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# Electronic Report to the Board

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## Extension of C19RM Timeline and Operational Flexibility for COVID-19

GF/B43/ER11 – Final version 23 September 2020

### Board Decision

Purpose of the paper: This paper seeks Board approval to extend the time limit for the award of funds from the Global Fund COVID-19 Response Mechanism (C19RM), and to extend the duration of the Secretariat's delegated authority to grant limited exceptions to the pre-shipment sampling and testing requirements under the Quality Assurance Policies.

## Decision

### **Decision Point: GF/B43/EDP12: Extension of C19RM Timeline and Operational Flexibility for COVID-19**

***The Board agrees that COVID-19 continues to pose a grave threat to the Global Fund's mission to fight HIV/AIDS, tuberculosis, and malaria and strengthen systems for health, and that continued support for country responses to COVID-19 is critical to safeguard Global Fund programs and country health systems. The Board acknowledges its previous decisions establishing the Global Fund COVID-19 Response Mechanism (C19RM) to provide additional support for country responses to COVID-19 (GF/B42/EDP11), and approving certain time-bound operational flexibilities to ensure the continued delivery of the Global Fund mission during the pandemic (GF/B42/EDP10). Noting that COVID-19 continues to jeopardize country health systems and impede progress in the Global Fund's mission, and that additional funds may become available for C19RM, the Board:***

- 1. Approves that the Secretariat may approve requests for C19RM funds through 15 April 2021;***
- 2. Affirms that all other previously approved principles under GF/B42/EDP11 will continue to apply to C19RM;***
- 3. Requests the Secretariat to return to the Board, through its Committees as relevant, for additional consideration and approval should further extensions of C19RM be required as the pandemic continues to evolve, or if total additional funding for C19RM exceeds USD 500 million; and***
- 4. Approves 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 for Expert Review Panel-approved products, vector control products, and condoms, where such testing may delay the delivery of products to countries, will apply through 15 April 2021.***

**Budgetary implications (included in, or additional to, OPEX budget):** Incremental OPEX costs directly attributable to the proposed extension of C19RM will amount to around USD 1.5 million, depending to some extent on the quantum of incremental funds deployed over the period. These costs will be included in the OPEX budget submission for 2021. This is on top of approximately USD 2.4 million of incremental costs in 2021 attributable to C19RM and grant flexibility approvals already made.

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

# Executive Summary

As of 10 September 2020, COVID-19 has caused over 899,916 deaths globally, with more than 27.7 million cases reported. Beyond its immediate toll, the pandemic threatens devastating consequences for global health and the Global Fund's mission, jeopardizing years of hard-won gains in the fight against HIV, tuberculosis and malaria. Modelling carried out early in the crisis by WHO, Stop TB and UNAIDS painted a bleak picture of the potential impact of COVID-19 on the three diseases, suggesting hundreds of thousands of additional deaths from HIV, tuberculosis and malaria over 2020. While actual data on the impact of COVID-19 on the three diseases is extremely scarce, there is no doubt that the pandemic continues to disrupt prevention and treatment programs and health systems – posing a critical risk to the Global Fund's mission.

The Global Fund has taken swift and decisive action in the fight against COVID-19, establishing grant flexibilities and the COVID-19 Response Mechanism (C19RM), under which a combined total of over USD 723 million has been approved to support countries' COVID-19 responses. Yet this funding covers only a fraction of the need for the COVID-19 response: the Secretariat has estimated that in the countries in which the Global Fund invests, some USD 28.5 billion is required to respond to COVID-19 and mitigate the impact on HIV, TB and malaria over the next 12 months, at least half of which is likely to remain unfunded. While both grant flexibilities and C19RM funding are nearing exhaustion, resource mobilization efforts continue and it remains probable that the Global Fund will secure at least some additional resources to support country responses to COVID-19.

Ongoing Global Fund support for the fight against COVID-19 is critical to protecting the Global Fund's core mission and to delivering the Global Fund's 2017-2022 Strategy. This support is essential to ensure health and community systems are not overwhelmed, treatment and prevention programs are not disrupted, and resources are not diverted away from core programs. Continued and increased support is also critical in light of the rapid progress in the development of tools to fight the disease, as the Global Fund can play a key role in ensuring the poorest and most vulnerable get access to innovations as soon as they become available.

In light of the continuing threat COVID-19 poses to Global Fund programs, and the possibility of additional funding becoming available, the Secretariat proposes to extend the timeline for the award of C19RM funds to 15 April 2021. This extension will facilitate ongoing resource mobilization efforts and is necessary to ensure the uninterrupted, rapid deployment of any additional funds received to support implementer countries' COVID-19 responses and protect Global Fund programs. This extension will also align timelines with scheduled committee meetings such that any further extension of C19RM that might be required can be considered first by committees before recommendation to the Board. The Secretariat also recommends extension of a previously-approved operational flexibility designed to avoid program disruptions, which authorizes the Secretariat to grant very limited exceptions to the requirement for pre-shipment sampling and testing under the Global Fund Quality Assurance (QA) Policies. The Secretariat's recommendations seek to ensure that the Global Fund can continue to deploy support to countries to mitigate the impact of COVID-19, and ensure uninterrupted program delivery in the fight against HIV, tuberculosis and malaria.

## Input Sought

The Board is requested to approve the following decision point:

- Decision Point: GF/B43/EDP12: Extension of C19RM Timeline and Operational Flexibility for COVID-19.

## Input Received

- The Board Coordinating Group has been consulted on this proposal. Board Leadership, in consultation with the Coordinating Group, have agreed that the current proposal for a limited extension to C19RM justifies use of the expedited decision-making approach.

## What is the need or opportunity?

1. COVID-19 will be one of the world's leading causes of infectious disease death in 2020. As of 10 September 2020, over 27.7 million COVID-19 cases and 899,916 deaths have been reported globally<sup>1</sup>, exceeding the 770,000 deaths from HIV and 405,000 deaths from malaria in 2018 and threatening to exceed the 1.5 million deaths per year from TB<sup>2</sup> by the end of the year. Beyond its immediate impact, the pandemic threatens to have dire consequences for the fight against HIV/AIDS, TB and malaria, as it overwhelms health and community systems, disrupts treatment and prevention programs, and diverts resources. Over the last few months, COVID-19 has increased rapidly in almost all of the low- and middle-income countries (LMICs) that the Global Fund supports. For example, India and the African region have surpassed 3.6 million and 1 million COVID-19 cases respectively<sup>3</sup>. The pandemic has caused global economic contraction and has greatly increased the vulnerability of many key affected populations; it may push up to 71 million additional people into extreme poverty before the end of 2020<sup>4</sup>.
2. Modelling carried out early in the crisis by WHO, Stop TB and UNAIDS presented a bleak picture of the potential impact of COVID-19 on the three diseases. According to projections by UNAIDS and WHO, deaths from HIV and AIDS in sub-Saharan Africa could double in 12 months over 2020-2021 with 534,000 additional deaths compared to 2018 – reversing more than a decade of progress. According to the Stop TB Partnership, the COVID-19 pandemic could result in an additional 525,000 TB deaths globally in 2020 compared to 2018 levels. On malaria, COVID-19 threatens to reverse 20 years of progress. According to WHO estimates, in sub-Saharan Africa, COVID-19 could result in an additional 382,000 malaria deaths in 2020 alone. This would take worldwide deaths from malaria back to levels not seen since 2000. Actual data on COVID-19 related excess morbidity and mortality from HIV, TB and malaria is extremely scarce. While this devastating scenario may have been averted in the short term, not least because of the urgent actions taken by the Global Fund and key partners, including PEPFAR, PMI, UNAIDS and WHO, it is nonetheless clear that policies designed to stem the spread of COVID-19, including lockdowns, curfews and physical distancing, as well as diversion of financial, human and laboratory resources from other programs to the COVID-19 response have already had a serious impact on the delivery of HIV, TB and malaria programs.
3. A survey of Global Fund programs across more than 100 countries shows up to 75 percent of HIV, TB and malaria programs have been disrupted. For example, TB case finding has been impeded by the diversion of domestic resources, TB-specialized staff, equipment and TB referral hospitals to the COVID-19 response, as well as increased stigma and discrimination due to similarity in the symptoms of COVID-19 and TB. TB case notifications in India and the Philippines have declined by more than 50% compared to the same period in 2019. Significant reductions in TB case notifications during COVID-19 lockdowns heighten the risk of transmission from the large numbers of undiagnosed and untreated cases, while TB treatment interruptions risk increased drug resistance. HIV programs are also facing significant disruption as access to treatment and prevention programs is limited due to restrictions on movement or fear of visiting health facilities. In some instances, harm reduction centers have been closed down on the claim that they are not essential services. Key populations for HIV face both an elevated risk for reduced access to services and a higher risk of acquiring COVID-19 due to high mobility and close physical contact with others, and are especially vulnerable to the consequences of lockdowns and other efforts to contain COVID-19. For example, some countries have designated 3 days a week for men to leave the house and 3 days for women, resulting in numerous trans women being arrested and humiliated by police for going out on the women's days. In other countries, COVID-19 laws have been used to target gay men and other men who have sex with men and sex workers, for instance arresting them for living in a shelter or breaching physical distancing restrictions in other ways. Similarly, sex workers cannot access social relief grants where sex work is criminalized, leading to loss of livelihood, loss of shelter, food insecurity and inability to access healthcare. Reports are also emerging about sex workers living with HIV who are unable to take ARVs due to severe nutritional insecurity. Malaria programs have also faced significant obstacles, as bed net distribution campaigns have been delayed or cancelled,

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<sup>1</sup> WHO Coronavirus Disease (COVID-19) Dashboard <https://covid19.who.int/>

<sup>2</sup> WHO Global Tuberculosis Report 2019, UNAIDS 2019 Data, World Malaria Report 2019

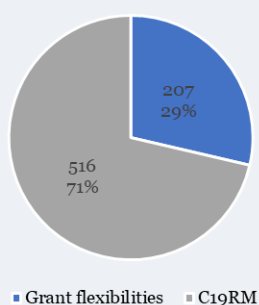
<sup>3</sup> WHO Coronavirus Disease (COVID-19) Dashboard <https://covid19.who.int/>

<sup>4</sup> World Bank Projected Poverty Impacts of COVID-19 <https://www.worldbank.org/en/topic/poverty/brief/projected-poverty-impacts-of-COVID-19>

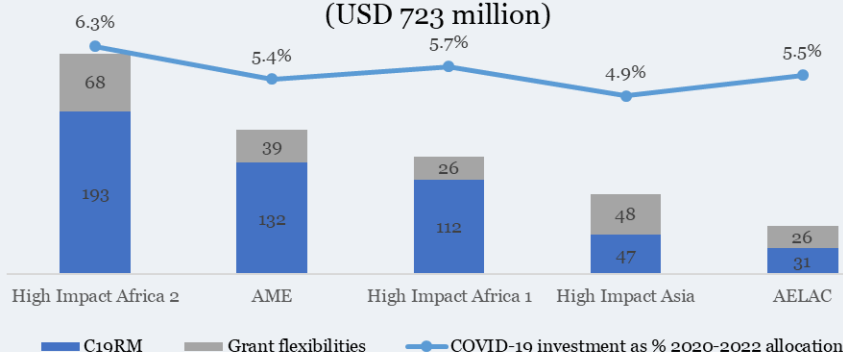
programs face supply chain disruptions, and sick individuals hesitate to seek treatment at health facilities.

4. Recognizing the fundamental threat posed by COVID-19 to the Global Fund’s mission, the Secretariat introduced grant flexibilities in early March 2020<sup>5</sup>, enabling countries to use grant savings and reprogramming opportunities to fund their initial responses to the pandemic, including urgent adaptations to HIV, TB and malaria programs, with a theoretical capacity of up to USD 500 million (but true availability of around USD 200-250 million). Acknowledging that grant flexibilities were unlikely to be enough to meet countries’ urgent needs, in April 2020 the Global Fund Board established the COVID-19 Response Mechanism (C19RM) to provide additional support to country responses to COVID-19<sup>6</sup>. An initial USD 500 million was made available under C19RM to finance three areas: (i) 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; (ii) 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 (iii) addressing critical gaps in health systems (e.g. strengthening laboratory networks, supply chains and community engagement). The total capacity for C19RM increased to USD 665 million following additional external contributions of USD 165 million. This support has been, and continues to be, essential to ensure health and community systems are not overwhelmed, treatment and prevention programs are not disrupted, and resources are not diverted away from core programs.
5. Similarly, to mitigate risks of disruption to the in-country supply of health products due to COVID-19, including travel restrictions preventing inspectors from accessing manufacturing sites, reduced capacity of laboratories supporting QA testing, and freight and logistics challenges translating to delays in getting health products to people that need them, the Board approved operational flexibilities to ensure continued operations during COVID-19 by delegating authority to the Secretariat to grant limited exceptions to the QA Policies’ pre-shipment inspection and testing requirements, where delays would result in negative program impact that cannot be mitigated<sup>7</sup>.
6. As of 10 September 2020, the Global Fund has approved a total of USD 723 million (USD 516 million C19RM and USD 207 million grant flexibilities) to support the COVID-19 response across 104 countries and 12 multi-country programs. Of the USD 516 million from C19RM, USD 180 million (35%) has been awarded for mitigating COVID-19’s impact on HIV, TB and malaria programs; USD 279 million (54%) for reinforcing national COVID-19 responses; and USD 57 million (11%) for urgent improvements in health and community systems. This also includes funding of USD 103 million for COVID-19 diagnostics and USD 169 million for Personal Protective Equipment (PPE). All awards have been consistent with WHO technical guidance and were made based on Country Coordinating Mechanism (CCM)-endorsed requests.

COVID 19 Response by Funding Source (USD 723 million)



COVID 19 Response by Region and as % of 2020-22 allocation (USD 723 million)



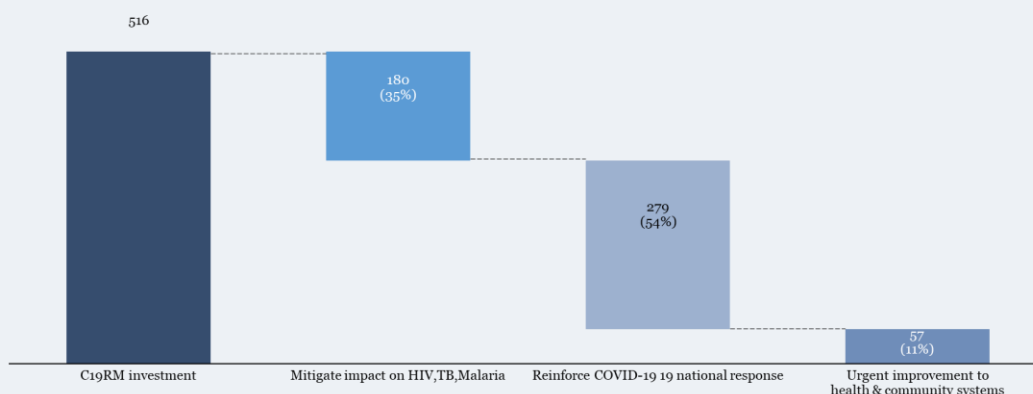
Note: all values in USD million

<sup>5</sup> [https://www.theglobalfund.org/media/9397/core\\_covid-19\\_guidancenote\\_en.pdf](https://www.theglobalfund.org/media/9397/core_covid-19_guidancenote_en.pdf)

<sup>6</sup> GF/B42/ER09 - Revision 1 <https://www.theglobalfund.org/board-decisions/b42-edp10/>

<sup>7</sup> GF/B42/EDP11 <https://www.theglobalfund.org/board-decisions/b42-edp11/>

C19RM Awards by Priority Area (USD 516 million)



7. Support for COVID-19 responses through grant flexibilities and C19RM has enabled Global Fund implementer countries to undertake successful mitigation measures to help safeguard disease programs. For example, in Niger, the National Malaria Control Program has been able to continue bed net campaigns while avoiding crowds at pick-up points by delivering 8 million bed nets door-to-door, including in the most rural communities. In Costa Rica, with access to PPE, transgender women resumed in-person activities by implementing one-on-one activities in the streets instead of group activities in enclosed spaces, and civil society organizations' virtual prevention activities are being complemented with delivery to clients of condoms by post. In Cuba, implementers introduced a strong program of contact tracing by using community health workers that are placed in each neighbourhood. With rapid training, distribution of PPE and an increase in information sharing among the different neighbourhoods and provinces, programs were able to contact-trace and follow-up during quarantine. In Myanmar, patients with suspected COVID-19 infection also receive a chest X-ray to detect TB. In addition, TB patients receive medications for three months to avoid multiple visits to health facilities. Patients are also monitored through mobile phone calls to avoid crowding in health facilities and all staff in direct contact with TB patients receive PPE. Sputum transportation was also strengthened to ensure that presumptive patients do not need to visit testing sites.

8. Some other examples of interventions being funded by C19RM include:

- Procuring COVID-19 Diagnostic Tests, including directly procuring COVID-19 automated PCR diagnostic cartridges (Cepheid and Abbott), and working through the WHO-led Diagnostics Consortium (now the Supply Workstream within the ACT-A Diagnostics Partnership) to supply other automated PCR and manual tests.
- Purchasing PPE, including for formal healthcare staff, community health workers, volunteers during LLIN campaigns and laboratory personnel.
- Providing support for scaling up investments for oxygen equipment and therapy.
- Reinforcing treatment and care for TB, HIV and malaria, including multi-month dispensing of ARVs and TB treatments.
- Strengthening laboratory capacity through purchasing laboratory equipment (including GeneXpert instruments) and consumables, minor infrastructure projects and sample transportation.
- Scaling up testing across the three diseases, including HIV testing (facility, community, self-testing), malaria RDTs and TB testing through GeneXpert.
- Supporting interventions aimed at AGYW, GBV, Human Rights and KP outreach, including community capacity building and support.
- Providing nutrition support for the most vulnerable and severely malnourished TB and HIV patients.
- Supporting the training of health care workers.
- Supporting communication and sensitization activities.

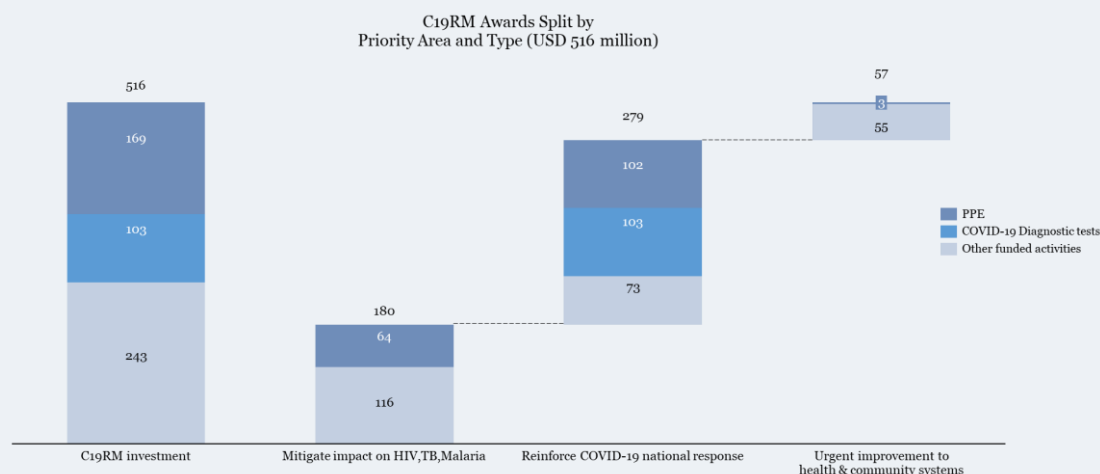
9. By 31 July 2020, 100% of the USD 500 million of initial funds available had been approved for investment. While precise definitions differ, this compares to an average 50% approved funding rate across peer funding mechanisms, as at 28 August 2020. Furthermore, apart from the World Bank, C19RM has, as of 28 August 2020, one of the broadest geographic footprints, having reached 78 countries and multi-country programs compared to an average of 45 countries and regional programs across peer mechanisms with public data available.



10. While the existing C19RM funding is expected to be exhausted this September, and the scope for using grant flexibilities is diminishing rapidly as countries near the end of the current grant cycle, country needs for resources to respond to COVID-19 are both escalating and evolving. Against currently uncommitted capacity of around USD 149 million, there remains a projected demand pipeline of roughly USD 500 million. This includes approved registered unfunded demand of around USD 150 million and 66 funding requests to be reviewed or submitted (including “top ups” to access additional funding), with projected total demand of around USD 350 million. Approximately USD 150 million of the total projected demand in the C19RM pipeline is expected to be approved by 30 September 2020, thus fully utilizing current capacity.
11. The current C19RM demand pipeline reflects only a small fraction of countries’ needs as they respond to COVID-19, since countries were asked to cap funding requests at an amount equivalent to 10% of their 2020-2022 allocation, and were told that total C19RM funding would be limited. The Secretariat has estimated that in the countries in which the Global Fund invests, some USD 28.5 billion is required to respond to COVID-19 and mitigate the impact on HIV, TB and malaria over the next 12 months. This analysis is consistent with estimates developed by the Access to COVID-19 Tools Accelerator (ACT-A) partnership. While some of these incremental funds will be provided by other external partners, such as the World Bank, or through domestic resources, more than half this funding requirement currently appears unfunded.

All values in USD billion	Resource Need for Global Fund Implementing Countries	Global Fund Share
Adapt HIV, TB and Malaria Programs	2.7	1.0
Protect Front-line Health Workers	10.8	1.8
Reinforce Systems for Health	2.3	0.9
Fight COVID-19	12.7	2.3
Diagnostics	4.9	1.9
Therapeutics	7.8	0.4
<b>TOTAL</b>	<b>28.5</b>	<b>6</b>
Global Fund resources already made available through grant flexibilities and C19RM	1	
<b>TOTAL ADDITIONAL RESOURCES REQUIRED</b>	<b>5</b>	

12. Ongoing Global Fund support for the fight against COVID-19 is critical to protecting the Global Fund’s core mission and to delivering the Global Fund’s 2017-2022 Strategy. The COVID-19 pandemic threatens to reverse many years of hard-won gains in the fight against HIV, TB and malaria. Continuing to support countries’ responses to COVID-19 is essential to ensure health and community systems are not overwhelmed, treatment and prevention programs are not disrupted, and resources are not diverted away from core programs. Further targeted support is also vital to mitigating the pandemic’s potentially disastrous impact on gender equity and human rights. In addition, delivering COVID-19 support through the Global Fund rather than other channels encourages consideration of the knock-on impact of the pandemic on HIV, TB and malaria in country responses to COVID-19, and places focus on reinforcing gaps in RSSH as well as supporting and leveraging community systems.
13. Continued and increased support for country responses to COVID-19 is also necessary considering the rapid progress in developing tools to fight the disease. With USD 103 million for diagnostics approved to date through C19RM, the Global Fund has played a critical role in ensuring countries get access to high quality automated PCR tests, albeit at volumes far below what countries need. With significantly cheaper, high performing antigen RDTs becoming available for the first time over the next few weeks, there is an opportunity to scale up testing even in the most remote and resource-constrained areas, if the Global Fund can secure volume from manufacturers. On the therapeutic front, the publication of WHO guidelines for corticosteroids including dexamethasone on 2 September<sup>8</sup> opens up the opportunity to provide countries with lifesaving treatments for severe cases. Rapid progress on novel treatments, notably monoclonal antibodies, offers the prospect of potentially significant reductions in mortality rates. However, securing access to such novel treatments for LMICs requires action now. On both diagnostics and therapeutics, ACT-A partners and implementer countries are looking to the Global Fund to play a key role in ensuring the poorest and most vulnerable get access to innovations as soon as they become available.
14. As the epidemic evolves, countries are also recognizing the imperative to protect front-line health workers, including community workers, through training and provision of PPE. Already some countries are seeing health system performance undermined by health workers falling sick or having to isolate, and in some countries health workers without PPE are encountering hostility. Thus far, USD 169 million has been approved via C19RM for PPE, but this represents a tiny fraction of the underlying need.



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15. While the remaining USD 150 million of C19RM funding is expected to be exhausted over the course of September 2020, additional funds may be received. Since March 2020, the Secretariat has been in dialogue with existing and potential donors seeking additional support. Donors have shown great interest in the response of the Global Fund, both to mitigate the impact on HIV, TB and malaria programs and to ensure effective responses to COVID-19. This outreach resulted in additional contributions being announced in May (Italy) and June (Canada, Germany and FIFA Foundation). Thanks to these additional pledges, the Global Fund has been able to sustain its support to countries through C19RM in August and September. There is good reason to expect additional financial

<sup>8</sup> <https://www.who.int/publications/i/item/WHO-2019-nCoV-Corticosteroids-2020.1>

<sup>9</sup> The split of PPE by Priority Area is based on C19RM awards and funds integrated into grants, as well as estimates of remaining awards pending integration.



contributions to be announced in the coming months. There are three reasons to believe this will be possible: (1) outreach by the Global Fund and its partners is gaining momentum with donors increasingly focused on the potentially catastrophic impact on LMICs and the reversal of hard-won gains against other epidemics; (2) the ACT-A collaboration is planning and implementing a high-profile joint advocacy campaign for the entire partnership that will focus on funding gaps; and (3) the Global Fund is seen by partners, implementers countries and donors as playing a pivotal role in supporting LMICs, in procuring and delivering treatments, diagnostics and PPE, in mitigating the impact on HIV, TB and malaria, and in shoring up health systems, given the partnership's established mechanisms for investment and delivery, and what has already been achieved through grant flexibilities and C19RM.

## What do we propose to do and why? What is the proposal?

### C19RM Extension

16. The Secretariat proposes to extend the existing timeline for the award of C19RM funds. Under GF/B42/EDP11, the Secretariat can approve requests for C19RM funds through September 2020, and funds may be used by countries through 30 June 2021. However, the Board reserved the possibility of extending these timelines based on updated information on needs as the pandemic evolves. The Board also decided that C19RM is a Board-approved initiative for which the Global Fund may mobilize additional resources from private and public donors, and noted that additional contributions received through the end of 2020 would be invested through C19RM. In light of the continuing threat COVID-19 poses and the need to sustain a swift and decisive response in coordination with partners to control its impact on the Global Fund mission and country health systems, the Secretariat proposes to extend the timeline for award of C19RM funds to 15 April 2021<sup>10</sup>. This extension will facilitate ongoing resource mobilization efforts and is necessary to ensure the uninterrupted, rapid deployment of any additional funds received to support implementer countries' COVID-19 responses and protect Global Fund programs. The Secretariat recommends a revised deadline of 15 April 2021 to align C19RM timelines with scheduled committee meetings such that any further extensions of C19RM that may be required can be considered by committees before recommendation to the Board, and to allow for more in-depth lessons-learned, including findings from the OIG's ongoing review of C19RM, to be considered in future decisions.
17. Apart from the extensions noted above, all previously approved principles under GF/B42/EDP11 will continue to apply to C19RM: funds will continue to (i) finance interventions consistent with WHO guidance on COVID-19 and national Strategic Preparedness and Response Plans; (ii) finance interventions across the 5th and 6th replenishment periods; (iii) be administered within the established internal control framework of the Global Fund; (iv) be additional to amounts approved by the Global Fund for programming towards COVID-19 interventions under existing grants<sup>11</sup>; and (v) be available 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. Any changes to the existing governing principles for C19RM will require approval by the Board.
18. The Secretariat proposes that up to an additional USD 500 million can be invested under C19RM using the principles approved under GF/B42/EDP11, as funding of approximately this magnitude will be invested to support the same kinds of interventions as have already been supported through C19RM. If additional funding of up to this sum is secured, it will be used to meet demand already queued, or additional demand expressed by countries through streamlined updates to submitted requests, including scale-up or continuation of priority interventions already funded.
19. For additional funding up to USD 500 million, the Secretariat will continue to follow the existing investment approach, which takes account of available funding through C19RM and grant flexibilities, and links support for the COVID-19 response to a country's 2020-2022 allocation. This ensures that C19RM resources are focused on mitigating the impact of COVID-19 on the Global Fund's mission to fight HIV, TB and malaria. When C19RM was initially launched, countries were

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<sup>10</sup> This extension applies only to the award of C19RM funding, and will not affect the management of cut-off principles for 5<sup>th</sup> replenishment grant funds under the Amended and Restated Comprehensive Funding Policy. The timeline for use of C19RM funds remains at 30 June 2021.

<sup>11</sup> As announced by the Global Fund on 4 March 2020, [https://www.theglobalfund.org/media/9397/core\\_covid-19\\_guidancenote\\_en.pdf?u=637189162540000000](https://www.theglobalfund.org/media/9397/core_covid-19_guidancenote_en.pdf?u=637189162540000000).

given an indicative guideline that submissions for COVID-19-related support for any one country, including grant flexibilities and C19RM, should not exceed an amount equivalent to 10% of a country's 2020-2022 allocation. Since 10% of the total 2020-2022 country allocation represents USD 1.27 billion, this substantially exceeded the initial capacity of C19RM and grant flexibilities, but enabled the creation of a register of unfunded demand, which could be fulfilled as additional funds became available and avoided the burden on CCMs of having to submit repeated requests. Taking account of available funds, the C19RM Investment Committee has used 6% of 2020-2022 allocation as the indicative investment target for approved requests, adjusting as appropriate based on the technical merit of the funding requests, the epidemiological situation in each country and the availability of grant flexibilities. Decisions on adaptations to HIV, TB and malaria programs have been informed by technical guidance and consultations with partners through the Situation Rooms. Decisions on COVID-19 responses and health systems enhancements have been aligned with WHO guidance, national COVID-19 response plans and the ACT-A partnership (such as the allocation methodology for diagnostics).

20. As now, all funding requests will need to be endorsed by the relevant CCM(s) and must demonstrate participation of key and vulnerable populations in developing the request. Funding requests also continue to use existing Global Fund Principal Recipients that are verified to have the capacity to deploy Global Fund resources. To ensure a funding request review process that balances speed and rigor, each request is reviewed independently by Global Fund technical teams, including Risk, Supply Operations, Finance, Technical Advice and Partnerships, Community Rights and Gender department as well as the relevant Country Team(s). The technical review ensures that awards are in line with WHO technical guidance and respond to the respective country contexts, aligned with national COVID-19 response plans and coordinated with in-country investments from donors and other sources. In addition, the C19RM Investment Committee seeks to ensure coherence and coordination across the various Global Fund funding sources (e.g. grants, C19RM, portfolio optimization and Emergency Fund) and takes account of the quality of investments, risk acceptance, potential operational policy implications and consistency across the global portfolio.
21. At the time of the creation of C19RM, the Secretariat proposed that any incremental OPEX relating to the implementation and management of C19RM be absorbed within the existing OPEX budget for 2020 through the redeployment of existing resources. This remains the case. The extension of C19RM now proposed would entail additional Secretariat costs (including for prolonging the existence of the C19RM Secretariat for a further 6 months in 2021) costing an estimated USD 0.9 million. Added to this would be the costs of further LFA oversight, in addition to what has already been commissioned, estimated at about USD 0.6 million. These costs will be additional to the "surge" resources the Secretariat has already added for core operations, which are necessary in any case given the disruption and additional complexities the pandemic has created for core grant-making and execution activities. These figures will all be factored in to the Secretariat's OPEX budget submission for 2021.
22. Should further extensions of C19RM be required, or if additional funds over this extension period exceed USD 500 million, the Secretariat will seek further guidance and steer from the Board (and its committees, as relevant) on changes to the current C19RM model that may be required to appropriately invest and manage funding on a larger scale and in line with the global context at such time.

#### Limited exceptions to Quality Assurance Policies

23. To mitigate risks of disruption to the supply of health products in-country, through B42/EDP10, the Board approved operational flexibilities to ensure continued operations during COVID-19, which delegated authority to the Secretariat to grant limited exceptions to the QA Policies' pre-shipment inspection and testing requirements, where delays would result in negative program impact that cannot be mitigated. Requests to waive these requirements are considered on a case-by-case basis, through risk-based decision making, for three categories of health products (Expert Review Panel (ERP)-approved products, vector control products and condoms) only where (i) 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 (ii) where a delay would result in negative program impact that cannot be mitigated (e.g., missing an insecticidal net distribution campaign).
24. The Secretariat has established a cross-functional Health Product Risk Committee (HPRC) to undertake a risk-based review of each request and recommend specific exceptions on a case-by-case basis. To date, the HPRC recommended 12 waivers related to 10 countries for ERP-approved

medicines for tuberculosis and for vector control products (LLIN and IRS), and 7 waiver requests for these categories of products were not granted. Waivers were approved in instances of critical programmatic need and limited out-of-specification concerns from historical testing results. In these cases, shipments were authorized ahead of receipt of test results; implementers were informed of this and that testing results would be shared as soon as they become available.

25. In view of the continued disruptions due to COVID-19, including travel restrictions preventing inspectors from accessing manufacturing sites, reduced capacity of laboratories supporting QA testing, and freight and logistics challenges translating to delays in getting health products to people that need them, the Secretariat recommends an extension of the Board-approved limited exception to QA policies for pre-shipment inspection and quality control testing of specific products where withholding shipment authorization until test results are available would delay the timely delivery of products to countries and negatively impact programs. The Secretariat proposes that this delegated authority is extended for an additional 6-month period to 15 April 2021, subject to renewal by the Board.

#### Why is this the recommended option?

26. The extension of the C19RM timeline for the award of funds to 15 April 2021 is the most efficient and effective way to ensure the continued and uninterrupted award of any additional funds that may be made available for C19RM. The fact remains 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. Similarly, the extension of the limited exception to QA policies for pre-shipment inspection and quality control testing of specific products is vital to the timely response to COVID-19 and to mitigate its negative impact on Global Fund programs. As noted above, without swift action, COVID-19 may not only prevent progress in the Global Fund's mission – especially true in the context of safeguarding the upcoming 6<sup>th</sup> replenishment grants – but threatens to undo years of gains. These extensions also facilitate ongoing resource mobilization efforts for additional support for Global Fund programs to mitigate the impact of COVID-19 and to support implementer countries in their efforts to contain and respond to the pandemic. The 15 April 2021 date for C19RM will allow for further consultation with relevant Committees at the late-March Committee meetings, in advance of Board consideration of any subsequent extension or revisions to C19RM, and will also allow for consideration of any lessons identified through the OIG's review of C19RM, which are expected to be available by the end of 2020.

#### **What are the lessons learned, risks and proposed mitigations?**

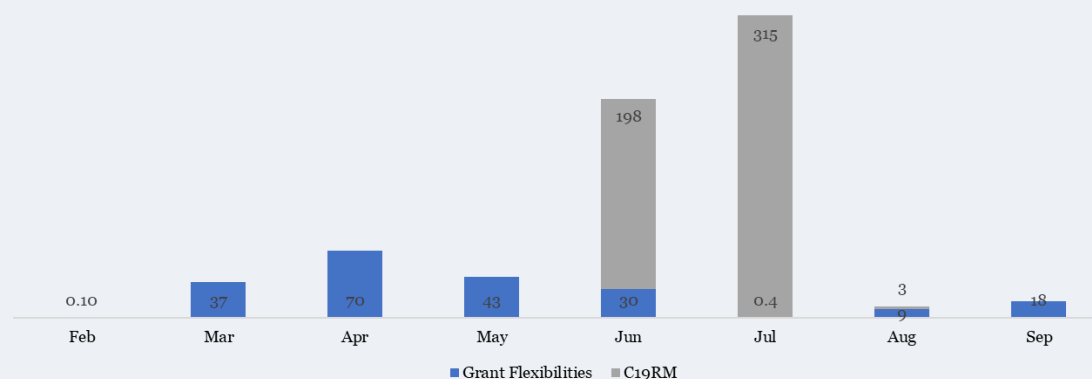
27. When C19RM was initially established, most applicants were already in the midst of preparing funding requests for the 2020-2022 allocation period. Nonetheless, the majority of C19RM funding requests were well thought through, technically robust and consistent with WHO and other partner guidance. This allowed for swift decision-making by the C19RM Investment Committee and the approval of 78 funding requests and iteration of 2. Country Teams and technical partners have played important roles in supporting applicants in submitting robust requests. Moreover, the quality of requests continues to improve over time, as more technical guidance becomes available, the robustness of National COVID-19 Response Plans improves, CCMs become accustomed to operating in virtual mode, and the links between CCMs and national COVID-19 responses are strengthened, with needs for PPE and COVID-19 tests becoming more clearly defined at country level. While it is too early to make a considered assessment of the long-term impact of C19RM on the COVID-19 response in countries and its impact on the three diseases, some preliminary lessons can already be derived from the process based largely on qualitative observations on what has worked well and where challenges have been encountered. The OIG is also undertaking a review of C19RM, and detailed findings from this review are expected to be available by the end of 2020.

#### Preliminary lessons learned

28. Launching two distinct support mechanisms has proved useful. The launch of grant flexibilities in early March provided many countries with vital early funding, with extremely rapid decision-making, while C19RM has been invaluable in providing countries with equally rapid but more substantive support in their responses to the pandemic. Use of grant flexibilities has proved to be a highly flexible and extremely swift way to unlock relatively smaller sums of money already available in grants and ready for immediate implementation, but in some early cases, in-country

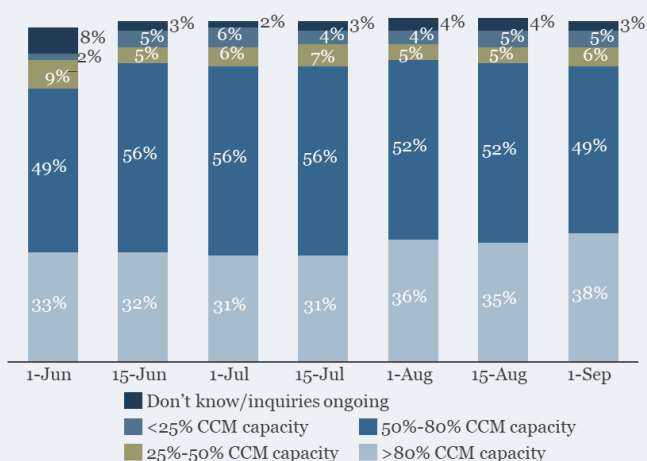
decision-making was not as inclusive as intended. The C19RM funding request process, while slower, is more robust and has demonstrated more inclusivity, with the CCM playing a central role.

Timing of COVID 19 Awards by Funding Type  
(USD 723 million)

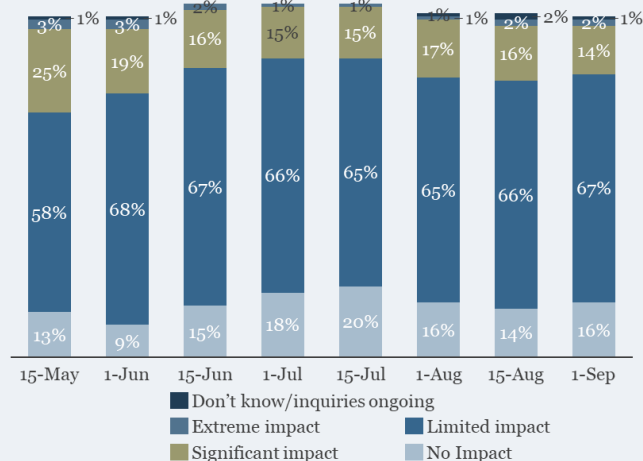


29. C19RM was slower than anticipated to get going, but has been highly effective in converting funding requests into approval decisions. C19RM had one of the slowest set up rates among peer mechanisms with available information. It took 55 days from Board approval of C19RM for the first approval of funding to be made, largely due to CCMs taking longer to submit funding requests than expected. This compares to an average of 25 days for selected peer mechanisms. However, once the first approval was made, C19RM was one of the fastest mechanisms to get to 25% of funding approved – out of the 80 notification letters that were sent to countries, 65 were sent within 10 business days from the date of receipt of the completed application (81% KPI achievement) and a total of 75 (94%) were sent within 11 business days.
  
30. Requiring that C19RM funding requests be channeled through CCMs has been vital, but also not without challenges. Full CCM participation and endorsement of funding request, including by key and vulnerable populations, is required, including for multi-country programs. Some CCMs struggled to be sufficiently inclusive, particularly in the early weeks of the crisis, and some CCMs were not sufficiently linked to their country’s broader COVID-19 response, which in some cases was still under development. Lack of overview of the full needs for PPE and COVID-19 tests at times led to insufficient focus on this in funding requests. Disruptions from lockdowns, lack of connectivity, and the requirements on inclusivity and full endorsement from all CCM members contributed to slowing down submissions, particularly where CCMs were not accustomed to operating in a crisis mode. In some cases, the immediate availability of grant flexibilities meant CCMs felt that they could take more time to submit C19RM funding requests.

CCM capacity constraints impacting the development of the Funding Request



Inclusive engagement facilitation between CCM's and community actors and KPs disruption



Source: Global Fund COVID-19 Country Monitoring Tool 1 September results

31. Countries' perceptions of their needs are evolving as the pandemic progresses. Early submissions were very focused on mitigating the impact of lockdowns on disease programs. Now there is much more focus on the impact of COVID-19 itself, and thus on the need for PPE to protect front line health workers, and to scale up testing and treatment. Some countries that submitted early applications have been awarded additional funding for PPE and other evolving needs through a C19RM funding top-up. Following additional sources of funds (USD 165 million) becoming available, the C19RM Investment Committee awarded USD 108.5 million to finance approved unfunded demand and top up funding requests for 30 countries, out of which additional need of USD 56.3 million (52%) for PPE and USD 17.2 million for COVID-19 diagnostics was covered. At the same time, the C19RM Investment Committee has noted that many countries have struggled to submit funding requests relating to some of the more challenging areas, such as programs on gender-based violence or human rights. The Secretariat will be conducting a more comprehensive analysis of community engagement during the C19RM process and the nature and magnitude of investments for gender-based violence and human rights-related barriers to accessing health services.
32. Some of the Global Fund's operational processes need further streamlining and adaptation to enable the speed and flexibility required in a crisis and to minimize transaction costs. For example, incorporating C19RM approvals through grant revisions has proved somewhat burdensome and has taken more time than anticipated. The Global Fund's procurement processes are also not optimally configured for an environment where there is a requirement to move swiftly to secure access to scarce commodities before there is clarity on country-by-country demand, and where allocation of volumes does not always align with allocation of funding (which is one of the reasons the Secretariat sought the Board approval of the proposal to allow non-Global Fund financed procurement of COVID-19 commodities through Wambo<sup>12</sup>). While coordination of procurement, allocation and supply across partners has been essential, it has also proved challenging, given distinct priorities, operating models and funding models.
33. This list of preliminary lessons learned is neither comprehensive nor final. The Secretariat is reviewing lessons from the first few months of C19RM, with a particular emphasis on how to streamline processes or enhance risk management. Moreover, a more extensive lessons-learned review will be conducted by the OIG by the end of the year, which will provide the relevant committees with assurance on the robustness of the application processes as well as the governance and decision-making mechanisms of the C19RM.

Key risks and mitigations

34. By far the biggest risk is that of a massive shortfall between what countries need in terms of external financial support for their COVID-19 responses, and what is provided, either through C19RM or through other sources. In mitigating the impact on countries affected by HIV, TB and malaria the Global Fund estimates that in the countries in which it invests, some USD 28.5 billion is required over the next 12 months. These figures are broadly consistent with the latest ACT-A estimates. While

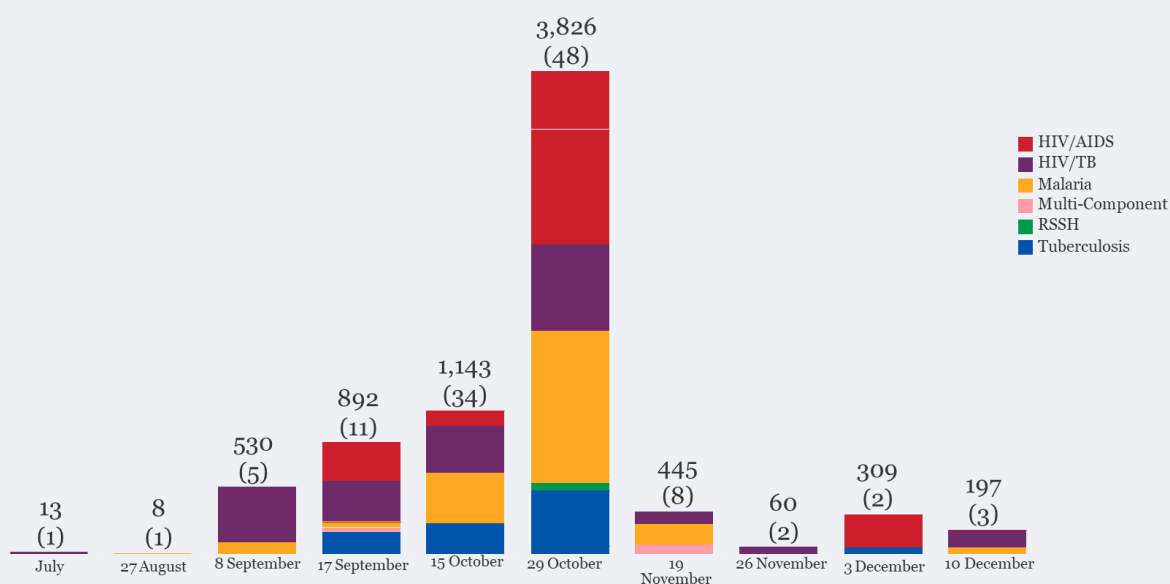
<sup>12</sup> GF/B43/EDP07 <https://www.theglobalfund.org/board-decisions/b43-edp07/>

it is extremely difficult to assess how much of this need is currently being met by external partners or through domestic resourcing, it seems plausible that at least half this total is currently unfunded. In a number of areas, including diagnostics, therapeutics and PPE, there is a rapid shift from a situation in which access to volume was the primary constraint, to one in which access to funding becomes by far the bigger issue. For example, current negotiations around antigen RDTs and monoclonal antibody treatments indicate that mobilizing the funding for these important new tools is a significant barrier to their deployment in Global Fund countries. While there are other potential sources of funding, both implementer countries and ACT-A partners are looking to the Global Fund to play a central role in ensuring LMICs gain access to such new tools. If the Global Fund is unable to provide such support, and countries fail to mount an effective response to COVID-19, or to sustain the adaptations to HIV, TB and malaria programs once C19RM and grant flexibility funding is exhausted, countries will likely see escalating disruption to key life-saving programs. The primary mitigating action for this risk is to continue the intense resource mobilization efforts, both for the Global Fund itself, and, though ACT-A, for the overall response. Continuing to be able to demonstrate the speed, flexibility and effectiveness of C19RM as a deployment mechanism is a critical component of the resource mobilization case.

35. A second risk is that too much Secretariat, CCM and partner resources and attention get diverted from the core mission to the COVID-19 response. While C19RM is vitally important, the mechanism has so far deployed a total of USD 516 million, a number far exceeded by the amount that will be invested by the Global Fund during 2020 in the final year of the 5th replenishment grants, which amounts to substantially over USD 4.2 billion, and even more by the USD 12.7 billion being translated into 6th replenishment grants through the ongoing funding request, TRP and grant-making processes. While C19RM is designed to protect the core mission, by helping countries mitigate the potentially catastrophic impact of the pandemic, it must operate in a manner that minimizes incremental operational burden, particularly during a period where resources should be focused primarily on development of 6th replenishment grants. The mitigating action for this risk is to continue to keep the decision-making process rigorous but streamlined, to leverage existing processes as far as possible, and to simplify wherever possible. To manage the inherent trade-offs the Secretariat has established a process for end-to-end monitoring of C19RM processes, and Business Contingency Planning monitoring also complements early flagging of portfolios that exhibit unusually high risks.

Grants registered for GAC recommendation in second half of 2020.

*(115) grants representing USD 7.4 billion registered for GAC recommendation, and Board approval, in the second half of 2020 with a total of around USD 10 billion expected.*



Note: all values in USD million. Bracketed figures represent number of grants registered for GAC.

36. A third risk relates to the fact that the rapid deployment of C19RM resources and COVID-19 health products (diagnostics/PPE) has meant that there has been limited opportunity to assess the

adequacy of downstream arrangements, including warehousing, distribution and control of use. For example, early approvals for PPE using grant flexibilities and C19RM supported procurement through national systems recognizing that this entailed taking on risks around quality, fair pricing and procurement irregularities. Given the high demand and limited supply, these health products could be prone to diversion. While in most cases existing in-country supply chain systems have been used, it has also been necessary to provide flexibilities to enable support of established national response mechanisms where routine Global Fund assurance providers have limited oversight. Mitigating actions for these risks include targeted reviews by LFAs in select high investment/high risk countries and more recently, a shift to procuring PPE through Wambo/UNICEF. More generally, most Principal Recipients have been using existing inventory management systems and, where alternative systems are being used, implementers have been asked to elaborate on the distribution assumptions, distribution arrangements, and their plans to mitigate the risk of diversion and misuse. In addition, implementers are required to address mismanagement of waste as part of infection control. Furthermore, to ensure effective in-country storage and distribution of COVID-19 related commodities, the Secretariat has assessed and identified private sector capabilities that can be contracted and leveraged. Along with partners, the Global Fund is actively exploring tools that will be able to support the tracking of commodities to avert theft and the delivery of sub-standard or falsified diagnostics, therapeutics and vaccines to intended beneficiaries.

37. A fourth risk relates to the possibility that funds for C19RM will not be used for the intended purpose and in accordance with the provisions of the grant agreement. This risk is assessed to be relatively low, not least because C19RM is administered under the same assurance framework as standard Global Fund grants.
38. A fifth risk relates to the potential for under-absorption. This is also seen to be relatively low, partly because the need for the spend far exceeds the available financial resources, and partly because a substantial proportion of the spend will be used for procurement of diagnostics and PPE through the Global Fund's Pooled Procurement Mechanism (PPM). Procurement through the PPM will mitigate the risk of quality issues and delays, speeding up the procurement process to ensure the timely delivery of high-quality goods to meet program objectives.
39. Finally, it is important to acknowledge that the current environment constrains oversight by assurance providers, mainly due to travel restrictions, which creates the potential for escalation of risks across the portfolio. In this regard, the Global Fund has developed detailed guidance for LFAs to undertake targeted risk-based reviews in select countries to mitigate the fiduciary risk<sup>13</sup>. The guidelines outline contingency measures to address challenges in executing assurance activities caused by COVID-19 disruptions, including to agree on risk-based prioritization of LFA services, mitigating impact of delays and to facilitate remote reviews, as appropriate.

## What options did we consider?

### What are the options?

40. The Secretariat considered whether to allow C19RM to lapse as of 30 September 2020 and seek Board approval for extension only if and when additional contributions are received. However, this approach would undermine ongoing resource mobilization efforts, which rely in part on the existence of an active channel for the swift investment of additional funds, and would lead to a delay in getting funding to countries while Board approval is sought - undesirable in an emergency context. The Secretariat also considered a more extensive revision of C19RM parameters, but considered this unnecessary for additional amounts under USD 500 million, as this amount of funding can effectively be invested to support the same kinds of interventions as have already been supported through C19RM. With additional funding up to this amount, C19RM will be able to meet demand already queued, or additional demand expressed by countries through streamlined updates to submitted requests, including scale-up or continuation of priority interventions already funded.
41. The Secretariat also considered, and discussed with the Coordinating Group, an extension to 31 December 2020. An extension to 15 April 2021 was considered preferable, as it (1) enables consideration of any subsequent extension through the relevant committee(s) in Q1 2021 in line with scheduled committee meetings; and (2) allows for consideration and incorporation of findings

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<sup>13</sup> [https://www.theglobalfund.org/media/10087/covid19\\_lfariskassurance\\_guidelines\\_en.docx?u=637346387265100000](https://www.theglobalfund.org/media/10087/covid19_lfariskassurance_guidelines_en.docx?u=637346387265100000)

from the OIG's review of C19RM, due by end-2020, ahead of any further recommendations to the Board. In addition, an extension to December 2020 would require additional effort from both governance and the Secretariat in Q4 2020 to consider any subsequent extension, also noting the year-end holiday period for many regions.

## **What do we need to do next to progress?**

### What is required to progress the proposal?

42. The Board is requested to approve the proposed Decision Point on page 2. Extension of the C19RM timeline will allow for prompt investment of any additional funds made available for C19RM, and will facilitate ongoing resource mobilization efforts. Continued and timely support for country responses to COVID-19 will be critical to safeguarding 6<sup>th</sup> replenishment grants, which will start at the beginning of 2021. The extension of limited QA policy exceptions will mitigate program disruptions due to COVID-19.

### What will the Board/Committees have to do next?

43. All committees will have sessions devoted to discussing COVID-19, including C19RM, at their meetings in October 2020. Committees will have an opportunity to discuss C19RM at length in these sessions and inputs will be used to guide the future of C19RM as the pandemic evolves. Committee conclusions will be reported to the Board in November 2020 under their routine reporting. If any additional funds become available for C19RM, the Audit and Finance Committee will be requested to approve the availability of these funds for investment as under standard Board policy, in accordance with its authority under the Amended and Restated Comprehensive Funding Policy.
44. The Board and its relevant committees will be engaged for further guidance if global circumstances should require any further changes to the timelines or other parameters of C19RM. The date of the current extension will allow for consultation with relevant committees in advance of Board consideration of any further extension. If total additional funding for C19RM exceeds USD 500 million, the Secretariat will return to the Board and its relevant committees for additional consideration of the global context and scope of C19RM and approval of any required decisions.

### What would be the impact of delaying or rejecting the decision to progress?

45. If the current C19RM timeline is not extended, investment of C19RM funds will cease as of 30 September 2020. This limits the possibility of ensuring continued and uninterrupted award of any additional funds that may be made available for C19RM. Allowing C19RM to lapse would also undermine ongoing resource mobilization efforts for additional support for Global Fund programs to mitigate the impact of COVID-19, as there will be no active mechanism for the deployment of additional funds. Similarly, in view of the continued disruptions due to COVID-19, not extending the limited exceptions to the QA Policies' pre-shipment inspection and testing requirements would risk disruption to the supply of health products in-country and to people that need them and negatively impact programs.

## **Recommendation**

The Secretariat recommends the Decision Point presented on page 2 to the Board for approval.



## Annex 1 – Relevant Past Decisions

Relevant past Decision Point	Summary and Impact
<b>GF/AFC13/EDP01: Approval of Available Sources of Funds for the C19RM Mechanism (July 2020)</b>	The Audit and Finance Committee, in accordance with its delegated authority from the Board, approved USD 165 million as available sources of funds to be applied to C19RM pursuant to Board decision point GF/B42/EDP11.
<b>GF/B42/EDP11: Approval of COVID-19 Response Mechanism (April 2020)<sup>14</sup></b>	The Board approved 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 with initial funding of up to USD 500 million. The Board decided that (i) 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; (ii) the Secretariat may approve requests for C19RM funds for an initial six-month period through 30 September 2020; and (iii) C19RM funds may be used through 30 June 2021. These dates could be extended by the Board, based on updated information on needs as the pandemic evolves. The Board also requested the Secretariat to further operationalize the investment and management modalities for C19RM.
<b>GF/B42/EDP10: Approval of Operational Flexibilities to Ensure Continued Operations during COVID-19 (April 2020)<sup>15</sup></b>	The Board approved (i) 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; (ii) Secretariat authority to 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; and (iii) 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 Board approved the flexibilities described in (ii) and (iii) above for an initial six-month period, subject to renewal by the Board and the flexibility described in (i) through 30 June 2021.
<b>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)</b>	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/SCO4/DP02.

<sup>14</sup> <https://www.theglobalfund.org/board-decisions/b42-edp11/>

<sup>15</sup> <https://www.theglobalfund.org/board-decisions/b42-edp10/>

Relevant past Decision Point	Summary and Impact
<b>GF/B41/DP05: Approval of the Amended and Restated Policy on Restricted Financial Contributions (May 2019)</b> <sup>16</sup>	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.
<b>GF/B39/DP09: Approval of CCM Evolution: Code of Conduct for CCMs and CCM Policy (May 2018)</b> <sup>17</sup>	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.
<b>GF/B37/DP12: Approval of Amended and Restated Global Fund Quality Assurance Policy for Diagnostic Products (May 2017)</b> <sup>18</sup>	The Board approved the amended and restated Global Fund Quality Assurance Policy for Diagnostic Products.
<b>GF/B36/DP04: Approval of Amended and Restated Comprehensive Funding Policy (November 2016)</b> <sup>19</sup>	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.
<b>GF/B22/DP09: Approval of Amendment to the Quality Assurance Policy for Pharmaceutical Products (December 2010)</b> <sup>20</sup>	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.

<sup>16</sup> <https://www.theglobalfund.org/board-decisions/b41-dp05/>

<sup>17</sup> <https://www.theglobalfund.org/board-decisions/b39-dp09/>

<sup>18</sup> <https://www.theglobalfund.org/board-decisions/b37-dp12/>

<sup>19</sup> [https://www.theglobalfund.org/media/4256/bm36\\_02-comprehensivefunding\\_policy\\_en.pdf](https://www.theglobalfund.org/media/4256/bm36_02-comprehensivefunding_policy_en.pdf)

<sup>20</sup> <https://www.theglobalfund.org/board-decisions/b22-dp09/>