41st Board Meeting

Recommendation on Eligibility of Venezuela Malaria for the 2020-2022 Allocation Period

GF/B41/ER04 Electronic Decision

Board Decision

Purpose of the paper: To present to the Board the Strategy Committee's recommendation relating to paragraph 11 of the Global Fund Eligibility Policy to make Venezuela's malaria component eligible for an allocation for the 2020-2022 allocation period based on the recommendation of the malaria technical partner's and the Secretariat in light of a significant resurgence in malaria.



Decision

Electronic Board Decision Point: GF/B41/EDP06: Eligibility of Venezuela's Malaria Component for the 2020-2022 Allocation Period

Based on the recommendation of the Strategy Committee described in GF/B41/ER04, the Board:

- 1. Notes that the Eligibility Policy (GF/B39/02) provides that certain non-eligible countries may be recommended to be eligible for malaria in the event of a significant resurgence in malaria cases;
- 2. Acknowledging the Secretariat and technical partners' recommendation described in GF/B41/ER04, decides that Venezuela's malaria component will be eligible for funding for the 2020-2022 allocation period due to significant resurgence; and
- 3. Notes that any resultant grant(s) will be subject to and governed by existing policy and processes.

Budgetary implications: If Venezuela receives an allocation, funds to come from available sources of funds for 2020-2022 country allocations, however there will likely be future budgetary implications on Secretariat OPEX.

A summary of relevant past decisions providing context to the proposed Decision Point can be found in Annex 3.

Executive Summary

Context

- The Eligibility Policy which was approved by the Board at its 39th Board Meeting in May 2018 allows for malaria partners to recommend that a non-eligible, non-high-income country experiencing a significant resurgence of malaria be eligible to receive malaria funding, subject to availability of funds, for a given allocation period.
- Malaria partners have recommended that Venezuela, a non-eligible upper-middle income country, be eligible for an allocation for the 2020-2022 allocation period due to the significant upsurge in malaria cases. In 2018 there were 404,924 malaria cases reported.¹ In 2017, Venezuela accounted for 53% of all malaria cases in Latin America.² The Strategy Committee is presenting this recommendation to the Board now as the 2020 Eligibility List the list that will be used to determine eligibility for country allocations for the 2020-2022 allocation period will be finalized in the Fall of 2019.

Questions this paper addresses

- A. What do we propose to do and why?
- B. What do we need to do next to progress?

Conclusions

- A. In line with paragraph 11 of the Eligibility Policy, WHO and partners, following a comprehensive review across all countries, are recommending that Venezuela be eligible for a malaria allocation for the 2020-2022 allocation period. This recommendation is based upon the significant upsurge of malaria in Venezuela, the potential for the outbreak to deteriorate further with continuing high numbers of cases in 2019, the impact that it is having on the region, and the lack of national capacity to respond to the upsurge.
- B. The Secretariat notes that while Global Fund resources for malaria would help alleviate the situation, a comprehensive and holistic response to malaria and health in Venezuela is needed, which will require significant financial resources. The Strategy Committee discussed, reviewed and endorsed the partner and Secretariat recommendation at its 10th Meeting in July 2019 and is recommending to the Board that Venezuela be exceptionally made eligible for the 2020-2022 allocation period due the significant resurgence of malaria.

Input Sought

• The Board is requested to approve, based on the Strategy Committee's recommendation, the Decision Point: GF/B41/EDPo5: Eligibility of Venezuela's Malaria Component for the 2020-2022 Allocation Period.

Input Received

- In line with the Eligibility Policy, the malaria partners' recommendation draws on risk assessments from 2018 and March 2019, the Pan American Health Organization (PAHO) Public Health Situation Analysis (PHSA) from February 2019, as well as information from the Venezuela Events Information Site (EIS) from May 2019. PAHO has also provided input through WHO.
- The Strategy Committee reviewed this recommendation at its 10th Meeting and unanimously agreed to recommend the Decision Point to the Board for electronic decision.

¹ Annex 1, Partner Recommendation

² World Malaria Report 2018, page 89

What is the need or opportunity?

- 1. In 2017 and 2018 the Strategy Committee undertook a review of the Global Fund Eligibility Policy³. During the review of the malaria disease burden indicators and thresholds, malaria partners recommended the continued use of WHO malaria burden data from the year 2000 to determine eligibility for upper-middle income countries, as data from this period is the best metric to assess a country's potential for malaria transmission intensity. At the time malaria partners noted that the use of 2000 data precludes responsiveness, in terms of eligibility, to recent and significant upsurges in malaria. They therefore recommended that a clause be included in the revised Eligibility Policy to allow technical partners to recommend, based on a risk assessment in line with principles outlined in the WHO Emergency Response Framework (ERF)⁴, that a non-eligible and non-high-income country be eligible for an allocation in the event of a significant resurgence.⁵
- 2. This clause, paragraph 11 of the Eligibility Policy, allows for technical partners to recommend to the Secretariat, in the event of a significant increase in malaria cases in a non-eligible upper-middle income country or a country that (i) has been certified as malaria-free by WHO or that is on the official WHO register of areas where malaria elimination has been achieved, or (ii) is on the WHO 'Supplementary List' of countries that are malaria free but not certified by WHO, that a country become eligible for a malaria allocation for a specific allocation period. ⁶ The Secretariat may then, in turn, recommend to the Board that such country be eligible to receive funding, subject to the availability of funds.
- 3. The 2020 Eligibility List, which will be published prior to the end of 2019, is the list that will be used to determine which country components are eligible to receive an allocation for the 2020-2022 allocation period. Malaria partners in May 2019 reviewed the portfolio of malaria components currently ineligible to receive a Global Fund allocation to assess whether there are countries that have had a significant upsurge in malaria and where there are capacity constraints at the national level (as detailed further in paragraph 8 below).
- 4. In line with the Eligibility Policy, this paper presents the technical partners', the Secretariat's and the Strategy Committee's recommendation to the Board that Venezuela, an otherwise ineligible country, become eligible for an allocation for malaria based on the technical partner assessment. Annex 1 provides further details from malaria partners on the rationale for their recommendation, which considers input from PAHO.
- 5. Due to the need to have a decision on Venezuela's eligibility for its malaria component prior to the finalization of the 2020 Eligibility List, which is expected to be published in the Fall of 2019, the Board is requested to approve the Decision Point on page 2 via electronic decision.

What do we propose to do and why?

6. For the purposes of determining Global Fund eligibility, "[r]esurgence, defined as an usual increase in malaria burden, will be confirmed by WHO in collaboration with country malaria control programs, ministries of health, WHO countries and other partners as relevant".

³ GF/B39/02

⁴ http://apps.who.int/iris/bitstream/10665/258604/1/9789241512299-eng.pdf?ua=1 (page 24)

⁵ GF/B₃9/03 - Revision 1

⁶ Annex 1 to GF/B39/02

⁷ Annex 3, para 10(b) to GF/B39/02

- 7. As noted in Annex 3 of GF/B39/O2, the risk assessment/situational analysis of an identified resurgence will assess the impact of the resurgence, including the scope, scape and functionality of the health system, the capacity of the country to respond, and availability of financial resources and/or potential of the country to raise additional resources, either domestic or international, to respond to the resurgence.
- 8. In order to assess a country's capacity to respond, the principles outlined in the WHO ERF will be applied, which consider impact (scope and scale, conditions of the affected population, functionality of national health system) and the operational environment (response capacity, access and gaps, overall strategic humanitarian priorities, context and/or conflict analysis).

Process undertaken

- 9. Consultation with technical partners was facilitated through the RBM partnership Country & Regional Support Partner Committee (CRSPC) Sub-group, which includes representatives from WHO, ALMA, RBM partnership, USAID PMI, Malaria No More UK, UN Foundation, UCSF, Gates Foundation and UNITAID. PAHO was also consulted. WHO reviewed the current malaria situation of all non-eligible countries and identified one country as having a significant upsurge in malaria Venezuela.
- 10. Noting the availability of existing relevant information and sufficient data, WHO did not conduct a separate risk assessment, but rather reviewed the 2018 WHO Rapid Risk assessment (RRA) of Venezuela and the updated March 2019 RRA; the February 2019 PHSA and the EIS from May 2019.

Partner Recommendation

- 11. Malaria partners reviewed the information provided by WHO and PAHO and fully agreed with the recommendation that Venezuela become exceptionally eligible for a malaria allocation for the 2020-2022 allocation period due to the significant upsurge in malaria cases. The resurgence is expected to continue in 2019 and there is limited capacity (both financial and human resource) in the country to respond to the upsurge, which has been steadily increasing in the last 3 years and has affected other countries in the region. The on-going socio-political and economic crisis makes it unlikely that there will be additional domestic or international resources to support the response to malaria in the near future.
- 12. Based on WHO risk assessments and situational analyses and latest available data, malaria partners are recommending that Venezuela be eligible for a malaria allocation for the 2020-2022 allocation period. Technical partners note that the "epidemic in Venezuela calls for a comprehensive response including prevention actions, early access to diagnostics and treatment, and management of social determinants. Without which there remains a high risk to the population of Venezuela and the region." This is based on the significant increase in malaria cases 404,924 malaria cases were reported in 2018. While the majority of cases are located in three border states Bolívar, Amazonas and Sucre there has been an increase of cases in other states ¹² and there has been an increase of imported cases of malaria in bordering countries.

 $^{^{\}rm 8}$ Rapid Risk Assessments and PAHO Public Health Situation Analysis are not public documents.

⁹ Venezuela is not eligible for Global Fund financing for malaria as it does not meet the burden criteria and thresholds that are required for upper-middle income eligibility.

¹⁰ Annex 1, Partner Recommendation

¹¹ Annex 1, Partner Recommendation.

¹² Anzoátegui, Barinas, Miranda and Nueva Esparta

13. With the socio-economic situation continuing to deteriorate there has been a high influx of people into certain areas in search of subsistence work and proximity to the borders of Colombia and Brazil. The healthcare system, which has been severely impacted due to the economic situation, is not able to sufficiently respond to the increase in malaria. Partners note the increasing numbers of people who are at high risk of malaria¹³, including severe complications and death due to insufficient access to diagnosis, treatment, and vector control (long-lasting insecticidal nets (LLINs) and indoor residual spraying (IRS) and surveillance).

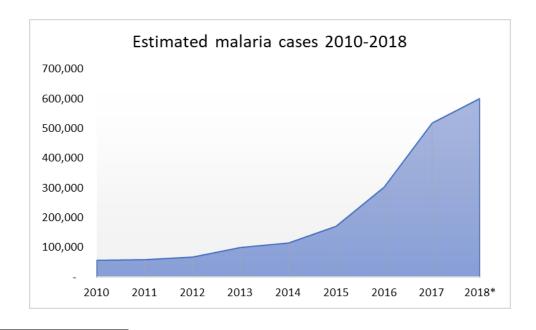
Secretariat Recommendation

14. The Secretariat supports the partner's recommendation and notes that malaria in Venezuela has experienced a significant increase in cases—from 57,257 in estimated cases in 2010 to 519,109 in 2017¹⁴—which has been accompanied by a steady deterioration of the health system—including lack of antimalarial drug and essential commodities—and movement of people. The Secretariat notes this figure is likely to be underreported and some sources estimate actual cases in 2018 may have exceeded 1 million.¹⁵ According to the World Malaria Report 2018, Venezuela was one of the top 10 countries in which total malaria cases exceeded more than 300,000 cases in 2017 and showed an increase of more than 100,000 cases between 2016 and 2017¹⁶. In terms of malaria incidence per 1000 population, it was 7.3 for the Americas region in 2017, and 47.5 for Venezuela.¹⁷ This situation is not expected to improve in the short-to-medium term, with potential negative implications for malaria elimination in the region. While providing Global Fund resources for malaria would help alleviate the situation, significant additional financial resources from other sources and changes in the political situation will be required before malaria can be controlled again in Venezuela.

Figure 1: Estimated Malaria Cases for 2010-2018.

Source: 2010-2017 data World Malaria Report

*2018 data corresponds to estimates for January-June 2018 from the Alianza Venezolana por la Salud



¹³ The World Malaria Report 2018, indicates that approximately a third of the population (10,914,252 in 2017) is at risk for malaria Annex 3-F, page 131. UN population estimates for Venezuela are 31.9 million.

¹⁴ The World Malaria Report 2018, Annex 3-F: Population at risk and estimated malaria cases and deaths ,2010-2017.

¹⁵ Research presented at the European Congress of Clinical Microbiology & Infectious Diseases (ECCMID) in April; https://www.eurekalert.org/pub_releases/2019-04/esoc-vet041219.php

¹⁶ The World Malaria Report 2018, Figure 6.4, page 40.

¹⁷ World Malaria Report 2018, Figure 6.5 (a) and Venezuela incidence calculated using data from Annex 3-F.

- 15. The Secretariat notes that the recommendation to make Venezuela eligible with respect to its malaria component would not affect the Secretariat's ability to request an additional year of exceptional funding for Venezuela HIV and TB under the approach to non-eligible countries in crisis. Depending on the timing of such request, support for essential malaria commodities may also be included, noting the timing of 2020-2022 allocation decisions and subsequent likelihood of funds being made available. Any such request for exceptional funding would be subject to Board approval and availability of funds.
- 16. While supporting the recommendation for Venezuela to become eligible for a malaria allocation, the Secretariat notes that the operating context in Venezuela is likely to remain extremely challenging and that the design of implementation arrangements will need to reflect this, noting that any decisions regarding implementation arrangements would be made in accordance with existing processes (i.e. during country dialogue and the development of the Funding Request). Based on current external risk indices, Venezuela would likely be classified as a Challenging Operating Environment (COE) and be managed under the Additional Safeguard Policy in order to manage risks. The Secretariat notes that the funding that has been provided to Venezuela under GF/B39/ER10 to purchase ARVs and support social monitoring is managed directly through PAHO and UNAIDS, and there are currently no dedicated Secretariat staff for Venezuela; should Venezuela become eligible for malaria and receive an allocation there will be resource implications on the Secretariat.

Strategy Committee Recommendation

17. At its 10th Meeting in July, the Strategy Committee reviewed the technical partners' recommendation and unanimously supported the recommendation to make Venezuela eligible for an allocation for the 2020-2022 period, noting that this is a decision regarding eligibility only and that implementation arrangements, as well as any associated risks, would be described to the Board as part of its existing approval process for grants – as is the case for all eligible country components. The Strategy Committee noted the need for timely investment in the context of the on-going resurgence that has limited government capacity and resources available to address the overall health system. It also acknowledged that the situation in Venezuela is having an impact on the region and encouraged an aligned regional response, where possible, and the need for investment from others beyond the Global Fund.

What do we need to do next to progress?

18. A Board decision on whether to endorse the Strategy Committee, Secretariat and malaria partners' recommendation to make Venezuela's malaria component exceptionally eligible for an allocation for the 2020-2022 allocation period is required before September 2019, as an approval would require that Venezuela be included in the Global Fund 2020 Eligibility List, which will be finalized in the Fall of 2019. A delay in such Board decision would mean that Venezuela would not be eligible for a malaria allocation and could potentially have consequences on the timing of the Global Fund 2020 Eligibility List, which is a critical input into the allocation methodology for the 2020-2022 allocation period.

Recommendation

19. The Strategy Committee recommends the Decision Point presented on page 2 to the Board for approval.

Annexes

The following items can be found in Annex:

- Annex 1: Partner recommendation
- Annex 2: Summary of Previous Committee Input
- Annex 3: Relevant Past Board Decisions
- Annex 4: Links to Relevant Past Documents & Reference Materials

Annex 1 – Partner Recommendation

Process

The recommendation draws upon (i) Rapid Risk assessment (RRA) of 2018 and the updated RRA in March 2019; (ii) the PAHO Public Health Situation Analysis (PHSA) from February 2019; (iii) Venezuela Events Information Site (EIS) from May 2019.

Recommendation

We recommend that Venezuela be eligible for a malaria allocation for the 2020-2022 allocation period, as the epidemic in Venezuela calls for a comprehensive response including prevention actions, early access to diagnostics and treatment, and management of social determinants. Without which there remains there is a high risk to the population of Venezuela and the region.

Rationale

The level of risk for Venezuela is very high due to the ongoing socio-political and economic crisis, movement of immunologically naïve populations, lack of prompt and adequate treatment services, hampered vector control programs and weak surveillance and reporting.

Venezuela has the highest burden of malaria in the Americas. Malaria cases in Venezuela have been steadily increasing during the past decade with an average of a 65% increase per year (range: 49.9% - 76.4%) between 2014 and 2017. In 2018, a cumulative total of 404,924 new malaria cases were reported.

In Venezuela, there are many people who are at high risk of malaria, severe complications and death, including the growing mobile population in the region. Most cases in 2017, were reported by three states - Bolívar, Amazonas (bordering Brazil, Colombia, Guyana) and Sucre (close to Trinidad and Tobago), and municipalities within these states are considered at high to very high risk for malaria transmission according to the annual parasite index.

Since 2016, there has been reported increase in cases in other states including Anzoátegui, Barinas, Miranda, and Nueva Esparta (Isla de Margarita) states have reported an increase in cases since 2016.

The overall regional risk is considered high due to population movement from Venezuela. The export of sporadic cases to countries free of malaria poses a challenge for the early detection and prevention of complications associated with the disease.

There is insufficient access to diagnosis and treatment, inadequate prevention programs and surveillance activities in Venezuela. As the burden of disease increases the healthcare system will not be able to respond. PAHO / WHO recommends improved diagnosis and treatment in endemic areas by providing services closer to the communities at risk. In endemic areas with active transmission, periodic analysis of the data should allow the identification of clusters of cases and populations at risk and improve the timeliness of diagnosis and treatment. In areas with low transmission, the occurrence of new cases should trigger investigation of each case.

There is a need to ensure the quality of parasitological diagnosis and prevent the shortage of medicines. Vector control interventions should complement case detection and management strategies. Indoor residual spraying (IRS) and the mass distribution of long lasting insecticide treated nets (LLINs) are key interventions in the control of malaria vectors.

Vulnerabilities

- Highly mobile population with movement across Venezuelan states and towards other countries in the Region (mainly Brazil, Chile, Colombia, Ecuador, Guyana, Panama, Trinidad and Tobago, and the United States).
- Delays in the detection, treatment, and follow-up of cases.
- Insufficient and frequent shortages of anti-malarials during 2016-2017. Shortage
 of medicine at local level.
- Insufficient capacity for adequate vector control.
- Rapid diagnostic tests (RDTs) were not available during most of 2016 and 2017 (300,000 and 46,000 tests were donated in 2017 and 2018 respectively).
- Human resources for diagnosis/treatment and surveillance are massively overburdened (i.e. one microscopist examining over 120 slides in a day).
- Precarious and insufficient infrastructure for diagnosis (which is heavily needed near mining environments).
- Logistical gaps for accessing diagnosis and treatment services (infrastructure, microscopes, reagents, motorcycles, boats, etc.).
- Critical deficiencies in strategies for drug distribution and management.
- Technical and logistical gaps in case management of severe malaria.
- Under-utilization of other resources (i.e. laboratory capacity in hospitals).
- Active case finding, investigation and follow-up of cases is extremely limited by logistical/operative gaps.
- Vector control interventions are insufficient or of inadequate quality. Number of at-risk persons protected by IRS has declined significantly from 2.7 million in 2015 to 30,000 people in 2016 (99% decline).
- Bed nets and insecticides for IRS are insufficiently available and always in low quantities.
- Logistical gaps for IRS and bed net distribution (i.e., transportation, human resources)

Annex 2 – Summary of Committee Input

GF/SC06/19 SC Chairs Summary Notes, paragraph 48(c)

https://tgf.sharepoint.com/sites/ESOBA1/GFBC/StrategyCommitteeSC/SC%20Meetings/6th%20SC%20Meeting%2020-

<u>22%20March%202018/Chair's%20Notes/GF%20SC06%2019%20SC%20Chair's%20Summary%20Notes_SENT.pdf</u>

GF/SCo₅/20 SC Chairs Summary Notes, page 14, paragraph 4(c)

https://tgf.sharepoint.com/sites/ESOBA1/GFBC/StrategyCommitteeSC/SC%20Meetings/5th%20SC%20Meeting%2011-

13%20October%202017/GF%20SC05%2020%20Chair's%20Summary%20Notes.pdf

Annex 3 – Relevant Past Decisions

Relevant past Decision Point	Summary and Impact
GF/SC10/DP03: Recommendation on the Eligibility of Venezuela's Malaria Component for the 2020-2022 Allocation Period	The Strategy Committee unanimously endorsed the technical partners' and Secretariat's recommendation to make Venezuela eligible for a malaria allocation for the 2020-2022 allocation period in light of the significant resurgence of malaria and in line with Paragraph 11 of the Eligibility Policy (GF/B39/DP03).
GF/B39/DP03: Revised Eligibility Policy (May 2018) ¹⁸	Approved the Revised Eligibility Policy, which stipulates the criteria to determine eligibility of country disease components. Paragraph 11 of the policy allows for partners to recommend that an otherwise non-eligible country be eligible for funding, based on a risk assessment by WHO and technical partners, in the event of an unusual upsurge or increase in malaria cases.
GF/B39/DP04: Global Fund Approach to Non-eligible Countries in Crisis (May 2018) ¹⁹	Approved a framework for potential engagement with non-eligible countries in crisis noting that a health crisis may emerge in an ineligible non-high income country that could have an adverse impact on the global response against HIV/AIDS, tuberculosis, and/or malaria, and that the health crisis may be of such a magnitude that the Global Fund should consider providing support. With respect to malaria the paper specifically referenced malaria resurgence and references the same assessment criteria as the Revised Eligibility Policy.

¹⁸ https://www.theglobalfund.org/board-decisions/b39-dpo3/

¹⁹ https://www.theglobalfund.org/board-decisions/b39-dp04/

Annex 4 – Relevant Past Documents & Reference Materials

Global Fund Eligibility Policy GF/B39/02:

https://www.theglobalfund.org/media/7409/bm39 02-eligibility policy en.pdf

Global Fund Approach to Non-Eligible Countries in Crisis GF/B39/03: https://www.theglobalfund.org/media/7397/bm39 03-approachtononeligible countries in crisis report en.pdf

Approval of Funding to Address the Health Crisis in Venezuela https://www.theglobalfund.org/board-decisions/b39-edp11/

WHO Emergency Response Framework http://apps.who.int/iris/bitstream/10665/258604/1/9789241512299-eng.pdf?ua=1

World Malaria Report 2018 https://www.who.int/malaria/publications/world-malaria-report-2018/report/en/