
Electronic Report to the Board

COVID-19 Response for Business Continuity and Country Support

GF/B42/ER09 – Revision 1

Board Decision

Purpose of the paper: The Board is requested to approve operational flexibilities and additional support to countries to enable the Global Fund and countries to effectively respond to the negative impact of the COVID-19 pandemic.

Decision

GF/B42/EDP10: Operational Flexibilities to Ensure Continued Operations during COVID-19

The Board acknowledges the severe negative impact COVID-19 is having on country health systems and Global Fund programs to fight the three diseases. The Board agrees with the need for temporary flexibilities to ensure the continued delivery of the Global Fund's core mission during a prolonged period of disruption.

Based on the recommendation of the Secretariat, as presented in GF/B42/ER09 – Revision 1, the Board approves the following:

- 1. In order to account for delays in the supply chain due to COVID-19 disruptions, the Secretariat may allow additional flexibility for the deadline for delivery of goods and services under Global Fund programs to be funded from the 2017-2019 allocation period, up to a maximum of 180 days after the implementation period end date;*
- 2. In order to ensure swift deployment of portfolio optimization funds, the Secretariat may approve the increase of grant amounts to integrate awards of portfolio optimization funds approved by the Secretariat in line with the Strategy Committee-approved prioritization framework, where such funds have been approved as available by the AFC, with subsequent reporting to the Board; and*
- 3. In order to mitigate risks of disruption to the supply of health products in-country, the Secretariat may grant limited exceptions to the Quality Assurance Policies, to waive the requirement for pre-shipment sampling and testing for Expert Review Panel-approved products, vector control products, and condoms, where such testing may delay the delivery of products to countries.*

The Secretariat may apply the temporary flexibilities described in paragraphs 2 and 3 above for an initial six-month period, subject to renewal by the Board. The Secretariat may apply the flexibility described in paragraph 1 through 30 June 2021.

Budgetary implications (included in, or additional to, OPEX budget): *The cost of implementing these decisions will be absorbed within the current 2020 OPEX budget.*

GF/B42/EDP11: Additional Support for Country Responses to COVID-19

The Board agrees that the COVID-19 pandemic poses a global public health emergency and that failure to control the pandemic threatens to derail the Global Fund's mission to fight HIV/AIDS, tuberculosis, and malaria and strengthen systems for health. The Board acknowledges that without immediate action, health facilities, communities and geographies served by Global Fund programs will be severely impacted. As a major actor in global health, the Global Fund is uniquely positioned to deliver rapid support to countries developing responses to control the COVID-19 pandemic. In light of the urgency of the situation, and the need to take swift and decisive action with partners to control the impact of COVID-19 on the Global Fund mission and country health systems, the Board:

- 1. Approves the creation of a temporary COVID-19 response mechanism (C19RM) to provide additional support for country responses to the pandemic and to*

ensure the continuity of the fight against HIV, tuberculosis, and malaria. C19RM will:

- a. Support the rapid deployment of funds to support implementer countries' COVID-19 responses, using expedited decision-making approaches determined by the Secretariat and coordinated with partners;**
 - b. Finance interventions consistent with World Health Organization (WHO) guidance on COVID-19 and national Strategic Preparedness and Response Plans, including:**
 - i. COVID-19 control and containment interventions, including personal protective equipment, diagnostics, treatment, communications and other public measures as specified in WHO guidance;**
 - ii. COVID-19-related risk mitigation measures for programs to fight HIV/AIDS, tuberculosis, and malaria; and**
 - iii. Expanded reinforcement of key aspects of health systems, such as laboratory networks, supply chains, and community-led response systems, to address advocacy, services, accountability, and human-rights based approaches;**
 - c. Finance interventions across the 5th and 6th replenishment periods;**
 - d. Be administered within the established internal control framework of the Global Fund; and**
 - e. Be additional to amounts approved by the Global Fund for programming towards COVID-19 interventions under existing grants.¹**
- 2. Approves initial funding for C19RM of up to USD 500 million, comprised of:**
- a. USD 180 million from the USD 300 million of available funds approved by the Audit and Finance Committee on 16 March 2020 under GF/AFC12/DP01; and**
 - b. Up to USD 320 million of additional funds approved as available by the AFC under section E.6 of the Amended and Restated Comprehensive Funding Policy.**
- 3. Agrees that C19RM funds may be used to procure COVID-19 products approved under the WHO Emergency Use and Listing procedures or under other emergency procedures set up by any Stringent Regulatory Authorities as defined under the Quality Assurance Policy for Pharmaceutical Products and Quality Assurance Policy for Diagnostic Products.**
- 4. Agrees that C19RM is a Board-approved initiative for which the Global Fund may mobilize additional resources from private and public donors, in accordance with existing policy.**
- 5. Agrees that the Secretariat may approve requests for C19RM funds for an initial six-month period through 30 September 2020, and that C19RM funds may be**

¹ As announced by the Global Fund on 4 March 2020, https://www.theglobalfund.org/media/9397/core_covid-19_guidancenote_en.pdf?u=637189162540000000.

used through 30 June 2021. These dates may be extended by the Board, based on updated information on needs as the pandemic evolves.

- 6. Requests the Secretariat to further operationalize the investment and management modalities for C19RM, including working with partners to deliver critical technical assistance, ensuring the appropriate involvement of Country Coordinating Mechanisms and alignment with the Global Fund's underlying principles of gender equity and human rights, and providing the flexibility to take rapid action, including at global and regional level, in close collaboration with WHO and other critical partners, and provide regular reporting to the Board on the operationalization of C19RM, including on any investments made with C19RM funds.*

Budgetary implications (included in, or additional to, OPEX budget): *The cost of implementing these decisions will be absorbed within the current 2020 OPEX budget.*

A summary of relevant past decision providing context to the proposed Decision Point can be found in Annex 1.

Executive Summary

Context

- The COVID-19 pandemic is rapidly spreading across the globe and threatens to derail HIV, TB, and malaria programs, overwhelm community and health systems, and cause significant morbidity and mortality. The pandemic has already affected Global Fund Secretariat operations and threatens to have significant to catastrophic impact on the low- and middle-income countries where the Global Fund provides support. Without swift action, COVID-19 may not only prevent progress in the Global Fund's mission to end HIV, tuberculosis, and malaria, but threatens to undo years of gains.
- The Secretariat has been working rapidly with partners to ensure that the Global Fund can effectively ensure continuity of its core mission and directly support countries during the COVID-19 pandemic. This paper presents two decisions on temporary, extraordinary measures to: 1) enable flexibilities needed to ensure business continuity and delivery of the Global Fund's core mission; and 2) provide direct support to countries to respond rapidly to the COVID-19 pandemic and mitigate the negative impact of the pandemic on HIV, TB, and malaria programs and systems for health. These are time-bound, limited scope measures to respond to an unprecedented public health emergency that threatens to entirely derail the fight against HIV, TB, and malaria and to build resilient systems for health.
- Acknowledging the urgency of the situation and in consultation with the Board Coordinating Group (Coordinating Group)², it was agreed that urgent and exceptional decisions be brought directly to the Board for electronic consideration. These decisions have been consulted with the Coordinating Group.

Questions this paper addresses

- A. What flexibilities are needed to enable business continuity of the Global Fund and delivery of the Global Fund's core mission during this pandemic?
- B. What actions are proposed to support rapid country responses to COVID-19 in line with WHO guidance, mitigate risks to HIV, TB, and malaria programs, and support health and community systems during this pandemic?

Conclusions

The Secretariat has taken immediate action to assess and plan for the impact of the COVID-19 pandemic on all Global Fund stakeholders and partners. The Secretariat is proposing two decisions for Board consideration, describing temporary measures to help countries address the extraordinary circumstances, with the aim of protecting the delivery of the Global Fund's core mission:

- A. GF/B42/EDP10: In order to preserve business continuity for the core Global Fund mission during this pandemic, the Secretariat is requesting that the Board approve flexibilities to: a) extend the maximum period for the delivery of goods and services funded from the 2017-2019 allocation period to account for potential disruptions in the supply chain due to COVID-19; b) delegate authority to the Secretariat to approve the integration of approved portfolio optimization funds into existing grants; and c) waive certain requirements of Quality Assurance Policies³ for pre-sampling and testing of specific products in the event such testing may delay the timely delivery of products to countries. These measures are time-bound and are focused on helping countries navigate disruptions to continued program implementation.
- B. GF/B42/EDP11: In order to rapidly respond to COVID-19 related needs and mitigate its risk on HIV, TB, and malaria programs as well as health and community systems, the Board is requested to approve the creation of a COVID-19 Response Mechanism (C19RM), with an initial

² The Coordinating Group comprises the Chair and Vice-Chair of the Board, and the Chair and Vice-Chair of each of the Committees of the Board. https://www.theglobalfund.org/media/6009/core_coordinatinggroup_tor_en.pdf

³ GF/B22/DP09: [Quality Assurance Policy for Pharmaceutical Products](#) and GF/B37/D12 [Quality Assurance Policy for Diagnostic Products](#).

capacity of up to USD 500 million, of which USD 180 million would be made immediately available from funds already approved by the Audit and Finance Committee (AFC) at its 12th Meeting, and which could be further complemented by up to USD 320 million of additional funds subsequent to AFC approval. This decision further allows the purchase of COVID-19 products included in the WHO Emergency Use List. Awards from C19RM may be made for an initial period of six months, through 30 September 2020, with funds to be used by 30 June 2021. The Board may extend these periods depending on how the situation evolves.

Input Sought

The Board is requested to approve the Decision Points below:

- GF/B42/EDP10: Operational Flexibilities to Ensure Continued Operations during COVID-19
- GF/B42/EDP11: Additional Support for Country Responses to COVID-19

Input Received

- In light of the urgency of the situation, and the need to take swift and decisive action to control the impact of COVID-19 on the Global Fund mission and country health systems, these decisions on temporary, extraordinary measures are being presented directly to the Board for approval. Board Leadership in consultation with the Coordinating Group have agreed that the current urgent and exceptional circumstances justify an expedited decision-making approach.
- The Secretariat has engaged with Board Leadership and the Coordinating Group prior to submission of the proposed decisions to the Board, and the Executive Director provided a briefing to the Board on 27 March 2020.

What is the need or opportunity?

1. The COVID-19 pandemic is rapidly spreading across the globe and threatens to derail HIV, TB, and malaria programs, overwhelm community and health systems, and cause morbidity and mortality at a speed and scale likely not seen since the 1918 influenza pandemic.
2. The pandemic has already impacted Global Fund Secretariat operations. Switzerland currently has one of the highest infection rates per capita in the world and is one of the top 10 countries with the highest number of confirmed cases.⁴ All staff at the Global Health Campus are now working from home, schools in Switzerland are closed, and the government has declared an “Extraordinary Situation” instructing citizens to stay at home, closing borders and banning gatherings of more than 5 people. This has limited the Secretariat’s capacity, particularly for staff with young and school-age children, and those who are sick or caring for sick or vulnerable relatives.
3. While the outbreak to date has been concentrated in China, Europe, and the United States, it threatens to have significant to catastrophic impact on the low- and middle-income countries (LMICS) where the Global Fund provides support. Recent modeling suggests that without control measures, COVID-19 could cause “7.0 billion infections and 40 million deaths globally in the coming year.”⁵ According to this modeling, aggressive control measures could reduce this number in half, resulting in 20 million deaths, while a full suppression strategy implemented early could reduce the death toll to approximately 1.3 million. If accurate, this modeling confirms the imperative of a rapid and effective response and suggests that in most scenarios, the COVID-19 pandemic may well become the leading cause of infectious disease death globally over the next 12 months, exceeding the 1.5 million deaths per year from TB, 770,000 from HIV, and 405,000 from malaria in 2018.⁶

⁴ As of 1 April 2020, Switzerland had approximately 17,000 cases of COVID-19 and 465 deaths.

⁵ [The Global Impact of COVID-19 and Strategies for Mitigation and Suppression](#), Imperial College COVID-19 Response Team 26 March 2020.

⁶ Source: WHO Global Tuberculosis Report 2019, UNAIDS 2019 Data, World Malaria Report 2019.

4. There is limited data to date on the direct impact of the COVID-19 pandemic on HIV, TB, and malaria programs and people living with these diseases, but there is reason for extreme concern. People living with TB have compromised lung function which may increase the severity of their COVID-19 illness, programmatic staff and diagnostics may be diverted to the COVID-19 response, and critical activities to find missing cases will likely be impaired. Malaria interventions including bed net distribution, seasonal malaria chemoprophylaxis (SMC), and treatment of childhood fever require face-to-face interactions that may be restricted to limit the spread of COVID-19. People living with HIV with low CD4 counts and compromised immune systems, whether aware of their status or not, are likely to be prone to severe COVID-19 illness and HIV prevention programs have already been impacted by the pandemic. There will be challenges to providing continuing access to treatment during closures and lockdowns, and the most vulnerable people will likely continue having the least access to quality health care. Furthermore, national control measure responses to COVID-19 are contributing to supply chain interruptions of key health products needed to diagnose, treat, and prevent the three diseases.
5. Every country is now focused on preventing, detecting, and responding to COVID-19. This response is the focus of Ministries of Health and governments, critical country implementers, and is understandably taking precedence over implementation of other programs. The shift in attention to COVID-19 is already beginning to impact HIV, TB, and malaria programs as evidenced by concerns about delays to funding requests for the next grant cycle. However, the full impact could be far greater, as the eventual spread of the virus threatens to entirely overwhelm community and health systems. In a matter of weeks, the virus has exceeded the health care capacity of Italy's high income and high-quality health system, and there is increasing evidence that this is occurring in other high-income settings. Lesser resourced community and health systems in LMICs that are overwhelmed with COVID-19 will be unable to provide services that prevent and treat HIV, TB, and malaria or serve other critical health needs. Epidemic responses in these contexts are reliant on extensive cadres of community health workers and volunteers who may require personal protective equipment (PPE) and training to protect themselves and to continue to play critical roles in serving health needs.
6. The impact of COVID-19 will likely look different in different regions of the world. Seasonal and climatic differences may impact transmission of the virus. There is a correlation between countries having higher incomes and older population demographics. Therefore, the significantly higher case fatality rate of COVID-19 among older populations may mean COVID-19 has less impact among the generally younger populations of LMICs. However, the underlying prevalence of co-morbidities of other infectious and chronic diseases, and overall living conditions among populations in LMICs, may increase disease severity, and the higher proportion of individuals over 65 years of age living with younger family members in low income countries will likely increase viral transmission to elderly populations, and therefore increase the impact of the virus in lower income settings.
7. Physical distancing interventions adopted to slow the spread of the virus in China, Europe, and elsewhere will need to be tailored for poorer settings. People living in slums, refugee camps, detention facilities, and high-density urban settings will face significant challenges in maintaining "physical distance" from people. Millions of daily wage earners may lose their entire income and be compelled to put themselves at risk of exposure to COVID-19 to keep food on the table. LMICs have limited if any domestic capacity to deliver 'financial stimulus packages' or 'social and income protection' for the poor and marginalized, and slowed or contracted economic growth will impact revenue collection and thus LMICs' capacity to increase domestic investment in health. As evidenced in the Ebola outbreaks across western Africa and in the HIV pandemic, supporting community engagement, leadership and community-led responses will be critical across LMICs in the fight against COVID-19. Hospital bed and intensive care capacity is also significantly more limited in LMICs than in the upper income countries where we have seen the impact of COVID-19 to date. Among the countries in which the Global Fund invests, there are some with less than 10 intensive care unit (ICU) beds for the entire country. It is highly likely that case fatality rates will be higher where extensive hospital support for ill patients cannot be provided.
8. The impact of COVID-19 on the Global Fund Secretariat and the significantly greater impact on the countries we support requires a rapid and evolving response from the Global Fund partnership and Board. This response must be closely coordinated with the WHO as lead of the global response, implementing countries, and major donors and partners including the World Bank and other regional multilateral development banks, Gavi, UN agencies, UNITAID, the Bill & Melinda Gates

Foundation, the private sector and other bilateral partners who have recently announced COVID-19 response funding. This paper presents two decisions for Board consideration. The first decision outlines the flexibilities needed to ensure the delivery of the Global Fund's core mission during this pandemic. These flexibilities form part of the overall Secretariat business continuity strategy to navigate expected delays and challenges in implementation, and include measures to address potential supply chain disruptions, mitigate the impact of program delays, and support the rapid integration of portfolio-optimized funds into grants. The second decision is aimed at providing direct time-bound and targeted support to countries to respond rapidly to the COVID-19 pandemic and protect existing programs and systems, supporting procurement flexibilities for WHO-recommended COVID-19 commodities, and raising additional private and public funds. This second decision is built upon the fact that fighting COVID-19 and reducing the negative impact of the pandemic on HIV, TB, and malaria programs and systems for health are inseparable and urgent objectives for the Global Fund.

What do we propose to do and why?

Business Continuity Actions

9. The Secretariat has taken immediate action to plan holistically for the impact of the COVID-19 pandemic on all Global Fund stakeholders and partners, preparing for a variety of risk scenarios across a number of key risk drivers. Contingency measures are being developed and rolled out across the core business, with the focus on ensuring continued delivery of impact from the current grant cycle, and the development of funding requests and grants for the 2020-2022 allocation period. The Secretariat's contingency planning aims to balance the reality of expected severe limitations on country capacity and resources, while seeking to maintain quality and minimum standards where possible. Flexibilities are designed to help countries adjust to the current circumstances and support them in maintaining delivery of their core programs.
10. For the current cycle of grants, the Secretariat has developed plans to ensure the continued ability to disburse funds to Global Fund programs, mitigate and manage risks associated with expected supply chain disruptions, make adjustments to reporting requirements, and streamline the process for integrating additional funds into grants. In all cases, the focus is on ensuring the continued delivery of Global Fund programs under any circumstances.
11. For the next cycle of grants, severe disruptions to funding request development are expected, which will compromise countries' abilities to develop robust funding requests and the subsequent development of grants. Challenges in holding inclusive country dialogue are already being observed, as travel and meeting restrictions, intermittent connectivity, and technological limitations restrict the ability of in-country stakeholders to communicate. In-country resources and attention are also being diverted to COVID-19. Planning for upcoming funding request submission and review and grant making is currently under development, with a view to accommodating the expected capacity constraints in-country and developing alternative approaches where normal standards cannot be met. The Secretariat is developing additional communications on revised approaches for funding request development and grant-making as quickly as possible and aims to release further information to countries in the coming days.
12. A subset of flexibilities to be put in place entail exceptions to Board or Committee-approved policies and are presented in this paper for Board approval. This represents only a portion of the flexibilities being developed as part of the overall contingency planning being undertaken by the Secretariat and we anticipate we may need additional Board decisions in the coming weeks. Flexibilities presented for Board approval are described below.
13. **Extension of deadline for the delivery of goods and services to be funded from the 2017-2019 allocation period:** In order to accommodate delays in the supply chain due to COVID-19 disruptions, the Secretariat is requesting additional flexibility for the deadline for delivery of goods and services under Global Fund programs to be funded from the 2017-2019 allocation period, up to a maximum of 180 days after the implementation period end date. This proposal would entail a change to the cut-off principles in place to ensure that allocations do not

overlap, as required under the Amended and Restated Comprehensive Funding Policy (CFP)⁷. Under the operationalization of the current policy, in exceptional circumstances, payments relating to goods and/or services delivered after the end of an allocation utilization period may be funded from that period when delivery of the goods and/or services is completed within a maximum of 90 days of the period end date, if two additional criteria (i.e., timely order placement and delivery delays beyond the implementing entity's control) are met.

14. The impact of the COVID-19 response on health product supply chains, from active pharmaceutical ingredients, to finished pharmaceutical products, to logistics and shipping, continues to evolve rapidly. The 90-day period is likely insufficient to permit the smooth and continuous flow of needed health products. Further, it may contribute to artificial pressure on supply chains driven by budget guidelines that may not necessarily result in delivery of products to countries most in need. Extending the delivery date limit from 90 days to 180 days beyond the current allocation utilization period for goods and/or services will remove Global Fund grant-cycle induced pressures on supply chains and would allow additional flexibility for implementers facing delays outside of their control. The requirement for timely order placement would remain in place. This flexibility will extend to all goods and services.
15. **Swift integration of portfolio optimization funds:** There are currently USD 120 million of AFC-approved portfolio optimization funds⁸ that have been approved by the Secretariat, through the Grant Approvals Committee (GAC) and in line with the Strategy Committee-approved prioritization framework⁹, but that have yet to be incorporated into grants. Under existing policy, Board approval is required to incorporate these amounts into existing grants. In order to ensure swift incorporation of portfolio optimization funds, the Secretariat seeks delegated authority to approve increases of grant amounts to integrate already approved awards of portfolio optimization. Awards awaiting integration have been reviewed and discussed with Technical Partners prior to GAC approval. The Secretariat will report to the Board on the incorporation of approved portfolio optimization funds into grants. This flexibility is anticipated to save approximately 3-4 weeks of time, allowing the incremental funding to be deployed more quickly. Given the rapidly escalating pressures on implementers, we are keen to see the latest portfolio optimization funds integrated into grants as quickly as possible. We propose that this delegated authority remains in place for 6 months, unless renewed by the Board.
16. **Limited exceptions to Quality Assurance Policies:** In order to mitigate risks of disruption to the supply of health products in-country, the Secretariat requests delegated authority to grant limited exceptions to the Quality Assurance Policies' requirements for pre-shipment sampling and testing for Expert Review Panel-approved products, vector control products, and condoms, where such testing may delay the delivery of products to countries. Such exceptions would be made on a case-by-case basis, through risk-based decision making, only where 1) sampling and quality control (QC) testing may not be physically possible due to the unavailability (and likely continued unavailability) of sampling or QC services due to COVID-19, and 2) where a delay would result in negative program impact which cannot be mitigated (e.g., missing an insecticidal net distribution campaign).
17. The risk with this approach would be to ship products not 100% tested before shipment, although such products would be produced based on a manufacturing process qualified to produce product in line with expected quality standards (GMP Good Manufacturing standard), therefore the risk of sub-standard quality product being delivered is low. A number of mitigations and controls have been put in place to control the remaining risk. All attempts will be made to find alternative means for quality assurance (e.g., through post-market surveillance, Quality Assurance Notice). No exceptions will be approved in situations where there are any quality-assurance issues confirmed and/or under investigation with the supplier. Based on our experience, the risk of pre-shipment failure tests related to pre-qualified suppliers who comply with the GMP standard is limited. These controls and mitigations reduce the level of potential risk and ensure a more robust risk reward trade-off. While it is acknowledged the risk cannot be completely eliminated, we believe this exception is justified because the alternative, such as programmatic impact of missing an

⁷ GF/B36/DP04 <https://www.theglobalfund.org/board-decisions/b36-dp04/>

⁸ Portfolio optimization funds are used to fund eligible unfunded quality demand (UQD) interventions which have been recommended by the Technical Review Panel (TRP).

⁹ GF/SC04/DP02

insecticidal net distribution campaign, would be much worse. Adopting this approach would not change the Global Fund's legal position should the products prove substandard. The legal liability remains with the supplier. We propose that this delegated authority remains in place for 6 months, unless renewed by the Board.

18. **Additional decisions:** As described above, the Secretariat's contingency planning is still under development and is rapidly evolving to reflect the changing global circumstances. The flexibilities requested for approval under this paper represent the necessary Board decisions that have been identified to date. It is likely that additional flexibilities will be required and that further approvals from the Board may be requested.
19. For example, a critical area in which adjustments to approach may be required concerns CCM eligibility requirements, in particular the requirement¹⁰ that a CCM demonstrate that it has carried out a transparent and inclusive application development process. The Secretariat is firmly committed to ensuring that an ongoing inclusive country dialogue process forms part of the grant lifecycle, from funding request development and throughout implementation, and will support CCMs as they reach out to key constituents remotely, including key and vulnerable populations. At the same time, challenges faced by country stakeholders may require a more flexible assessment in determining whether inclusive dialogue has been demonstrated. The Secretariat will work with in-country stakeholders during the funding request stage to ensure a CCM's intention for inclusivity and to supplement the voice of key and vulnerable populations as necessary. The Secretariat may also, as necessary, accommodate a differentiated screening of supporting documentation on a case-by-case basis and defer the review of certain requirements to later stages in the grant cycle (e.g. during grant making and/or early implementation). In the exceptional event that a funding request cannot demonstrate transparent and documented inclusive dialogue, the Secretariat will seek exception from the Board at the time of submission of such grant to the Board for approval. In the interim, the Secretariat recommends maintaining CCM eligibility requirements, and will continue to provide all possible support to ensure inclusive country dialogue during the funding request, grant-making and grant implementation stages.

Country Support Actions

20. The Secretariat believes that COVID-19 represents a significant threat to the fight against HIV, TB, and malaria, and therefore, that the Global Fund should act decisively to support implementer countries in their efforts to contain and respond to the pandemic. The second Decision Point proposes specific, timebound actions the Global Fund can take to support countries' responses to the COVID-19 pandemic, including investments to implement national Strategic Preparedness and Response Plans, the funding of actions to mitigate risks to existing HIV, TB and malaria programs, and the financing of interventions to reinforce critical aspects of the health system, including community systems for health. The actions under this decision point will enable the Global Fund to provide extraordinary additional funding to implementer countries¹¹ for COVID-19 responses utilizing available funds identified by the AFC¹², fund products approved pursuant to the WHO Emergency Use and Listing during a Public Health Emergency of International Concern, and provide a demonstrably effective channel for donors wanting to provide additional financial contributions to support implementer countries' COVID-19 responses.
21. The Global Fund has already taken action to make existing grant funds available to implementers to meet immediate COVID-19 response requirements. On 4 March 2020, within the Secretariat's delegated authority, the Global Fund issued COVID-19 guidance¹³ allowing countries to redeploy underutilized assets funded by the Global Fund, reprogram grant savings up to 5% of the grant total, and reprogram current grants up to an additional 5% of the grant total on written approval. The guidance requires that all proposed activities must follow WHO guidance on COVID-19 and must be aligned with a national Strategic Preparedness and Response Plan. As of 2 April 2020, 40 countries and 2 regional grants have utilized this guidance for a total of USD 50.8 million in funds. This approach has proved highly effective as a rapid mechanism to meet immediate country

¹⁰ CCM Policy, [GF/B39/DP09 https://www.theglobalfund.org/board-decisions/b39-dp09/](https://www.theglobalfund.org/board-decisions/b39-dp09/)

¹¹ Implementer countries in this context includes existing country and regional/multi-country recipients that are receiving funding from the Global Fund.

¹² GF/AFC12/DP01

¹³ https://www.theglobalfund.org/media/9397/core_covid-19_guidancenote_en.pdf

needs. However, the scope and impact of this pandemic will far exceed the funds available through these flexibilities. Some countries have very limited savings within existing grants (or have reprogrammed them already). Most countries are reluctant to propose significant reprogramming, since this could jeopardize core interventions for the three diseases or undermine critical investments in health systems.

22. To complement the grant flexibilities already implemented, and as an additional action to provide timely support to country responses to COVID-19, the Secretariat proposes the creation of a COVID-19 Response Mechanism (C19RM) to provide time-bound, targeted and additional support for country responses to COVID-19. The Secretariat does not consider C19RM to be a change in the remit of the Global Fund, rather it is a tactical response to an unprecedented public health emergency that threatens to entirely derail the fight against HIV, TB, and malaria. A dedicated mechanism is important to establish because it will:
 - a. facilitate rapid and tailored request and decision-making processes, reflecting the nature of the emergency;
 - b. enable use of funds across the 5th and 6th replenishment periods;
 - c. facilitate distinct Board and public reporting of deployment of funds under a time-bound, limited-scope measure;
 - d. does not rely on existing UQD requests from countries for portfolio optimization that do not include COVID-19 response.
23. The Secretariat proposes initial funding for C19RM of up to USD 500 million, of which USD 180 million would be made immediately available from the USD 300 million of available funds approved by the AFC on 16 March 2020. This amount has been determined noting that approximately USD 120 million of the USD 300 million total has already been assigned to previously identified priorities on the UQD register, prioritized with technical partners in line with the Strategy Committee-approved prioritization framework. The Secretariat recommends that the remaining USD 180 million be deployed through C19RM for COVID-19 responses and related activities to mitigate the impact of the pandemic on HIV, TB, and malaria programs and to support systems for health. To achieve the proposed initial capacity of up to USD 500 million, the Secretariat proposes an additional sum of up to USD 320 million be made available for CR19RM subject to approval by the AFC under its delegated authority under the CFP. In a sense C19RM can be seen as a mechanism to enable the rapid deployment of USD 500 million of funds remaining available from the 5th replenishment cycle to help counter the threat of COVID-19 in order to protect the Global Fund's ability to invest USD 13.6 billion in the fight against HIV, TB and malaria and to reinforce health systems in the 6th replenishment cycle.
24. Committing up to USD 500 million of funds available from the 5th replenishment period means these funds will no longer be available for portfolio optimization. However, there is very limited scope for further portfolio optimization in this cycle, since funds deployed via portfolio optimization must be used before the end of the cycle (unlike under C19RM). Moreover, in-country partners have very little appetite or capacity to submit portfolio optimization requests right now. Their priority, and where they want help, is COVID-19 response and mitigation activities for existing programs.
25. Funds made available through C19RM would be used to support implementer countries¹⁴ by financing activities and/or commodities in three areas: 1) supporting direct COVID-19 responses in countries (e.g. purchase of diagnostics and protective equipment, support for emergency response centers), in line with WHO technical guidance on COVID-19 and national Strategic Preparedness and Response Plans for COVID-19; 2) funding risk mitigation activities related to HIV, TB, and malaria programming (e.g. additional support for LLIN distribution activities to protect against COVID-19), in line with WHO technical guidance and in close collaboration with partners; and 3)

¹⁴ The Secretariat recommends that all implementer countries that receive Global Fund financing be eligible to access these funds.

addressing critical gaps in health systems (e.g. strengthening laboratory networks, supply chains and community engagement).

26. Global Fund support through C19RM will be closely coordinated with WHO and other partners, including the World Bank, Gavi, and key bilateral partners such as PEPFAR. All requests will be scrutinized for conformance with WHO guidance, alignment with national Strategic Preparedness and Response Plans and coordination with relevant partners. Given the Global Fund's ability to deploy funds very rapidly, we anticipate that Global Fund resources will prove particularly useful in financing early planning, program adaptation and initial COVID-19 requirements (e.g. PPE, diagnostics) that can then be supplemented when additional funds become available from other partners.
27. A rigorous and rapid approval process for these funds is critical. The current approval process for reprogramming funds for COVID-19 responses within grants provides rapid decision-making and transparent and frequent reporting on the use of funds. The Secretariat will leverage existing review and approval processes, with any adjustments necessary to reflect the emergency nature of the interventions. For requests for COVID-19 support, as with grant flexibilities, the Secretariat will review to ensure consistency with WHO guidance, country SPRPs, and alignment with support provided by other partners (World Bank, USAID, UNICEF, etc.). For requests for risk mitigation activities for HIV, TB, malaria, and community and health systems, the Secretariat will review for consistency with WHO and Global Fund disease and systems guidance, discuss with relevant technical partners (UNAIDS, Stop-TB, RBM, WHO) and coordinate with other partner funding (e.g. PMI for malaria funding). Any large-scale procurement of COVID-19 commodities will be managed through WHO-led taskforces such as the Diagnostics Supply Consortium for COVID-19 to ensure coordination with WHO, World Bank, BMGF, CHAI, UNICEF, and other major procurers of health products.
28. The Secretariat will rely on WHO technical guidance on COVID-19 and will only fund requests that conform to the relevant technical guidance. Continuous alignment with WHO guidance will allow for swift adjustments to interventions based on any updates as they emerge, enabling funding under C19RM to be deployed with the necessary speed and agility, while ensuring interventions reflect the latest technical guidance. Funding will also be closely coordinated with other partners including other multilaterals, such as the World Bank, Gavi, UNITAID, and regional development banks, and bilateral partners. The Secretariat notes the Technical Review Panel's (TRP) continuing and critical role in reviewing the \$12.7b of allocated funds for the 2020-2022 allocation period and will ensure coordination with the TRP's review of country applications, particularly on consideration of risk mitigation activities for HIV, TB, malaria, community and health systems.
29. Regarding allocation of funds from C19RM, the Secretariat will continue to work closely with the WHO and other significant providers of support to countries including the World Bank, Gavi and bilateral donors. Funding will be determined dynamically based upon epidemiology and in coordination with these partners. The Secretariat does not propose an up-front allocation formula for this funding but will consider funding requests against a country's total population at risk, level of income and current allocation amounts, as well as any available information on the current or projected impact of COVID-19 on the country's health system. Consideration will also be given to whether there is scope to reprogram funds or utilize savings in line with existing Global Fund guidance on COVID-19. Based on the proposed initial capacity of USD 500 million for C19RM, the Secretariat envisages adopting as an indicative guideline that COVID-19 related support for any one country, including funds from both the previously communicated grant flexibilities and C19RM, should not exceed 10% of the 2020-2022 country allocation.
30. Upon approval, C19RM will be administered within the established internal control framework of the Global Fund. Similar to grants and strategic initiatives, C19RM will be an integral part of the overall Asset and Liability Management (ALM) and financial performance reporting (forecast and actuals monitoring) with robust investment and management modalities. Given the close proximity to the end of the current grant cycle, C19RM funds may be accessed across the 5th and 6th replenishment periods, with funding to be used by 30 June 2021. Any funds uncommitted at this time will become part of the 6th replenishment sources of funds, unless otherwise decided by the Board.

31. The Secretariat is committed to fully transparent and frequent reporting on these emergency investments and will report regularly to the Board on all such investments. Specifically and in addition to existing reporting on grant reprogramming for COVID-19, the Secretariat will provide grant totals for C19RM by country, component (HIV, TB, malaria, RSSH), total by region and globally, and the purpose of the funding at a high-level (specific COVID-19 interventions, risk mitigation activities for a disease, community or health systems strengthening.) This information will be updated on a weekly basis on the Global Fund COVID-19 website (<https://www.theglobalfund.org/en/covid-19/>), reported to the Board upon request, to the AFC as part of the financial performance update and integrated into future Country Funding Updates for the Strategy Committee. Further information on disbursement and in-country expenditure will be provided to the Board and AFC, integrated into regular reporting on uses of funds.
32. The decision point delegates to the Secretariat the ability to make funding decisions through C19RM until 30 September 2020, subject to renewal by the Board. Funds deployed under C19RM can be used up until 30 June 2021.

Leveraging WHO Emergency Use and Listing

33. Currently, policies for Pharmaceutical and Diagnostics Products state that when Global Fund grant funds are used to procure non-core products (i.e. essential medicines and diagnostics products not used for HIV, tuberculosis, malaria and hepatitis B, hepatitis C and syphilis co-infections), the quality assurance requirements are limited. For pharmaceutical products, there is no specific QA requirement except that products must be registered in the country of use. For diagnostics products, the products procured should have their quality Management Systems certified, as well as comply with WHO guidance or with applicable national guidelines.
34. The WHO declared a Public Health Emergency of International Concern (PHEIC) for COVID-19 on 30 January 2020. The proposed approach to respond to the COVID-19 emergency is to rely on WHO's and stringent Regulatory Authorities' emergency processes during a PHEIC. This would ensure efficient support to country efforts in facing serious public health emergencies while maintaining an adequate level of assurance on the quality, safety and efficacy/performances of the pharmaceuticals and diagnostic products procured with Global Fund resources, as well as avoid reliance on national regulatory authorities for which there is no evidence of stringent requirements and practices.
35. The proposed decision provides that for the duration of the PHEIC, which has already been declared for COVID-19, products approved pursuant to the WHO Emergency Use and Listing (EUL) procedures shall be available to implementers for procurement using grant funds. Furthermore, products approved pursuant to any other emergency procedure set up by one of the stringent Regulatory Authorities as defined under the QA Policy for Pharmaceutical Products and QA Policy for Diagnostic Products shall be available to implementers for procurement using C19RM funds.
36. Given the current emergency and the scarcity of diagnostic products, the Secretariat is exploring ways to rapidly secure volumes of such products and is notably working with the WHO and the Bill and Melinda Gates Foundation which has expressed capacity to directly engage with manufacturers and make early volume commitments. Based on the outcome of discussions on early volume commitments, and the actual risk that the Global Fund may have to support in committing funds from C19RM for advance orders of COVID-19 commodities to be subsequently allocated to countries, the Secretariat will consider the need for additional Board approvals for these operations.

Raising and Deploying Additional Private and Public Funds

37. In addition to providing grant funding to countries and enabling procurement flexibilities for COVID-19 commodities, the Global Fund can support country responses by providing an effective fundraising and delivery platform for rapid translation of private and public donor funds into the COVID-19 response.
38. There are already substantial funds announced as available for COVID-19 responses from bilateral donors and multilateral donors including the World Bank, IMF, Gavi, and regional development

banks. Under the Global Action Plan's Sustainable Financing for Health Accelerator, multilateral donors are closely coordinating their funding. However, despite the announced funding to date, it is likely that pandemic response needs far outstrip available funding in LMICs.

39. Furthermore, there are aspects of the Global Fund model that may make it particularly well suited to help countries rapidly respond to COVID-19 and protect existing health programs and systems.
40. First, the Global Fund has long-term funding and implementation relationships with Ministries of Health and Ministries of Finance in almost every LMIC. These relationships have delivered billions of dollars of funding to fight the three diseases and build systems with robust oversight, financial and programmatic risk management processes.
41. Second, the Global Fund also has extensive relationships with NGOs and community organizations in LMICs. These organizations are an essential component of a resilient system for health, can reach those whom the health system cannot or will not serve, and will be a critical component of the response to COVID-19 and protecting the gains made against HIV, TB and malaria.
42. Third, the Global Fund has proven it can rapidly move funding in emergency and challenging situations. From working through international NGOs during conflict and natural disasters to provide essential services, to providing innovative interventions like mass drug administration during the West African Ebola outbreak to save lives and reduce fevers to better fight Ebola, to the already rapid reprogramming of funds announced on 4 March 2020 for COVID-19, the Global Fund has shown its ability to rapidly respond to crises and effectively move funds.
43. Finally, the Global Fund partnership has proved adaptable to changing circumstances, from the early challenges of establishing an emergency response to HIV, TB and malaria, to enacting the major reforms of 2011, to continuing to adapt to the challenges of reducing human rights barriers to service, sustainability and transition of programs, and of going beyond saving lives and working to reduce disease incidence.
44. The combination of existing and robust implementation arrangements with government Ministries, NGOs and community organizations, rapid response capability, and responsive and adaptable governance mechanisms suggest the Global Fund could potentially play an important role in funding for the COVID-19 response.
45. Under the Amended and Restated Policy on Restricted Financial Contributions (PRFC), which was approved in May 2019¹⁵, the Global Fund can receive restricted contributions from Private Sector donors and eligible public mechanisms¹⁶. These contributions can be either for specific grants or can be for Board-approved catalytic investment priorities or other Board-approved initiatives.
46. Increased private sector resources can be mobilized to scale-up responses to COVID-19 within the current policy framework. As a Board-approved initiative, C19RM can receive complementary restricted funding contributions in accordance with the Policy on Restricted Financial Contributions. The Secretariat proposes that any additional Private Sector funds mobilized to address and mitigate the impact of COVID-19 are programed through C19RM and follow the same approach as described above in order to ensure a rapid integration of these funds into grants.
47. The Secretariat also believes there is potential to mobilize and utilize additional public sector funds for the COVID-19 response, to strengthen systems for health and for the protection of existing HIV, TB and malaria programs if donors so choose. The Secretariat expects that for the remainder of 2020, any additionally contributed public sector donor funds would be rapidly used through C19RM for COVID-19 responses and related activities to mitigate the impact of the pandemic on HIV, TB and malaria programs and to support systems for health.¹⁷

¹⁵ https://www.theglobalfund.org/media/8525/bm41_06-review-update-prfc_report_en.pdf

¹⁶ The Global Fund can either receive 'complementary restricted financial contributions (CRFCs)' or 'restricted financial contributions (RFCs)'. CRFCs allow the donor to both target a specific Board-approved activity and increase funding for this activity. RFCs are notionally targeted to Board-approved activities without increasing the funding to these activities. RFCs free-up an equal amount of Sources of Funds to support other Board-approved activities.

¹⁷ Subject to any necessary approvals in line with Board policy.

What do we need to do next to progress?

48. Board approval of the first Decision Point will enable the Global Fund to put in place temporary flexibilities for business continuity needed to ensure the delivery of the Global Fund's core mission during this pandemic.
49. Board approval of the second Decision Point will enable the Global Fund to provide time-bound additional direct support to countries to respond to the COVID-19 pandemic, enact procurement flexibilities to increase impact, and raise additional private and public funds to improve health during this pandemic.
50. The Secretariat anticipates this response will continue to evolve, and that additional flexibilities and adjustments may be required in the future. The Secretariat will continue frequent Board updates with the Executive Director and will provide transparent and frequent reporting on the Global Fund's response to COVID-19 and implementation of these decisions if approved. An expanded section of the Global Fund website is already reporting the latest COVID-19 related developments: <https://www.theglobalfund.org/en/covid-19/>.
51. Recognizing the unique circumstances of this pandemic and time-bound nature of these decisions, The Secretariat recommends the following specific time constraints:
 - a. GF/B42/DP10:
 - i. Point 1 of the decision will automatically expire on 30 June 2021;
 - ii. Points 2 and 3 of the first decision will remain in force until 30 September 2020, unless extended by the Board;
 - b. GF/B42/DP11:
 - i. Funding decisions for C19RM may be made through 30 September 2020, unless extended by the Board;
 - ii. Funds approved for deployment through C19RM during this period can be used until June 2021.

Recommendation

The Secretariat recommends the Decision Points presented on page 2 to the Board for approval. The Board is exceptionally requested to consider this decision in an expedited manner.

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.

Annex 1 – Relevant Past Decisions

Relevant past Decision Point	Summary and Impact
GF/AFC12/DP01: Approval of Available Sources of Funds for Portfolio Optimization and Financing Unfunded Quality Demand for the 2017-2019 Allocation Period (March 2020)	The Audit and Finance Committee, in accordance with its delegated authority from the Board approved USD 300 million as available sources of funds for financing prioritized and costed areas of need on the register of unfunded quality demand for the 2017-2019 allocation period, according to the prioritization process adopted by the Strategy Committee, pursuant to GF/SC04/DP02.
GF/B41/DP05: Approval of the Amended and Restated Policy on Restricted Financial Contributions (May 2019)¹⁸	The Board approved revisions to the Amended and Restated Policy on Restricted Financial Contributions in order to further enhance the effectiveness of the policy as a resource mobilization tool.
GF/B39/DP09: CCM Evolution: Code of Conduct for CCMs and CCM Policy (May 2018)¹⁹	The Board replaced the Guidelines and Requirements for Country Coordinating Mechanisms, as approved by the Board under GF/B23/DP17, with the CCM Policy as set out in Annex 3 of GF/B39/04 – Revision 1 (the “CCM Policy”), delegated authority to the Strategy Committee to approve amendments to the CCM Policy and requested the Secretariat to operationalize the CCM Policy and regularly report on its implementation to the Strategy Committee.
GF/B37/DP12: Amended and Restated Global Fund Quality Assurance Policy for Diagnostic Products (May 2017)²⁰	The Board approved the amended and restated Global Fund Quality Assurance Policy for Diagnostic Products.
GF/B36/DP04: Amended and Restated Comprehensive Funding Policy (November 2016)²¹	The Board approved amendments to the Amended and Restated Comprehensive Funding Policy to: (i) align terminology with the refined allocation methodology adopted by the Board in April 2016; (ii) integrate the portfolio optimization mechanism developed over the 2014 – 2016 allocation period; and (iii) update the methodology for determining sources of funds for an allocation period.
GF/B22/DP09: Amendment to the Quality Assurance Policy for Pharmaceutical Products (December 2010)²²	The Board approved the amendment and restatement of the Quality Assurance Policy for Pharmaceutical Products. The Board requested the Secretariat to explain to grant recipients in writing the implications of the termination of the Interim Exception and the changes to the eligibility criteria for the review of Finished Pharmaceutical Products by the Expert Review Panel (ERP) as specified in the policy.

¹⁸ <https://www.theglobalfund.org/board-decisions/b41-dp05/>

¹⁹ <https://www.theglobalfund.org/board-decisions/b39-dp09/>

²⁰ <https://www.theglobalfund.org/board-decisions/b37-dp12/>

²¹ https://www.theglobalfund.org/media/4256/bm36_02-comprehensivelifunding_policy_en.pdf

²² <https://www.theglobalfund.org/board-decisions/b22-dp09/>