Electronic Report to the Board

Second Exceptional Funding Request to Address the Health Crisis in Venezuela

GF/B41/ER10 24 October 2019

Electronic Board Decision

Purpose of the paper: In line with the Board-approved approach to non-eligible countries in crisis (GF/B39/O3 - Revision 1), this paper presents to the Board the Strategy Committee and Secretariat recommednation on the second exceptional funding request to respond to the continued health and economic crisis in Venezuela. While Venezuela has been exceptionally made eligible for malaria for the 2020-2022 allocation period (GF/B41/ERO4), it remains ineligible for HIV and tuberculosis



Decision

<u>Electronic Board Decision Point: GF/B41/EDP14 Approval of Additional Funding to</u> Address the Health Crisis in Venezuela

The Board:

- 1. Expresses continuing concern about the public health crisis in Venezuela, a country that has been made eligible for Global Fund funding for malaria only for the 2020-2022 allocation period, under GF/B41/EDP06, and its adverse impact on the fight against HIV, tuberculosis and malaria in Venezuela and the region;
- 2. Acknowledges the new proposal for exceptional funding presented by the Secretariat, and developed in consultation with partners and civil society, in accordance with the approach for potential engagement with non-eligible countries in crisis approved by the Board through GF/B39/DP04;
- 3. Recognizes that the emergency circumstances in Venezuela continue to require unique implementation and management arrangements, which differ substantially from the standard Global Fund funding model and applicable policies, as described in GF/B41/ER10 and Annex 1;
- 4. Accepts that the proposed implementation and management arrangements continue to entail unique risks, as described in GF/B41/ER10 and Annex 1, including that the Office of the Inspector General will not be able to provide the Board with assurance, whether through audit or investigation work, over the funds disbursed under the proposed funding arrangements and that civil society oversight may not be able to provide adequate assurance as envisaged in GF/B41/ER10 and Annex 1;
- 5. Based on the recommendation of the Strategy Committee, approves the investment and terms set forth in Annex 1, to provide an additional USD 6,000,000, for the year 2020, to support the procurement of critical HIV, TB and malaria health products for Venezuela and social monitoring of the investment; and
- 6. Calls for continuous engagement from relevant partners, donors and other stakeholders to further support a regional response to the health crisis in Venezuela.

<u>Budgetary implications: USD 6,000,000, funded through available sources of funds identified by the Audit and Finance Committee under GF/AFC09/DP01.</u>

A summary of relevant past decisions providing context to the proposed Decision Point can be found in Annex 6.

Executive Summary

Context

- When the Board approved the approach for non-eligible countries in crisis it acknowledged that the standard Global Fund operating model of accessing and implementing funding would likely not be the most effective or practical and that there would be a need for flexible arrangements that respond to such contexts. The Board also acknowledged that "effectively responding in ineligible crises environments where the Global Fund has never engaged or already exited would be operationally challenging and may require compromises on risk assurance, OIG access, programmatic oversight and other areas".¹
- On 24 September 2018, the Board approved the first request under this approach to provide funding to Venezuela a non-eligible country- to provide antiretrovirals (ARVs) and support civil society social monitoring of the Global Fund investment. As of 1 August 2019, 29,950 people living with HIV were receiving TLD, corresponding to approximately 53% of the projected cohort of adults living with HIV on ART, thanks to this investment. Global Fund support (together with support from other partner organizations) has allowed civil society to monitor the Global Fund investment, although not without substantial constraints due to the overall environment.
- The overall situation and context in Venezuela has continued to deteriorate and currently the
 response to HIV, TB and malaria is almost entirely reliant on donations (both financial and inkind) for essential life-saving commodities.

Questions this paper addresses

- A. What do we propose to do and why?
- B. What options were considered?
- C. What do we need to do next to progress?

Conclusions

A. The economic crisis in Venezuela continues to severely impact the population's ability to access basic healthcare. In 2019 insufficient availability of key essential commodities (alternative and pediatric ARV regimens, anti-TB drugs, anti-malarials, diagnostics and key prevention commodities for HIV and malaria) has continued to have a significant impact on the lives of people living with or affected by the three diseases. To help alleviate the situation and provide life-saving HIV, TB and malaria commodities, the Strategy Committee and the Secretariat are recommending that an additional USD 6 million be made available to procure essential HIV, TB and malaria commodities (including ARVs, 1st and 2nd line TB drugs, anti-malarials), as well as essential diagnostics for the three diseases to support the people of Venezuela in 2020.³ If the Board should subsequently approve this investment, this would bring the total investment to USD 11 million for a two year period. The Strategy Committee and the Secretariat call on other partners to join the Global Fund in supporting the people of Venezuela and to continue or increase their donations to the three diseases noting the significant and critical gaps in country.

¹ GF/B39/O3 - Revision 1, as approved through GF/B39/DP04

² The number of people living with HIV receiving ARVs – TLD - is sourced from PAHO and UNAIDS, which have complied records from the national AIDS program. Civil Society reports, through their monitoring, that 13,702 persons have been prescribed TLD. The Secretariat has not been able to verify the numbers.

³ As noted in GF/B41/ER04, "...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."

- B. The Secretariat considered not requesting additional funding for 2020, however based on the results of the current investment, the Secretariat did not feel that the latter option was feasible in light of the moral responsibility to continue to ensure the availability of ARV treatment for Venezuelan people living with HIV. With the imminent stock-out of anti-tuberculosis medicines and the scale of the malaria resurgence in the country, the Strategy Committee and the Secretariat believe that support should also be provided to help alleviate TB and malaria gaps.
- C. As with the current investment, this second exceptional funding request represents a short-term humanitarian response to assist the people of Venezuela in meeting high priority health needs for HIV, TB and malaria. More fully addressing the health needs of the Venezuelan people will require additional commitments from other donors and partners in the near-term, and ultimately a resolution of the economic and political situation so that the Venezuelan government can provide for the health of its people.

Input Sought

- The Board is requested to approve the Decision Point: GF/B41/EDPXX: Approval of Additional Funding to Address the Health Crisis in Venezuela.
- As the Board considers the proposed investment case, it is requested to recall that the
 proposed implementation arrangements for non-eligible countries in crisis are by necessity
 different from traditional grants arising from country allocations. As the Board reviews this
 request, the following questions should guide deliberations:
 - Does the Board agree with the Strategy Committee and Secretariat's assessment that the economic and epidemiologic crisis indicates a degree of severity in line with the Board decision and discussion on non-eligible countries in crisis?
 - O Does the Board agree that the proposed additional investment of USD 6 million to address the crisis in Venezuela has strong strategic value and is consistent with the Global Fund's mission and strategic goals, and the intent of the Board decision on noneligible countries in crisis?
 - Does the Board agree to use the proposed source of funds funds identified for portfolio optimization - for this purpose, recognizing the trade-offs against other possible uses of those funds, including scale up in eligible countries?
 - Ones the Board agree that the implementation and assurance arrangements are consistent with the intent of the investment and to accept the risks inherent in these arrangements in light of the expected strategic value of the investment?

Input Received

- The Secretariat has received input from the Pan American Health Organization (PAHO), UNAIDS and Civil society in the development of this request see Annexes 2 and 3.
- The Secretariat has consulted with the Office of the Inspector General (OIG) and has sought and received the OIG's advice, noting that the proposed implementation arrangements are the same for this second request as for the first request. Considering the exceptional circumstances of this funding, the emergency context, and other relevant factors outlined by the Secretariat in this paper, the OIG does not have any objection related to the lack of access rights in this case and it acknowledges the risk-acceptance decision implied in the Board's approval of this funding.
- The Secretariat has also consulted with HIV and TB Situation rooms (which include a number of partners) and the RBM partnership Country & Regional Support Partner Committee (CRSPC) Sub-group on the proposed prioritization of resources.

What is the need or opportunity?

Background

- 1. Since 2013, Venezuela has experienced a protracted economic crisis that has severely impacted the provision of basic services to the population, including essential health services. The continued shortage in 2019 of basic commodities in particular food and essential medicines (including critical HIV, TB and malaria commodities) and the protracted crisis has resulted in the emigration of an estimated 4.3 million Venezuelan refugees and migrants, who for the most part (approximately 3.5 million) have fled to neighboring Latin American and Caribbean countries.⁴
- 2. In May 2018, the Board approved an approach to non-eligible countries in crisis which was developed to allow the Global Fund to potentially engage and support non-eligible countries facing emergencies that adversely impact progress against HIV, TB and malaria. Under this approach, exceptional funding is time-limited to an initial 12-month period with the possibility of an extension in exceptional cases.⁵ While the Board recommended that the total amount of funds awarded to non-eligible countries in crisis not exceed USD 20 million for a three-year period, there is no dedicated source of funds for non-eligible countries in crisis for the 2017-2019 allocation period. As such, available funds must be identified by the Secretariat.
- 3. On 24 September 2018, the Board approved, on the Strategy Committee's recommendation, an exceptional funding request of USD 5 million to support the procurement of ARVs (USD 4.9 million) and civil society social monitoring (USD 100,000), which was funded through the available sources of funds identified by the Audit and Finance Committee (AFC) for portfolio optimization for eligible grants. With this approval, the Board acknowledged that this investment entailed unique risks which could not be fully mitigated with the proposed implementation and management arrangements; that support provided by the Global Fund represented a short-term humanitarian response to assist the people of Venezuela; and that the available funding was insufficient to meet more than a fraction of the total need which extended (and continues to extend) beyond HIV, TB and malaria. At the time of approval, the Strategy Committee and the Secretariat noted that there likely would be a continuing need for funding beyond the initial 12-month period and initial USD 5 million investment.
- 4. This paper presents an update on the implementation of the current investment (approved under GF/B39/EDP11), updated economic and epidemiological information, and a request that the Board provide an additional investment of USD 6 million for 2020. This additional investment will help mitigate the effects of the on-going crisis by procuring essential HIV, TB and malaria commodities (including ARVs⁸, first and second line anti-TB drugs for adults and children, anti-malaria drugs), as well as essential diagnostics for the three diseases.
- 5. To support this request, PAHO and UNAIDS have prepared an update to the original Master Plan,⁹ which is available in Annex 2 and contains more detailed information, including an updated situation analysis for the three diseases, progress related to the Global Fund's donation, as well as updated needs for treatment, diagnostic and prevention commodities, as well as critical health system strengthening actions for Years 2 (2020) and 3 (2021).¹⁰ Venezuelan civil society has also

⁴ Source: Regional Inter-Agency Coordinating Platform, August 2019: https://data2.unhcr.org/en/situations/platform.

⁵ <u>GF/B39/03 – Revision 1</u>, paragraph 18.

⁶ GF/B39/ER10

⁷ GF/B₃9/ER₁₀, paragraph 29.

⁸ Which will include sufficient quantities of ARVs (TLD) to ensure access to uninterrupted treatment for patients currently on ARV treatment or expected to be on treatment by the end of December 2019 through March 2021.

⁹ The Master Plan ("Plan Maestro para el fortalecimiento de la respuesta al VIH, la tuberculosis y la malaria en la República Bolivariana de Venezuela desde una perspectiva de salud pública") was included as Annex 2 to GF/B39/ED10 and was endorsed by the Venezuelan Ministry of Health in June 2018. This plan presented a prioritized list of essential interventions that are needed over a three-year period. While essential for the Global Fund, this plan was also used to solicit additional donations and support from other potential donors.

¹⁰ The Secretariat requested that PAHO and UNAIDS provide an addendum to the Master Plan with the latest available information (31 July 2019) in order for the Secretariat to assess whether or not to request additional funding for Venezuela under the non-eligible countries in crisis approach. In the case of malaria, the Secretariat requested that PAHO provide an updated gap

provided an update on the implementation of the social monitoring component, which is available in Annex 3. The data contained in these updates have not been independently verified by the Secretariat; the Secretariat is relying on PAHO, UNAIDS and Venezuelan civil society for data accuracy and acknowledges that there may be limitations on the data. While the Secretariat acknowledges that the data reported by partners and civil society does not always coincide, it notes that, in the absence of verifiable official data, it is the best available data at this time.

6. The needs to establish functional HIV, TB and malaria programs are significant and well exceed potentially available resources from the Global Fund. There is a need for continued support from partners to help bridge gaps in essential commodities, either through additional financial contributions or in-kind donations, in 2020 until the government of Venezuela provides for the health of its people.

Update on the implementation of GF/B39/EDP11

- 7. Since the September 2018 Board approval of the exceptional funding request for Venezuela, the Secretariat has provided regular updates to the Strategy Committee on the implementation of this funding, as part of the Update on Country Funding and Portfolio Optimization, including challenges and bottlenecks.¹¹ This information contained below is the latest available information as of 1 August 2019.
- 8. In summary, the current funding is being implemented directly through PAHO (USD 4.9 million, to purchase ARVs through the PAHO Strategic Fund (the "Strategic Fund")12) and UNAIDS (USD 100,000, to support Venezuelan civil society in oversight and monitoring of the delivery of ARVs to patients) and has been fully disbursed. As of 1 August 2019, PAHO has executed USD 4,857,476 of the budget to purchase tenofovir/lamivudine/dolutegravir (TLD) (fixed dose combination) antiretrovirals, which is expected to cover the treatment needs of up to 83% of the projected cohort of adults living with HIV on ART in 2019. As of 31 July 2019, according to records compiled by PAHO and UNAIDS, 29,950 people living with HIV were receiving TLD which corresponds to approximately 53% of the projected cohort of adults living with HIV on ART and eligible for TLD. Under the terms of the Contribution Agreement dated 22 October 2018 between the Global Fund and PAHO, all shipments of TLD purchased with Global Fund resources have been consigned directly to the PAHO country office, which has undertaken the customs clearance process and ensured that the drugs have arrived at the central warehouse. Venezuelan civil society representatives were present for two of the three deliveries to the central warehouse; however, due to tensions with the Venezuelan Ministry of Health, they were not present for the third delivery. Nevertheless, a representative of PAHO Venezuela was present for all three deliveries. To date, there have been two distributions (February and May 2019) of ARVs purchased with Global Fund resources to 37 pharmacies that distribute ARVs 13, which was made possible due to logistical support provided by PAHO and UNAIDS as the Venezuelan Ministry of Health was unable to cover transport costs.
- 9. Civil society organizations have been engaged in social monitoring of the Global Fund's investment since Board approval, however there was a delay in finalizing the agreement between UNAIDS and Civil Society.¹⁴ Support from UNAIDS has been complemented by financial and technical support from Open Society Foundations (OSF) and ICASO to fill emergency gaps in social monitoring and support advocacy. The project has not been able to be implemented as originally envisaged and

analysis for a three-year period in light of the Board decision to make Venezuela exceptionally eligible for malaria due to the significant malaria resurgence (GF/B41/EDP06).

¹¹ GF/SC09/13 and GF/SC10/06

 $^{^{12}}$ The Strategic Fund is a regional pooled procurement mechanism for essential medicines and health commodities that procures on behalf of member states.

¹³ The Secretariat notes the discrepancies in the number of pharmacies that is reported by PAHO/UNAIDS and Civil Society. Based on the Secretariat's understanding, ARVs were distributed to 37 official pharmacies and some further distributed to other delivery service points. In 2018 there were 51 pharmacies/ARV delivery points in total. Civil Society has reported that they have identified 44 pharmacies.

¹⁴ "Search, retaining and linking people with HIV to the health system and community monitoring of the management of antiretroviral drugs (ARV) in Venezuela done by civil society: Venezuelan Network of Positive People (RVG +), Acción Ciudadana contra el Sida (ACCSI) and NGO Coalition on HIV in the Interior of the Country (COVIP)"(May 2019/ May 2020).

since February 2019, despite advocacy from civil society and from partners, the Venezuelan Ministry of Health and the national program have been reticent to engage and allow civil society presence in pharmacies. Despite this, civil society has contracted monitors to cover 20 states and they have found creative ways to continue to monitor and report on results and advocate for people living with HIV in Venezuela. Civil society has been particularly affected by the overall political and social climate and has been subject to harassment and in some instances violence and detention. This is reflected in the report submitted by them in Annex 3.

10. More detailed information is available in Annexes 2 and 3 to this paper.

Challenges

11. The implementation of the Global Fund donation has faced challenges, some of which are related to the overall situation in the country (e.g., chronic fuel shortages, electricity cuts, reduction in official working hours, overall lack of basic goods and services, lack of health workforce), while others are related to the national HIV/AIDS program (e.g. lack of capacity, non-automated inventory control system, resistance to dialogue with civil society, lack of essential commodities (treatment for opportunistic infections and sexually transmitted infections) and diagnostics (rapid tests and viral load) and the delivery of TLD to intended beneficiaries (e.g., resistance to change to a new regimen)). As noted above, the civil society social monitoring component has been implemented different from originally envisaged due constraints not within the control of civil society or partners and these challenges are expected to continue. These challenges are described in detail in Annexes 2 and 3 to this paper. The failure of the Venezuelan Ministry of Health to purchase any HIV-related commodities through the Strategic Fund during 2019, or through other sources, is problematic as the program is being entirely maintained through donations. 15 The lack of sufficient pediatric (in accordance with WHO guidelines) and alternative ARV regimes remains an issue and while pediatric ARVs were covered in the past by UNICEF there is no guarantee at this time that these will be covered going forward. While additional donations of ARVs have been mobilized and are in country, quantities remain insufficient to cover needs and incomplete regimens may result in interruptions of treatment.

Updated contextual information¹⁶

Economic situation

12. Venezuela, despite the continued economic crisis, continues to be classified by the World Bank as an upper-middle income country ¹⁷ and continues to remain one of the world's most indebted countries with a debt-to-GDP ratio of 161.99%. ¹⁸ Venezuela's main source of income is revenue generated from oil exports, which has slowed in 2019 due to changes in the global market, a decrease in demand, and US sanctions on the state oil company PDVSA. ¹⁹ The economic outlook for Venezuela remains poor with the inflation rate for 2019 expected to remain at 10,000%. ²⁰

Humanitarian response and contextual factors

13. The humanitarian response at country level has been boosted since the Humanitarian Coordinator (HC) designation in May 2019, which has enabled the establishment of the Humanitarian Country Team (HCT) and the Inter-Cluster Coordination Group. Under its leadership the United Nations

¹⁵ In the past, the Venezuelan Ministry of Health procured HIV commodities through the Strategic Fund.

¹⁶ Unless otherwise referenced the source of data and information is from Annex 2, Master Plan update, and the data has not been independently verified by the Secretariat.

¹⁷ Venezuela has not reported official GNI per capita data since 2015 for the World Bank fiscal year 2015 (July 2014-June 2015) when it was classified as a high-income economy. The Secretariat requested clarification from the World Bank regarding Venezuela's upper-middle income classification for the fiscal year 2020 (July 2019-June 2020). The World Bank noted that it relied on internal estimates when evaluating GNI per capita for the World Bank 2020 Fiscal Year. The lack of reported economic data is an issue: in May 2018 the International Monetary Fund issued a declaration of censure to Venezuela for not providing the required data under the IMF Articles of Agreement (Article VIII, Section 5).

¹⁸ http://worldpopulationreview.com/countries/countries-by-national-debt/

¹⁹ Since April 2019, US companies are prevented from doing business with PDVSA, which has had a significant impact as the US was one of the top purchasers of Venezuelan crude oil. Cf. https://www.reuters.com/article/us-venezuela-politics-crude-sanctions-ex/explainer-u-s-sanctions-and-venezuelas-trade-and-oil-industry-partners-idUSKCN1V420P

²⁰ Source: IMF World Economic Outlook April 2019. The average consumer price index (CPI) is a measure of a country's average level of prices based on the cost of a typical basket of consumer goods and services in a given period. The rate of inflation is the percent change in the average CPI.

Office for the Coordination of Humanitarian Affairs (OCHA) has prepared the Humanitarian Response Plan to mitigate the humanitarian impact of the ongoing crisis in Venezuela ²¹. The Secretariat notes that while Venezuela is not classified as a Grade 2 or Grade 3 emergency by WHO nor Level 3 emergency by the Inter-Agency Standing Committee (IASC), it continues to be managed as an administrative emergency by PAHO.

14. Since the establishment of the HCT, a health cluster has been established, which includes 24 incountry health partners and is coordinated by PAHO. UN agencies in the country have scaled-up efforts significantly and at the regional level, the UN has set up a Regional Inter-Agency Coordination Platform for Venezuelan migrants and refugees. The on-going economic crisis is one of the main factors that is pushing Venezuelan's to migrate to neighboring countries. Migration continues to increase and according to UNHCR, approximately 4 million Venezuelans have left the country, making them one of the largest displaced populations. The majority of displaced Venezuelans continues to migrate to neighboring countries (1.4 million in Colombia, 853,000 in Peru, 330,000 in Ecuador, 170,000 in Brazil), including an estimated 8,000 Venezuelans living with HIV. ²²

Epidemiological situation

15. The crisis affecting Venezuela has worsened in the last 18 months and has severely impacted health and the general welfare system. The Humanitarian Response Plan for Venezuela highlights that access to health care, especially critical and essential services, has been impacted by the migration of health care workers and specialists, reduced maintenance of medical equipment, disruption in the supply and distribution of medicines and medical supplies, and interruptions in public services, including electricity, water, communications and transportation. These limitations have disproportionately affected the most vulnerable populations, people with chronic diseases, and has resulted in increased incidence of communicable diseases such as malaria and tuberculosis.

HIV

- 16. The latest available official data estimates that in 2018 there were 120,000 people living with HIV (PLWH) in Venezuela. While Venezuela has not provided official updated information on new infections and AIDS related deaths, there were 4,012 new HIV infections in 2018 and 2,032 AIDS-associated deaths in 2017 (source: HIV program, Ministry of Health; data on AIDS-associated deaths are preliminary and currently under revision). Adult prevalence in the general population was estimated at 0.56% in 2016. There continues to be a lack of official data on HIV prevalence among key populations. However, updated, preliminary data emerging from an integrated biobehavioral survey commissioned by PAHO /UNAIDS in 2019 indicates HIV prevalence among men who have sex with men (MSM) to be 23.3% in an estimated population of 210,836 people.
- 17. In 2019, the national AIDS response has continued to deteriorate. According to PAHO, UNAIDS and civil society organizations, there is no treatment available for opportunistic infections, insufficient availability of ARVs for alternative (non-TLD), third-line or rescue regimens, stockouts of pediatric ARVs, no viral load monitoring, limited treatment for STIs, and insufficient access to essential prevention commodities (*i.e.* condoms). The government has not made any purchase of HIV treatment, monitoring and prevention commodities through the Strategic Fund and (as of the date of this paper) has not indicated that it has any plans to do so.
- 18. Additional donations of ARVs have been received from other partner organizations (PAHO, UNICEF, UNFPA, UNAIDS, Aid for AIDS), and the government of Brazil, as well as Roche, Mylan and Merck pharmaceuticals. UNICEF, UNFPA, PAHO and AIDS Healthcare Foundation (AHF) have also provided donations for STI treatments, contraceptives for people living with HIV, male and female condoms and HIV/STI tests. These donations, while important, are insufficient to cover the needs.

²¹ https://reliefweb.int/sites/reliefweb.int/files/resources/20190814 HRP VEN EN.pdf

²² https://www.unhcr.org/news/press/2019/6/5cfa2a4a4/refugees-migrants-venezuela-top-4-million-unhcr-iom.html and Annex 2.

19. In addition, there has been international support for neighboring countries to support the influx of Venezuelan migrants, most notably in Colombia, a Global-Fund eligible country, where, for example, the US government has committed to providing 12,000 doses of ARV treatment for Venezuelan migrants. In Ecuador, also a Global-Fund eligible country, the Global Fund provided USD 279,287 in emergency funding to the Ecuadorian Ministry of Health in April 2019 to ensure the treatment of Venezuelan migrants living with HIV in Ecuador.

Tuberculosis

- 20. According to the latest epidemiological information made available to PAHO, preliminary information for 2018 indicates that there were 10,574 new cases of tuberculosis in Venezuela and TB incidence is estimated at 33.2 per 100,000 inhabitants, which represents an increase of 2.5% from 2017. More than half of the cases of TB are in the Capital District and 5 states (Carabobo, Miranda, Zulia, Portuguesa and Anzoátegui), with persons deprived of liberty (16%) and indigenous persons (5.6%) the most affected populations. In 2018, treatment coverage (measured as the ratio of notified cases to estimated incidence) was 80% and treatment success rate, 85%. The number of drug-resistant TB cases has decreased from 81 cases in 2017 to 43 cases in 2018, which is likely due to the lack of laboratory capacity and availability of diagnostic supplies.
- 21. Based on the information in the updated Master Plan, in 2019 80% of the estimated needs for 1st and 2nd line drugs were covered by the government and by donations from PAHO and the Spanish Agency for International Development (AECID). The lack of real-time inventory at the central warehouse is a constraint in understanding the actual availability of stocks at the national level. Based on the latest available information, stock-outs of 1st line drugs are expected to begin in October 2019 for the second phase of some treatment regimens. TB partners are aware of this situation and are looking for ways to alleviate the imminent stock-outs noting that these will occur before any drugs procured with Global Fund resources arrive in country.
- 22. Diagnostic also remains a significant challenge. In 2018 AECID donated 2 GeneXpert machines and 2,050 cartridges to cover one-year needs. A centrifuge and biosafety cabinet for the National Reference Laboratory was purchased with funding from a Global Fund regional TB grant. However, the central laboratory is severely understaffed. The main method of diagnosing and confirming TB remains sputum-smear microscopy, technology which requires adequate diagnostic supplies and capacity, both of which are lacking.

Malaria

- 23. In 2018, Venezuela reported 404,924 confirmed cases of malaria, which accounts for more than 50% of the total reported cases for the Americas Region. Based on this sustained increase in cases since 2015, the Board decided exceptionally to make Venezuela eligible for malaria for the 2020-2022 allocation period, based on the technical assessment of partners.²³
- 24. As referenced in the update to the Master Plan, while the number of cases reported in 2018 was slightly lower than in 2017, endemicity remains at very high levels and has spread to additional municipalities and states (from 12 to 20 states). As of mid-August 2019, 262,750 new cases of malaria and 70,834 cases relapses/recurrences had been reported, with the states of Bolivar, Sucre and Amazonas reporting the highest number of cases. While the number of deaths related to malaria increased in 2017 (333) compared to 2016, a decrease was reported for 2018 (257) and preliminary data through late July 2019 indicates a reduction in malaria mortality of approximately 61% compared to 2018.
- 25. Unlike HIV and tuberculosis, the increase in malaria in Venezuela has affected neighboring countries and is affecting countries control and elimination efforts. The number of imported cases from Venezuela is increasing and, in some cases, e.g. Guyana Region VII accounting for the majority of malaria cases. In 2018, Brazil (4,860) and Colombia (1,179) reported the largest number

²³ GF/B41/ER04the. The Global Fund Eligibility Policy (GF/B39/02) allows for partners to recommend that a non-eligible (non-high income) country be made eligible for an allocation, based on a significant resurgence of a disease.

- of imported case and in the case of Trinidad and Tobago 13 of the 17 cases of malaria were imported from Venezuela.
- 26. The availability of antimalarials in 2019 has been largely maintained through donations, with the government of Venezuela nevertheless purchasing 200,000 RDTs at the end of 2018. PAHO, including the PAHO emergency program (Project Echo II), AECID, and the United Nations Foundation have purchased or donated anti-malarials and diagnostics.
- 27. Focused and targeted efforts by the International Committee for the Red Cross (ICRC) and Médicins sans Frontières (MSF) have been instrumental in supporting the malaria response in municipalities of El Cayao, Tumeremo and Domingo Sifontes in the Bolivar state, which has the highest number of malaria cases, and in the case of Domingo Sifontes, the highest disease burden in the country. This support has included the provision of diagnosis and treatment as well as the distribution of long-lasting insecticidal treated nets (LLINs).
- 28. While antimalarials and some diagnostic supplies were available as of July 2019, they remain insufficient to fully cover needs in 2020 as there are gaps in key supplies for case management, commodities and treatment.

Assessment conclusions

29. Based on the available epidemiological and economic data and the updates provided by PAHO, UNAIDS and civil society, the Strategy Committee and the Secretariat have concluded that the severity of the situation in Venezuela, which has further deteriorated since 2018 and is unlikely to improve in the medium term, warrants consideration under the Board's approach on providing support to non-eligible countries in crisis.

What do we propose to do and why?

What is the proposal?

- 30. The health sector continues to be severely affected by the economic situation and insufficient resources (both human and commodities). The needs associated with strengthening HIV, TB and malaria programs continue to be far greater than the resources that could be potentially available through the Global Fund.
- 31. The Strategy Committee and Secretariat recommend that an additional USD 6 million be made available for 2020 that would allow for the procurement²⁴ of antiretrovirals (including pediatric regimens), anti-tuberculosis drugs and antimalarials, as well as critical diagnostics for the three diseases, and funding to continue to support civil society oversight and social monitoring. The Strategy Committee and the Secretariat recommend that USD 5.85 million be provided to PAHO for the procurement of commodities, and that USD 150,000 be provided to UNAIDS to support social monitoring and civil society oversight in 2020. The Strategy Committee and the Secretariat recommend that USD 4,820,000 million be used to procure ARVs and diagnostics²⁵ and support civil society oversight and monitoring,²⁶ USD 830,000 be used to purchase 1st and 2nd line anti-

²⁴ This amount includes up to USD 240,0000 for support and administration of the procurement processes. The PAHO Director General has agreed to exceptionally waive the standard overhead of 13% in recognition of the unique circumstances in Venezuela. This also includes associated costs related to the importation, customs clearance and delivery to service delivery points. The Global Fund expects that the Ministry of Health or other in-country partners provide transport and if there are no other sources of funds available from in-country partners, funds will be made available, subject to agreement from the Secretariat, to transport commodities to service delivery points.

²⁵ The estimated amount has considered the availability of existing stocks of TLD in country or expected to arrive that have been financed with the 1st Exceptional Funding Request and will ensure uninterrupted treatment for the existing PLWH cohort for all of 2020, provide a 3-month buffer stock (March 2021), and ensure treatment for newly diagnosed patients eligible for TLD. This amount also includes funds to purchase pediatric ARV regimens, in the event that no other sources of funds (either financial or in-kind donations) are available. The Secretariat will continue to advocate with partners to take up the costs associated with pediatric ARVs.

²⁶ This includes USD 100,000 to continue social monitoring activities and USD 50,000 to support the Venezuelan Society of Infectious Disease Specialists – a non-governmental organization. This investment will be complemented by a grant from the Open Society Foundations (approximately USD 135,000) to support Venezuelan civil society advocacy efforts in 2020.

- tuberculosis drugs and diagnostics²⁷ and USD 350,000 be used to support the procurement of antimalarials and commodities.²⁸
- 32. To ensure that resources are used optimally the Secretariat is requesting flexibility to reprogram the budget to be able to adjust amounts for commodities in line with updated stock information, expected donations (financial or in-kind), government orders and/or any savings achieved through the procurement process. Any reprogramming would be subject to approval by the Secretariat.
- 33. The Strategy Committee and the Secretariat are recommending that the implementation arrangements approved for the first funding request, as described in GF/B39/ER10, be maintained for this second request. As noted previously, it was acknowledged by the Board that funding requests resulting from the non-eligible countries in crisis approach would not follow traditional Global Fund implementation arrangements, noting the need to respond rapidly and efficiently in a crisis or emergency context. Therefore, as already stated in connection with the first request, the implementation of this proposed investment entails significantly higher levels of risk and lower levels of assurance than standard funding requests. The Board is invited to consider these risks.

Proposed Implementation Arrangements

PAHO Strategic Fund

- 34. The Strategy Committee and the Secretariat recommend that USD 5.85 million be provided directly to PAHO to support the procurement of essential commodities for the three diseases. The benefits of using the Strategic Fund have been previously described to the Board in GF/B39/ER10, paragraph 35.
- 35. While the government of Venezuela has purchased essential medicines and commodities in the past, no orders have been placed through the Strategic Fund in 2019. Additional orders by the government for antimalarials were made in December 2018.
- 36. As with the current investment, PAHO, which has permission from the relevant authorities to operate in Venezuela, will manage the procurement process for commodities for the three diseases, which will include support to the national AIDS/HIV program, the national TB program and the national malaria control program and the Venezuelan Ministry of Health in the quantification of needs, distribution plans and procurement and delivery of commodities to the designated warehouse. All commodities will be procured taking into consideration the latest availability of stocks, any orders in process as well as any donations anticipated to be received.
- 37. As is the case under the current investment, PAHO will be responsible for delivering the commodities procured with Global Fund resources to the port of entry and will, in coordination with relevant authorities, clear customs and ensure transfer and delivery to the central warehouse (or other designated warehouse)²⁹. The Global Fund will not have recourse against any entity for loss, destruction, or misuse of the commodities once they have been delivered to the central warehouse (or designated warehouse).
- 38. In terms of monitoring and providing technical support, PAHO and UNAIDS (for HIV) will continue to provide technical assistance to the Venezuelan Ministry of Health and the national programs.

UNAIDS

39. The Strategy Committee and the Secretariat recommend that USD 150,000 be provided to UNAIDS to support the Venezuelan civil society in continuing to engage in social monitoring and advocacy for people living with HIV. This investment will be complemented by funding from OSF, which is anticipated to match the amount to be made available by the Global Fund, and technical assistance

 $^{^{27}}$ The estimated amount considers the availability of existing 1st and 2nd line anti-TB drugs and will allow for the provision of 1st and 2nd line treatment regimens through March 2021.

²⁸ The estimated amount includes procurement of primaquine (noting there are sufficient stocks of chloroquine in country) and rapid diagnostic tests.

²⁹ The Strategic Fund's responsibility normally stops at port when commodities are procured with national funds. Commodities will be delivered according to CIP ("Carriage and Insurance Paid to") Incoterms. https://iccwbo.org/resources-for-business/incoterms-rules/incoterms-rules-2010/

from ICASO. UNAIDS will continue not to charge any overhead or direct costs. These funds would be used to support civil society's continued efforts in monitoring existing stock levels of ARVs at the service delivery points, as well as contribute to on-going advocacy efforts. The future agreement will detail how these funds will be used to support civil society considering the changing situation in country, reflect what is feasible in light of the current climate and ensure that there is no overlap or duplication of efforts with other partners.

Variations to the Standard Global Fund Operating Model and Policies

- 40. The Strategy Committee and the Secretariat are proposing the same implementation arrangements - funding through PAHO and UNAIDS - for Venezuela for this present request as for the first request and confirm that the principles highlighted to the Board at its 39th Board Meeting and in the request to the Board in September 2018 still apply.³⁰ As the traditional Global Fund model does not apply, accountability for the recommended investment will be limited to the procurement and delivery of commodities, customs clearance and delivery to the central warehouse, and downstream monitoring activities. In the event that Global Fund resources are used to facilitate the transportation of commodities to service delivery points, responsibility will end there. Further distribution of commodities to the intended beneficiaries will continue to be the responsibility of the Venezuelan Ministry of Health (and the relevant national programs), who will have no formal or binding obligation to complete this distribution. As such, this investment comes with attendant risks, which were considered by the Strategy Committee and which the Board is requested to explicitly consider as part of its deliberations. The Strategy Committee and the Secretariat note that approval of this funding entails acceptance of these risks, which the Strategy Committee and the Secretariat believe is necessary in order to deliver impact in an appropriate and efficient manner in light of the context and lack of other viable options.
- 41. The Strategy Committee and the Secretariat note that the main risk associated with the proposed arrangements is that commodities may be diverted and not delivered to the intended beneficiaries. The Strategy Committee and the Secretariat acknowledge that there have been delays in the delivery of ARVs under the current investment. Challenges at state levels are in part a consequence of the overall economic context (e.g. chronic fuel shortages and power outages, lack of transportation, lack of healthcare providers), while others relate to a lack of capacity at the national program and to a politically tense environment. The Secretariat has no information at this time that would indicate that ARVs purchased through the Global Fund donation are being diverted or sold on the black market.
- 42. Annex 4 to this paper describes variations between the proposed arrangements and the Standard Global Fund operating model, as well as the related risks and, where applicable, related mitigation measures. There has been no substantive change compared to the variations reported to the Board in GF/B39/ER10.

Sources of Funds

43. As there is no dedicated source of funds for requests under the non-eligible countries in crisis approach for the 2017-2019 or 2020-2022 allocation periods, the Secretariat must identify a source of funds for this investment.³¹ The Strategy Committee and the Secretariat recommend that USD 6 million be made available, from the USD 250 million made available by the AFC in March 2019 to

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³⁰ In the Board paper on the Global Fund approach to non-eligible countries (GF/B39/03 – Revision 1), the Secretariat indicated that requests to fund non-eligible countries in crisis would not follow traditional Global Fund arrangements. Specifically, the Secretariat noted that "[i]mplementation arrangements are unlikely to follow traditional Global Fund arrangements (e.g. CCMs, funding request, grant making, etc.) due to the uniqueness of crises, likely absence of previous Global Fund implementing partners in the country, and need for rapid responses. It is expected that such a response will be led by in-country partners with implementation arrangements that provide sufficient and responsible oversight of funding and impact, taking appropriate account of the specific political situation and circumstances of the crisis, including considering use of civil society, multilateral, or other non-government actors as the primary funding channels when a health crisis in HIV, TB, or malaria is not acknowledged by a national government." In addition, the Board, when approving the Global Fund approach to non-eligible countries in crisis, noted that investments in non-eligible countries in crisis would likely contemplate non-traditional implementation arrangements and a higher level of risk acceptance.

³¹ The Emergency Fund is only for eligible countries and cannot be used to finance requests under this approach.

- finance prioritized interventions on the register of Unfunded Quality Demand (UQD) through Portfolio Optimization.³²
- 44. The Secretariat has assessed this investment against the current UQD register, currently valued at USD 2.994 billion, which was reviewed in detail, in consultation with technical partners, by the Secretariat in April 2019. The Grant Approvals Committee (GAC) agreed with setting aside these funds for a future request for Venezuela, noting the availability of funds to invest in priority interventions that are time-sensitive.
- 45. The Strategy Committee and the Secretariat have weighed the trade-offs in investing in eligible countries with UQD against providing additional support to Venezuela, which is currently not eligible for Global Fund funding, and will become eligible for malaria only for the 2020-2022 allocation period. While the Strategy Committee and the Secretariat acknowledge that there remain gaps across eligible countries, they note that time-sensitive prioritized needs are able to be addressed with existing funds and that additional funds were made available for portfolio optimization by the AFC in October 2019, that the majority of the grants under the 2017-2019 allocation period will end in December 2020, and that on-going in-country optimization and reprogramming has allowed for some interventions from the UQD register to be funded.

Why is this the recommended option?

- 46. The health situation in Venezuela has continued to deteriorate in 2019 and the economic outlook has not improved. The Strategy Committee and the Secretariat note that there are critical gaps across the responses to the three diseases and that any Global Fund support would help cover only a fraction of the overall needs. The Strategy Committee and the Secretariat have considered the current and projected availability of medicines for the three diseases, as well as the anticipated timing of potential malaria funding for the 2020-2022 allocation period.
- 47. Even with the Global Fund's investment and donations from partners and international civil society, there will continue to remain significant critical gaps in key commodities, as well as other core areas needed to ensure a functioning program, for the three diseases (with the most critical shortcomings being HIV viral load, treatment for opportunistic HIV infections, HIV prevention commodities, diagnostics for tuberculosis, antimalarials and vector control). The Secretariat will continue to engage with UN partners, bilateral development agencies and international civil society organizations to address these gaps. However, the longer-term solution will be dependent on an improvement of the economic and political situation and the ability of the government of Venezuela to provide for the health of the Venezuelan population.
- 48. The Strategy Committee and the Secretariat continue to believe that the proposed implementation arrangements with PAHO and UNAIDS, while different from traditional grant arrangements, will be the most effective arrangements possible and likely to deliver the expected outcomes in the crisis context in a rapid and efficient way. Both agencies have in-country presence, established working relationships with government counterparts and civil society, and have the capacity to provide oversight over the proposed investment. In addition, the supplementary support from OSF and ICASO will ensure that civil society has sufficient support to engage in social monitoring of HIV. The Strategy Committee and Secretariat have carefully considered the risks associated with this investment and the Board is requested to consider the identified risks, including the limitations described in this paper, if it decides to approve this second exceptional funding request to support the people of Venezuela.
- 49. The Secretariat has consulted with the Office of the Inspector General (OIG), and sought and received the OIG's advice. Taking into account the exceptional circumstances of this funding, the emergency context, and other relevant factors outlined by the Secretariat in this paper, the OIG does not have any objection related to the lack of access rights in this case and it acknowledges the risk-acceptance decision implied in the Board's approval of this funding.

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³² GF/AFC09/DP01

What options did we consider?

What are the options?

50. The Strategy Committee and Secretariat note that there are only two options in this context. The first option, followed here, is to request new funding for another year under the non-eligible countries in crisis approach. The second option is not to request new funding. Considering the situation and that overall implementation of the initial request has achieved successes, the Strategy Committee and Secretariat do not consider the second option a feasible option, particular in light of the risk that treatment for people living HIV would cease to be available as of mid-2020, in the absence of additional funding.

What do we need to do next to progress?

What is required to progress the proposal?

- 51. The Board is requested to approve a new investment of USD 6 million for Venezuela for 2020 in line with the Board-approved approach for non-eligible countries in crisis.
- 52. A decision to delay approval could result in stock-outs of ARVs (depending on the length of the delay) and prolonged stock-outs of TB and malaria drugs and affect the health of the Venezuelan people.

Recommendation

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

Annexes

The following items can be found in Annex:

- Annex 1: Terms of Investment in Venezuela
- Annex 2: Update to the Master Plan
- Annex 3: Civil Society Report the Secretariat
- Annex 4: Variations between proposed implementation arrangement and the Standard Global Fund Operating Model
- Annex 5: Summary of previous Committee Input
- Annex 6: Relevant Past Decisions
- Annex 7: Relevant Past Documents & Reference Materials

Annex 1 - Terms of Investment in Venezuela

1. Amount: USD 6,000,000 (total)

2. Duration: one year

3. Funding recipients: PAHO (USD 5,850,000); UNAIDS (USD 150,000)

4. Activities to be funded:

a. PAHO:

- i. Procurement of ARVs and HIV diagnostics in accordance with a procurement plan to be agreed with the government of Venezuela and the National AIDS Program, clearance of ARVs through customs at port of entry and delivery of ARVs to the central warehouse (or to service delivery points, in the event that no alternative is available).
- ii. Procurement of anti-tuberculosis medicines and TB diagnostics in accordance with a procurement plan to be agreed with the government of Venezuela and the National Tuberculosis Program, clearance of anti-tuberculosis medicines through customs at port of entry and delivery of medicines to the central warehouse (or to service delivery points, in the event that no alternative is available).
- *iii*. Procurement of anti-malarial medicines and malaria diagnostics in accordance with a procurement plan to be agreed with the government of Venezuela and the National Malaria Control Program, clearance of anti-malarial medicines through customs at port of entry and delivery of medicines to the central warehouse (or to service delivery points, in the event that no alternative is available).
- b. <u>UNAIDS</u>: provision of support to civil society for post-delivery monitoring of stocks at central and sub-national warehouses and dispensation sites, and delivery of treatment to patients.

5. Indicative Budget:

Area	Amount
HIV, TB, Malaria commodities (to be procured through the Strategic Fund)	USD 5,610,000
PAHO costs ³³	USD 240,000
Support for civil society monitoring and oversight (through UNAIDS)	USD 150,000
Total	USD 6,000,000

This indicative budget may be subject to reprogramming, in agreement with the Secretariat.

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³³ As with the current investment, and in recognition of the partnership between the Global Fund and PAHO, the Director General of PAHO has agreed to waive its standard overhead of 13%. This is a maximum amount, the actual amount will depend on the total value of the actual procured commodities.

$6. \quad \text{Terms of the investment that differ from standard Global Fund grants:} \\$

Variation	Description
Scope of Investment and Accountability	Legal accountability to the Global Fund for the commodities ends after delivery to the central warehouse (or other designated warehouse), beyond which the government of Venezuela assumes responsibility over transport through the supply chain and delivery to patients. Traditional assurance and accountability mechanisms (including but not limited to: a local fund agent, independent audit, investigations, and sanctions) will not be present.
Access Rights	The funding arrangements do not provide the Global Fund unrestricted access to books, records, personnel or sites relating to the funded activities, including as required under the Charter of the Office of the Inspector General. 34
Audit	Contributions to PAHO and UNAIDS will be subject to their respective internal and external auditing procedures and will not be subject to independent audit.
Recoveries	PAHO will be responsible only for procurement and delivery of commodities to the central warehouse (or other designated warehouse). If commodities are misused or diverted after delivery, the Global Fund will have no recovery action against any entity.
Quality and Supplier Assurance	Procurement will be conducted in accordance with PAHO's quality and supplier assurance policies, rather than those of the Global Fund.
Reporting	The agreement will not follow standard Global Fund grant financial or programmatic reporting.
Internal Policies	Recipients of the funds will not be subject to standard obligations under the Global Fund Grant Regulations. PAHO and UNAIDS' policies and procedures will apply.
Country Funding Request	The request has not been developed or submitted by a Country Coordinating Mechanism.
Technical Review	Technical assessment of the proposal has been provided by PAHO and UNAIDS. The Technical Review Panel has not reviewed this request.
Sustainability	The Global Fund contribution is not designed to be a sustainable investment.

 $^{^{\}rm 34}\,Approved$ under GF/B31/DP11.

Annex 2: Update to the Master Plan

INSERT LINKS TO OBA PORTAL

Annex 3: Civil Society Report to the Secretariat

INSERT LINKS TO OBA PORTAL

Annex 4: Variations between proposed implementation arrangement and the Standard Global Fund Operating Model

Variation	. Description/Related Risk	Mitigation
. Scope of Investment and Accountability	The design of the funding arrangements intrinsically puts a practical limit on the assurance and oversight which can be provided under the proposed arrangements. The proposed investment is limited to procurement and delivery of commodities to port, customs clearance and delivery of commodities to the central warehouse, with some limited downstream monitoring activities. In the absence of alternative funding, PAHO's responsibility may extend to transportation to service delivery points. In all events, the government of Venezuela would assume responsibility for transport through the supply chain to patients. However, the government of Venezuela will have no binding contractual obligations to ensure such delivery to intended beneficiaries. Traditional assurance and accountability mechanisms (e.g. LFA, independent audit, investigations, sanctions, etc.) will not be present.	 PAHO and UNAIDS will provide monitoring and assurance activities that will indicate whether the commodities reach patients as intended. Both PAHO and UN partners have presence in country and have strong existing relationships with relevant governmental counterparts. PAHO has agreed to conduct extraordinary verification exercises beyond delivery at port (at the central warehouse or other designated warehouse), in coordination with the government of Venezuela and the National AIDS Program, National TB Program and National Malaria Control Program, to verify delivery of the commodities and to provide verification reports. UNAIDS will be supporting civil society in-country to perform monitoring and stock verification at dispensation sites, as per the distribution plan to be developed and agreed.
Access Rights	The funding arrangements do not provide the Global Fund unrestricted access to books, records, personnel or sites relating to the funded activities, including as required under the Charter of the Office of the Inspector General. 35 PAHO has not agreed to grant the Global Fund access to its books, records, or sites, or those of its suppliers. UNAIDS has not agreed to grant the Global Fund access to its books and records nor guarantees of collaboration into accessing sites and personnel,	Other than up to USD 240,000 for PAHO's costs, the PAHO contribution will only be used for the procurement and delivery of drugs through port to the central warehouse (or other designated warehouse). Verification of procurement and delivery can be achieved through means other than access to financial books and records. Therefore access (or subsequent OIG audit or investigation) is unlikely to add meaningful assurance given the scope of PAHO and UNAID's responsibilities.

 $^{^{35}}$ Approved under GF/B31/DP11.

	but will ensure Global Fund access to the books and records of any contracted civil society organizations receiving Global Fund funds.	 PAHO has no downstream implementation partners. The agreement with UNAIDS will allow for the verification of downstream expenditures of civil society organizations conducting monitoring activities.
Audit	All contributions to PAHO and UNAIDS are subject to their internal and external auditing procedures and are not subject to independent audit.	 PAHO's and UNAIDS' organizational audits would provide assurance that the funds are managed in line with their respective accounting and procurement processes and under applicable accounting standards. PAHO will notify the Global Fund in the event that PAHO becomes aware of information that necessitates further assurances or integrity-related actions in connection with the activities.
Recoveries	PAHO will be responsible only for procurement and delivery of commodities to the central warehouse (or other designated warehouse). If commodities are misused or diverted after delivery to the central warehouse (or service delivery points), the Global Fund will have no recovery action against any entity.	• Additional monitoring and verification to be conducted by PAHO and UNAIDS will indicate whether drugs are reaching the intended beneficiaries. If there is evidence that drugs are not reaching patients as intended, no additional funding will be provided to help address the crisis in Venezuela.
. Quality and Supplier Assurance	This proposal does not include references to Global Fund policies with respect to quality assurance and supplier conduct.	 PAHO's quality assurance policies and supplier qualifications are available on its website and provide adequate assurance. These policies will be incorporated by reference, as applicable, in the agreement with PAHO. Products procured by PAHO are pre-qualified by WHO, registered in the National Regulatory Authorities of reference medicines of the region or evaluated through internal processes for the assurance of quality.
Reporting	The arrangement will not follow standard Global Fund grant financial or programmatic reporting.	• The disbursement schedule and reporting requirements will be set out in the agreement with PAHO in order to ensure adequate procurement and delivery.

		•	PAHO will provide the Global Fund with a final report, approved by its director of finance, when delivery is completed. The agreement with PAHO will confirm that funds will only be used to procure the approved commodities. Any unused funds will be returned to the Global Fund or used for the purchase of additional commodities after Global Fund approval.
Internal Policies	Receipt of the Global Fund contribution will not trigger standard obligations as provided by the Global Fund Grant Regulations (e.g., compliance with codes of conduct and anti-money laundering provisions). The Global Fund will rely on PAHO's and UNAID's internal policies and there is a risk that not all of the Global Fund's policies and principles will be applied to this arrangement.	•	PAHO has its own anti-corruption and anti-terrorism policies in place, which cover the key aspects of the Global Fund's policies on such matters and provide adequate assurance given (1) the nature of PAHO's activities under this arrangement and (2) the fact that PAHO only deals with pre-qualified suppliers that are not on the UN sanctions list or suspended or debarred by the World Bank. PAHO requires its suppliers to sign the UN Supplier Code of Conduct, which addresses matters related to conflicts of interest, proper labor and human rights practices and corruption matters and which provides adequate assurance in lieu of applying the Global Fund Code of Conduct for Suppliers and Code of Conduct for Recipients of Grant Funds.
Country Funding Request	The request has not been submitted by a Country Coordinating Mechanism, which is the standard mechanism for submitting a funding request for country allocations. As such, it has not been developed in the same manner as regular funding requests.	•	The assessment and recommendation are based on information available from technical partners, civil society, as well as published economic data. The Secretariat has chosen to confirm PAHO as the implementing partner because it has regional expertise, in particular through the Strategic Fund, and experience to operationalize the planned activities, notably the procurement of ARVs. The government of Venezuela has procured through the Strategic Fund and PAHO has permission from the relevant authorities to operate in country.

Technical Review	The Technical Review Panel has not reviewed this request; the recommendation from the Strategy Committee and the Secretariat is based on an incountry technical assessment undertaken by PAHO and UNAIDS.	•	There has been active engagement with partners, in particular with PAHO and UNAIDS, as well as civil society and Venezuelan government counterparts, in particular the National AIDS Program, in preparing the technical assessment of the HIV, TB and malaria situation on which the present request is based. The original Master Plan annexed to the initial requested has been updated to help prioritize critical areas, as well as to facilitate coordination with other potential international donors.
Sustainability	The Global Fund contribution is not designed to be a sustainable investment.	•	The Global Fund's decision on non- eligible countries in crisis has generated interest from other donors and partners and as such the Secretariat has engaged in efforts to develop a coordinated support mechanism and determine ways to support the country and/or the neighboring region affected by the influx of migrants from Venezuela.

Annex 5 – Summary of Previous Committee Input

Strategy Committee Chairs Notes – 9th Meeting, paragraph 64

https://tgf.sharepoint.com/sites/ESOBA1/GFBC/StrategyCommitteeSC/SC%20Meetings/09%20SC%20Meeting%2028-

29%20March%202019/GF%20SC09%2018%20Chair's%20Notes/GF%20SC09%2018 %20 Chair's%20Notes SENT.pdf

Strategy Committee Chairs Notes – 10th Meeting, paragraphs 22 & 24,

 $\frac{https://tgf.sharepoint.com/sites/ESOBA1/GFBC/StrategyCommitteeSC/SC%20Meetings/100th%20SC%20Meeting%2018-$

19%20July%202019/04%20Chair's%20Summary%20Notes/GF-SC10-Chair's%20Summary%20Notes.pdf

Annex 6 - Relevant Past Decisions

Relevant past Decision Point	Summary and Impact
GF/SC11/DP01: Recommendation of Additional Funding to Address the Health Crisis in Venezuela	The Strategy Committee unanimously decided to recommend to the Board for approval a second exceptional funding request for Venezuela in the amount of USD 6,000,000 to provide life-saving HIV, TB and malaria commodities and support civil society social monitoring using the same implementation arrangements outlined in GF/B39/ER10.
GF/B41/EDP06: Eligibility of Venezuela's Malaria Component for the 2020-2022 Allocation Period (August 2019) ³⁶	The Board decided that Venezuela's malaria component would be eligible for funding for the 2020-2022 allocation period due to a significant resurgence in malaria cases.
GF/B39/EDP11: Approval of Funding to Address the Health Crisis in Venezuela (September 2018) ³⁷	The Board approved the provision of USD 5,000,000 in exceptional funding for Venezuela for the procurement of ARVs and civil society social monitoring. The Board acknowledged the unique risks entailed by the proposed implementation and management arrangements, due to Venezuela's exceptional circumstances.
GF/B39/DP04: Potential Engagement with Non-eligible Countries in Crisis (May 2018) ³⁸	The Board acknowledged that a health crisis of significant magnitude may occur in a non-eligible country, which may warrant Global Fund support. The Board directed the Secretariat, in consultation with partners, to present potential investment cases that meet the criteria described in GF/B39/O3- Revision 1 to the Strategy Committee for recommendation to the Board.
GF/B37/DP11: Health Situation in Venezuela (May 2017) ³⁹	The Board directed the Strategy Committee and the Secretariat to discuss exceptional circumstances in non-eligible countries as part of the ongoing review of the Eligibility Policy.
GF/B28/EDP16 (March/2013): Revised Charter of the Office of the Inspector General and Terms of Reference for the Inspector General ⁴⁰ GF/B31/DP11 (March/2014): Revision to the OIG Disclosure Policy and the OIG Charter ⁴¹	Providing requisite access and audit rights to fulfil its mandate under the Board-approved "Terms of Reference of the Inspector General" and the "Charter of the Office of the Inspector General", it limits the scope of the OIG's work and consequently its capacity to fulfill its mandate.
Charter	The OIG Charter, as initially adopted in March 2013, and most recently amended in March 2014, notes under Article 17 that the Office of the

³⁶ https://www.theglobalfund.org/board-decisions/b41-edpo6/

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³⁷ https://www.theglobalfund.org/board-decisions/b39-edp11/

³⁸ https://www.theglobalfund.org/board-decisions/b39-dpo4/

³⁹ https://www.theglobalfund.org/board-decisions/b37-dp11/

⁴⁰ https://www.theglobalfund.org/board-decisions/b28-edp16/ 41 https://www.theglobalfund.org/board-decisions/b31-dp11/

Relevant past Decision Point	Summary and Impact
	Inspector General will have the authority to access, inspect, review, retrieve and make copies of all 1) books, records and documents maintained by the Global Fund Secretariat; and 2) books and records relating to grants funded by the Global Fund or the implementation of Global Fund financed programs and operations, whether maintained by Principal Recipients, Sub-Recipients, LFAs or LFA subcontractors, suppliers and service providers or other individuals and entities who are engaged in, or involved in, carrying out or participating in Global Fund financed programs or operations, and those who have received Global Fund monies or assets, either directly or indirectly.
	It further authorizes the Office of the Inspector General to seek any information required from personnel of the Global Fund and those that are external, including Principal Recipients, Sub-Recipients and, suppliers and service providers involved in Global Fund financed programs and operations and require such personnel to cooperate with any reasonable request made by the Office of the Inspector General.
	If the decision point presented in this paper is recommended by the Strategy Committee and approved by the Board, it will restrict the access rights of the OIG and accordingly, the OIG will not be able to provide any assurance (audit or investigation) on the use of funds or any other aspects of this arrangement.

Annex 7 – Relevant Past Documents & Reference Materials

<u>GF/B37/21 – Revision 1: Update and Discussion on the Health Situation in Venezuela -</u>

<u>GF/B39/03 – Revision 1: Global Fund approach to non-eligible countries in crisis – </u>

GF/B39/ER10: Approval of Funding to Address the Health Crisis in Venezuela

GF/B41/ER04: Eligibility of Venezuela's Malaria Component for the 2020-2022 Allocation Period

GF/SC11/06: Second Exceptional Funding Request to Address the Health Crisis in Venezuela