Extension of C19RM and COVID-19 Operational Flexibility

Electronic Report to the Board

GF/B46/ER06 – **Version of 15 December 2021 for decision**

Board Decision

Purpose of the paper: This paper seeks Board approval for (i) a further extension of the timelines for the receipt and award of funds for the COVID-19 Response Mechanism (C19RM); (ii) a revision to the Board approval thresholds for C19RM awards; and (iii) a further extension of the Secretariat's delegated authority to grant limited exceptions to the Quality Assurance Policies to waive the requirement for pre-shipment sampling and testing.

Decision

Decision Point: GF/B46/EDP06: Extension of the COVID-19 Response Mechanism and COVID-19 Operational Flexibility

1. ***Based on the rationale provided in GF/B46/ER06, the Board:***

    a. ***Approves that any additional 6th Replenishment pledges received through 30 September 2022 will be used to support the COVID-19 Response Mechanism (C19RM);***

    b. ***Approves that any additional C19RM funds may be awarded through 31 March 2023;***

    c. ***Approves to revise the thresholds for Board approval of C19RM awards set out in paragraph 5.d of GF/B44/EDP18 based on the total additional C19RM funding made available, as follows:***

        i. ***If up to US$ 1 billion of additional funding for C19RM is made available, the Board approval threshold will increase to US$ 45 million, and the Secretariat will have delegated authority to increase Board-approved C19RM awards by up to US$ 15 million, where such increases scale-up interventions approved by the Board;***

        ii. ***If more than US$ 1 billion of additional funding for C19RM is made available, the Board approval threshold will increase to US$ 55 million, and the Secretariat will have delegated authority to increase Board-approved C19RM awards by up to US$ 20 million, where such increases scale-up interventions approved by the Board; and***

        iii. ***Threshold amounts will continue to be measured in aggregate by country, not including any amounts awarded under the fast-track approach or C19RM funds awarded in 2020;***

    d. ***Agrees that all other parameters of C19RM under GF/B44/EDP18 remain unchanged; and***

    e. ***Approves that the Secretariat may continue to grant limited exceptions to the Quality Assurance Policies to waive the requirement for pre-shipment sampling and testing (as originally approved under paragraph 3 of GF/B42/EDP10) through 31 December 2023.***

Budgetary implications (included in, or additional to, OpEx budget): Incremental management and operating costs directly attributable to C19RM will continue to be covered by up to 3% of any funds made available for C19RM.

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

Executive Summary

The COVID-19 pandemic continues to have a devastating impact on countries and communities across the world, overwhelming health systems and threatening the Global Fund's mission to fight HIV, tuberculosis (TB) and malaria. The recent identification of the Omicron variant underscores the continuing volatility of the pandemic. The ACT-Accelerator (ACT-A) has published a budget identifying a US$ 23.4 billion funding requirement through September 2022, of which US$ 16.4 billion is needed for the non-vaccine components of the COVID-19 response, including tests, treatments and personal protective equipment (PPE). Global leaders have committed to fund these needs, as equitable access to the full spectrum of COVID-19 tools is vital to the success of the global response.

The Global Fund's COVID-19 Response Mechanism (C19RM) has been the largest provider of grant funding to low and middle-income countries for the non-vaccine components of their COVID-19 responses. With its track record for efficacy and scale, C19RM is uniquely placed to continue providing such desperately needed funding for COVID-19 responses in Global Fund-supported countries, while simultaneously safeguarding the Global Fund's core programs. Yet C19RM's ability to receive additional pledges expires on 31 December 2021.

This paper proposes (i) an extension of the deadline by which C19RM can receive and award additional funds, so that additional support can be provided to Global Fund countries for their COVID-19 responses and the Global Fund can play its role in supporting the objectives of ACT-A; (ii) a revision of the Board-approval thresholds for C19RM awards, should additional funding become available, so as to maintain both a broadly consistent level of Board oversight and the speed and responsiveness of the mechanism; and (iii) an extension of the Secretariat's delegated authority to grant limited exceptions to the pre-shipment sampling and testing requirements under the Quality Assurance Policies, to mitigate the risks arising from COVID-19-related supply chain disruptions. The rationale for this proposal and related risks are set out below.

Context

1. The COVID-19 pandemic continues to have a catastrophic impact on lives and livelihoods across the world, both directly and through the knock-on impact on other health services, including HIV, TB and malaria programs supported by the Global Fund. As of 30 November 2021, there were more than 260 million confirmed cases of COVID-19 and approximately 5 million deaths globally.[1] Officially reported data underestimates the total number of global deaths from COVID-19, which may be over to 17 million.[2] During 2021, the Delta variant caused a global surge of COVID-19 cases, resulting in third or fourth waves in many Global Fund-supported countries. With testing numbers in many countries still significantly below WHO recommendations, the true number of infections is also likely far higher than reported, particularly in Global Fund-supported countries where access to diagnostics remains limited. Continued high rates of transmission increase the risk that new and more infectious variants may emerge, as demonstrated by the recent identification of the Omicron variant. While relatively little is currently known about the potential impact of this new variant, its emergence highlights the continuing uncertainties about the outlook for the pandemic. Whether or not Omicron proves to be more transmissible, virulent or capable of vaccine or treatment escape, it seems prudent to assume that there will be further variants with such characteristics.

2. The rapid development and deployment of COVID-19 vaccines have contributed tremendously to positive progress against COVID-19, but inequitable access has led to a striking disparity between wealthy and poor countries: only 7.5% of the population in low-income countries has received a single dose of the vaccine,[3] compared to 64% in high-income countries. Some countries in the world have vaccinated less than 2 percent of their populations.[4] Recent analysis indicates that G-20 countries have received 15 times more vaccines per capita than Sub-Saharan Africa[5] and about half the world's population has yet to receive a single dose of a COVID-19 vaccine.[6]

3. While vaccines are our most powerful weapon in the fight against COVID-19, Delta and now Omicron have demonstrated that vaccines alone will not defeat this pandemic. Success will require a comprehensive response, using all the tools available, including diagnostics, therapeutics and PPE. The inequities in vaccine provision are matched or exceeded by the inequities in access to testing. This undermines efforts to contain transmission, provide care to those infected, and detect the emergence of new variants. A key priority for ACT-A is to enable every country to test at a rate of at least 100 tests per 100,000 population per day.

[1] https://covid19.who.int/
[2] https://www.economist.com/graphic-detail/coronavirus-excess-deaths-estimates
[3] https://data.undp.org/vaccine-equity/
[4] For example, less than 0.16% of the population in DRC and 1.2% in Chad has received at least one dose, Source: WHO Coronavirus (COVID-19) Dashboard, accessed 30 November 2021 https://covid19.who.int/region/afro/country/cd
[5] https://www.unicef.org/press-releases/g20-members-have-received-15-times-more-covid-19-vaccine-doses-capita-sub-saharan
[6] https://ourworldindata.org/covid-vaccinations/, accessed 30 November 2021

4. On the treatment front, critical gaps in medical oxygen persist, with a direct impact on mortality. A number of new, promising therapeutics are now poised to enter the market, including molnupiravir[7] from Merck and PAXLOVID[8] from Pfizer, both of which appear to significantly reduce the risk of hospitalization and death in non-hospitalized adult patients with mild-to-moderate COVID-19 when administered within a few days of the onset of symptoms. However, to realize the potential of these new antivirals, low- and middle-income countries must have equitable access to these life-saving medicines, particularly as these therapeutics will also be in high demand in developed countries and will need to scale up testing and put in place effective "test and care" clinical pathways.

5. Acknowledging the continuing significant needs across all pillars of the global COVID-19 response, ACT-A, of which the Global Fund is a founding partner, has recently published a budget for the period to end-September 2022, which includes US$ 16.4 billion for non-vaccine components of the response, alongside more than US$ 7 billion for vaccine deployment.[9] The ACT-A budget forms part of an estimated US$ 43 billion overall global investment needed to end the acute phase of COVID-19.

6. In recognition that current global COVID-19 response needs go far beyond the current level of funding available, and that equitable access to COVID-19 tools is necessary to control the global pandemic, donors have signalled their intent to step-up resources to support the response in low- and middle-income countries. In October 2021, G20 leaders reiterated support for all pillars of ACT-A, committing to "advance our efforts to ensure timely, equitable and universal access to safe, affordable, quality and effective vaccines, therapeutics and diagnostics, with particular regard to the needs of low- and middle-income countries".[10] In addition, following the Global COVID-19 Summit hosted by President Biden on 22 September 2021, the United States is hosting a series of high-level meetings to seek to address the gaps in the global response, including the shortfalls in funding for the non-vaccine components of the global COVID-19 response.

7. C19RM has been the largest provider of funding for diagnostics, therapeutics and PPE to low- and middle-income countries throughout the pandemic. To date, C19RM has channeled approximately 62% of ACT-A's overall non-vaccine funding (US$ 3.1 out of US$ 5.1 billion), and is the largest contributor to three of the four ACT-A pillars (Diagnostics, Therapeutics, and the Health Systems Response Connector). C19RM has been widely recognised as a highly effective mechanism for channelling non-vaccine support to countries, given its rigor, transparency, inclusivity and speed. C19RM remains firmly anchored in countries' needs and contexts, with requests developed and endorsed by Country Coordinating Mechanisms, aligned with national strategic preparedness and response plans, and developed in consultation with national response coordinators. Bilateral and technical partners are also engaged through the

[7] On 1 October 2021, MSD (Merck Sharp & Dohme AG) and Ridgeback Biotherapeutics announced that molnupiravir (MK-4482, EIDD-2801) significantly reduced the risk of hospitalization or death in at risk, non-hospitalized adult patients with mild-to-moderate COVID-19. An Emergency Use Authorization (EUA) application to the U.S. Food and Drug Administration (FDA), from which a decision is pending, on 11 October 2021 and on 4 November 2021 the United Kingdom's Medicines and Healthcare Products Regulatory Agency (MHRA) granted conditional marketing authorization for molnupiravir.

[8] The Pfizer's investigational novel COVID-19 oral antiviral candidate is called PAXLOVID. https://www.pfizer.com/news/press-release/press-release-detail/pfizers-novel-covid-19-oral-antiviral-treatment-candidate; https://www.science.org/content/article/unquestionably-game-changer-antiviral-pill-cuts-covid-19-hospitalization-risk

[9] https://www.who.int/publications/m/item/act-accelerator-strategic-plan-budget-october-2021-to-september-2022

[10] G20 Rome Leaders' Declaration, 31 October 2021. https://www.consilium.europa.eu/media/52732/final-final-g20-rome-declaration.pdf

funding request development and review process. C19RM's cross-cutting support to ACT-A, and high level of partner engagement at all levels mitigates the risk of silos developing across the global COVID-19 response and facilitates a more coherent, complementary and collaborative response across partners.

8. In 2021, C19RM has awarded US$ 3.2 billion to 121 applicants, including US$ 2.4 billion to support national COVID-19 responses, US$ 340 million to mitigate the impact of COVID-19 on HIV, TB and malaria programs, and US$ 450 million to support the urgent reinforcement of health and community systems. The Global Fund has awarded more than US$ 700 million of funding for diagnostics, which will procure more than 145 million tests, approximately US$ 490 million for oxygen and other clinical care-related products, and US$ 486 million for the purchase of PPE and related products. C19RM awards extend beyond the financing of health products to support the strengthening of the health and community systems supporting Global Fund HIV, TB and malaria programs.

9. In addition to US$ 3.2 billion of awards, US$ 1.03 billion of critical unfunded demand across 72 countries has been registered through C19RM. This figure massively understates the actual need, since it only captures needs included in C19RM funding requests, where the total amount of funding was a known constraint. Since many of the medical commodities funded through C19RM are consumables, there is an unmet (and largely unregistered) need for repeat purchases. Moreover, the emergence of new and effective antivirals will create a new set of funding requirements.

Proposal and Rationale

C19RM Extension

10. There is no question that the pandemic will continue through 2022, and thus the threat to Global Fund countries, communities and the very core of the Global Fund mission. The recent identification of the Omicron variant only underscores how far the world remains from the end of the pandemic. Yet, without extension by the Board, C19RM will close in December 2021. This would represent a very odd message for the Global Fund to send to the communities we serve, to our partners, and to our donors. Since C19RM has been ACT-A's principal channel for providing funding for the non-vaccine components of the response thus far, closing it would likely have a material impact on ACT-A's ability to achieve its objectives.

11. The Secretariat therefore proposes to keep C19RM open to receive additional pledges for the duration of ACT-A's new budget, which extends to 30 September 2022. The Secretariat also proposes to extend the period during which awards can be made to 31 March 2023, recognising that it can take up to six months to convert donor contributions into awards to implementers.

12. Under current Board policy, C19RM can accept pledges from donors until 31 December 2021, and make awards until 31 March 2022. Given the continuing needs for COVID-19 responses in Global Fund countries, and the potential for additional resources to be made available for this end, the Board is requested to approve that any additional 6th Replenishment pledges received

through 30 September 2022 will be channelled to C19RM, with awards to be made by 31 March 2023. Limiting potential additional C19RM funding to 6th Replenishment pledges will both align with the expected timelines for use of C19RM funds (as the December 2023 use deadline effectively limits use of funding to 6th Replenishment grants) and avoids any overlap with 7th Replenishment pledges.

13. Enabling C19RM to continue to receive additional funds beyond 31 December 2021 will ensure that C19RM is able to continue operating, not only as a direct response to COVID-19, but as a critically important mechanism to mitigate the knock-on impact on HIV, TB and malaria. As evidenced in the 2020 Results Report,[11] COVID-19 has had a devastating impact on HIV, TB and malaria programs. Channelling funding for the COVID-19 response through C19RM enables countries to use at least a portion of the funds to mitigate the knock-on impact on HIV, TB and malaria. This would not be the case if the same funds were routed through other channels.

Revising the Thresholds for Board Approval

14. The Board is also requested to revise the Board approval threshold for C19RM awards, which is currently set at US$ 35 million.[12] Over 2021, out of US$ 2.63 billion of full funding request awards,[13] the Board will approve awards for up to 25 countries amounting to US$ 1.75 billion, or 66%, of the C19RM portfolio. If this threshold were left unchanged, the cumulative effect of aggregating awards across 2021 and 2022 would likely result in the Board being asked to approve a number of relatively small awards. This would materially reduce the ability of C19RM to respond swiftly to emerging needs, since Board approval adds approximately two weeks to the decision process, in addition to having a significant impact on Board and Secretariat workload.

15. To maintain broadly the equivalent level of Board oversight, the Secretariat proposes to increase the Board approval threshold to US$ 45 million if up to US$ 1 billion of additional C19RM funding is made available, and US$ 55 million should more than US$ 1 billion be made available. This represents a roughly proportional increase that maintains the threshold at around 1% of total available C19RM funding. The intent is to ensure that the Board continues to approve, on an individual award basis, roughly two-thirds of C19RM funding for broadly the same cohort of countries (approximately 25-27 high impact and core portfolios). As in 2021, all funding requests, regardless of size, will be put to the Grant Approvals Committee (GAC) and COVID-19 Technical Advisory Group (CTAG) Partners for input before award decisions are made.

16. The approach to assessing whether awards meet the revised thresholds will remain consistent with the approach the Board approved for 2021. Awards will continue to be measured in aggregate by country, taking account of awards made in 2021, excluding funding awarded under the fast-track approach or C19RM funds awarded in 2020. Moreover, as in 2021, the Secretariat may seek Board approval for awards under these thresholds where the non-

[11] https://www.theglobalfund.org/media/10103/corporate_2020resultsreport_report_en.pdf
[12] As measured in aggregate by country and not including any fast-track funding or C19RM funds awarded in 2020, as set out in paragraph 5.d of GF/B44/EDP18.
[13] Includes full funding requests submitted as well as those still in the pipeline.

commodity components of an award are of a nature and scale to raise significant concerns about risk and complexity.

17. Extending the logic of the proposed revision to the Board approval threshold, the Secretariat also proposes to revise its delegated authority to increase awards already approved by the Board from the current level of US$ 10 million to US$ 15 million if additional C19RM funds are up to US$ 1 billion, and to US$ 20 million if additional C19RM funds exceed US$ 1 billion, where such increases scale up interventions already approved by the Board.

18. As in 2021, any awards of C19RM funding made under authority delegated to the Secretariat will continue to be reported to the Board and made public (including details of all individual awards made),[14] ensuring continued full oversight and visibility over all C19RM awards.

Extending the Limited Exceptions to Quality Assurance Policies

19. Global supply chain disruptions linked to COVID-19 continue to challenge the timely movement of health products from production sites to ports of entry in countries where they are needed, with increased lead times observed across nearly every product category compared to even this time last year. For products for which pre-shipment sampling and testing is required (i.e., Expert Review Panel (ERP)-approved products, vector control products and condoms), lead times are even longer as shipment is not authorized until test results become available. As most recently demonstrated by the identification of the Omicron variant, the COVID-19 situation remains unstable, and on short notice, international borders may be closed, access to work sites by inspectors may be restricted and quality control testing facilities may have a back-log of work requests, linked to COVID-19 case surges. Under these circumstances, maintaining a rigid approach to pre-shipment sampling and testing may lead to missed campaigns to distribute quality-assured insecticidal nets or prolonged stock-outs of lifesaving drugs.

20. Through GF/B42/EDP10, the Board delegated authority to the Secretariat to grant limited exceptions to Global Fund Quality Assurance Policies' pre-shipment sampling and testing requirements where delays in shipments would result in negative program impact that cannot be mitigated through other means. A Health Product Risk Committee (HPRC) has been established to consider individual exception requests with representation from diverse perspectives across the Secretariat. While the exception has been used in limited cases (and no additional requests have been considered by the HPRC since those reported in September 2020),[15] the Secretariat recommends extending this flexibility until 31 December 2023, as it provides a tool for navigating the continued uncertainty around the impact of COVID-19 on inspection and testing services and overall, longer lead times due to global supply chain disruptions. Extending the flexibility through 31 December 2023 would permit the Secretariat to

[14] A full list of C19RM awards made by country can be found at https://data-service.theglobalfund.org/file_download/covid_approved_funding_report/excel. Details on individual C19RM country awards can be found on the Global Fund's Data Explorer http://data.theglobalfund.org by country under "Documents".

[15] To date the Global Fund has received 19 requests to waive QA policies' pre-shipment inspection and testing requirements; 12 waivers for 7 countries for ERP-approved medicines for tuberculosis and for vector control products (LLINs and IRS) have been granted, and 7 waivers were not granted. For the 12 waivers that were granted, all products were held upon arrival until the results of the pre-shipment sampling and testing were known; no non-compliance issues were detected in these cases. As noted in GF/B44/ER11, waivers were approved based on critical programmatic needs and limited out-of-specification concerns from historical testing results, and shipments were authorized ahead of receipt of test results. The HPRC did not grant waivers in 7 instances where there was insufficient demonstration of an urgent programmatic need or where there was a history of out-of-specification test results from a prior shipment.

act rapidly to consider the individual circumstances of any specific waiver request and take informed decisions in consideration of risks from multiple perspectives to potentially minimize supply disruptions (e.g., permitting the authorization of shipment in parallel to testing) where rigid adherence to policy requirements could compromise the timely arrival of quality-assured lifesaving health products.

What are the Risks and Proposed Mitigations?

21. In addition to the risks outlined in previous Board papers on C19RM,[16] the Secretariat acknowledges that there are additional specific risks related to this extension.

22. *Diversion of resources from either the 6th or 7th Replenishment.* Incremental funds for C19RM in 2022 will be derived from any new, and clearly additional, 6th Replenishment pledges made during the period January-September 2022. C19RM funding in 2022 will not come from either existing 6th Replenishment pledges, nor from – or compete with - 7th Replenishment pledges.

23. All new 6th Replenishment pledges between January – September 2022 will be directed to C19RM. Funds provided in fulfilment of 6th Replenishment pledges made before the establishment of C19RM in April 2020 will not be used for C19RM in 2022, so resources pledged in Lyon at the 6th Replenishment cannot be repurposed in this way. Moreover, resources made available through portfolio optimization of 6th Replenishment funds will not be used for C19RM in 2022, but will be awarded through the well-established prioritization approach to meet unfunded quality demand. The Secretariat will work with donors to ensure that any new pledges for C19RM are not at the expense of ensuring the full conversion of existing 6th Replenishment pledges.

24. C19RM pledges will also be distinct from 7th Replenishment pledges. While we may well see pledges to C19RM and pledges for the 7th Replenishment during 2022, these will be for distinct time periods and different purposes. Any pledges to C19RM in 2022 must be awarded by end March 2023, and fully utilized by end December 2023, the end of the 6th Replenishment grant cycle. By contrast, pledges for the 7th Replenishment will be to fund grants beginning in January 2024, the beginning of the 2024-2026 grant cycle. There is therefore no overlap between the time period in which C19RM can be used, and the time period for the deployment and use of 7th Replenishment funds. This also means these funds will be sourced from distinct periods from a donor perspective. Furthermore, C19RM resources will remain directed towards the immediate crisis response, including COVID-19 commodities and interventions, actions to mitigate the impact on HIV, TB and malaria, and urgent strengthening of health systems. 7th Replenishment resources will not be used for C19RM's crisis response, but will be used to sustain and scale up investments in HIV, TB and malaria programs and in building the resilience and strength of health systems, including community systems for health.

25. The Secretariat will work with donors to ensure that any new pledges for C19RM are not at the expense of ensuring the full conversion of existing 6th Replenishment pledges, nor compete with prospective pledges for the 7th Replenishment. The Secretariat anticipates that any further pledges for C19RM in 2022 will be sourced outside existing development assistance for health budgets, since these are already fully committed, most likely from supplementary or emergency

[16] GF/B44/ER12-Rev2; GF/B43/ER11

budget allocations created as part of donor countries' broader response to the next phase of the pandemic.

26. *Diversion of effort towards raising funds for COVID-19 versus the 7th Replenishment*. The 7th Replenishment is and must be the top priority for 2022, and the Secretariat's and the partnership's resources will be focused on this ambition. A highly successful 7th Replenishment, securing increased funding for the fight against HIV, TB and malaria, is absolutely essential if we are to deliver the new Global Fund Strategy and get back on track towards ending the three epidemics by 2020. This will therefore be the primary focus of the Secretariat's and partnership's resource mobilization efforts in 2022. Any resource mobilization for C19RM will be in the context of the broader global response through ACT-A and will be carefully differentiated from the 7th Replenishment campaign.

27. In fact, continuing to play a leading – and highly effective – role in the COVID-19 response will contribute to the Global Fund's 7th Replenishment effort, rather than detract from it. By demonstrating the Global Fund's agility and effectiveness in helping countries respond to the pandemic and its impact on HIV, TB and malaria, C19RM will strengthen the Investment Case. By reinforcing health and community system responses to the pandemic, C19RM will evidence the role the Global Fund can play in pandemic preparedness and response Without a successful global response to COVID-19, Global Fund programs to fight HIV, TB and malaria will start the next grant cycle even further behind than they already are.

28. *Burden on Secretariat resources*. While the pandemic has undeniably created significant additional pressures on the Secretariat, incremental operational and management costs associated with C19RM will continue to be covered within the Board-approved limit of 3% of C19RM funds approved. Given the demand for global health expertise, and the constraints of the pandemic, it has taken time to recruit and onboard the extra temporary resources recruited to support C19RM, leading to acute workload pressures in some parts of the Secretariat, but as the new personnel come on board and become effective, these pressures should be mitigated. Moreover, much of the heavy lifting to build the necessary new infrastructure and processes (including for the funding request review and award process, grant revision process, and the monitoring and oversight approach for C19RM investments) has been completed. The Secretariat will continue to monitor staffing needs and adapt as necessary. Meanwhile, the Audit and Finance Committee continues to be closely engaged on C19RM operational and management costs, and will continue its oversight and monitoring of Secretariat resourcing.

29. *Implementation challenges and under-absorption*. Strengthening monitoring and oversight over the implementation of interventions funded by C19RM has been a priority in 2021, with significant organizational effort directed towards developing new reporting tools and strengthening internal processes. The new reporting tools that have been implemented include Pulse Checks, Supply Chain and Health Services Spot Checks and Procurement Progress Updates. These tools have been designed to increase visibility of C19RM implementation from procurement through to COVID-19 and HIV, TB and malaria product and service availability, and the impact of disruption on HIV, TB and malaria programmatic performance through monitoring progress on grant targets, KPIs and fund utilization. While these tools will be refined based on lessons learned from initial reporting rounds, there is an expectation that they will

quickly start to provide valuable insight into implementation challenges and highlight areas where the Secretariat and partners can support countries to address bottlenecks.

30. In addition to a focus on strengthening visibility of C19RM implementation, there has also been a focus on strengthening internal processes for data use and action. From July onwards, operational leads across the Secretariat have been meeting on a regular basis to review data already available, linked to upstream processes and procurements through wambo/PPM, to ensure organizational visibility of blockages and delays and responsive root cause analysis and problem solving. The Secretariat has also been developing the infrastructure for more holistic cross-cutting reviews of implementation, leveraging data coming through Pulse Checks and Spot Checks. These will be conducted on a quarterly basis drawing data from a range of sources and covering both upstream processes and in-country implementation. These quarterly implementation reviews will be led by the C19RM Investment Committee and will be used to prioritize specific countries for follow-up and action and to identify thematic or portfolio-wide issues and bottlenecks that require intervention. The first round of data collection through Pulse Checks is complete and data collection through Spot Checks has started. Key insights coming from these reporting tools will be shared with the Board starting in Q1 2022 through regular C19RM reporting and through Board calls. GAC and CTAG will also be used as forums for the global partnership to discuss key findings from this data and address programmatic challenges to accelerate implementation. The ongoing OIG audit (expected to be finalized in February 2022) and TERG evaluation will also yield insights that the Secretariat will use to improve C19RM delivery and implementation.

What is Required to Progress the Proposal?

31. The Board is requested to approve the Decision Point on page 2. Any additional 6th Replenishment pledges that would be channeled to C19RM will continue to be approved as available by the Audit and Finance Committee in line with Board policy.

32. Any further proposed extension of C19RM will be presented to relevant Committees of the Board in July 2022 before recommendation to the Board. At the Committee and Board meetings, in March and May 2022 respectively, there will be opportunity for strategic discussion regarding the longer-term future of C19RM as a response mechanism, both within the specific context of the evolution of the COVID-19 pandemic, and as part of the Global Fund's longer-term role in pandemic preparedness and response.

Annexes

The following items can be found in Annex:

- Annex 1: Relevant Past Board Decisions
- Annex 2: Links to Relevant Past Documents & Reference Materials

Annex 1 – Relevant Past Board Decisions

Relevant past Decision Point	Summary and Impact
GF/B45/EDP12: Increases to the COVID-19 Response Mechanism's (C19RM) Fast-track Investment Ceiling **August 2021**[17]	The Board delegated authority to the Audit and Finance Committee to increase the overall C19RM Fast-track ceiling amount by up to a further USD 700 million due to the continuing threat of the COVID-19 pandemic and the urgent need to scale-up country responses.
GF/B44/EDP18: Second Extension of C19RM Timeline and Operational Flexibility for COVID-19 **March 2021**[18]	The Board approved a further extension of the timelines for the receipt, award, and use of funds for the Global Fund COVID-19 Response Mechanism based on further modifications proposed by the Secretariat.
GF/B43/EDP12: Extension of C19RM Timeline and Operational Flexibility for COVID-19 **September 2020**[19]	The Board: (i) decided that the Secretariat may approve requests for C19RM funds through 15 April 2021; (ii) affirmed that all other previously approved principles under GF/B42/EDP11 would continue to apply to C19RM; and (iii) requested the Secretariat to return to the Board, through its committees as relevant, for additional consideration and approval should further extensions of C19RM be required, or if total additional funding for C19RM exceeds USD 500 million; and (iv) approved that the operational flexibility under paragraph 3 of GF/B42/EDP10, delegating authority to the Secretariat to grant limited exceptions to the quality assurance policies to waive the requirement for pre-shipment sampling and testing, would apply through 15 April 2021.
GF/B42/EDP11: Additional Support for Country Responses to COVID-19 **April 2020**[20]	The Board approved the creation and initial funding up to USD 500 million of a COVID-19 response mechanism to finance interventions consistent with WHO guidance on COVID-19 in the context of national Strategic Preparedness and Response Plans across the 5th and 6th replenishment periods.

[17] https://www.theglobalfund.org/board-decisions/b45-edp12/
[18] https://www.theglobalfund.org/board-decisions/b44-edp18/
[19] https://www.theglobalfund.org/board-decisions/b43-edp12/
[20] https://www.theglobalfund.org/board-decisions/b42-edp11/

Annex 2 – Relevant Past Documents & Reference Materials

GF/B45/ER11*:* Increases to the COVID-19 Response Mechanism's Fast-track Investment Cap

GF/B44/ER12: Second Extension of C19RM and Operational Flexibilities

GF/B43/ER10: Extension of C19RM Timeline and Operational Flexibility for COVID-19

GF/B42/ER09: COVID-19 Response for Business Continuity and Country Support