Third Exceptional Funding Request to Address the Health Crisis in Venezuela

Electronic Report to the Board

GF/B43/ER16

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 to the Board the Strategy Committee's recommendation on the third exceptional funding request to respond to the continued health and economic crisis in Venezuela. Venezuela continues to remain ineligible for financing for HIV and TB and has exceptionally received a malaria allocation for the 2020-2022 allocation period (GF/B41/ER04).

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Decision

<u>Electronic Decision Point: GF/B43/EDP16 Approval of Additional Funding to Address the Health Crisis in Venezuela</u>

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 in 2021 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/B44/ER16 and Annex 1;
- 4. Accepts that the proposed implementation and management arrangements continue to entail unique risks, as described in GF/B44/ER16 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/B44/ER16 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 US\$ 6,000,000, for the year 2021, to support the procurement of critical HIV & TB 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: US\$ 6,000,000, funded through available sources of funds identified</u> by the Audit and Finance Committee under GF/AFC12/DP01.

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 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
- To date the Global Fund has approved two exceptional funding requests for Venezuela², under this approach for a total of US\$11 million. Through these two requests, the Global Fund has been able to support the procurement of life-saving HIV, TB and malaria commodities and support civil society oversight.
- The crisis in Venezuela has continued to deteriorate in the last twelve months and has severely impacted health and community systems. The economic crisis has been exacerbated by COVID-19, leading to increased poverty, loss of livelihoods, and the collapse of health and social welfare systems. As highlighted in the Humanitarian Response Plan for Venezuela, the health system has been weakened by emigration of healthcare workers, supply shortages of medicines and other health products, damaged infrastructure with reduced maintenance, and interruptions in the supply of electricity, water and gasoline. The spiraling economic crisis and the weaknesses of the health system have a disproportionate impact on the most vulnerable populations, including people affected by HIV, TB and malaria.
- The Secretariat calls 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.

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 proposal recommends an additional US\$ 6 million be provided to Venezuela in line with the Board-approved approach for non-eligible countries in crisis to ensure the availability of life-saving HIV and TB treatment. The rationale for this recommendation is that Venezuela continues to be affected by a protracted economic crisis that severely impacts the population's ability to access basic healthcare, including HIV, TB and malaria services. Currently, the Global Fund is the primary source of funding for ARVs in the country which has ensured that almost

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

² Venezuela has never been eligible for Global Fund financing for HIV and TB. In 2019, Venezuela was made exceptionally eligible for malaria for the 2020-2022 allocation period (GF/B41/ER04) due to the significant resurgence in malaria.

45,000 people living with HIV are on treatment and, since April 2020, is the sole funder of antituberculosis medicines. With the continued economic downturn, which is further exacerbated by the COVID-19 pandemic and economic sanctions in place, it is highly unlikely that the government of Venezuela will purchase any HIV, TB or malaria commodities in 2021. An absence of additional funding would result in stock-outs of lifesaving HIV and TB medicines and likely result in a significant increase in mortality for people living with HIV and people with tuberculosis. The Secretariat recommends that an additional US\$ 6 million be made available to procure essential HIV and TB medicines (including ARVs, 1st and 2nd line TB drugs), as well as some essential HIV and TB diagnostics in 2021. The Secretariat does not recommend including funds for malaria in this request as Venezuela was made exceptionally eligible for malaria during the 2020-2022 allocation period, receiving an allocation of US\$19.8 million. Should the Board subsequently approve this investment, this would bring the Global Fund's total exceptional funding for Venezuela to US\$ 17 million over a three-year period, which is within the ceiling of US\$ 20 million for three-years.

- B. Based on the results of the current investment, the Secretariat considers that it is necessary to request additional funding for 2021in light of the moral responsibility to continue to ensure the availability of HIV and TB treatment for the Venezuelan people.
- C. As with the current investment, this third exceptional funding request represents a short-term humanitarian response to assist the people of Venezuela in meeting high priority health needs for HIV and TB. 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/B43/EDP16: Approval of Additional Funding to Address the Health Crisis in Venezuela, noting the considerations of the Strategy Committee leading to this recommendation, as outlined under "Input Received", below.

Input Received

- In reaching its recommendation to the Board, the Strategy Committee considered the proposed investment case, and was 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 Strategy Committee reviewed this request, the following questions were shared by the Secretariat to guide deliberations:
 - → Does the Strategy Committee agree with the 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?
 - → Does the Strategy Committee agree that the proposed additional investment of US\$ 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 non-eligible countries in crisis?

- → Does the Strategy Committee agree to use the proposed source of funds for this purpose, recognizing the trade-offs against other possible uses of those funds, including scale up in eligible countries?
- → Does the Strategy Committee agree that the implementation and assurance arrangements are consistent with the intent of the investment and to accept the risks inherent in these arrangements considering the expected strategic value of the investment?
- The Secretariat has received input from the Pan American Health Organization (PAHO),
 UNAIDS, UNICEF 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 third request as for the previous two 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 has also consulted with the HIV and TB Situation rooms on the proposed prioritization of resources.

Report

What is the need or opportunity?

- 1. For the last 7 years, 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). In 2019, Venezuela was ranked 176 out 195 countries by the Global Health Security (GHS) Index³ in terms of overall global health security capabilities. The already weakened health system is now grappling with a rising COVID-19 epidemic. As of 12⁴ October 2020, according to the John Hopkins Coronavirus dashboard, Venezuela had over 83,000 cumulative cases and over 690 deaths.⁵ These numbers are likely underreported and have added even more strain to the already severely weakened and fragile healthcare system. As of September 2020, there were an estimated 5.1 million Venezuelan refugees, migrants and asylum seekers who have sought refuge in other countries (primarily neighboring Central and South American countries.⁶ Some of these migrants have returned to Venezuela in recent months as a result of the COVID-19 crisis in neighboring countries.
- 2. In May 2018 the Board approved the approach to non-eligible countries in crisis⁷, which enables the Secretariat to request exceptional funding for non-eligible countries facing emergencies that adversely affect HIV, TB and malaria programs. Exceptional funding under this approach is time-limited to an initial 12-month period and may be extended in exceptional cases subject to Board approval and availability of funds. Under this approach, the Board recommended that the total amount of funds made available does not exceed US\$ 20 million over a three-year period for all countries who may access funding under this approach. As there is no dedicated source of funding for non-eligible countries, the Secretariat is required to identify a source of available funds for such investments.
- 3. When approving the non-eligible countries in crisis approach, the Board acknowledged that funding requests resulting from this approach would not follow traditional Global Fund implementation arrangements and that investments under this approach would entail significantly higher levels of risk and lower levels of assurance than standard funding requests.
- 4. To date, the Board has approved two exceptional funding requests for a total of US\$ 11 million to help mitigate the impact of the public health crisis in Venezuela.⁸ Through these investments, life-saving HIV, TB and malaria commodities have been purchased through the Pan-American

³ The Global Health Security Index "is the first comprehensive assessment and benchmarking of health security and related capabilities across the 195 countries that make up the States Parties to the International Health Regulations (IHR [2005])." The report summarizes a country's capacity across 6 areas (prevent, detect, respond, health, norms and risk). Source: https://www.ghsindex.org/about/

⁵ https://coronavirus.jhu.edu/map.html, accessed 12 October 2020

⁶ https://data2.unhcr.org/en/situations/platform , last updated 5 September 2020

⁷ GF/B19/03-Revision 1

⁸ 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) and the 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).

- Health Organization (PAHO) and critical support has been provided to civil society through UNAIDS to ensure social monitoring of Global Fund investments and civil society engagement.⁹
- 5. This paper presents updated economic and epidemiological information and an update of the implementation of the previous investments, and requests that the Board approve an additional investment of US\$ 6 million for 2021 which will help ensure the availability of life-saving HIV and TB medicines as well as essential diagnostics. Funding for malaria has not been included in this request, noting that Venezuela was made exceptionally eligible for a malaria allocation in the 2020-2022 allocation period, for which it received an allocation of US\$ 19.8 million.¹⁰
- 6. This paper is supported by a progress update on the implementation of the Master Plan¹¹ that has been prepared by PAHO, UNAIDS and UNICEF (Annex 2). This update provides updated epidemiological information, progress related to the Global Fund donation and is complemented by updated resource needs for HIV and TB for 2021.¹² Venezuelan Civil Society has prepared a report which provides a progress update on access to HIV care and treatment for the period of January July 2020 which is provided as Annex 3.
- 7. As with previous years, the needs to ensure functional HIV, TB and malaria programs continue to significantly outweigh resources. The need for additional and continued support from partners to help bridge the gap in essential commodities either through financial or in-kind contributions remains critical for 2021. 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.¹³

Updated Contextual Information¹⁴

Economic Situation

8. Venezuela's economic crisis has continued to deepen in 2020 and for the 7th year in a row its economy is expected to contract and, in 2020 UNDP forecasts a further 14-28% contraction of the nation's GDP.¹⁵ The country has the second-highest national debt-to-GDP ratio in the world, reaching 214% in 2020¹⁶. The economic outlook for Venezuela continues to remain poor with

⁹ The first request only provided for the purchase of ARVs, while the second request enabled the purchase of ARVs, anti-TB drugs, anti-malarials and a small amount of diagnostics for HIV and TB.

¹⁰ The Board exceptionally agreed to make Venezuela eligible for malaria for the 2020-2022 allocation period based on the sustained increase in malaria cases since 2015 (GF/B41/ER04) in line with the Global Fund eligibility policy provisions (GF/B39/02) which allows for partners to recommend a non-eligible (non-high income country) be eligible for a malaria allocation based on a significant disease resurgence.

¹¹ The Master Plan ("Plan Maestro para el fortalecimiento de la respuesta al VIH, la tuberculosis y la malaria en la República Bolivariana Venezuela desde una perspectiva de salud pública") was included as Annex https://www.theglobalfund.org/media/7840/bm39 edp11 report en.pdf This plan presented a prioritized list of essential interventions that are needed over a three-year period. This plan has been used to support the Global Fund request as well as solicit additional donations. 12 As Venezuela has received a malaria allocation for the 2020-2022 allocation period, 2021 needs for malaria are not presented in this request. However, based on the Funding Request that was submitted, the estimated needs for malaria for 2021-2023 were US\$ 44.5 million.

¹³ The 2021 review of eligibility will also look at the approach for non-eligible countries in crises.

¹⁴ Unless otherwise referenced, the source of epidemiological data is from Annex 2 which has been prepared by partners and has not been independently verified by the Secretariat.

https://www.latinamerica.undp.org/content/rblac/en/home/library/crisis_prevention_and_recovery/el-impacto-economico-del-covid-19-en-venezuela--la-urgencia-del-.html

¹⁶ https://worldpopulationreview.com/countries/countries-by-national-debt

the inflation rate in 2020 projected to be 15,000%.¹⁷ Oil continues to be Venezuela's main source of income representing over 95% of Venezuela's exports.¹⁸ Stringent economic and financial sanctions and a concomitant global collapse in the fuel market have led to plummeting oil prices in 2020. UNDP predicts a 48-83% reduction in oil revenue in 2020 compared to 2019¹⁹.

- 9. According to the 2019-2020 *Encuesta de Condiciones de Vida* (Encovi) (Living Conditions Survey), which is published by a consortium of Venezuelan universities, 96% of Venezuelans were living in poverty and 79% in extreme poverty, meaning that 8 out of 10 Venezuelan households are unable to buy enough food. Over 600,000 children under 5 are chronically malnourished²⁰. Results of a food security assessment by the World Food Programme undertaken in 2019, estimated that one out of three Venezuelans (32.3%) was food insecure and in need of assistance.²¹
- 10. The appointment of the Humanitarian Coordinator for Venezuela and the development of the Humanitarian Response Plan (HRP) have improved the coordination of the in-country humanitarian response. Under the HRP, UN agencies in the country and region are collaborating with international NGOs and in-country partners to scale up the provision of humanitarian assistance. The Humanitarian Coordinator oversees the Humanitarian Country Team (HCT) and eight thematic clusters. The health cluster is coordinated by PAHO and combines the efforts of 24 in-country partners to mitigate the impact of the crisis on the population's health. While Venezuela is not classified as a Grade 2 or 3 emergency by WHO, nor a Level 3 emergency by the Inter-Agency Standing Committee (IASC), it continues to be managed as an administrative emergency by WHO/PAHO.
- 11. As of September 2020, 5.1 million Venezuelan refugees, migrants and asylum seekers have sought shelter in other countries. Most (4.3 million) Venezuelans fleeing the country have emigrated to neighboring countries in Southern and Central America²². The UN has set up the Regional Inter-Agency Coordination Platform for Venezuelan migrants and refugees to strengthen coordination between UN agencies and humanitarian organizations working with refugees and migrants from the country. The effects of the COVID-19 on neighboring countries has resulted in some migrants returning to Venezuela. According to OCHA, between April and July 2020, 72,517 migrants have returned to Venezuela.

Epidemiological Context

12. Like much of the rest of Latin America, Venezuela is currently experiencing sustained community transmission of COVID-19. With the Venezuelan Health Ministry decision to stop publishing epidemiological bulletins at the end of 2016, there is limited official information regarding health in the country, including the actual number of COVID-19 cases. As of 12

¹⁷ Source: IMF World Economic Outlook April 2020, https://www.imf.org/en/Countries/VEN. 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 percentage change in the average CPI.

¹⁸ https://www.focus-economics.com/countries/venezuela

¹⁹ https://www.latinamerica.undp.org/content/rblac/en/home/library/crisis_prevention_and_recovery/el-impacto-economico-del-covid-19-en-venezuela--la-urgencia-del-.html

²⁰ https://www.proyectoencovi.com/informe-interactivo-2019

²¹https://reliefweb.int/sites/reliefweb.int/files/resources/Main%20Findings%20WFP%20Food%20Security%20Assessment%20in%20Venezuela_January%202020-2.pdf

https://data2.unhcr.org/en/situations/platform

October 2020, according to the John Hopkins Coronavirus Dashboard, Venezuela had 83,000 cumulative cases and over 690 deaths. A nationwide quarantine first imposed in March 2020 resulted in further economic shock beyond forecasts. Loss of income for firms and households alike has caused declines in both supply and demand. A major reduction in remittances, a key source of income for Venezuelan households, has further constrained Venezuelans' ability to purchase basic goods. The fiscal measures taken by high-income countries and China to stabilize the economy are not feasible in Venezuela, as the use of limited domestic resources is predicted to only further aggravate the hyperinflation and depreciation of the Bolivar²³. An effective COVID-19 response in Venezuela is reliant on the availability of foreign currency and external financing. Further, since 60% of the economically active population operates in the informal sector²⁴, many people would not be reached by financial policies, lack health insurance and cannot continue to earn an income during quarantine.

- 13. Access to health services, which was already challenging due to the overall context, has been further impacted by the pandemic. The arrival of COVID-19 has resulted in further adjustments to the availability of health services (hospitals, clinics, pharmacies), including those for HIV, TB, and malaria. The already stretched health care system has been focused on treating COVID-19. This is further impacted by chronic shortages of drugs, clinical supplies and equipment, including personal protective equipment (PPE) for health workers. For example, COVID-19 outbreaks in three pharmacies and three HIV clinics in Caracas resulted in the infection of at least six health personnel and a temporary closure that affected the provision of services to more than 5,000 people with HIV. To support Venezuela, US\$ 1,972,680 was made available under the Global Fund's COVID-19 Response Mechanism (C19RM), which was complemented by the reprogramming of US\$ 7,320 in savings under the 2nd Exceptional Funding Request.
- 14. The government of Venezuela has not made any purchase of HIV, TB, malaria treatment, monitoring and prevention commodities through the PAHO Strategic Fund in 2020 nor, based on information available from partners, has budgeted funds for the purchase of HIV, TB, malaria medicines in 2020 nor 2021.

<u>HIV</u>

15. The overall national AIDS response continued to deteriorate in 2020 with COVID-19 exacerbating the strain on the health systems and further constraining overall access to health services. A 46% decrease in hospitalization was reported for people living with HIV. UNAIDS estimates that there were 110,000 people living with HIV in Venezuela in 2019.²⁵ There were 4,052 new HIV infections in 2019, noting that limited availability of HIV testing has significantly impacted the program's ability to diagnose new infections. 2,365 AIDS-related deaths were recorded in 2015. Overall prevalence in adults in the general population was estimated at 0,61% in 2019. Two prevalence studies carried out in 2019 indicate HIV prevalence of 3.7% in sex

²³ https://www.latinamerica.undp.org/content/rblac/en/home/library/crisis_prevention_and_recovery/el-impacto-economico-del-covid-19-en-venezuela--la-urgencia-del-.html

²⁴ https://www.bancaynegocios.com/expertos-conozca-por-que-el-desempleo-se-puede-ubicar-sobre-40-en-2019/

²⁵ 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.

- 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).
- 16. According to the latest available data, there are 44,912 people²⁶ registered in the National AIDS Program who are actively in care and are receiving ARV treatment, including 1,064 children under 14 years of age. Of those on treatment 91% (41,125) received TLD²⁷, however there remains an estimated percentage of the cohort who cannot take TLD.²⁸ In 2019 PAHO supported a study on viral suppression on those people who had started or transitioned to dolutegravir-based regimens. Preliminary results of this study indicated high therapeutic effectiveness -97.1% viral suppression after at least 6 months of DTG-based treatment²⁹.
- 17. The Global Fund continues to remain the main source of funding for treatment. UNICEF, UNFPA, UNAIDS and Aids Healthcare Foundation (AHF) have donated HIV and syphilis rapid tests. AID for AIDS has donated medicines for opportunistic infections medicines and alternative ARVs, male condoms and milk substitutes. Female and male contraception has been donated by UNFPA and AHF. These donations while important are insufficient to cover the needs and significant gaps in the national program remain, including limited to no availability of medicines for opportunistic infections.

<u>Tuberculosis</u>

- 18. In 2020, the national TB response has further deteriorated, as evidenced by the significant drop in reported cases in 2020. The response is constrained by a shortage of supplies, a reduction in the number of functional laboratories, difficulties with sample transportation, and a reduction in the availability of GeneXpert MTB/RIF tests.
- 19. According to the 2019 World Tuberculosis Report, incidence was estimated at 48/100,000³⁰, however the latest epidemiological information made available by the National TB Program, and provided in Annex 2, reports an incidence of 38.1/100,000 in 2019.³¹ Similarly latest available data estimates that there were 970 deaths from TB in 2019, and 10,293 new cases of TB were reported. More than half of the cases of TB were concentrated in the Capital District and four other states. In the first three months of 2020, 2,064 cases of TB were reported corresponding to 20% less than the same period in 2019. Persons deprived of liberty, malnourished people and indigenous populations were the most affected populations. In 2019, treatment coverage (measured as the ratio of notified cases to estimated incidence) was 80% and treatment success

²⁶ 44,912 corresponds to 41% treatment coverage of the estimated co-hort of PLWH. 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.

²⁷ Tenofovir/lamivudine/dolutegravir

²⁸ 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.

²⁹ 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.

30 https://apps.who.int/iris/bitstream/handle/10665/329368/9789241565714-eng.pdf?ua=1, page 279

³¹ The 2019 World Tuberculosis Report estimated incidence at 48/100,000 based on 2018 data.

rate was 84%, stable compared to the previous year. There were 35 recorded cases of drugresistant TB in 2019, a decrease from 81 cases in 2017, which is a reflection of limited diagnostic capacity in the country.

- 20. In 2019 it was noted that existing stocks were insufficient to bridge the gap for the period when drugs financed by the Global Fund would realistically arrive in country.³² Donations from the Spanish Agency for International Development (AECID) and USAID/GDF helped bridge the gap, however there were stock-outs of 1st line drugs from March to June 2020 which resulted in a significant number of people diagnosed with TB failing to receive treatment. These stock-outs were due to delays in the arrival of medicines in country, related to COVID-19-mediated disruption of the global supply chain.
- 21. There remains limited diagnostic capacity in country. There are currently two GeneXpert machines in Venezuela and another four which have been financed under C19RM are expected to arrive in the country in the coming weeks, together with cartridges. These additional machines will most likely be utilized for COVID-19 testing initially. The C19RM request included some sputum-smear kits for diagnosing TB, however these are insufficient to cover the needs through 2021. In the short-term, the main method for diagnosing and confirming TB is likely to remain via sputum-smear microscopy and there is a need to ensure sufficient diagnostics to ensure people are timely diagnosed and treated.

Malaria

- 22. Although the Venezuelan government has not publicly reported epidemiological data since the end of 2016, there has been a sustained increase in malaria cases since 2015, with 404,924 confirmed cases of malaria in 2018 more than 50% of the total reported cases for the Americas region. Amazonas, Bolivar, and Sucre states have the highest rates of malaria in the country. High levels of population movement within and outside the country increase the risk of transmission both within the country as well as to neighboring countries.
- 23. The national malaria program's ability to effectively implement effective actions to reduce malaria continues to be affected by the overall situation in the country a continued lack of financial and operational resources. In 2019, Venezuela reported 398,285 confirmed cases of malaria, concentrated in five high disease burden states with spillover to neighboring countries due to the movement of migrants and asylum seekers. By Week 29 of 2020, 108,934 cases of malaria³³ had been reported, a 55.6% decrease compared to the same period in 2019. In the same period, 25 malaria deaths were reported (representing a 70% reduction) The main factors accounting for these reductions relate to transport restrictions to endemic areas, fuel shortages and more recently the COVID-19 pandemic. These restrictions are also may be affecting access to diagnosis and treatment and reporting in the short-term.
- 24. In 2020, Venezuela's malaria response has received support from AECID and PAHO for the purchase of treatment commodities. Médecins Sans Frontières (MSF) has provided mosquito nets, rapid tests, drugs, diagnostic equipment and supplies and logistical support in the

³² GF/B41/ER10, paragraph 21

³³ The majority cases concentrated in two states Bolívar (60.7%) and Sucre (16.6%).

municipality of Sifontes and the International Committee of the Red Cross (ICRC) has provided support for the municipality of El Callao. Although this support has been effective in addressing the emergency, it is still insufficient to cover the needs. The 2020-2022 allocation of US\$19.8 million is expected to cover a significant portion of the needs over the next three years but gaps will remain.

Update on implementation of the Second Exceptional Funding Request

- 25. The Board approved the second exceptional funding request of US\$ 6 million for Venezuela in November 2019.³⁴ The information below is the latest available information as of 17 August 2020, however due to COVID-19 related restrictions some of the information is only available through June 2020. More detailed information is available in Annexes 2 and 3 and below is a summary from these reports.
- 26. As with the first exceptional request, the second investment is being implemented through PAHO (US\$ 5.85 million to purchase commodities for HIV, TB and malaria through the PAHO Strategic Fund) and UNAIDS (US\$150,000 to support Venezuelan civil society in social monitoring and oversight activities, including support to the Venezuelan Society of Infectious Diseases). The Secretariat has disbursed the entirety of the funds to PAHO and UNAIDS.
- 27. Through the PAHO Strategic Fund, ARVs (primarily TLD, as well as other alternative regimens³⁵) and 25,000 viral load tests (covering 30% of estimated needs) have been procured. Alternative regimens and viral load tests were able to be procured within the ceiling of funds that were made available for HIV (US\$ 4.82 million) with confirmation from UNICEF that they would be able to support pediatric ARV regimens for 2020. The decision to purchase alternative regimens as well as a limited number of viral load tests was made in consultation with HIV partners.³⁶ Production delays and the subsequent COVID-19 related restrictions resulted in delays of the delivery of alternative ARVs which began arriving in July 2020. According to National AIDS Program records, of the 44,912 persons who collected ARVs in June 2020, 41,125 collected TLD or 91% of people on ARVs.³⁷ Due to the lack of funds, PAHO, UNAIDS and UNICEF have assumed the costs for private transport of ARVs from the central warehouse to dispensation sites. The first distribution of ARVs in 2020 to the 44 pharmacies in the public health system occurred in April 2020, noting that the lack of gasoline resulted in a delay in distribution.
- 28. As with the first exceptional request, funding (US\$100,000) was 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

³⁴ GF/B41/ER10

³⁵ 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.

³⁶ The Secretariat consulted with HIV Situation Room partners in January 2020 and presented epidemiological information justifying the need to procure alternative regimens. Thanks to partners, Roche granted Venezuela access to the global access price for lower-middle income countries which made the purchase of viral load no longer cost-prohibitive.

³⁷ Civil society reporting notes this number to be 40,923 based on their reporting. Since mid-2019 pharmacies have been doing multi-month dispensations for 3-months.

organizations have engaged in monitoring and follow-up of drug management, and the searching, retaining and linking of people living with HIV to treatment services. The arrival of COVID-19 has required these organizations to adapt their approach (including ensuring monitors have adequate personal protective equipment) and, in some cases, they have not been able to carry out their monitoring. However, in spite of restrictions, monitors were able to visit 24 HIV clinics in 16 states and 25 ARV dispensation sites in 17 states. Through its reporting, civil society has confirmed that the majority of newly diagnosed people living with HIV (1406 from January – July 2020) have been prescribed TLD in line with WHO recommendations. 617 people on TLD have indicated adverse effects and lack of access to laboratory. Civil society also reported that there were stock-outs in between February-March of TLD in two sites in the state of Bolívar due to inadequate stock levels - these have since been resolved when ARVs were distributed in March/April. This, and the arrival of COVID-19 and the actions taken to control the pandemic, has likely resulted in a number of people living with HIV to suspend treatment. In July civil society was informed of stock-outs in two municipalities of Anzoátegui affecting more than 1500 people living with HIV which were resolved in August.³⁸ According to records compiled by civil society, 417 people living with HIV died between January and June 2020. This number is likely to be underreported due to issues related to mortality tracking by the Ministry of Health. Civil society notes that some HIV-positive persons – including pregnant women and children- received expired ARVs (not funded through the Global Fund donations).

- 29. Under the current investment, US\$ 50,000 has been provided to UNAIDS to support the Venezuelan Society of Infectious Diseases (VSI)³⁹ 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. However, due to the pandemic, there has been a delay in starting the course. Funds for both these projects are being administered by the UNAIDS office in Venezuela as economic sanctions make it impossible for NGOs to access funds held in foreign accounts. The UNAIDS office in 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.
- 30. To support the TB program, US\$830,000 was allocated 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. Further shipments are expected in September and October. It was originally envisaged that the Global Fund contribution would provide for first- and second-line treatments until March 2021, and this is likely to remain the case, although further verification of stock levels is needed. GeneXpert equipment with cartridges, as well as centrifuges and biosafety cabinets, have also been acquired. However

³⁸ Due to COVID, there were issues at the central warehouse which resulted in delays in distribution. ARVs were distributed in August with logistical support from UNICEF.

³⁹ 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.

- there remains limited diagnostic capacity and at present there are no confirmed donations from other partners.
- 31. 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, way below the international recommendation of ensuring 100% HIV testing coverage in people living with TB. PAHO, together with the National TB Program, will be undertaking a quantification exercise to ensure that future procurements of anti-TB drugs are aligned with available stocks and estimated cases. In the short-term TB diagnosis is likely to be limited to smear-microscopy.
- 32. Anti-malarials were also financed under the current investment (2,030,000 primaquine tablets) and malaria diagnostics (230,000 RDTs) and they arrived in country in July. When the lockdown began, diagnostic and treatment posts were equipped with a 6-month supply to ensure services could still be offered. As noted above, the malaria response was complemented by donations from other donors and the Global Fund grant is expected to be operational in 2021.
- 33. The COVID-19 pandemic has exacerbated existing challenges and has resulted in delays in the receipt of commodities. Distribution of commodities in the country was possible in April but may present challenges in the future as the pandemic evolves. HIV, TB and malaria programs are impacted by a lack of PPE for health care providers and lockdowns that have constrained access to health care. Due to global supply chain disruptions, alternative ARV regimens only arrived in July 2020. There were particular challenges in acquiring DRV (delivery expected end of August) and AZT/3TC (delivery expected December 2020). Although 95% of ARVs had been delivered in July, distribution has been delayed due to cases of COVID-19 amongst the personnel at the central warehouse.

Assessment conclusions

34. The Secretariat has considered the latest available economic, epidemiological and contextual data, as well as the updates and information provided by partners and civil society. The Secretariat notes that situation in Venezuela has continued to deteriorate since 2019, and is exacerbated by the COVID-19 pandemic, and is unlikely to improve in the near or medium term. The Secretariat therefore concludes that an additional funding request merits consideration under the Board-approved approach to non-eligible countries in crisis.

What do we propose to do and why?

What is the proposal?

35. As with the previous exceptional investments from the Global Fund in Venezuela, the needs significantly outweigh the needs available resources. The health sector continues to be severely impacted by the overall economic situation, and is now further impacted by COVID-19. There continues to be insignificant resources (both financial and human) to ensure functioning HIV, TB and malaria programs. The 2020-2022 malaria allocation of US\$19.8 million will provide a significant amount of funding to help fill the gaps; however, there is limited to no support for HIV and TB programs.

- 36. The Strategy Committee and the Secretariat are recommending that an additional US\$ 6 million be made available for 2021 for Venezuela. These funds together with the two previous investments would bring the total investment in Venezuela over a 3-year period to US\$17 million, which is below the cumulative ceiling of US\$ 20 million over three years that was recommended by the Board. This additional investment will ensure the continued availability of antiretrovirals (primarily TLD, as well as some alternative regimens for those patients who cannot take TLD) and anti-tuberculosis drugs (1st and 2nd line), as well as critical HIV and TB diagnostics, and continued support for civil society oversight and social monitoring. The Strategy Committee and the Secretariat recommend that US\$ 5,850,00040 be provided to PAHO for the procurement of commodities through the PAHO Strategic Fund and US\$ 150,00041 be provided to UNAIDS to support social monitoring and civil society oversight in 2021 of the HIV investment.
- 37. The Strategy Committee and the Secretariat recommend that US\$ 4.8 million be used to procure antiretrovirals, as well as some diagnostics, and support civil society and social monitoring. The Strategy Committee and the Secretariat note UNICEF's commitment to continue to provide pediatric ARVs in 2021, however even with this investment, there will remain significant gaps in the program, in particular for prevention and medicines for opportunistic infections. In order to ensure continued availability of anti-tuberculosis medicines, the Strategy Committee and the Secretariat recommend that US\$ 1.2 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.
- 38. As with the 2nd Exceptional Funding Request, 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. Any such reprogramming would be subject to approval from the Secretariat.

Proposed Implementation Arrangements

39. The Strategy Committee and the Secretariat recommend continuing the existing implementation arrangements which were approved for both the 1st and 2nd exceptional funding requests described in GF/B39/ER10 and GF/B41/ER10. Procurement of all HIV and TB drugs and

⁴⁰ This amount includes up to US\$ 240,000 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.

⁴¹ Of this amount, US\$100,000 will be to ensure continued civil society-led social monitoring of the HIV investment and US\$50,000 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.

⁴² This amount considers existing stocks in country of TLD and pending which will arrive in 2020 financed under the 2nd exceptional funding request. With these additional funds it is anticipated that ARV treatment will be available for the existing cohort, as well as eventual new inclusions, through the end of March 2022. A 2021 needs assessment exercise for ARVs and HIV diagnostics (RDTs and viral load) will take place at end of September/beginning of October. The ARV needs assessment will be performed using the new PAHO QUANTMET tool and will inform the final procurement plan.

⁴³ The estimated amount considers the availability of existing TB drugs in-country or due to arrive in country in 2020 and is anticipated to cover treatment needs through the end of March 2022.

- commodities will continue to be directly procured through the PAHO Strategic Fund noting the benefits previously described in GF/B39/ER10, paragraph 35.
- 40. PAHO has permission from the relevant authorities to operate in Venezuela and, as with the two 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.
- 41. As with the two previous investments, PAHO will be responsible for delivery commodities to the port of entry and will, in coordination with relevant authorities, undertake customs clearance and delivery to the designated warehouse. ⁴⁴ As with previous investments, 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.
- 42. UNAIDS will continue to support 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. UNAIDS will continue to provide technical assistance to civil society and the Venezuelan Society of Infectious Diseases a non-governmental organization. It is anticipated that the funds for social monitoring and civil society and training will ensure social monitoring and training of Venezuelan physician's through April 2022.
- 43. Due to the current economic sanctions in place⁴⁵, UNAIDS Venezuela country office will administer the funds for both projects as currently NGOs are not able to hold. UNAIDS trained staff from the different organizations in UNAIDS policies and procedures and will continue to support them to ensure efficient implementation of the activities. For 2021, the majority of funds will be provided to existing civil society organizations RVG+, ASCCI and COVIP to support their independent monitoring of the distribution and delivery of ARVs. The future agreement with UNAIDS will detail how plans for support both to civil society organizations and the Venezuelan Society of Infectious Diseases will be adapted considering the current situation in country and the COVID-19 pandemic.

Variations to the Standard Global Fund Operating Model and Policies

44. The Strategy Committee and the Secretariat are proposing the same implementation arrangements – i.e. direct funding through PAHO and UNAIDS – for this third exceptional funding request and notes that the principles previously highlighted to the Board still apply.⁴⁶

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]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

The Strategy Committee and the Secretariat note that as the standard Global Fund operating model and policies do not apply, 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 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.

- 45. As with previous investments, this investment comes with attendant risks which should be considered explicitly by the Board as it considers its approval of this third investment to the Board. The main risk 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 have been related to the supply chain and transport disruptions associated with the COVID-19 pandemic. The in-country challenges (e.g. chronic fuel shortages, power outages, lack of transportation and lack of healthcare providers, limited access to health services) 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.
- 46. 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 and GF/B41/ER10.

Source of Funds

47. 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 in March 2020 for portfolio optimization (PO) for 5th replenishment grants in line with the Strategy Committee approved prioritization framework. Efficiencies and savings from awarded PO investments were identified for reinvestment and the Grant Approvals Committee (GAC) agreed with setting aside these funds for a future request 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?

48. The overall situation in Venezuela has continued to deteriorate in 2020 and has worsened due to the COVID-19 pandemic. The Strategy Committee and the Secretariat note there continues to be critical gaps across the three diseases and, while the 2020-2022 allocation for malaria will

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.

- alleviate some of those gaps, gaps for HIV and TB programs have limited to no funding. The Strategy Committee and the Secretariat are recommending that a third investment of US\$ 6 million be provided to Venezuela to procure essential HIV and TB medicines and diagnostics under the Board-approved non-eligible countries in crisis approach, noting that this will only cover a fraction of the needs. This recommendation considers existing and projected availability of medicines in the country. Noting the US\$ 19.8 million allocation for malaria, the Strategy Committee and the Secretariat do not recommend providing any exceptional funding for malaria.
- 49. The Strategy Committee and the Secretariat note that even with additional investment by the Global Fund and donations from partners and international civil society, there will remain critical shortages of essential commodities, in particular treatment for opportunistic infections, HIV prevention commodities and diagnostics (rapid tests and viral load), as well as diagnostics for TB and TB preventative treatment. As with the previous investments, the Secretariat will continue to work with partners and civil society to advocate for additional donations to alleviate the gaps, however a longer-term solution is dependent on the improvement of the economic and political situation and the ability of the government of Venezuela to provide for the health of its people.
- 50. The Strategy Committee and the Secretariat consider that continuing with the existing implementation arrangements through PAHO and UNAIDS to be to be the most effective option 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 is also 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.
- 51. The Strategy Committee and the 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, as it considers its approval of this request.
- 52. 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 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?

53. The Strategy Committee and the Secretariat note that there are only two options in this context. The first option is to request additional funding for 2021 under the non-eligible countries in crisis approach. The second option is not to request additional funding which would likely result in stock-outs of life-saving HIV and TB treatments. The Strategy Committee and the Secretariat, considering the current situation in Venezuela and the impact of the previous and current investments, does not consider the second option a feasible option.

What do we need to do next to progress?

What is required to progress the proposal?

- 54. In line with the Board-approved approach to non-eligible countries in crisis, the Board is requested to approve an additional investment of US\$ 6 million for Venezuela in 2021 in order to ensure the continuity of life-saving HIV and TB treatment.
- 55. 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 Strategy Committee and the Secretariat recommends the Decision Point presented on page 2 to the Board for approval.

Document Classification: Internal.

Document Circulation: Board Members, Alternate Board Members, Constituency Focal Points and Committee Members.

This document may be shared by the Focal Points within their respective Board constituency. The document must not however be subject to any further circulation or otherwise be made public.

Annexes

The following items can be found in Annex:

- Annex 1: Terms of Investment in Venezuela
- Annex 2: Progress Update, Master Plan
- Annex 3: Progress Update January- July 2020 from Civil Society
- Annex 4: Variations between proposed implementation arrangements and the Standard Global Fund Operating Model
- Annex 5: Summary of Previous Committee Input
- Annex 6: Relevant Past Board Decisions
- Annex 7: Links to Relevant Past Documents & Reference Materials

Annex 1 - Terms of the 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).
- 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 commodities (to be procured through the Strategic Fund)	USD 5,610,000
PAHO costs ⁴⁷	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.

6. Terms of the investment that differ from standard Global Fund grants:

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.

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.

 $^{^{\}rm 48}$ Approved under GF/B31/DP11.

Annex 2 – Progress Update, Master Plan Annex 3 – Progress Update January- July 2020 from Civil Society

Annex 4 – 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.	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.
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. 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	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 UNAIDS's responsibilities.

⁴⁹ Approved under GF/B31/DP11.

	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.	 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.
, loodiumoo		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	The disbursement schedule and reporting requirements will be set out in the agreement with PAHO in order

	financial or programmatic reporting.	•	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. A progress update to the original Master Plan 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 5 – Summary of Previous Committee Input

Strategy Committee Chairs Notes - 9th Meeting, paragraph 64

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

Strategy Committee Chairs Notes -11th Meeting, paragraphs 33-42

Draft (subject to minor revisions) Strategy Committee Chairs Notes – 14th Meeting:

Non-eligible countries in crisis

Presentation

- 56. The Secretariat provided an overview of the most salient points in the paper and decision point, noting the pre-call discussions and the availability of the recorded presentation:
 - i. This is the third exceptional funding request for Venezuela under the Board-approved noneligible countries in crisis approach.
 - ii. This new request asks for an additional US\$ 6 million in funding for 2021, which would result in a total US\$ 17 million in funding over three years, in line with the 3-year recommended ceiling of US\$ 20 million. As of July 2020, over 40,000 people were receiving TLD which had been financed through the Global Fund.
 - iii. Since Venezuela has become exceptionally eligible for malaria in the 2020-2022 allocation cycle and the Venezuela malaria grant is in grantmaking, the third request includes funds for HIV and TB commodities only.
 - iv. The proposed implementation arrangements and approach to risk remain the same as the two previous funding requests.
 - v. COVID-19 has further exacerbated the political, social and economic crisis in Venezuela.

SC Discussion

- 57. The SC, as well as input received from other constituencies, raised matters pertinent to the decision point but beyond the scope of the session that would require further discussion at a later time. These included:
 - i. the effect of the COVID-19 pandemic on the Global Fund's eligibility criteria,
 - ii. whether the non-eligible countries in crisis approach should be reviewed in light of the experience with Venezuela,
 - iii. the Global Fund's role in global health security, and,
 - iv. how discussions surrounding crisis funding in non-eligible countries should be incorporated into discussions on the Global Fund's next strategy.
- 58. The SC members expressed their support for a third exceptional funding request for Venezuela.

Secretariat Response

The Secretariat thanked the SC members and constituencies for their statements and answered
the questions raised within them. In particular, the Secretariat indicated that it did not foresee a
revision of the approach to non-eligible countries in crisis but would look at this during the review

of the eligibility policy which will begin in 2021. The Secretariat also clarified the rationale for why Venezuela has not meet the eligibility criteria to date and that there is nothing precluding the Secretariat from requesting additional support for Venezuela in 2021, recalling that the 20 million referenced in the Board paper is a recommended ceiling for a three-year period to align with the funds that were made available for the Emergency Fund for 2017-19 allocation period.

Action Points

59. The SC unanimously supported the decision point that recommends the approval of the third exceptional funding request for Venezuela to the Board.

Annex 6 - Relevant Past Board Decisions

Relevant past Decision Point	Summary and Impact
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 ⁵⁰	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/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) ⁵¹	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/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	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

https://www.theglobalfund.org/board-decisions/b41-edp14/https://www.theglobalfund.org/board-decisions/b41-edp06/https://www.theglobalfund.org/board-decisions/b39-edp11/https://www.theglobalfund.org/board-decisions/b39-dp04/https://www.theglobalfund.org/board-decisions/b37-dp11/

Relevant past Decision Point

and Terms of Reference for the Inspector General⁵⁵

GF/B31/DP11 (March/2014): Revision to the OIG Disclosure Policy and the OIG Charter⁵⁶

Summary and Impact

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, 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.

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

https://www.theglobalfund.org/board-decisions/b31-dp11/

Annex 7 – 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/SC11/06: Second Exceptional Funding Request to Address the Health Crisis in Venezuela

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

GF/SC14/02, Revision 1: Third Exceptional Funding Request to Address the Health Crisis in Venezuela