



RWANDA - HPV VACCINE SUPPORT
This Decision Letter sets out the Programme Terms

1. Country: Rwanda					
2. Grant Number: 1417-RWA-19b-X					
3. Decision Letter date: 05 December 2013					
4. Date of the Partnership Framework Agreement: 07 June 2013					
5. Programme Title: New Vaccine Support					
6. Vaccine type: HPV					
7. Requested product presentation and formulation of vaccine: HPV QUADRIVALENT					
8. Programme Duration¹: 2014 - 2017					
9. Programme Budget (indicative): (subject to the terms of the Partnership Framework Agreement)					
	2014	2015	2016	2017	Total²
Programme Budget (US\$)	US\$2,895,500	US\$2,399,000	US\$1,803,500	US\$1,874,000	US\$8,972,000
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		609,700			
Number of AD syringes		673,900			
Number of safety boxes		7,500			
Annual Amounts (US\$)		US\$2,895,500			
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.

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	27,200	22,400	13,900	14,400
Value of vaccine doses (US\$)	US\$122,742			
Total Co-Financing Payments (US\$) (Including freight)	US\$127,500	US\$105,500	US\$72,000	US\$74,500

15. Operational support for campaigns: N/A

	2014	2015
Grant amount (US\$)		

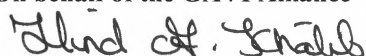
16. Additional documents to be delivered for future disbursements:

Reports, documents and other deliverables	Due dates
Annual Progress Report	15 May 2014

17. Clarifications: N/A**18. Other conditions: N/A**

Signed by

On behalf of the GAVI Alliance



Hind Khatib-Othman

Managing Director, Country Programmes

05 December 2013

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	Infant mortality rate	93.58/1000
Birth cohort	459,709	Govt. Health expenditure (World Bank)	20.1%
Surviving infants	416,688	GNI/capita	\$570
DTP3 coverage (administrative)	82% (JRF 2011) 97% (WHO/UNICEF)	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
HSFP	2013 - 2017

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 $\geq 85\%$ 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.