

4th Exceptional Funding Request to Address the Health Crisis in Venezuela

Electronic Report to the Board

GF/B46/ER02

Board Decision

Purpose of the paper: In line with the Board-approved approach to non-eligible countries in crisis (GF/B39/03- Revision 1), this paper presents, for Board approval, the Secretariat and Strategy Committee's recommendation for a 4th exceptional funding request for Venezuela for a total of US\$12 million to ensure the on-going availability of life-saving HIV and TB commodities, as well as support civil society oversight, through 2022 and 2023.

Decision

Decision Point: GF/B46/EDP02: Approval of Additional Funding to Address the Health Crisis in Venezuela

The Board:

- 1. Expresses continuing concern about the protracted public health crisis in Venezuela, which has been further exacerbated by the COVID-19 pandemic, and continues to adversely impact the fight against HIV, tuberculosis and malaria in Venezuela and the region;
- 2. Notes that while the Board exceptionally approved the eligibility of Venezuela's malaria component under GF/B41/EDP06, resulting in an allocation of US\$ 19,800,000 for the 2020-2022 allocation period, Venezuela's HIV and tuberculosis components were not eligible to receive allocations in the 2020-2022 allocation period;
- 3. Acknowledges the new proposal for exceptional funding in 2022 and 2023 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;
- 4. 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/B46/ER02 and Annex 1;
- 5. Accepts that the proposed implementation and management arrangements continue to entail unique risks, as described in GF/B46/ERXX 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/B46/ERXX and Annex 1;
- 6. Based on the recommendation of the Strategy Committee, approves the investment and terms set forth in Annex 1, to provide an additional US\$ 12,000,000, for the years 2022 and 2023, to support the procurement of critical HIV & TB health products for Venezuela and social monitoring of the investment; and
- 7. Calls for continuous engagement from relevant partners, donors and other stakeholders to further support a regional response to the health crisis in Venezuela.

Budgetary implications: up to US\$ 12,000,000, funded through available sources of funds identified by the Audit and Finance Committee under GF/AFC17/DP03.

A summary of relevant past decisions providing context to the proposed Decision Point can be found in Annex 4.

Executive Summary

Context

- When the Board approved an approach for non-eligible countries in crisis, it acknowledged that standard Global Fund operating modalities for accessing and implementing funding requests under this model would likely require the need for flexible arrangements that respond to country context. The Board also acknowledged that "effectively responding in ineligible countries in crisis 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 When approving this approach, the Board recommended that the overall ceiling to be made available during a three-year period not exceed US\$20 million.
- To date, the Global Fund has approved three exceptional funding requests for Venezuela² under this approach, for a total of US\$17 million, which have supported the procurement of life-saving HIV, TB and malaria commodities and supported civil society oversight. For the 2020-2022 allocation period, the Board exceptionally approved that Venezuela be made eligible for a malaria allocation, in line with the Eligibility Policy. Venezuela has also received US\$ 14.7 million through the COVID-19 Response Mechanism (C19RM).
- The on-going political, economic and humanitarian crisis in Venezuela has been exacerbated by the COVID-19 pandemic. Measures imposed to curb the spread of the virus have led to increased poverty, loss of livelihoods, and the collapse of already fragile health and social welfare systems. As the Global Fund is the primary source of funding for ARVs in the country and, since 2020, the sole funder of anti-tuberculosis medicines, a cessation in funding would result in stock-outs of lifesaving HIV and TB medicines and likely result in increased mortality for people living with HIV and TB.

Questions this paper addresses

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

Conclusions

A. The Secretariat and the Strategy Committee (SC) recommend to the Board that an additional US\$ 12 million for a two-year period (2022 and 2023) be provided to Venezuela to ensure the continued availability of life-saving HIV and TB treatment during this time.³ The rationale for this recommendation is that Venezuela continues to be affected by a protracted economic and social crisis, aggravated by COVID-19, which is unlikely to ameliorate in the near to mid-term. The crisis continues to severely impact the population's ability to access basic healthcare, including HIV and



¹ GF/B39/03- Revision 1, as approved through GF/B39/DP04

² <u>GF/B39/EDP11, GF/B41/EDP14</u> and <u>GF/B43/EDP16</u>.

³ The Secretariat is not recommending funding for malaria as Venezuela exceptionally received a malaria allocation of US\$19.8 million for the 2020-2022 allocation period which will be implemented by UNDP from 1 January 2021- 31 December 2023.

TB services and is due to political and social factors. The Secretariat and SC recommend that funding be approved for a two-year rather than a one-year period, i.e., for 2022 and 2023, in light of Venezuela's likely eligibility for HIV and potential eligibility for malaria during the 2023-25 allocation period, as well as the significant transaction costs for in-country stakeholders, partners, the Secretariat and the SC and Board). Should the Board subsequently approve this investment, the total amount of exceptional funding for Venezuela would be US\$ 29 million over a five-year period.⁴

- B. The SC and Secretariat considered not requesting additional funding but deemed it a non-viable option. This funding will ensure the continued availability of HIV and TB treatment for the Venezuelan people.
- C. The Board is requested to review the proposed investment and the implementation and assurance arrangements and approve GF/B46/EDP02: Recommendation of Additional Funding to Address the Health Crisis in Venezuela in 2022 and 2023.

Input Sought

• As the Board considers the proposed investment case, it is requested to recall that the proposed implementation arrangements for funding interventions through the non-eligible countries in crisis approach are by necessity different from traditional country grants.

Input Received

- In its deliberations, the SC was requested to consider the Secretariat's assessment of the economic and epidemiological situation and whether an additional investment of US\$12 million had strong strategic value and was consistent with the Global Fund's mission and goals and the intent under the Board's decision and discussion on non-eligible countries in crisis. The SC was also requested to agree to the proposed source of funds and consider the trade-offs against other possible uses of those funds, as well as consider the proposed implementation and assurance arrangements (which remain the same as previous investments) and acknowledge the inherent risks in these arrangements considering the expected strategic value of the investment.
- The Secretariat received input from the Pan American Health Organization (PAHO), UNAIDS, and Civil Society in the development of this request.
- The Secretariat consulted with the Office of the Inspector General (OIG) and sought and received the OIG's advice, noting that the proposed implementation arrangements are the same for this fourth request as for the previous three requests. 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 also consulted with the HIV and TB Situation rooms on the proposed prioritization of resources.



⁴ This is in line with the Board recommended ceiling that funding for non-eligible countries in crisis not exceed US\$ 20 million over a threeyear period as the total investment in Venezuela over a three-year period is US\$17 million.

Report

What is the need or opportunity?

- 1. In May 2018 the Board approved a flexible, light-touch approach that allows for the Global Fund to consider supporting non-eligible countries in crisis that are facing emergencies that adversely affect HIV, TB and malaria programs. Funding under this approach is subject to Board approval, availability of funds and is time-limited, and should not exceed US\$20 million over a three-year period for all countries accessing funding under this approach.⁵ When approving this approach, the Board acknowledged that funding under this approach would not follow traditional Global Fund implementation arrangements and that investments could entail significantly higher levels of risk and lower levels of assurance than standard funding requests.
- 2. To date, the Board has approved three exceptional funding requests for a total of US\$ 17 million to help mitigate the impact of the public health crisis in Venezuela.⁶ Through these investments, life-saving HIV, TB and malaria commodities have been purchased through the Pan-American Health Organization (PAHO) and critical support has been provided to civil society through UNAIDS to ensure social monitoring of Global Fund HIV investments and civil society engagement, as well as support to the Venezuelan Society of Infectious Diseases.⁷
- 3. In line with the Eligibility Policy, Venezuela was made exceptionally eligible for malaria for the 2020-22 allocation period and received an allocation of US\$19.8 million.⁸ Venezuela has also received US\$14.7 million under the COVID-19 Response Mechanism (C19RM) during 2020 and 2021 to support case management, improve diagnostic capacity, provide personal protective equipment (PPE) and strengthen civil society participation in the COVID-19 national response.
- 4. In GF/B43/ER16, the Secretariat noted that the situation in Venezuela would likely require sustained funding unless a change in the economic and political situation materialized.⁹ This change has not materialized and there is a need to ensure the continued availability of antiretrovirals and anti-TB medicines for the people of Venezuela in the near to mid-term. While the intent of the approach to non-eligible countries in crisis was meant to be a short-term emergency response, it continues to remain the only potential source of funding for life-saving HIV and TB commodities for Venezuela at this juncture.



⁵ Funding is initially time-limited to a 12-month period and may be extended by the Board in exceptional cases subject to availability of funds. The Board when approving this approach did not specify a maximum time-limit for investments under this approach but acknowledged that these would be short-term in nature.

⁶ The first exceptional funding request of US\$ 5 million was approved by the Board on 24 September 2018 (<u>GF/B39/ER10</u>, GF/B39/EDP11), second exceptional funding request of US \$ 6 million was approved by the Board on 7 November 2019 (<u>GF/B41/ER10</u>, GF/B41/EDP14) and third exceptional funding request of US \$ 6 million was approved by the Board on 28 October 2020 (<u>GF/B43/ER16</u>, GF/B43/EDP16).

⁷ The first request only provided for the purchase of ARVs, the second request enabled the purchase of ARVs, anti-TB drugs, anti-malarials and a small amount of diagnostics for HIV and TB, and the third allowed for the continued provision of ARVs, anti-TB drugs and a limited amount of diagnostics.

⁸ Clause 11, Revised Global Fund Eligibility Policy allows for partners to recommend exceptional eligibility of a non-eligible country in the event of a significant malaria resurgence due to the use of 2000 data to determine disease burden, this does not exist for HIV or TB as the latest available disease burden data is used".

⁹ Paragraph 7, "The Secretariat anticipates that there will be a need for continued exceptional support from the Global Fund beyond 2021, noting that the current approach does not preclude the Secretariat from requesting additional support for Venezuela."

5. This paper presents the Secretariat's assessment of the current situation and includes updated contextual and epidemiological information, and a brief summary of progress to date. The Strategy Committee was provided with a detailed progress update of the current (and previous) Global Fund investments as well as an update of the Master Plan¹⁰ which was submitted jointly by PAHO, UNAIDS, the Venezuela Society of Infectologists, Acción Ciudadana contra el SIDA (ACCSI) and Red Venezolana de Gente Positiva (RVG+).

Updated contextual and epidemiological information

- 6. This section provides updated contextual and high-level epidemiological (HIV and TB) information that was used to inform the Secretariat's assessment and conclusion. Unless otherwise referenced, the source of epidemiological data is from GF/SC17/18, Annex 2 which was prepared by partners and has not been independently verified by the Secretariat. As the malaria component became eligible for the 2020-2022 allocation period and is implementing a grant, a summary of the epidemiological context for malaria is not provided in this paper, however, GF/SC17/18, Annex 2 provided information as malaria is still part of the overall Master Plan.
- 7. For almost a decade, Venezuela has been experiencing a protracted economic and social crisis which has impacted the delivery of basic services to the Venezuelan people, including the provision of essential health services and commodities (including life-saving HIV, tuberculosis and malaria commodities). The economic outlook continues to remain poor, with a forecasted 10% contraction of national GDP in 2021 and a projected inflation rate of 5500%.¹¹ In 2021, Venezuela had the second-highest national debt-to-GDP ratio in the world, reaching 241.45%.¹² While currently unclassified by the World Bank,¹³ Venezuela's gross domestic product (GDP, US dollars) per inhabitant was reported by the IMF in 2021 as the fourth lowest in Latin America and the Caribbean.¹⁴ The impact on the economic crisis on the Venezuelan people has deepened with the COVID-19 pandemic which has resulted in the cessation of livelihoods, a reduction in remittances from abroad, increased food insecurity and malnutrition.¹⁵ According to data from the Encuesta de Condiciones de Vida (Encovi) (Living Conditions Survey), which is published by a consortium of Venezuelan universities, 94% of Venezuelans were living in poverty and 67% in extreme poverty in 2020, and 93% of households had food insecurity.¹⁶ The economic and political crisis has also resulted in an estimated 5.4 million Venezuelan's seeking refuge in other countries (with 4.6 million residing in neighboring Central and South American countries).¹⁷ A significant number of these



¹⁰ The original 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 <u>GF/B39/ER10</u>. This plan was used to support the three previous requests for exceptional funding (as well as solicit additional donor donations). An updated plan in Spanish has now been articulated for the period of 2022-24 and a courtesy English translation were provided to the SC (not the Board, as stated in a prior version of this report). In the event of inconsistency between the original Spanish version and the courtesy English translation, the Spanish version will control.*

¹¹ <u>https://www.imf.org/en/Countries/VEN</u>

¹² https://worldpopulationreview.com/countries/countries-by-national-debt

¹³ As per the World Bank, Venezuela has been temporarily unclassified in July 2021 pending release of revised national accounts statistics.

¹⁴ Venezuela was ranked above Honduras, Nicaragua and Haiti, who are all classified by the World Bank as lower-middle income countries.

¹⁵ Venezuela was among the 10 worst food crises in 2019, however it was not able to be included in <u>the 2021 Global Report on Food Crises</u> due to insufficient evidence.

¹⁶ <u>https://insoencovi.ucab.edu.ve/indicador-pobreza/</u>

¹⁷ The impact of the COVID-19 pandemic in neighboring countries that are hosting Venezuelan migrants, refugees and asylum seekers has resulted in a number of Venezuelan's returning home. The UN estimates that 151,000 people entered Venezuela from mid-March 2020-early March 2021. Source: <u>Humanitarian Response Plan, Update 2021</u>

refugees, migrants and asylum seekers lack documentation allowing them to stay in host countries, which affects their ability to access basic public services, including healthcare.¹⁸

- 8. The COVID-19 pandemic has resulted in a further weakening of the health system (and diversion of healthcare personnel) and has added to the complex humanitarian crisis that has been affecting the country since 2016.¹⁹ As of 16 November 2021, Venezuela had over 418,900 confirmed cases of COVID-19 and over 5,019deaths.²⁰ These numbers likely represent a fraction of the actual cases within the country, due to low testing rates and possible underreporting of cases.²¹ There continues to be limited testing capacity and availability of vaccines (as of 15 November approximately 32% of Venezuelans had been fully vaccinated against COVID-19²²)²³, as well as insufficient availability of healthcare workers, PPE, safe water and hygiene.²⁴ Stringent measures have been put in place to curb the spread of the pandemic, with Venezuela ranking 75 out 100 (100=strictest) by the Oxford Covid-19 Government Response Tracker as of early November 2021.²⁵ These measures have had a significant impact on the people's daily subsistence, particularly for the large informal sector which has had to defy restrictions in order to ensure basic needs are met²⁶, and has further impeded access to health services, including HIV,TB and malaria treatment and prevention services.
- 9. With a worsening economic outlook and the strong likelihood that the COVID-19 pandemic will continue to accelerate, Venezuela is unlikely to purchase any essential life-saving HIV, TB, or malaria commodities in the short to near term. As of the date of this paper, the government of Venezuela has not made any purchases of HIV, TB or malaria treatment or prevention commodities through the PAHO Strategic Fund since November 2018 nor does it anticipate any purchases in the near (2022) to medium-term (2023). While the eligibility and subsequent allocation and grant for malaria during the 2020-2022 allocation period has alleviated the immediate gaps in the malaria program, there is no viable source of funding to ensure the continued availability of HIV and TB treatment in 2022 and 2023. The HIV and TB response has been funded to a large extent by the Global Fund through the exceptional funding that has been received under the approach to non-eligible countries in crisis.²⁷

²⁴ OCHA Humanitarian Response Plan, 2021 Update

²⁶ https://foreignpolicy.com/2021/07/29/venezuela-vaccines-covid-pandemic-maduro-protest/



¹⁸ <u>https://data2.unhcr.org/es/documents/download/82927</u>

¹⁹ https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(21)00924-7/fulltext

²⁰ WHO Coronavirus Dashboard: <u>https://covid19.who.int/region/amro/country/ve</u>, accessed 16 November 2021.

²¹ https://www.thenewhumanitarian.org/news-feature/2020/06/04/coronavirus-data-Venezuela

²² Our World in Data, <u>https://ourworldindata.org/covid-vaccinations?country=OWID_WRL</u>, accessed 15November 2021.

²³ Venezuela has purchased vaccines from Russia (Sputnik V) and China (Sinopharm) and is one of the self-financing countries in the COVAX Facility and a first shipment of 693,600 doses (out of a total of 12,068,000 doses) of COVID-19 vaccines arrived in September 2021.On 10 October, Venezuela received a second batch of 2.5 million doses of COVID-19 vaccines via the COVAX mechanism. A third batch of an additional 2.5 million doses were received on 13 November.

²⁵ https://www.bsg.ox.ac.uk/research/research-projects/covid-19-government-response-tracker, accessed 15 November 2021.

²⁷ AIDS FOR AIDS, Brazil, Haiti UNFPA, ONUSIDA, UNICEF and PAHO have provided resources to the HIV response either through in-kind donations or purchase of commodities, including but not limited to pediatric ARVs (UNICEF), condoms, rapid HIV and syphilis tests, syphilis treatment, and other ARVs and viral load tests. Additional donor contributions for TB have been minimal, however the Spanish Agency for International Development Cooperation (AECID), USAID and Peru have provided in-kind donations or purchased commodities.

HIV

- 10. According to the latest UNAIDS estimates there were approximately 104,240 people living with HIV (PLHIV) in Venezuela in 2020.²⁸ There were 4,970 new HIV infections (an increase of 918 cases from 2019) in 2020 with the majority (74%) of new cases occurring in men and in the 20 to 49 age group (77%). The latest available official data on AIDS-related deaths indicates 17,551 people died from AIDS during the period of 2010-2017, with an increase in mortality from 2010 (6.35 per 100,000) to 7.85 in 2016). Overall prevalence in 2020 adults in the general population was estimated at 0.53% in 2020, however HIV prevalence in key populations is significantly higher -3.7% in sex workers, 22.3% in men who have sex with men and 35.8% in transgender individuals (for estimated populations of 210,800 men who have sex with men and 15,000 transgender people).
- 11. According to the latest available data, there are 56,038 (54.74% coverage) people²⁹ registered in the National AIDS Program who are actively in care and are receiving ARV treatment, including 1,298 children under 15 years of age³⁰. Of those on treatment, 46,893 (85%) received TLD³¹, however there remains a percentage of the cohort who cannot take TLD.³² In 2020 PAHO supported a study on viral suppression on those people who had started or transitioned to dolutegravir-based regimens. Results of this study indicated high therapeutic effectiveness -97.1% viral suppression after at least 6 months of DTG-based treatment³³.

Tuberculosis

- 12. The COVID-19 pandemic affected the National TB response in 2020 and in the first semester of 2021, resulting in reduced access to diagnostic, treatment and care services. Notification of cases in 2020 represents a decrease of 11% compared to 2019. The response continues to be constrained by a shortage of supplies, a reduction in the number of functional laboratories, difficulties with sample transportation, and lack of human resources. The implementation of rapid molecular tests for the diagnosis of TB is still very nascent. In 2020, only 2% of new cases and 23% of previously treated cases received a testing for the detection of rifampicin resistance.
- 13. According to the latest available WHO data (2019), incidence is estimated at 45/100,000³⁴, however the latest epidemiological information made available by the National TB Program, and provided in Annex 2, reports an incidence of 32/100,000 in 2020 with 9150 new cases (including



²⁸ The Master Plan noted that there were 120,000 PLWHA in 2016. This decrease in number of people coincides with the estimated number of PLWHA (8,000-10,000) that have migrated from Venezuela.

²⁹ Treatment for this cohort has been primarily financed by the Global Fund, with AIDS for AID International, the Government of Brazil, UNICEF (for children) and other technical cooperation agencies providing donations. ³⁰ UNAID Spectrum data estimates that there approximately 3,267 HIV-positive children under the age of 15.

³¹ Tenofovir/lamivudine/dolutegravir

³² Based on updated projections endorsed in November 2019 by PAHO, UNAIDS, Ministry of Health (MOH), Venezuelan Infectious Diseases Society and civil society of PLHIV, it is estimated that 50,500 PLWH are eligible for TLD. Reasons for not being able to take TLD include 1) contraindication for the use of TDF or previous documented failure on a TDF-containing regimen (may use DTG, but with optimized NRTI backbone; 2) adverse effects after initiating a DTG-based regimens (may use a PI-based regimen); 3) previous demonstrated multi-drug resistance and require a third line treatment (noting that in these cases they will need TLD or DTG plus a protease inhibitor e.g. DRV/r. The outcome of the new needs estimate which will occur in September/October is expected to provide further information regarding estimated number of PLWH who need alternative ARV treatment.

³³ More information about the study is available in Annex 2. The study had to be paused due to COVID-19 lockdowns and is expected to resume once lockdown measures are eased, however the majority of the samples from the study have been received and processed. ³⁴ Global Tuberculosis Report 2020

relapses) which represents a significant decrease and illustrates the impact of COVID-19 on an already fragile program. The latest available data estimates that there were 750 deaths from TB in 2019, and 10,293 new TB cases of TB were reported. The most affected age group is 25 to 34 years old with 2,666 (28.6%) of cases, with a predominance of men. Among new cases, the most vulnerable populations are people deprived of liberty (20%), indigenous persons (7%), people with diabetes (4%), and people living with HIV (4%). 55.4% of new cases are concentrated in 6 federal entities (Distrito Capital, Miranda, Carabobo, Zulia Anzoátegui and Bolívar). Treatment coverage has decreased in recent years and, according to preliminary data from WHO, is estimated at 69% for 2020, while treatment success rate is stable at 84%. There were 22 recorded cases of drug-resistant TB in 2020, a decrease from 35 cases in 2019. This is a result of lack of laboratory supplies, personnel, and available laboratories with the capacity to perform smear microscopy. Smear microscopy remains the primary diagnostic method in Venezuela.

Implementation Update

<u>HIV</u>

- 14. This section provides a summary of the implementation of the previous and current exceptional funding requests for Venezuela, and is focused on HIV and TB, noting that no funds for malaria were included in the 3rd exceptional funding request and previous reports have provided information.³⁵ Annex 2 provides a detailed update on the implementation of the Global Fund investments to date.
- 15. Approximately 85% of the funds approved to date have been used to procure ARVs, primarily TLD, as well as other alternative regimens.³⁶ These investments have translated into a rebounding of coverage back 2016 levels (e.g., before the humanitarian crisis) and Venezuela is now one of the leading countries in the region in terms of migration to TLD after Brazil and Haiti. According to national records, as of end December 2020, 46,893 patients were on TLD- 84% of the treatment cohort (56,038 above 10 years old). As of July 2021, a total of 6 ARV distributions to dispensation sites have been made (3 in 2019, 2 in 2020 and 1 in 2021).³⁷ Multi-month dispensation (3 months) is being implemented to adapt to COVID-19 constraints. There is sufficient stock of TLD until June 2022 and December 2022 for alternative ARVs.
- 16. To date US\$300,000 has been provided to UNAIDS to support civil society organizations (Venezuelan Network of Positive People (RVG+), Citizen Action Against AIDS (ACCSI) and NGO Coalition on HIV in the Interior of the Country (COVIP)) to undertake social monitoring of the Global Fund's HIV investments in Venezuela. These organizations have engaged in monitoring and patient follow-up, as well as active searching for and linking of people living with HIV to treatment services. COVID-19 has required these organizations to adapt their approach (including ensuring monitors have adequate personal protective equipment) and, in some cases, monitoring activities



³⁵ A total of US\$ 17 million has approved to date of which US\$15.6 million has been disbursed to PAHO for the procurement of commodities through its Strategic Fund and \$400,000 to UNAIDS to support civil society monitoring and the Venezuelan Society of Infectious Diseases ³⁶ Alternative ARV regimens were procured to ensure treatment options for those adolescents and adults with adverse reactions to TLD,

contraindication to the use of one of the ARVs in the fixed dose combination, or who require rescue treatment due previous multiple drug failures. In addition, 25,000 viral load tests (covering 30% of the estimated needs) were procured in 2020.

³⁷ PAHO, UNAIDS and UNICEF have assumed the costs for private transport of ARVs from the central warehouse to dispensation sites due to lack of government funding.

have not been able to be undertaken. However, despite restrictions, monitors were able to visit 27 HIV clinics and 26 ARV dispensation sites during 2020 and 2021. Through its reporting, civil society has confirmed that the majority of newly diagnosed PLHIV have been prescribed TLD in line with WHO recommendations. It also reports that a total of 9,122 PLHIV were reintegrated into the program in 2020, and between January and April 2021, approximately 4900 PLHIV were reintegrated or started on ART. According to data compiled by civil society, 417 people living with HIV died in 2020. This number is likely to be underreported due to issues related to mortality tracking by the Ministry of Health. Civil society also notes that some HIV-positive persons – including pregnant women and children– received expired ARVs (not funded through the Global Fund donations).

- 17. Under the current investment, US\$ 100,000 has been provided to UNAIDS to support the Venezuelan Society of Infectious Diseases (VSI)³⁸ a non-governmental organization to support a distance education project for the certification and recertification of doctors to treat people living with HIV in Venezuela. As of July 2021, 1,571 individuals were enrolled of which 1,080 were active, and 171 had completed 50% of the program.
- 18. Both projects are administered by the UNAIDS Country office in Venezuela as economic sanctions make it impossible for NGOs to access funds held in foreign accounts. UNAIDS Venezuela continues to conduct advocacy work with health authorities to enable the work of civil society, and as a result, access to pharmacies and information has improved although some limitations continue in specific states. However, the Ministry of Health still does not grant civil society access to the central warehouse where drugs are stored.
- 19. Since the launch of the Master Plan in 2019, approximately US\$ 1.7 million has been donated by UNAIDS, UNFPA, PAHO, USAID and UBRAF. Aid for HIV/AIDS has covered ARV treatment for 7,098 patients since 2019, AHF has provided donations for the prevention of mother-to-child transmission of HIV and syphilis, pediatric ARVs, rapid HIV and syphilis tests, medicines for opportunistic infections, male condoms and milk substitutes, and PAHO has also contributed 3,000 viral load tests. UNICEF's contribution toward pediatrics and vertical transmission prevention totals an additional US\$1.7 million and there is a continued commitment to fund pediatric regimens in 2022. Support to civil society has been provided by ICASO and Open Society Foundations.

<u>TB</u>

20. A total of US\$ 2,030,000 has been provided to date to purchase first and second-line anti-TB drugs and TB diagnostics through the PAHO Strategic Fund. In early 2020, USAID and GDF provided a donation of first-line drugs to cover the gap before the Global Fund funding could be operationalized. TB drugs financed by the Global Fund began arriving in the country at the end of April 2020 and distribution began in July. Thirteen GeneXpert machines have been procured (7 pending delivery) through Global Fund support (including through C19RM). Of the planned Xpert



³⁸ The Venezuelan Society of Infectious Diseases is a non-governmental scientific association made up of specialists in infectious diseases who work in Venezuela. VSI trains and updates medical personnel and plays a broad role in the fight against HIV as its members are the main doctors who care for people with HIV.

MTB/Rif cartridges, 15,500 have been procured 9,500 pending delivery). At mid-2021, there are 5,000 cartridges in the central warehouse and 1,000 in the Carabobo and Caracas NTPs.

- 21. The lack of TB prevention activities and current limitations around diagnosis is problematic. For example, only 42% of TB patients were aware of their HIV status in 2019, significantly below international recommendations.³⁹ The QuantTB tool has been used by PAHO, together with the National TB Program, to increase inventory efficiency and projections and to reduce the risk of losses due to expired drugs. According to partners, there is stock available to cover estimated needs up to the first semester of 2022 for 1st and 2nd line treatment.
- 22. There have been limited donations from other partners to support the TB program. AECID, USAID, Peru have provided targeted support to bridge gaps in drugs and diagnostic equipment. In 2020-2021, new resources were mobilized from AECID and the Hipólito Unanue Agreement to procure essential laboratory supplies.

Secretariat Assessment

23. Based on an assessment of the current economic and epidemiological situation in Venezuela, the Secretariat concludes that an additional funding request merits consideration under the Boardapproved approach to non-eligible countries in crisis. The Secretariat does not anticipate that the economic, social or political situation will improve in the near to mid-term and with low testing and vaccination rates the COVID-19 pandemic is likely to worsen before it improves.

What do we propose to do and why?

- 24. The Secretariat and SC recommend that the Global Fund continue to provide exceptional funding for Venezuela through the Board-approved approach to non-eligible countries in crisis and that an additional US\$ 12 million be approved for a two-year period (2022 and 2023) to ensure the continued availability life-saving HIV and TB commodities and civil society oversight. As malaria is receiving funding through standard Global Fund grant processes, no funding is requested or recommended for malaria. The Secretariat acknowledges that this funding continues to be a gap-filler and represent a small fraction of the overall programmatic needs which significantly outweigh available resources. Additional and continued support from partners to help bridge the gap in essential commodities, either through financial or in-kind contributions, will be imperative for 2022 and 2023.
- 25. As Venezuela has met a first determination of eligibility under the current Eligibility Policy for HIV in 2021 and could be eligible for malaria again in the 2023-25 allocation period⁴⁰, the SC agrees with the Secretariat's recommendation that funding be approved for a two-year rather than a one-year period.⁴¹ A two-year funding period would allow for a bridge between the exceptional funding and any future funding in the 2023-25 allocation period.



³⁹ According to WHO's End TB Strategy: the recommended target for TB patients who know their HIV status is 100%.

⁴⁰ The current eligibility policy allows partners to request a non-eligible country be made exceptionally eligible for malaria based on significant resurgence

⁴¹ This presumes that there will not be significant changes in the eligibility criteria for upper-middle income countries that restricts eligibility.

- 26. The Secretariat notes that according to the latest available data on TB incidence, Venezuela is unlikely to meet the current eligibility thresholds for upper-middle income countries for TB eligibility. Venezuela has not received an income classification by the World Bank this year, and it is possible that when their national accounts are revised that they may move into the lower-middle income bracket (Venezuela has been classified as a UMI since 2016).
- 27. The additional US\$ 12 million would bring the total amount of investment in Venezuela over a five-year period to US\$ 29 million. When the Board approved the approach for non-eligible countries in crisis it recommended that there be a cumulative ceiling of US\$ 20 million over a three-year period. The first three investments were US\$17 million and therefore within the recommended cumulative ceiling. This additional investment for 2022 and 2023 remains within the recommended cumulative ceiling over a three-year period and will ensure the continued availability of antiretrovirals (primarily TLD, as well as some alternative regimens for those patients who cannot take TLD) and anti-TB medicines (1st and 2nd line), as well as provide for a small amount of diagnostics, and ensure continued support for civil society oversight, social monitoring and capacity building. While there are significant needs in diagnostics, testing, medicines for opportunistic infections and prevention, the Secretariat recommends that the Global Fund's investments continue to be focused on life-saving commodities which is in line with the focus of previous investments.
- 28. The Secretariat and SC recommend that US\$ 11,700,000⁴² be provided to PAHO for the procurement of commodities through the PAHO Strategic Fund and US\$ 300,000⁴³ be provided to UNAIDS to support civil society social monitoring, oversight and capacity building in 2022-23. The Secretariat and SC recommend that US\$ 10 million be used to primarily procure antiretrovirals in order to maintain treatment for the existing cohort, as well projected inclusions, through the end of 2023, and that US\$ 2 million be made available to ensure the continued availability of 1st and 2nd line anti-tuberculosis medicines, as well as provide for the purchase of some diagnostics. This recommendation considers existing and projected availability of medicines in the country.
- 29. As with the 2nd and 3rd Exceptional Funding Requests, the Secretariat is requesting flexibility to reprogram the budget to be able to adjust amounts for commodities in line with updated quantification and stock availability, as well as anticipated or new donations, or savings achieved through the procurement process. Disbursements will be made on a yearly basis in line with approved procurement plans and budgets. Any such reprogramming would be subject to approval from the Secretariat.
- 30. The Secretariat recommends continuing the existing implementation arrangements which were approved for the three previous exceptional funding requests and are described in GF/B39/ER10, GF/B41/ER10 and GF/B43/ER16. All HIV and TB drugs and commodities will continue to be



⁴² This amount includes up to US\$ 480,000 for PAHO for the administration of the procurement process. The PAHO Director General has agreed, as with previous requests, to exceptionally waive the standard overhead of 13% in recognition of the unique circumstances in Venezuela. This amount also includes cost associated with the importation, customs clearance and delivery of the commodities procured. The Global Fund expects that the Ministry of Health or other in-country partners will provide transport of commodities to the service delivery points, however in the event that there are no other sources of funds available funds may be made available, subject to agreement with the Secretariat, to ensure the transportation of commodities to service delivery points.

⁴³ Of this amount, it is anticipated that US\$200,000 will be to ensure continued civil society-led social monitoring of the HIV investment and US\$100,000 to continue to support the Venezuelan Society of Infectious Disease Specialists – a non-governmental organization. UNAIDS, as with the two previous investments, will not charge any overhead or direct costs.

directly procured through the PAHO Strategic Fund noting the benefits previously described in GF/B39/ER10, paragraph 35.

- 31. PAHO has permission from the relevant authorities to operate in Venezuela and, as with the three previous investments, will manage the procurement process and support the National HIV and TB programs with the quantification of needs, distribution and the procurement and delivery of commodities to the designated warehouse. All commodities to be procured will consider the latest available stock information, orders in process and anticipated donations.
- 32. As with the three previous investments, PAHO will be responsible for delivery of commodities to the port of entry and will, in coordination with relevant authorities, undertake customs clearance and delivery to the designated warehouse⁴⁴, and the Global Fund will not have recourse against any entity for loss, destruction, or misuse of the commodities once they arrive at the designated warehouse. To date the Secretariat has not been aware of any such issues with commodities procured with Global Fund resources.
- 33. UNAIDS will continue to support and provide technical assistance to Venezuelan civil society in its monitoring and advocacy efforts. While social monitoring of the Global Fund investments is focused on the delivery and distribution of ARVs to people living with HIV in Venezuela, civil society is also providing anecdotal information regarding access to TB diagnosis and treatment and the overall situation in Venezuela.
- 34. Due to the current economic sanctions in place⁴⁵, UNAIDS Venezuela will administer the funds for both projects and will continue to support them to ensure efficient implementation of the activities. Funds will continue to be provided to existing civil society organizations – including, but not limited to, RVG+, ASCCI and COVIP - to support their independent monitoring of the distribution and delivery of ARVs and to the Venezuelan Society of Infectious Diseases to continue capacity building activities.
- 35. The Secretariat is proposing to maintain existing implementation arrangements i.e. direct funding through PAHO and UNAIDS for this fourth exceptional funding request and notes that the principles previously highlighted to the Board with respect to assurance and risk still apply and the SC agrees with this approach.⁴⁶ The standard Global Fund operating model and policies will continue not to apply as this investment will be limited to the procurement and delivery of commodities to port of entry, customs clearance and delivery to the designated warehouse and downstream monitoring activities. In the event Global Fund resources are required to facilitate the delivery of commodities to service delivery points, responsibility will end there. Further distribution



⁴⁴ The Strategic Fund's responsibility normally stops at the port of entry when commodities are procured with national funds. As with previous investments, commodities will be delivered according to CIP ("Carriage and Insurance Paid to") Incoterms.

⁴⁵ Current sanctions in place make it difficult for NGOs to access money held in foreign bank accounts.

⁴⁶ 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]implementation 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 would likely contemplate non-traditional implementation arrangements and a higher level of risk acceptance.

of commodities to intended beneficiaries will continue to be the responsibility of the Venezuelan Ministry of Health (and the relevant national programs) who will not have a formal or binding obligation to the Global Fund to complete this distribution.

- 36. As with previous investments, this investment comes with attendant risks which should be considered explicitly by the Board. The main risk, as with the previous investments, with the proposed implementation arrangements is that commodities may be diverted and not delivered to intended beneficiaries. While there were some delays with the delivery of ARVs under the first exceptional investment, delays in 2020 and 2021 were related to the supply chain and transport disruptions associated with the COVID-19 pandemic. The previous in-country challenges (*e.g.* chronic fuel shortages, power outages, lack of transportation and lack of healthcare providers, limited access to health services) continue to remain and have been further exacerbated by COVID-19. At this time the Secretariat has no information that would indicate that the commodities that have been procured with Global Fund resources have been diverted or sold on the black market.
- 37. Annex 4 to this paper describes variations between the proposed arrangements and the Standard Global Fund model, as well as the related risks and where applicable related mitigation measures. There has been no substantive change compared to the variations report in GF/B39/ER10, GF/B41/ER10, and GF/B43/ER16.
- 38. As there is no dedicated source of funds for non-eligible countries in crisis, the Secretariat must identify a source for any investment in Venezuela under this approach. The source identified is funds the Audit & Finance Committee (AFC) made available at its 17th meeting for portfolio optimization (PO) for the 2020-2022 allocation period in line with the Strategy Committee approved prioritization framework. The Secretariat and SC agree with the use of these funds for Venezuela and has weighed the trade-offs of further investing in eligible countries with UQD against providing additional support for Venezuela (HIV and TB).

Why is this our recommended option?

- 39. The overall situation in Venezuela has continued to deteriorate in 2021 and has worsened due to the COVID-19 pandemic. An absence of additional funding for the procurement of ARVs and anti-TB drugs would likely result in the cessation or discontinuation of life-saving treatment and an increase in HIV and TB mortality. The government has not committed to financing ARVs or anti-TB drugs and is unlikely to do so in the near to mid-term and the Global Fund is the sole funder of TLD and anti-TB drugs. While donations from partners and civil society have alleviated some of the gaps in essential commodities (including prevention), they are complementary to the financing that has been provided by the Global Fund and not duplicative. The Secretariat and the SC consider not requesting additional funding not to be a viable option at this juncture.
- 40. The rationale for requesting two-years of funding has been described above and would alleviate a significant amount of work by all stakeholders and allow focus on implementation and fundraising to meet remaining gaps. The Secretariat will continue to monitor this investment and should any

S THE GLOBAL FUND

information regarding misuse or deviation of resources come to light the Secretariat will update the SC on mitigation and remedial actions.

- 41. In terms of implementation arrangements direct funding through PAHO and UNAIDS the Secretariat and SC continue to feel that these are the most effective and most likely to deliver the expected outcomes in a rapid and efficient way. Both organizations have in-country presence, established relationships with both government counterparts and civil society as well as other in-country partners, and the capacity to provide oversight of the investment. Civil society continues to be supported by international civil society organizations, such as ICASO, which will help ensure local Venezuelan civil society will have sufficient support to undertake social monitoring, even though adaptations may be required to account for the evolving context in country.
- 42. The Secretariat and SC have again carefully considered the risks associated with this investment, including the limitations described in this paper and in previous papers, and the Board is requested to consider these as it considers its approval of this request.
- 43. A longer-term solution for Venezuela will continue to be dependent on an improvement in the economic and political situation and the ability and willingness of the government of Venezuela to provide for the health of its people. This fourth exceptional request of US\$ 12 million will only ensure the continuity of HIV and TB treatment over 2022-2023 and the gaps in essential commodities will remain. The Secretariat will continue to work with partners and civil society to advocate for additional investment and donations to help alleviate the gaps.
- 44. The Secretariat 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 and overall context, and other relevant factors outline by the Secretariat in this paper, the OIG has reaffirmed that it 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 decision point for recommendation to the Board.

What options did we consider?

What are the options?

- 45. The Secretariat and SC considered three options. The first option was to request one additional year of funding for 2022 under the non-eligible countries in crisis approach. The second option (preferred option) was to request two additional years of funding for 2022-2023 in light of the likely eligibility of HIV and the possibility to request malaria remain eligible for the 2023-25 allocation cycle. The third option was not to request additional funding, which would likely result in stock-outs of life-saving HIV and TB treatments and which the Secretariat and SC therefore do not consider a feasible option.
- 46. The Secretariat and SC consider requesting two years of additional exceptional funding to be the preferred option in light of the fact that three previous funding requests have been approved and implemented without significant issues, the likely eligibility of HIV and malaria for the 2023-25 allocation cycle, and the significant transaction costs for in-country stakeholders, partners Secretariat and SC and Board in approving yearly requests.



What do we need to do next to progress?

What is required to progress the proposal?

- 47. In line with the Board-approved approach to non-eligible countries in crisis, the Board is requested to approve an additional investment of US\$ 12 million for Venezuela in 2022 -2023 under the approach to non-eligible countries in crisis in order to ensure the continuity of life-saving HIV and TB treatment.
- 48. A decision to delay approval could result in stock-outs of ARVs (depending on the length of the delay) and stock-outs of anti-TB drugs and affect the health of the Venezuelan people.

Recommendation

The Secretariat and the Strategy Committee recommend the Decision Point presented on page 2 to the Board for approval.



Annexes

The following items can be found in Annex:

- Annex 1: Terms of Investment in Venezuela
- Annex 2: Variations between proposed implementation arrangements and the Standard Global Fund Operating Model
- Annex 3: Relevant Past Board Decisions
- Annex 4: Links to Relevant Past Documents & Reference Materials



Annex 1 – Terms of the Investment in Venezuela

- 1. Amount: US\$ 12,000,000 (total)
- 2. Duration: two years
- 3. Funding recipients: PAHO (US\$ 11,700,000); UNAIDS (US\$ 300,000)
- 4. Activities to be funded:
 - a. <u>PAHO</u>:
 - 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).
 - 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 Two-Year Budget:

Area	Amount	
HIV &TB commodities (to be procured through the Strategic Fund)	US\$ 11,200,000	
PAHO costs ⁴⁷	US\$ 480,000	
Support for civil society monitoring, oversight and capacity building (through UNAIDS)	US\$ 300,000	
Total	US\$ 12,000,000	

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

S THE GLOBAL FUND

⁴⁷ 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%. The actual amount will depend on the total value of the actual procured commodities.

6. 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. ⁴⁸
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.

⁴⁸ Approved under GF/B31/DP11.

Annex 2 – Variations between proposed implementation arrangements 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,	 Other than up to USD 240,000 for PAHO's costs, the PAHO contribution will only be used for the procurement and delivery of

\mathfrak{S} the global fund

	including as required under the Charter of the Office of the Inspector General. ⁴⁹ 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 but will ensure Global Fund access to the books and records of any contracted civil society organizations receiving Global Fund funds.	 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 UNAIDS's responsibilities. 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.

⁴⁹ Approved under GF/B31/DP11.

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 (<i>e.g.</i> , 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 in- country 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. A progress update and an updated Master Plan for 2022-2024 has been prepared to 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 3 – Relevant Past Board Decisions

Relevant past Decision Point	Summary and Impact
GF/SC17/DP05: Recommendation of Additional Funding to Address the Health Crisis in Venezuela in 2022 and 2023	The Strategy Committee unanimously decided to recommend to the Board for approval a fourth exceptional funding request for Venezuela for US\$ 12,000,000 to provide life-saving HIV and TB commodities and support civil society oversight during 2022 and 2023, using the same implementation arrangements outlined in GF/B39/ER10 and GF/B41/ER10.
GF/B43/EDP16: Approval of Additional Funding to Address the Health Crisis in Venezuela ⁵⁰	The Board approved an additional USD 6,000,000 in exceptional funding for Venezuela for the procurement of commodities for HIV and TB and civil society social monitoring. The Board acknowledged the unique risks entailed by the proposed implementation and management arrangements, outlined in GF/B39/ER10 and GF/B41/ER10.
GF/SC14/DP02: Recommendation of Additional Funding to Address the Health Crisis in Venezuela	The Strategy Committee unanimously decided to recommend to the Board for approval a third exceptional funding request for Venezuela for US\$ 6,000,000 to provide life-saving HIV and TB commodities and support civil society oversight using the same implementation arrangements outlined in GF/B39/ER10 and GF/B41/ER10.
GF/B41/EDP14: Approval of Additional Funding to Address the Health Crisis in Venezuela ⁵¹	The Board approved USD 6,000,000 in exceptional funding for Venezuela for the procurement of commodities for HIV, TB and malaria and civil society social monitoring. The Board acknowledged the unique risks entailed by the proposed implementation and management arrangements, outlined in GF/B39/ER10.
GF/B41/EDP06: Eligibility of Venezuela's Malaria Component for the 2020-2022 Allocation Period (August 2019)	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.

⁵⁰ https://www.theglobalfund.org/board-decisions/b43-edp16/
 ⁵¹ https://www.theglobalfund.org/board-decisions/b41-edp14/

\mathfrak{S} the global fund

GF/B39/DP11: Approval of Funding to Address the Health Crisis in Venezuela (September 2018) ⁵²	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) ⁵³	The Board acknowledged that a health crisis of significant magnitude may occur in a noneligible 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/B39/03- Revision 1 to the Strategy Committee for recommendation to the Board.
GF/B37/DP11: Health Situation in Venezuela (May 2017) ⁵⁴	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 ⁵⁵ GF/B31/DP11 (March/2014): Revision to the OIG Disclosure Policy and the OIG Charter ⁵⁶	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. 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 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,

⁵² https://www.theglobalfund.org/board-decisions/b39-edp11/ ⁵³ https://www.theglobalfund.org/board-decisions/b39-dp04/ ⁵⁴ https://www.theglobalfund.org/board-decisions/b37-dp11/ ⁵⁵ https://www.theglobalfund.org/board-decisions/b37-dp11/

⁵⁵ https://www.theglobalfund.org/board-decisions/b28-edp16/
 ⁵⁶ https://www.theglobalfund.org/board-decisions/b31-dp11/

${\boldsymbol{\varsigma}}$ the global fund

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 4 – Relevant Past Documents & Reference Materials

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

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

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

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

GF/B41/ER10: Second Exceptional Funding Request to Address the Health Crisis in Venezuela

GF/B43/ER16 - Third Exceptional Funding Request to Address the Health Crisis in Venezuela

