**Annex 3: Request Form for Gavi support for malaria vaccine programme scale up**

1. **Introduction**

A number of countries submitted applications for Gavi support for malaria vaccine programme implementation in 2022 and 2023. Considering the vaccine supply constraints at the time, countries were advised to focus their application on areas of greatest need (referred to as ‘Category 1’ of ‘Phase 1’ as defined by the [Framework for allocation of limited malaria vaccine supply)](https://cdn.who.int/media/docs/default-source/immunization/mvip/framework-for-allocation-of-limited-malaria-vaccine-supply.pdf). As the malaria vaccine supply situation has evolved since then, countries may wish to re-think their malaria vaccine introduction plans with a view to scale up vaccine introduction beyond the Category 1/ Phase 1 areas, prioritising areas with moderate and high transmission areas, in line with WHO’s recommendations.

1. **Purpose of this document**

This document outlines the requirements that countries whose applications were already recommended for approval by the Gavi IRC need to submit to request additional support from Gavi to scale up vaccine introduction beyond their initial approval. The requirements described below pertain to any malaria vaccine programme scale up and are not vaccine product dependent.

**Note:** The document is presented in two parts – **Part 1 being a dedicated Request Form and Part 2 being information that countries are asked to provide as an addendum to their New Vaccine Introduction Plans** (NVIPs)

**PART 1: REQUEST FORM**

**SECTION A. COUNTRY INFORMATION & REQUEST TYPE**

|  |  |
| --- | --- |
| Country |  |
| Contact details of the country focal point for this request | Name:Position:Email:Telephone: |

Please indicate which funding options are being requested (*tick all that apply*).

**□ Vaccine doses and VIG adjustment for scale up**

**□ Additional Technical Assistance for implementation support (beyond what was requested in the initial funding application to Gavi)**

**SECTION B. SUMMARY OF REQUEST AND RATIONALE**

Pleaseprovide a summary of the vaccine and funding requests selected above, with rationale. The summary should cover key elements of the scale up plan including linkages with Phase 1 roll out, targeted geographical regions and transmission settings, delivery strategy, dose schedule, etc.

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**SECTION C. VACCINE SUPPLY INFORMATION**

**[Note: The information requested in the table below is for target population and doses that is incremental beyond the population and doses covered in the initial application made to Gavi]**

**Summary of vaccine need and costs for scale up**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Category | Year  | Total target population  | Doses in Schedule  | Vaccines Need | Gavi Costs (USD) | Country Costs (USD) | Total Costs |
|  |
| Moderate to High\*  | 2024 |  |   |   |   |   |   |  |
| 2025 |   |   |   |   |   |   |  |
| 2026 |   |   |   |   |   |   |  |
|   |   |   |   |   |   |   |   |  |
| Low transmission (if applicable)  | 2024 |   |   |   |   |   |   |  |
| 2025 |   |   |   |   |   |   |  |
| 2026 |   |   |   |   |   |   |  |

**Calculation of vaccine doses needs for scale up.**

Due to limited visibility on the potential performance of this new programme, it is advised to the country to consider the use of standard reference points in **sub-Annex 1** below for the initial estimates. **Please provide justification below for targets which are different from the standard reference points**]

* Target population, coverages, and wastage rates for scale up phase.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Category | Year  | Target Population  | Target coverage (%) | Wastage (%) | Buffer (%) |  |
| First dose | Second dose | Third dose | Fourth dose | Fifth dose (if applicable) | **Vaccine Needs** |
| Moderate to High\*  | 2024 |   |   |   |   |   |   |  |  |  |
| 2025 |   |   |   |   |   |   |  |  |  |
| 2026 |   |   |   |   |   |   |  |  |  |
|  |
| Low transmission\*\* (if applicable)  | 2024 |   |   |   |   |   |   |  |  |  |
| 2025 |   |   |   |   |   |   |  |  |  |
| 2026 |   |   |   |   |   |   |  |  |  |
| Total |  |  |  |  |  |  |  |  |  |  |

\*moderate to high transmission settings - Category 1 to 5

\*\* low transmission

Please include justifications around the anticipated coverage in this targeted population and wastage rate and justification/ rationale for the proposed coverage and wastage rate.

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**SECTION D. Signatures**

**Government signature form**

The Government would like to expand the existing partnership with Gavi for the improvement of the immunisation programme of the country, and specifically hereby requests Gavi support for additional vaccine doses for the following antigen:

* Malaria

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

Any co-financing commitments, if applicable, in this application include the amount of support in either supplies or cash that is requested from Gavi, and the financial commitment of the Government for the procurement of this new vaccine.

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 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.[[1]](#footnote-2)*

|  |  |
| --- | --- |
| Minister of Health (or delegated authority) | **Minister of Finance (or delegated authority)** |
| Name | Name |
| Date | Date |
| Signature | Signature |

**Sub-Annex 1: GAVI’S RECOMMENDATION FOR DOSE REQUEST FOR THE MALARIA PROGRAM**

[Note: This recommendation is based on a set of standard reference points for coverage targets and wastage. Due to limited visibility on the potential performance of this new programme, it is advised to the country to consider the use of standard reference points below for the initial dose calculation. **Please provide justification for targets which are different from the standard reference points]**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Programme** | **Pop** | **Cov1** | **Cov2** | **Cov3** | **Cov4** | **Wastage** | **Buffer** |
| Routine | **Target population in phase 1****Source:**Population estimate based on micro-planning (country’s estimate) | **DTP3 to be used as proxy or country’s estimate with justification**National coverage approved by the Gavi High Level Review Panel (HLRP) will be used as proxy – countries which apply for a coverage higher than the one approved by the HLRP will be asked to justify their estimate. | **Drop-out derived from DTP1-DTP3** applied to Cov1 estimate | **MCV1 to be used as proxy (approved HLRP estimate)** or country’s estimate with justificationWhen Measles-containing vaccine programme is not supported by Gavi: 3-years average DTP3-MCV1 drop-out (source: WUENIC) applied to Cov2 estimate to be used | **MCV2 to be used as proxy (approved HLRP estimate)**. Or country’s estimate with justificationWhen Measles-containing vaccine programme is not supported by Gavi and/or MCV2 is not yet introduced or have recently introduced (insufficient data points available): the 3-yrs average of MCV1-MCV2 drop outobserved in countries in scope for support for Malaria will be used. | **7% based on WHO guidance for vaccine presentation** | **25% of vaccine requirement (defined as need for doses 1, 2, 3, 4 and wastage)** |

**PART 2: ADDITIONAL INFORMATION TO BE PROVIDED AS AN ADDENDUM TO THE NEW VACCINE INTRODUCTION PLAN (NVIP) INITIALLY SUBMITTED TO GAVI**

To apply for additional support from Gavi to scale up vaccine introduction beyond the initial Category 1/ Phase 1 areas targeted, countries are requested to respond to the additional requests and considerations as outlined below:

1. **Geographical scope, transmission settings and phasing of the scale up (*Mandatory requirement*)**

The addendum to the NVIP needs to describe:

* How the scale up will be phased i.e., whether the country plans to scale up in phases or all at once
* The geographical areas and malaria transmission settings that are envisaged. If scale-up will be phased, please delineate the geographical areas by phase;
* The proposed timelines for scale-up. If scale-up will be phased, include the envisaged timing for each phase.
* A rationale for inclusion of areas of low malaria transmission in case the country includes these areas considering that the prioritization of areas of moderate to high transmission is recommended
1. **Vaccine delivery strategy and immunization schedule (*Mandatory requirement – in case there are changes to what was provided in the NVIP initially submitted to Gavi)***

The addendum to the NVIP needs to describe:

* The proposed delivery strategy i.e., whether the country plans to deliver the vaccine through existing routine immunization systems using fixed immunization sites or other strategies
* The proposed immunization schedule for dose 1-4 and for dose 5 in case the scale up plans account for the potential need for a 5th vaccine dose in the event that malaria remains a significant public health problem in children a year after the 4th dose. The immunization schedule should also outline the optimal time interval proposed between dose 3 and 4
1. **Preparatory activities ahead of the scale up (*Mandatory requirement*)**

The addendum to the NVIP needs to describe:

* The status of cold chain equipment (CCE) capacity in relation to the proposed scale up
* Whether there is need for additional CCE capacity
* The quantum of the additional CCE capacity required
* The status of training of healthcare workers in relation to malaria vaccine introduction and the proposed scale up e.g. in terms of the vaccine delivery strategy, immunization schedule, vaccine administration etc.
* The status or readiness for communication, community engagement or awareness creation to support the scale up
* Whether there is need for additional investments in communication, community engagement or awareness creation to support the scale up

**Technical assistance (*Mandatory requirement*)**

The addendum to the NVIP needs to describe:

* The specific programmatic challenges that are anticipated in the scale up, thus the specific technical assistance (TA) support that the country will needs to address these challenges
* Any on-going TA support that may complement additional TA support being requested for

**[Note:**

**For countries that have a TA provider already contracted by Gavi, the information to be provided in the addendum should be incremental TA (if any) beyond what is covered by the contracted TA provider.**

**For all other countries, the information to be provided in the addendum should be on TA needs that address the programmatic gaps/ challenges the country envisages in implementing the proposed scale up scope beyond the TA requested in the initial application submitted to Gavi.]**

1. **Government and technical commitment to the scale up (*Mandatory requirement to be provided as an annex to the application*)**

In addition to the addendum to the NVIP, countries need to demonstrate:

* Confirmation of country decision to scale up the malaria vaccine programme as well as evidence of technical commitment/ endorsement of the scale up plans (e.g., Minister of Health sign off or minutes of a NITAG or ICC meeting where the scale up plans were presented, discussed and endorsed)
* Country financial readiness and commitment to meet co-financing obligation by having their applications signed off by:
	+ - Minister of Health (or their delegated authority), and
		- Minister of Finance (or their delegated authority)
1. **Regulatory affairs (*non-mandatory requirement*)**

Where feasible, countries are encouraged to provide information on:

* The status of regulatory registration of RTS,S/AS01 and R21/ MatrixM by the national drug authority

1. 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. [↑](#footnote-ref-2)