in Rwanda. Infection with HPV genotypes 16/18 cause approximately 70% of all cervical cancer cases. Rwanda has one of the highest global incidences of cervical cancer (estimated at 49.4/100,000). Cervical cancer was responsible for 22.5% of cancers among women in Butare in the early 1990s and 27.3% of female cancers in Kigale and Butare between 2000-2004.

Gender and equity issues

In the proposal it is stated that gender 'has been addressed in the introduction of new vaccines; every Rwandan child has equal opportunity to be vaccinated' but there is no actual text in the cMYP that addresses gender and/or socio-economic related barriers. It is also stated that no study or survey on socio-economic or gender barriers to the immunization program has been undertaken. Equity is not addressed (with the exception of a statement about reaching out-of-school girls with provision of vaccine through health facility delivery). The country does not routinely report sex-disaggregated data although, since HPV vaccine is only being offered to girls in Rwanda, data for this vaccine will obviously only apply to girls.

5. Comprehensive Multi Year Plan (cMYP) overview

The cMYP covers 2013-2017 and provides a good insight into the status of immunization in Rwanda. The period of the proposed HPV vaccine request is covered.

The goal of the Vaccine Preventable Diseases Division (VPDD), formerly EPI, is to contribute to the improved well-being of the Rwandan people through reduction of child morbidity and mortality due to vaccine-preventable diseases. Vaccines are routinely provided for TB, poliomyelitis, diphtheria, neonatal tetanus, pertussis, hepatitis B, *haemophilus influenzae* type b, measles, pneumococcus and rotavirus infections. The cMYP states that adolescent girls 10-14 years of age receive human papillomavirus vaccine (HPV) and pregnant women receive tetanus vaccine. In addition to a separate fast-tracked IRC request for MR vaccine, the country aims to introduce routine measles or measles/rubella (MR) to provide a second dose of measles to 9 month old infants in 2013 (MR) or measles vaccine to 12 year olds. There is no communication plan at the national level. Listed vaccine partners include GAVI, WHO, UNICEF and USAID. The EPI programme is supported by 13,000 community volunteers who work at the peripheral level with health workers, tracking defaulters and promoting immunization activities.

HPV vaccination programme
Using vaccine from the Merck donation, the documentation described an SIA with HPV vaccine over 3 rounds that targeted adolescent girls aged 9 -14 years in 2011, with coverage reported as 97%. It is not clear whether the denominator for the 97% includes coverage of (a) girls in a specific class or (b) only girls aged 9-14 year enrolled in school or (c) in that class or (d) all 9-14 year olds in the country.

According to Table 07 in the cMYP, 55% of the HPV vaccine stock had been distributed by end of 2011 (similar estimates applied to some other vaccines such as measles and OPV) and the CMYP stated that "more than the needed vaccines were ordered; for this reason, vaccine forecasting approach might have played a negative role in vaccine management process (inappropriate vaccine wastage rates used, unknown target population used or inappropriate distribution approach used in the country)".

6. New vaccine introduction plan

The continuation of this vaccine is appropriate. Having received a three-year donation of the quadrivalent HPV vaccine, Rwanda now seeks GAVI support to continue the programme for both vaccine and respective introduction grant. However, as per GAVI FAQ for HPV Vaccines, the country is not eligible for an introduction grant. National data have been used to support the HPV vaccine application. The cMYP states that the aim is to achieve HPV vaccine coverage with GAVI-supported vaccine from 95% in 2013 to 98% by 2017. However, coverage targets in Table 02 in the Introduction Plan are given as 24.03% for dose 3. The programme assumes wastage of 5%.

A vaccine introduction plan (dated August 2012) has been provided. This describes a continuation of the current national programme that uses Merck-donated HPV vaccine (GARDASIL®). The delivery approach is described in the cMYP as a campaign delivering 3 doses of HPV vaccine using both school-based and health centre-based approaches with community health worker support to reach out-of-school girls. The Introduction Plan describes some activities that presumably have already been conducted for the Merck donation (e.g. development of communication materials including posters etc. and an official launching ceremony set for April 2015). Justification of a second launching ceremony and development of additional communication materials is missing.

In April 2011 there were 98,972 eligible p6 pupils in Rwanda, of whom 94,141 (95%) were enrolled in school. This fulfils the GAVI requirement that >75% of the target cohort should be enrolled in school if a school-based approach is to be used. The Introduction Plan reports that the Merck vaccine donation was delivered as follows:

- Year 1 (starting in April 2011): all girls in P6 at primary schools with 3 dose coverage of 92% *(Binagwaho. Bull WHO 2012);* Parents and guardians had to attend school on day of dose 1.
- Year 2 & 3: girls in P6 and S3 (9th year of school; catch-up programme to cover older girls). Coverage data are not available.
- Year 4 (2014): girls in P6 (Merck donation would have ended at this point).
- Out-of-school girls who were aged 12 were traced by community health workers.

The proposal states that the Rwanda strategy "does not include a school-based strategy", but a combination of school-based (targeting specific school classes in 2,469 primary schools) and health centre-based vaccination delivery strategies (in 415 health facilities) is being proposed in the Introduction Plan. Section 6.1.2 states that the chosen age-cohort is 12 years old. However, in the Introduction Plan and in section 5.1.1 of the proposal it is stated that endorsement has been given for a mixed approach: school-based delivery

targeting adolescent girls aged 9-14 years and health centre-based targeting adolescent girls aged 12 years. The Plan then states that targeting by class is preferred (some girls do not know their ages and it is less disruptive). It is therefore assumed that all girls irrespective of age in a specific class will be vaccinated rather than just girls aged 9-14 years in these classes. The specific class that will be selected, and whether this is the same (P6) as the class selected for the final year of the Merck donation programme, is not explicitly specified. There are no data on the proportion of girls in the target age range who leave school before reaching the chosen class.

In Table 6.1.2b of the proposal, of 91,943 girls in the target group/age, 67,356 (73%) are estimated to be ≥14 years. It is not clear if these are to be included in the estimates of vaccine coverage. GAVI guidelines state "if the strategy targets girls in a selected school grade, then majority of girls must be between the ages of 9-13 with no more than 20% of the girls aged 14 or above".

Although the proposed plan is national, "each district will detail its own implementation plan, within the parameters set by the Ministry of Health." Dose 1 will be given on a designated "Health Day that includes the delivery of other interventions (a list of potential interventions is given but which might be included are not specified in the Introduction Plan). Dose 2 and 3 would be given at school without other interventions. Follow up will be done by community health workers. Monitoring appears to be through vaccine coverage. This will be complex for mixed age vaccination cohorts in schools and specific age cohorts for out-of-school girls and no clear monitoring targets are described.

Strategies to reach marginalized populations (who may not be registered with community health workers) is not really covered, even though these may be the most at risk from HPV infection and cervical cancer. The only statement is that "EPI is considering to take care" of them "depending on the numbers".

From the earlier HPV vaccine programme it is clear that there is an established collaboration between health services and schools. Teacher training, social mobilisation and supportive supervision activities are described in the Introduction Plan.

There is a detailed budget breakdown for HPV vaccine delivery (excluding vaccine and related consumables) in the Introduction Plan (total US$ 138,172). Some of these activities may have been covered in the previous programme (e.g. official launching ceremony; US$ 10,000, technical guidelines for health workers, adapting WHO training module) and those costs saved could be used to provide more social mobilisation materials. The timeline does not indicate when vaccine from GAVI will be given, and although the launch is scheduled for April 2015, in the document the vaccine has been requested for 2014. 25% buffer has been included for the vaccine.

The source of data for the target population does not seem detailed enough to allow us to estimate what the size of the target population is (and it is not clear who exactly is eligible for vaccination from these documents).

GAVI FAQ for HPV vaccination state that a country will need to have a national strategy or roadmap to develop a strategy for cervical cancer prevention and control or will need to demonstrate its intentions to develop such a strategy. A national strategy or roadmap is not mentioned in any of the documents provided.

The global goal for HPV vaccination (reduction of cervical cancer by 2015) is described in the objectives of the cMYP but this is unrealistic. It is not possible to reduce cervical cancer by 2015 since any effects of HPV vaccine on cervical cancer incidence will be expected to take at least 10-15 years.

7. Improvement plan

The EVM was conducted in July 2011. Progress has been reported including: a) multilog devices have been procured and are waiting to be installed; b) non-functioning fridge tag replacements were initiated; c) additional shelves in the cold rooms is under tender; d) UNICEF will procure three cold units; e) a functional computerized stock management system has been put in place, and training on SMT done.

8. Cold Chain capacity

The total vaccine storage capacity requirements, when HPV and MR vaccines are considered, exceed the available vaccine capacity of the central vaccine store. However, by increasing the number of vaccine shipments to twice per year, there will be no shortage of vaccine storage capacity at the central level until 2016. A cold chain equipment inventory will give a clear picture of the vaccine storage capacity at district hospital and health centre levels.

9. Financial Analysis

The country is requesting a vaccine introduction grant for HPV quadrivalent vaccine but is not eligible according to GAVI rules. HPV vaccine is budgeted from 2013. cMYP expenditures are forecast to increase from US$ 6.9 million per year to over US$ 31 million in 2016. These increases are due to new vaccine introductions (mainly rotavirus and HPV). GAVI are estimated to finance 73% of the NIP between 2013 and 2017. Government is calculated to finance 20%. The estimated funding gap (with secured funds only) from 2013-2017 is US$ 27,078,638 (19%) and US$ 13,418,788 (9%) with secured and probably funds. The Monitoring IRC 2012 noted "all traditional vaccines are now supported by the Government of Rwanda, with logistical support from UNICEF. The Introduction Plan states the Ministry of Finances commitment to support the continued co-financing of the nation program". The cMYP indicates the purchase of traditional antigens will continue to be undertaken using government funding.

10. Co-financing arrangements

The country belongs to the low income co-financing group and will co-finance at US$ 0.2/dose. Rwanda has never defaulted. There were outstanding financial management issues at the 2012 July Monitoring IRC in regard to cash windows. The CRO noted that the country has already demonstrated the capability to introduce HPV using a Merck donation.

11. Consistency across proposal documents

There are differences in infant mortality data between GAVI (93.5/1000) and section 5 of the proposal (50/1000 from 2011 DHS). There is some inconsistency in the proposed coverage goals for HPV vaccination (24% and ≥85% in the Introduction Plan and 95% in other documents). There is a very small variation in the target number to be vaccinated between the proposal (N=106,182 for 2014) and the HPV Roadmap (N=107,289). Item 2 in Table X in the Introduction Plan (Budget for HPV vaccination) relates to rotavirus follow-up activities. There are inconsistencies in how HPV vaccine delivery is being described for the Merck donation and the future programme. In the July 2011 EVM document, the cMYP is described the country as aiming to "introduce and use this vaccine through catch-up campaigns targeting 10-14 year old adolescent girls". The proposal discusses a mixed school and health centre approach of 9-14 year old girls, then states in 6.1.2 that the chosen age-cohort for vaccination is 12 years. The Introduction Plan describes a mixed school approach of 9-14 year old and a health centre approach to 12 year old girls. This is also stated in section 5.1.1

of the proposal. The start date for the GAVI vaccines is 2014 in the proposal and 2015 in the Introduction Plan timeline.

12. Overview of the proposal: Strengths & weaknesses

Strengths: There is a detailed cMYP and previous experience with HPV vaccine delivery with high coverage, and Rwanda has experience in introducing other new vaccines.

Weaknesses: The proposal is not very clear on the target group for vaccination, how this will be done, and how coverage estimates will be measured. Some details on delivery strategies for HPV vaccine requested in the proposal were not completed (eg. majority age in each grade, number of private schools; specification of whether a specific school grade would be targeted).

Risks: Rwanda has experience in delivering HPV vaccination with good coverage. It is not clear if the programme will continue to deliver this in the same way, and if the delivery strategy is changing then it is possible the country may not achieve the same coverage rates.

Mitigating factors: Previous experience in HPV vaccine delivery means that it should be possible for Rwanda to clarify the above points and provide a clearer explanation of how vaccine delivery will be done, who the target groups are and how monitoring of coverage will be measured.

13. Recommendations

Vaccine: **HPV**
Recommendation: **Approval with clarifications**

Clarifications:

1. Please provide an amended description the vaccine delivery strategy in school (which class/grade will be targeted) and who the target groups are for both in-school (all girls in class, only girls of a specific age in the class/grade) and out-of-school vaccination (age range).
2. Please clarify which denominator will be used for calculation of vaccine coverage.
3. Please provide evidence that temperatures in all cold rooms and vaccine refrigerators are continuously monitored and permanent records kept.
4. GAVI guidelines state that no more than 20% of the girls should be aged 14 or above if the delivery strategy targets girls in a selected school grade. Rwanda could consider targeting a lower grade than P6 since >70% of girls in P6 are older than 14 years.
5. Please clarify the approach for the addressing the large funding gap.
6. Please clarify the status of the national cervical cancer control strategy.

Please note Rwanda is not eligible for an Introduction Grant as it has already introduced the vaccine on a national scale.

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 ("Country") confirms that all funding provided by the GAVI Alliance for this application will be used and applied for the sole purpose of fulfilling the programme(s) described in this application. Any significant change from the approved programme(s) must be reviewed and approved in advance by the GAVI Alliance. All funding decisions for this application are made at the discretion of the GAVI Alliance Board and are subject to IRC processes and the availability of funds.

AMENDMENT TO THIS PROPOSAL

The Country will notify the GAVI Alliance in its Annual Progress Report if it wishes to propose any change to the programme(s) description in this application. The GAVI Alliance will document any change approved by the GAVI Alliance, and this application will be amended.

RETURN OF FUNDS

The Country agrees to reimburse to the GAVI Alliance, all funding amounts that are not used for the programme(s) described in this application. The country's reimbursement must be in US dollars and be provided, unless otherwise decided by the GAVI Alliance, within sixty (60) days after the Country receives the GAVI Alliance's request for a reimbursement and be paid to the account or accounts as directed by the GAVI Alliance.

SUSPENSION/ TERMINATION

The GAVI Alliance may suspend all or part of its funding to the Country if it has reason to suspect that funds have been used for purpose other than for the programmes described in this application, or any GAVI Alliance-approved amendment to this application. The GAVI Alliance retains the right to terminate its support to the Country for the programmes described in this application if a misuse of GAVI Alliance funds is confirmed.

ANTICORRUPTION

The Country confirms that funds provided by the GAVI Alliance shall not be offered by the Country to any third person, nor will the Country seek in connection with this application any gift, payment or benefit directly or indirectly that could be construed as an illegal or corrupt practice.

AUDITS AND RECORDS

The Country will conduct annual financial audits, and share these with the GAVI Alliance, as requested. The GAVI Alliance reserves the right, on its own or through an agent, to perform audits or other financial management assessment to ensure the accountability of funds disbursed to the Country.

The Country will maintain accurate accounting records documenting how GAVI Alliance funds are used. The Country will maintain its accounting records in accordance with its government-approved accounting standards for at least three years after the date of last disbursement of GAVI Alliance funds. If there is any claims of misuse of funds, Country will maintain such records until the audit findings are final. The Country agrees not to assert any documentary privilege against the GAVI Alliance in connection with any audit.

CONFIRMATION OF LEGAL VALIDITY

The Country and the signatories for the government confirm that this application is accurate and correct and forms a legally binding obligation on the Country, under the Country's law, to perform the programmes described in this application.

CONFIRMATION OF COMPLIANCE WITH THE GAVI ALLIANCE TRANSPARANCY AND ACCOUNTABILITY POLICY

The Country confirms that it is familiar with the GAVI Alliance Transparency and Accountability Policy (TAP) and will comply with its requirements.

ARBITRATION

Any dispute between the Country and the GAVI Alliance arising out of or relating to this application that is not settled amicably within a reasonable period of time, will be submitted to arbitration at the request of either the GAVI Alliance or the Country. The arbitration will be conducted in accordance with the then-current UNCITRAL Arbitration Rules. The parties agree to be bound by the arbitration award, as the final adjudication of any such dispute. The place of arbitration will be Geneva, Switzerland. The language of the arbitration will be English.

For any dispute for which the amount at issue is US$ 100,000 or less, there will be one arbitrator appointed by the GAVI Alliance. For any dispute for which the amount at issue is greater than US $100,000 there will be three arbitrators appointed as follows: The GAVI Alliance and the Country will each appoint one arbitrator, and the two arbitrators so appointed will jointly appoint a third arbitrator who shall be the chairperson.

The GAVI Alliance will not be liable to the country for any claim or loss relating to the programmes described in this application, including without limitation, any financial loss, reliance claims, any harm to property, or personal injury or death. Country is solely responsible for all aspects of managing and implementing the programmes described in this application.

USE OF COMMERCIAL BANK ACCOUNTS

The eligible country government is responsible for undertaking the necessary due diligence on all commercial banks used to manage GAVI cash-based support, including HSS, ISS, CSO and vaccine introduction grants. The undersigned representative of the government confirms that the government will take all responsibility for replenishing GAVI cash support lost due to bank insolvency, fraud or any other unforeseen event.