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Subject	<b>Funding Policy Review: Eligibility and Transition Policy and Co-Financing Policy</b>
Agenda item	<b>11b</b>
Category	<b>For Decision</b>

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## **Section A: Executive Summary**

### **Context**

The Eligibility & Transition Policy and Co-financing Policy are being reviewed as part of the Funding Policy Review. An independent evaluation and subsequent analysis and consultation concluded that these policies have been fundamental to the success of Gavi's sustainability model, but that some shifts could facilitate their implementation. Given the current political, economic environment and timepoint in Gavi's strategic cycle, the review has shifted to address two urgent issues: 1) countries in accelerated transition phase (ATP) face financial sustainability challenges that could impede their successful transition from Gavi support; and 2) the initial high cost of the malaria vaccine is a barrier to uptake and public health impact. These issues are exacerbated by slow economic growth and rising inflation, while the impacts of the pandemic, ongoing war in Ukraine, and increasing debt burden have created an uncertain and challenging fiscal and economic environment.

### **Questions this paper addresses**

This paper proposes to address these two issues via i) updates to the Eligibility & Transition and Co-financing policies: extending the duration of ATP from five to eight years and instituting a minimum 35% co-financing threshold for countries to move from preparatory transition to ATP; and ii) providing an exceptional time-limited approach for malaria co-financing.

Additionally, the paper proposes two provisions in the co-financing policy: i) following up from the discussion on the Fragility, Emergencies and Displaced populations policy approved by the Board, for there to be no co-financing required for refugee populations; and ii) formalising previous Board decisions which state that no co-financing is required for outbreak response campaigns.

### **Conclusions**

The Programme and Policy Committee (PPC) recommends to the Alliance Board to approve the updated Eligibility and Transition policy, the Co-financing policy, as well as the exceptional time-limited approach for malaria co-financing.

## **Section B: Co-financing and Eligibility & Transition Policies**

### **1. Introduction**

1.1 As highlighted in the review overarching paper (Doc 11a) and noting the Board's guidance on addressing the risks of unsuccessful transition, the focus of the review has been changed to address two urgent issues: i) supporting successful transition; and ii) the initial high cost of the malaria vaccine is a barrier to uptake and public health impact. Additionally, the paper sets out a recommendation to include in the Co-financing policy a provision of no co-financing requirement from countries for refugee populations nor for outbreak response campaigns.

### **2. Supporting Successful Transition**

2.1 Under the current Co-financing policy, Gavi-supported countries take on higher levels of co-financing as their GNI (gross national income) per capita increases. To date, the Co-financing policy has been an innovative and successful mechanism for increasing country ownership and promoting financial sustainability. Co-financing has generated more than US\$ 1.3 billion over the last 14 years<sup>1</sup> and has been sustained during the pandemic. As a direct result of these policies, 16<sup>2</sup> countries have successfully transitioned out of Gavi support, maintaining all their immunisation programmes. Therefore, whilst addressing the urgent challenges to countries in ATP and risk of low impact of the malaria vaccine described above, the intention is to maintain the core elements of the Co-financing.

2.2 The cohort of countries currently in, or entering ATP is quite different from those that have transitioned previously: 1) their GNI per capita is 27% lower; 2) their vaccine coverage rates are lower<sup>3</sup>; 3) they are going through transition at a time of economic uncertainty and low growth; and 4) their vaccine portfolios are larger. Further, given the current fiscal and economic environment, some ATP countries may be at risk of unsuccessful transition. For example, Lao PDR, Sao Tome & Principe, and Solomon Islands have requested an extension of Gavi support due to the fiscal and economic challenges. Four<sup>4</sup> countries have entered ATP at less than 20% co-financing and will face an exponential ramp up in co-financing over the next 5 years in a fiscally challenging environment.

2.3 A long term policy-level approach would reduce the potential number of upcoming requests for exceptions to the Board. To anticipate and manage the

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<sup>1</sup> 2008-2021

<sup>2</sup> 16 countries have transitioned from Gavi support as of 2021: Angola (2011), Armenia (2011), Azerbaijan (2011), Bhutan (2011), Bolivia (2011), Cuba (2011), Georgia (2011), Guyana (2013), Honduras (2011), Indonesia (2011), Kiribati (2011), Moldova (2011), Mongolia (2011), Sri Lanka (2011), Timor-Leste (2011), Vietnam (2015). Ukraine was excluded from the analysis due to the type of support it received.

<sup>3</sup> As measured by DTP3 coverage below 85%: 38% of current countries have three doses of coverage below 85%, vs. 25% of previously transitioned countries.

<sup>4</sup> Bangladesh, Kenya, Cote d'Ivoire, and Djibouti entered accelerated transition at less than 20% co-financing.

risk of unsuccessful transition, the PPC recommends that the Board approve the updated Eligibility & Transition and Co-financing policies, which include the following changes: a) extending the duration of ATP from five to eight years; and b) in addition to attainment of the GNI per capita eligibility threshold, a minimum threshold of 35% co-financing be set for countries to enter ATP. Detailed analysis of the options evaluated can be found in Appendix 1 to Doc 08b of the October 2022 PPC meeting. As the Board has approved tailored strategies for Nigeria and Papua New Guinea, this approach would not apply to them.

- 2.4 Consultations undertaken with a broad range of stakeholders found general support for the proposals described. The proposed approach allows additional time to strengthen programmatic performance and to manage the risk of unsuccessful transition associated with uncertain macro-economic conditions.
- 2.5 For Gavi, the financial implications of extending the duration of ATP from 5 to 8 years and introducing a minimum 35% co-financing threshold for countries to enter ATP are US\$ 188 million, made up of US\$ 53 million in Gavi 5.0 and US\$ 135 million in Gavi 6.0.
- 2.6 Following a request from the Board in June 2022, the Secretariat also analysed different options for ad-hoc freezing of transition and co-financing for ATP countries for one year. Both options were deemed to be expensive and inequitable approaches which left the key challenges unresolved.
- 2.7 The extension of ATP would require extending HSIS Support, Technical Country Assistance (TCA) and Equity Accelerator Funding (EAF)<sup>5</sup>. In Gavi 5.0, this would impact three<sup>6</sup> countries which would be granted a no cost extension for their current HSIS, TCA and EAF support. The level of additional HSIS support for eligible countries would be covered within the Board-approved HSIS Gavi 5.0 envelope. The level of HSS support for remaining ATP countries would be considered as part of the Gavi 6.0 planning.

### 3. Refugee Co-financing and Outbreak Campaign Co-financing

- 3.1 In countries where **refugee populations** are not yet integrated in national health care planning and budgeting, current co-financing requirements for refugee populations lead to stockout risks and high transaction costs for the Alliance associated with political challenges in mobilising co-financing from host countries. Co-financing for refugees amounted to 0.08% of Gavi vaccine costs over the last three years. In 2020 and 2021, no country hosting refugees paid for the corresponding co-financing obligation despite active engagement and outreach to countries. In this context, the Gavi Secretariat recommends not requiring co-financing for refugee populations. The Secretariat will continue to advocate strongly for countries to integrate refugee populations within their broader country demand for health care services and with a view

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<sup>5</sup> Equity Accelerator Funding is currently only available for the 2021- 2025 strategic period.

<sup>6</sup> Lao PDR, Solomon Islands and Sao Tome e Principe.

to avoid fragmented approaches. This policy shift will not apply to internally displaced populations.

- 3.2 The Secretariat takes this opportunity to formalise in the Co-financing policy previous Board decisions<sup>7</sup> which state that no co-financing is required for all **outbreak response campaigns** (see Annex B).

#### 4. Exceptional Time Limited Approach to Malaria Vaccine Co-financing

- 4.1 In December 2021, the malaria vaccine investment case was approved by the Board. At that time, the Secretariat was also tasked with ensuring co-financing would not be a barrier for uptake of the malaria vaccine. Under the first contract, the malaria vaccine price for 2023 is US\$ 9.30/dose<sup>8</sup>) and is therefore at the top of the price range (US\$ 2-10) considered in the initial investment case<sup>9</sup>. The current price for a 4-dose schedule is unaffordable to many countries and is four times the price of the current most expensive vaccine in Gavi's portfolio, PCV. In the short to medium term an exceptional mechanism is warranted as a bridge to facilitate uptake until market shaping measures take effect.

- 4.2 There is strong political commitment from malaria endemic countries to ensure the vaccine's timely introduction and the Gavi Board has reiterated the need to ensure the expedited introduction of the malaria vaccine. Gavi countries in ATP bear about 40% of the global malaria burden. Under usual co-financing rules and with the price of the currently available vaccine, the co-financing requirement would jeopardise the ability of countries with a significant disease burden to introduce and sustain a malaria vaccine programme.

- 4.3 The PPC recommends the approval of an exceptional time-limited co-financing approach for malaria, tailored by transition phase:

- For countries in initial self-financing phase, the current policy at US\$ 0.20/dose applies;
- Exceptionally, for countries in preparatory transition introduction at US\$ 0.20/dose with an increase of 15% per year in what the countries are paying (e.g. US\$ 0.23/dose the second year, US\$ 0.2645 per dose the third year etc.), and;
- Exceptionally, countries in ATP would introduce at 20% co-financing and be provided eight years to scale up co-financing to 100% (i.e. 30% the second year, 40% the third year etc.), regardless of their year in ATP.

The key objective of the approach is to ensure affordability and support the uptake of the malaria vaccine for countries that have deemed it a priority.

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<sup>7</sup> Yellow fever, Meningitis and Cholera (2016); and Ebola (2019).

<sup>8</sup> Equivalent to EUR 9.30 per dose using 31 August 2022 Bloomberg exchange rate

<sup>9</sup> Note: the weighted average price (WAP) of malaria vaccines is expected to come down over time.

- 4.4 This approach reduces the initial barrier to introduction and allows time for vaccine prices to decrease as market shaping measures take effect and supply expands<sup>10</sup>.
- 4.5 For countries in the Initial Self-Financing phase, the current policy facilitates affordability. For countries in the Preparatory and Accelerated Transition phase, the proposed approach lowers the barrier for malaria vaccine introduction and allows a relatively slower ramp up in co-financing levels. For countries in ATP, the proposed approach will mean reducing the average spending on malaria vaccine co-financing as a proportion of domestic general government health expenditure (GGHE-D) by about a third from 1.53% to 1.09% by 2030, facilitating affordability in the medium term.
- 4.6 At current prices, the financial implications of this approach for Gavi are US\$ 27 million in Gavi 5.0 and US\$ 198 million in Gavi 6.0.
- 4.7 The Secretariat recommends that the exceptional approach to malaria co-financing also apply to **Nigeria**, which accounts for about 70% of the malaria burden of ATP countries. Applying the current Board-tailored strategy for co-financing for malaria would mean that Nigeria only has 4 years to scale up co-financing to 100%, risking the medium and long-term sustainability of the malaria programme. Nigeria accounts for 10% of the additional costs noted above in Gavi 5.0 and 57% in Gavi 6.0.
- 4.8 Broader strategy for malaria: it is critical that the malaria vaccine is considered as one of a number of interventions to be deployed as part of effective prevention and control strategies. Maximising impact will require tailored approaches emanating from deliberate and intensive coordination between malaria control and immunisation programmes at global and country levels. The Secretariat will revisit this time-limited exceptional approach to malaria co-financing no later than 2027. This timeline aligns to the Alliance's current expectation for when the price of malaria vaccines will have decreased significantly. This timeline relies on additional pipeline vaccines (including a technology transfer of the existing RTS,S/AS01 vaccine to a lower cost manufacturer) being licensed and prequalified and recommended by WHO, noting that access to pipeline vaccines is expected to both result in lower prices and sufficient volumes to meet country demand.
- 4.9 The proposed approaches to extending ATP and the exceptional, time-limited approach to malaria vaccine co-financing would be implemented starting 1 January 2023. These changes to co-financing levels would be reflected in new Decision Letters to countries.
- 5. Classifying countries without economic data**
- 5.1 In accordance with the discussion on Middle-Income Country engagement at the June 2022 Board meeting regarding classification of countries without

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<sup>10</sup> A new product is anticipated to enter the market in 2026.

published economic data where Board members encouraged the delegation of the authority to assess country eligibility using the totality of available indicators in these situations to the CEO, a clause has been added to the Eligibility and Transition policy to clarify that countries classified as low-income by the World Bank without a published World Bank GNI p.c. may be determined by the CEO to be in initial self-financing phase, while countries without a published World Bank income classification will be treated on a case-by-case basis. It is anticipated that this would be a rare situation and would be done in consultation with technical partners with the Board kept informed.

#### **Section D: Actions requested of the Board**

The Gavi Alliance Programme and Policy Committee **recommends** to the Gavi Alliance Board that it:

- a) **Approve** the revised Eligibility & Transition Policy attached as Annex A to Doc 11b.
- b) **Approve** the revised Co-financing Policy attached as Annex B to Doc 11b.
- c) **Approve** the exceptional time-limited approach to malaria vaccine co-financing as follows, to be reviewed by the Programme and Policy Committee no later than 2027:
  - i. For initial self-financing countries: Country contributes US\$ 0.20 per dose (no annual increase).
  - ii. For preparatory transition countries: Country co-financing starts at US\$ 0.20 per dose in the first year of introduction and the price fraction increases by 15% annually; and
  - iii. For accelerated transition countries: Country contributes 20% of the price fraction in the first year of introduction and increases co-financing by 10 percentage points annually. Country should reach 100% co-financing after 8 years.
- d) **Note** that the Secretariat will return to the Programme and Policy Committee on malaria co-financing should market conditions change significantly.

#### **Annexes**

**Annex A:** Eligibility & Transition Policy

**Annex B:** Co-financing Policy

#### **Additional information available on BoardEffect:**

**Appendix 1 (in October 2022 PPC meeting book):** Appendix 1 to Doc 8b *Supporting Successful Transition*

**Appendix 2 (in October 2022 PPC meeting book):** Appendix 2 to Doc 8b *Addressing Malaria Vaccine Introduction*

**Appendix 3 (in October 2022 PPC meeting book):** Appendix 3 to Doc 8b *Approach to Co-financing Fluctuations and Evolution of the Funding Policy Review: Co-financing, and Eligibility and Transition Policies*

**Additional reference materials online:**

Current Eligibility & Transition Policy: <https://www.gavi.org/sites/default/files/document/gavi-eligibility-and-transition-policy.pdf>

Current Co-financing Policy: <https://www.gavi.org/sites/default/files/document/gavi-co-financing-policy.pdf>