Gavi Malaria Vaccine Support

Abbreviated form for countries participating in the Malaria Vaccine Implementation Programme (MVIP) to access continued malaria vaccine support through Gavi

1. The request to access Gavi support will need to be endorsed by the Minister of Health and Minister of Finance, or their delegated authority.
2. The completed request, together with any supporting documents must be submitted to Gavi by e-mail to proposals@gavi.org, copying the Senior Country Manager, by **13 September 2022**.
3. Following submission, the request will be tabled for review at the next meeting of the Independent Review Committee (IRC).

PART 1: COUNTRY REQUEST

Country	***KENYA***
Ministry	**MINISTRY OF HEALTH**
Contact details of the country focal point for this request	Principal Secretary Ministry of Health Email: ps@health.go.ke
Is there confirmation of the country's decision to continue malaria immunization in areas covered by MVIP beyond December 2023 (e.g. Minister of Health sign off, NITAG meeting minutes, Immunization Inter-agency Coordination Committee (ICC) minutes)?	Yes [x] No [ ] If yes, please submit the confirmation together with this request form.
Will the country maintain the joint EPI/ National malaria control program (NMCP) coordination mechanism (or other mechanism) that will continue to oversee the coordination of the malaria vaccine implementation beyond the life of the MVIP?	Yes [x] No [ ] If not, please provide further explanation.

A. Continuation of malaria vaccination in geographic areas covered by the MVIP (implementation and comparator areas)

Provide information on the requested doses, with a detailed calculation of how the **anticipated dose requirement** was calculated.

Year	Vaccine / presentation	Wastage	Target age	Population in target age cohort	Target population to be vaccinated according to coverage target
2024	2 dose	10%	< 1 year	275, 470	87%
2025	2 dose	10%	< 1 year	283,734	90%

Assumptions used: The source of population data is projected 2019 population census with a growth rate of 3%. The average administrative coverage for 2021, for the 1st dose was 83% despite the COVID-19 pandemic interruptions in the same year. With easing of the pandemic, and intensification of immunization catch up activities, a higher coverage is anticipated. An improvement of coverage to 87% is therefore expected in 2024 and 90% by 2025. A wastage rate of 10% is anticipated. A fully vaccinated child will receive 4 doses. Based on projected populations 2024/2025, below is the vaccine doses required for that period.

KENYA FORECAST OF VACCINES AND INJECTION DEVICES FOR MALARIA VACCINE INTRODUCTION			
Forecast period	**2024**	**2025**	**Total for 2 years**
Target population	275, 470	283,734	559, 204
Target Coverage	87%	90%	89%
No. of doses	3.5**	4	4
Wastage Factor	1.1	1.1	1.1
Buffer Stock	230, 905	280, 897	511, 802
Total Doses required	1,153,592	1,404, 484	2,558, 076
Total Vials	576, 796	702, 242	1, 279, 038
INJECTION DEVICES			
0.5 ML	1,060, 560	1,248,430	2, 308, 990
2ML	634, 476	772, 466	1,406, 942
Safety boxes	18, 645	22, 230	40,875
*Wastage factor applied for injection devices = 1.1 ** in 2024, the comparator sub counties will only need 3 doses of the vaccine while the current vaccinating sub counties will require 4 doses. 3.5 doses are therefore the average doses per child in 2024 and not 4 doses. Detailed calculation is in the attached excel sheet marked vaccine and injection devices projection			

Are there **plans to expand implementation** of the vaccine beyond the current areas covered under MVIP (implementation and comparator areas)? **Yes**

If yes, please elaborate)

The non-vaccinating areas outside the MVIP areas.-
The Western part of the Country with a high prevalence of malaria consists of 8 Counties and a total of 63 Sub counties. The MVIP area consists of all the 8 counties and 51 sub counties (26 vaccinating and 25 comparator). Currently the 26 sub counties are implementing the vaccines, whereas the 25 comparator sub counties are expected to start vaccination by the end of the year. The 12 sub counties, that are not part of the MVIP, were excluded because they were participating in other malaria vaccine related clinical trials, though they still have a high parasite prevalence rate for malaria ranging between >10% to 40% (KMIS 2020).

The National Malaria Control Program recommends that in the entire lake endemic region, malaria vaccine to be considered as an additional intervention. Operationally, due to socio-political setting, the National Vaccines, and Immunization Program, recommends that these sub counties be covered to ensure overall vaccine implementation success.
The country intends to do a full GAVI application in January 2023 for these 12 additional sub counties.

Year	Vaccine / presentation	Wastage	Target age	Population in target age cohort	Target population to be vaccinated according to coverage target
2024	2 doses	10%	Surviving infants	73, 336	87%
2025	2 doses	10%	Surviving infants	75,536	90%

Source: Projections based on 2019 Census.

B. Expansion of malaria vaccination into additional geographic areas and/or population groups not covered by MVIP (implementation and comparator areas)

Does the country want to include into this request an expansion of malaria vaccination beyond geographic areas / populations covered in MVIP, noting such expansion will be guided by the Framework for the allocation of limited malaria vaccine. **No**. (Detailed application will be done in January 2023).

If yes, please provide detailed information on the areas and requested doses.

PART 2: SUPPORTING INFORMATION

Below should heavily draw from available MVIP documentation. You may choose to refer to existing documentation or reports; please be as specific as possible in below responses where relevant information can be found (e.g. document name and page numbers); and attach the relevant documents.

1. Please describe strategies and plans that are in place to ensure the **use of the malaria vaccine** will continue, as was the case during the MVIP, **as a complementary intervention** that does not replace the package of existing malaria prevention and case management tools nor does it weaken routine immunization systems.

Governance, Leadership and Financing:

Malaria vaccination been included as a strategy in the National Malaria Strategic Plan addendum 2019-2023, page 3 as a complementary malaria control intervention in these plans. The National Immunization Policy and National Immunization Strategic Plan is also being revised to include malaria vaccine. The Kenya National Immunization Technical Advisory Group (KENITAG) has recommendation the roll out of Malaria vaccine in the entire Lake Endemic Region (8 MVIP Counties- 63 Sub Counties) and endorsed by the immunization coordinating committee (ICC).

The Malaria vaccine costs $10 dollars per dose and Kenya as a country in accelerated transition faces a steep increase in co-financing risking the potential of the country to sustain the Malaria vaccine in their portfolio. For Kenya, the first year of introduction would require a co-financing of $ 9 million dollars. This is 42% of the total co-financing cost for the country which constitutes co-financing for other vaccines (yellow fever, pneumococcal, pentavalent and rotavirus vaccine). Kenya is currently undertaking its medium-term expenditure framework review and it is recommended that the steep co-financing projection of $9 million dollars in the first year be reassessed by Gavi so that financing of other routine vaccines is not affected. The government will reactivate the Gavi transition committee to prepare the plans for funding, however for sustainability, Gavi needs to support transition of malaria vaccine over a period of 8 years.

Capacity Building, Service Delivery and Demand Generation.

In the malaria vaccine health managers and operations training package, malaria vaccine is well articulated as a complementary malaria intervention that is not meant to replace other existing malaria interventions. The same is reflected in the Malaria vaccine HCW guide and CHV sensitization package. A best practice that will continue to be implemented is the message to the community (through radio messages, PAS social mobilization, IEC materials) that the malaria vaccine is partially protective and that it complements and does not replace existing malaria interventions.

Malaria vaccination will leverage the existing routine immunization system. New visits created by the malaria vaccine will be utilized to address missed opportunities for other routine immunizations and child survival interventions, including MCV2 given in the 2nd year of life. Strengthening the 2nd year platform of life: The 4th dose of malaria vaccine given at 2 years, will be an opportunity to screen missed opportunities for the 2nd dose of Measles Rubella. Advocacy and communication around the malaria vaccine will integrate RI messaging and other malaria control interventions.

Malaria vaccine has also been integrated in the following documents: Routine Immunization schedule, Page 12 Community health Volunteers Guide. The malaria vaccine will be integrated into the routine reporting tools.

Collaboration with National Malaria Control Program

The immunization program will continue to collaborate with NMCP to ensure that the existing malaria control strategies are integrated with vaccination delivery.

Reference documents: Malaria vaccine Introduction Plan, Addendum of the Kenya National Malaria Control Strategy (Midterm Review), CHV guide

2. Please describe how this application for vaccine funding support will contribute to **increasing vaccine coverage**. Specifically, please describe strategies and plans (including the use of

digital health innovations) put in place to **enhance the coverage of the 4th dose** and reduce the drop-off between the 3rd and 4th dose observed during the MVIP.

The 4th dose of Malaria vaccine will be provided at 18-24 months to match MCV2 administered at 18 months. This will create common messaging to the caregiver for MCV2 and RTS,S 4th dose; reduced trips to the health facility and clear communication to the health workers to reduce drop out both for MCV2 and RTS,S 4.

Electronic systems such as the CHANJO eLMIS are being utilized to monitor stocks to ensure stock outs are prevented at service delivery points.

Use of electronic platforms such as KHIS to collect data during support supervision and monthly administrative data will enhance timely mitigation of challenges observed at service delivery levels.

Strengthen the Community Health Platforms: Use of community health volunteer guide for community health volunteers to facilitate defaulter tracking for both 4th dose of malaria vaccine and 2nd dose of Measles Rubella, and also create demand for the other antigens.

Strengthen RI defaulter tracking mechanisms at the service delivery points and linkages with communities and integrate the malaria vaccine into the existing defaulter tracking mechanism to reduce dropout rates between doses 2nd 3rd and 4th dose of the Malaria vaccine.
Other vaccination service delivery approaches to increase vaccine uptake such as outreaches, PIRI, Malezi bora (accelerated vaccination days) will be utilized.
Other innovative digital approaches could be explored including SMS reminders based on lessons learnt during Covid 19 vaccination, WhatsApp and video messages for healthcare workers.

3. Please describe strategies and plans that are in place (or will be developed) to create/ **sustain strong community engagement** to ensure **vaccine acceptance** and **resilient demand**.

1. Stakeholder engagement with national, sub-national and community level stakeholders before scale up of the malaria vaccine. This includes engagement of health professional associations e.g nurses associations, pediatrics associations, and religious organizations.
2. Use of social mobilization through radio messages, town criers, PA systems
3. Community engagement through community dialogue, outreaches, community sensitization activities to inform community members on the public health impact of the vaccine and the need to sustain the continuous use of other malaria control interventions including use ITN and IRS among others.
4. Train HCWs on interpersonal communication skills to continuously communicate the malaria vaccine as an additional tool to existing malaria interventions and ensure this information is passed to caregivers during clinic visits through one-on-one communications and health education sessions.
5. Media engagement through media tours, media workshops and cafes, expert interviews, Op-eds, call in sessions and social media engagement
6. Demand creation through IEC materials in local languages and community engagement efforts
7. Leveraging on key moments like World Malaria Day, Africa Vaccination Week, mass net distribution to create demand and raise visibility on the malaria vaccine.

8. Training of experts and focal persons in spokespersons training and risk communication to enable them to speak authoritatively about the malaria vaccine to different audiences.

4. Please describe steps the country has taken to strengthen the pharmacovigilance system to enable **continued pharmacovigilance** of the malaria vaccine.

1. Establishment of the Kenya National Vaccines Safety Advisory Committee with clear ToRs, to undertake causality assessments for serious Adverse Events Following Immunization.
2. Development and printing of Adverse Events Following Immunization Guidelines and distribution to the service delivery points.
3. Printing and distribution of Adverse Events Following Immunization reporting and investigation forms to the service delivery points to assist in data collection.
4. Training of National and County teams on AEFI investigation: pending training to the sub national teams.
5. Integration of the Adverse Events Following Immunization module in the malaria vaccine training package
6. Integration of malaria vaccine safety surveillance into the routine vaccine safety surveillance systems
7. Ensuring vaccine potency at all points through effective vaccine management and cold chain maintenance.

5. Please describe **how the routine immunisation programme and health system will be strengthened** so as to accommodate the additional work the malaria vaccine will create, including the need to provide the malaria vaccine at touch points (time points) not currently used in routine immunization.

1. Malaria vaccine will strengthen uptake of other health interventions e.g- Vitamin A uptake at 6months, MR vaccine at 9 months and 18-24 months. The malaria vaccine will be used to strengthen the second year of life platform.

2. Malaria Vaccine first dose given at 6 months will be provide an opportunity to screen for missed vaccinations and improve uptake of childhood vaccinations.

3. Additional cold chain equipment purchased during the pilot phase bridged the gaps at the sub county stores and health facilities.

4. Existing waste management systems will be assessed, improved or expanded to accommodate the additional waste generated.

5. Malaria vaccines will be integrated into existing data tools rather than stand-alone malaria vaccine documentation. This will reduce the additional workload by malaria vaccine.

6. The malaria vaccine training package has been integrated into the existing mid- Level Training Package and Operational Level training package.

7. Malaria Vaccine will be used to strengthen Routine immunization with the additional touch points at 6 months, 7 months and 24 months. The new visits will be used as opportunities to screen, identify and catch up on zero dose children and other missed opportunities.

8. The malaria vaccine will used to strengthen the routine AEFI surveillance system e.g through AEFI investigation at sub national level.

6. Please describe strategies or plans that are in place to enhance **monitoring, evaluation and learning** (MEL) and leverage on the learnings from the MVIP, including as relevant to inform the broader scale up.

The lesson from MVIP is that parallel data tools for Malaria vaccines increased workload at the health facility level. Beyond the pilot, malaria vaccine monitoring will be integrated into the existing routine tally and summary booklets.
MVIP used stickers to document malaria vaccine doses in the Mother and Child Handbook (Home based record) which remained at household level. Going forward, the Mother and Child handbook will be reviewed to include the malaria vaccine as one of the antigens to be recorded and monitored.
A malaria vaccine module was created in KHIS during the pilot. This greatly enhanced monitoring of the malaria vaccine at the various levels. Going forward, malaria vaccine analysis (coverage) will be fully embedded into the existing KHIS templates alongside other routine vaccines.

MVIP support provided opportunities for strengthening the overall M&E through printing and distribution of immunization data tools; supportive supervision and data review meetings at sub national level. This will be sustained beyond the pilot.

Malaria vaccine was included in the CHANJO electronic logistic management information system alongside other RI vaccines. This enhanced monitoring of malaria vaccine stock management at national and sub national levels will be maintained beyond the pilot.
During the pilot, supportive supervision was integrated with other routine vaccines. Moving forward, the malaria vaccine questions have been integrated into the KHIS.

Community based surveys by the national malaria program and Kenya Demographic and Health Surveys will include the malaria vaccine to measure utilization and perception at household level

7. Please explain **how past implementation challenges and lessons learned are being taken into account** for this request e.g. how challenges and lessons learnt from the MVIP will be leveraged to inform the continuation of malaria immunisation in the MVIP areas and/or introduction of the malaria vaccine in areas outside of the MVIP areas.

A lack of clear understanding on the eligibility criteria for children presenting late created confusion amongst health workers especially due to the new visits introduced by the malaria vaccines. Moving forward, this will be clarified during the trainings and other platforms such as job aids, one pager laminated guides and WhatsApp messages for health workers.

A high dropout rate for the 3rd dose and low uptake of 4th dose of the malaria vaccine was observed during implementation. Going forward, intensified community awareness on the need for completion of all doses of the malaria vaccine and other interventions provided in the second year of life will be emphasized. Other vaccine service delivery strategies such as outreaches and defaulter tracking to reach missed children will be strengthened.

Integration with the National Malaria Program was key as the vaccine and other prevention interventions complement each other and will be sustained through the various technical working groups.

Regular supportive supervision was critical in identifying and resolving challenges during implementation and will be sustained.

During the pilot, CHV training was rolled out late, yet community health workers played a critical role in creating and sustaining demand for vaccines. Going forward, CHVs training will be conducted alongside health facility training.

Fever as a side effect of the malaria vaccine was often cited as a deterrent for subsequent doses by caregivers. Going forward, emphasis will be made during healthcare worker training for the healthcare workers to communicate to caregivers on expected side effects and actions to take.

8. Please describe **technical assistance** (if any) that the country would need to enable continuation of malaria immunization in the MVIP areas (implementation and comparator areas) or expansion into additional areas, and whether sources for this TA have already been identified.

The Immunization program has capacity and experience in new vaccines roll out including malaria vaccine pilot phased introduction. Additional Technical Assistance provided by WHO, PATH will be leveraged. However, Technical Assistance will be required for the GAVI-Vaccine Alliance full application for the non MVIP areas.

9. Other comments/recommendations (optional): Provide any additional contextual information relevant to this request (any explanations that further clarify any possible linkages, routine monitoring, any considerations or data that informed this request)

Malaria vaccines will be integrated into routine immunization. Existing strategies (outreach, defaulter tracking, demand creation and community engagement) used to accelerate routine immunization will include malaria vaccines in all the Counties providing the malaria vaccine.

Kenya is currently undertaking its medium-term expenditure framework review and it is recommended that the steep co-financing projection of $9 million dollars in the first year be reassessed by Gavi so that financing of other routine vaccines is not affected. The government will reactivate the Gavi transition committee to prepare the plans for transition, however for sustainability, GAVI needs to support transition of malaria vaccine over a period of 8 years.

PART 3: GOVERNMENT SIGNATURE FORM

The Government of **Kenya** would like to expand the existing partnership with Gavi for the improvement of the immunization programme of the country, and specifically hereby requests Gavi support for:

Continuation of malaria vaccine implementation in the MVIP areas (implementation and comparator areas) beyond December 2023

The Government of **Kenya** commits itself to developing national immunization services on a sustainable basis in accordance with the national health and immunisation strategic plans. The Government requests that Gavi and its partners contribute financial and technical assistance to support immunisation of children as outlined in this application.

Please note that Gavi will not review this application without the signatures of both the Minister of Health and Minister of Finance or their delegated authority.

We, the undersigned, affirm that the objectives and activities in this request are fully aligned with the national health and immunisation strategic plans (or equivalent), and that funds for implementing all activities, including domestic funds and any needed vaccine co-financing[1] will be included in the annual budget of the Ministry of Health.

We, the undersigned, further affirm that the requested funding for salaries, salary top-ups/allowances, per diems and incentives does not duplicate funding from other sources (e.g. from other donors).

We, the undersigned, further affirm that the terms and conditions of the Partnership Framework Agreement between Gavi and the Country remain in full effect and shall apply to any and all Gavi support made pursuant to this application.[2]

Minister of Health (or delegated authority)	**Minister of Finance (or delegated authority)**
Name Nakhumicha S. Wafula	Name n/a
Date 11th November 2022	Date
Signature	Signature

PART 4: ATTACHMENTS & SUPPORTING DOCUMENTS

[1] Applications will not need to be accompanied by a pre-determined co-financing commitment. Countries whose applications are recommended for approval by the IRC will have an opportunity to review the new co-financing policy in early 2023 and consider the co-financial implications of their application for Gavi support.

[2] In the event the country has not yet executed a Partnership Framework Agreement, the terms and conditions of this application shall apply to any and all Gavi support made pursuant to this application.

I. Mandatory supporting documents:

Please ensure the following documents are provided together with this form to support your request:

- Clear calculation supporting the number of malaria vaccine doses requested
- Confirmation of country decision to continue with malaria immunization in the MVIP areas beyond December 2023 e.g., Minister of Health sign off, NITAG meeting minutes, Immunization Inter-Agency Coordination Committee (ICC) minutes, or other documented evidence

In the case that an expansion to areas not included in the MVIP is requested, you will need to also provide:

- Documentation of country decision to expand into additional areas
- Information on these additional areas and rational to include them, in line with the Framework for the allocation of limited malaria vaccine elements and a detailed calculation on the additional number of malaria vaccine doses requested
- A detailed plan for the introduction of the vaccine (new vaccine introduction plan)
- As applicable, a budget for a vaccine introduction grant (using the Gavi Budgeting & Reporting Template) for the introduction of the malaria vaccine in areas outside the MVIP areas.

II. Other supporting documents (not mandatory):

To support your request, you are encouraged to provide the following documents:

- If available, an updated **National Malaria Strategy** (or an addendum to it) that describes the country's plans to use the malaria vaccine within a comprehensive malaria control strategy as a complementary intervention that does not replace the package of existing malaria prevention and case management tools
- If available, an updated **National Immunisation Strategy** (or an addendum to it) that describes the country's plans to roll out the malaria vaccine within a comprehensive immunisation strategy such that the vaccine introduction or continuation of immunisation does not weaken routine immunisation systems