

External Evaluation of the ACT-Accelerator  
ACT-A Agency & Partner detailed inputs and  
corrections



#### More detailed comments from CEPI

In addition to the high level comments submitted, we set out some more detailed points:

##### ***Covax partnership:***

- COVAX was under discussion from January 2020 in parallel to CEPI's early investments in vaccine development. CEPI circulated a paper on the need for an end to end fair system for vaccine development, procurement, allocation and delivery in March of 2020. ACT-A helped serve as an umbrella and coordination forum, but did not lead to COVAX's creation.
- We note the finding that the vaccines pillar worked well due to longstanding relationships, but also note that the relationships between CEPI and partners were critical in the ideation of COVAX, and to thinking about end-to-end needs from early on when CEPI began making R&D investments.

**CEPI investments:** The timing of CEPI's funding, CEPI's technical advice, and CEPI's equitable access provisions are all part of what CEPI offers as well as financial support. We note:

- Vaccine development is high risk. The diversified portfolio offered the best chance of success
- CEPI's initial funding to Moderna, while limited, did accelerate their work
- CEPI's investment in the Oxford/Astra Zeneca vaccine was early (based on an existing partnership), secured equitable access to doses, and included technical support
- CEPI's support of the manufacturing network for Novavax played a critical role
- CEPI's investments in partners with validated platforms and others such as the University of Queensland and Clover will offer future benefits for pandemic preparedness
- CEPI's rapid response to Covid-19 relied significantly on investments made over decades into similar viruses. The world needs to continue to and ramp up investments in R&D for the most dangerous viral families.
- We welcome the comments on the Marketplace, and note CEPI has led the management of the Marketplace. CEPI is now also playing an active role in establishing a manufacturing network of preferred partner providers.

##### ***Financing***

- Financing did slow down the response in many areas, but CEPI made at risk investments from early January. A key learning is the need for agile systems and institutions as well as funds
- CEPI issued its investment case in March 2020, when funding was needed

##### ***Future needs***

- We agree surge funding is needed in future, at high speed. At risk investments are critical too
- Agreements for tech transfer are needed in advance, and will support regional manufacturing in an outbreak. Trade policy to facilitate transparent and sufficient supply of raw materials is critical too.
- Countries have a critical role as well as agencies who were members of ACT-A. This includes issues such as trade policies and donations.

#### ACT-A External Evaluation: Consolidated Comment

Page	Section	Comment/edit
3	Table of Contents	Unclear why FIND is called out individually here – please delete
15	Executive Summary	<p>Broaden this finding and corresponding action point to include diagnostics as well:</p> <p>Lack of vaccine *and diagnostic* manufacturing capacity identified as key external barrier of ACT-A</p> <p>Support efforts to establish *and expand* manufacturing capacity across regions *for vaccines and diagnostics*.</p>
32	2.3 Strengths and weaknesses ACT-A's operating model	Change from "Global Fund and Unitaid" to "Diagnostics and Therapeutics pillars"
56	4.3.1 Upstream performance of the Diagnostics Pillar	<p>change from "over 90" to "over 200 different COVID-19 test products"</p> <p>change from "upwards of US\$20 million" to "upwards of US \$55 million"</p>
71	6.4 Regional manufacturing and health systems	<p>Expand section to include challenges in manufacturing capacity for diagnostics as well as vaccines, and progress toward addressing these issues.</p> <p>Suggested change to: The lack of distributed manufacturing capacity, in particularly for vaccines *and diagnostics*, was identified as the key external barrier for ACT-A. Multiple efforts are underway to strengthen manufacturing capacity across regions, for example through WHO's mRNA hub and nodes in Africa, *as well as through Diagnostics pillar investments boost global production and strengthen local manufacturing capacity in Africa and Latin America.* Manufacturing capacity needs to be supported over the long term and needs to be part of planning for sustainable business models and routine immunization *and testing* market demand.</p>

#### ACT-A Evaluation Annexes: Edits

Page	Section	Comment
23	Annex 6. ACT-A Workstreams	<p>FIND Logo is incorrect – we have attached the correct logo for replacement</p> <p>#4 should be changed to: Country Support: UNICEF</p>

		<p>#5 should be changed to: Genomic Surveillance: WHO and Rockefeller Foundation</p> <p>Delete #6 (Strategic private sector engagement) and #7 (Advocacy/community engagement)</p>
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**Global Fund's response to External Evaluation of the Access To COVID-19 Tools  
Accelerator (ACT-A)**

18 October 2022

**Detailed Response**

**Inaccuracies concerning the Global Fund**

- **P55:** on oxygen, *"The taskforce is co-chaired by Wellcome and UNITAID and includes more than 20 UN and global health agencies that work together to support low- and middle-income countries to mitigate pandemic-related medical oxygen shortages. Between February – October 2021, Taskforce members mobilized more than \$US700 million in grant financing to help countries avert oxygen shortages "*
- **Global Fund response:** While it is correct that the Taskforce mobilized more than \$US700 million, most of this funding came from the Global Fund (during the timeframe, the Global Fund provided \$US475 million in grants to help more than 66 LMICs purchase oxygen supplies). As the Global Fund is not mentioned in the paragraph, the reader gets an inaccurate picture of the source of the funding – particularly as the report talks about WHO and UNICEF in connection to oxygen provision earlier in the chapter.
- **P57:** on Diagnostics: *"others argued that insufficient funding was not the challenge, and that funding was not disbursed and channelled quickly enough by the Global Fund, being the main procurement entity".*
- **Global Fund response:** Initially, funding was the constraint in ensuring equitable access. When funding was forthcoming, awards were made quickly to countries; in contrast, countries were often slow to convert grants into purchase orders, not least because their pandemic responses were evolving rapidly and the use cases for diagnostics were unclear in the absence of available treatments. The Global Fund had awarded over \$US400 million to diagnostics by June 2021, \$US 800 million by August 2021 and will have awarded over \$US900 million by the end of 2022. At the height of the pandemic, C19RM was making monthly awards as soon as additional donor pledges were made, making that funding available to countries within weeks of a pledge announcement and in advance of the contribution actually being paid to the Global Fund itself.
- **P61:** on grant disbursement *"Data shared by WHO indicates that some agencies found it challenging to quickly disburse the provided funding, indicating that systems were not fully equipped to respond to an acute emergency situation. The WHO data is from the first quarter of 2022; the situation might be different now (September 2022). We compared the allocated funding (which is lower than the total funding envelope) of agencies with the funding that was implemented by the first quarter of 2022 (January-March depending on the agency). The data indicates that WHO has implemented 78% of its allocated funding (US\$2.6 billion out of US\$2.9 billion), UNICEF 71% (US\$0.9 billion out of US\$1.3 billion), the World Bank 50%*

(US\$5.8 billion out of 11.7billion), the Global Fund (C19RM funding) implemented 40% (US\$1.7 billion out of US\$4.3 billion), and Gavi 34% (US\$3.8 billion out of US\$11.0 billion)”

- Global Fund response: This analysis by WHO used a definition of “funds implemented” that distorts the picture, overestimating absorption of funds for activities such as technical assistance (such as WHO largely provides) and underestimating the absorption of funds used for procurement (such as the Global Fund provides). The data ignores the question of when the funding was made available to the countries for them to plan and make orders.
- **P61:** on the C19RM audit *“For example, an audit of the C19RM 2020 mechanism also found that significant improvements were needed around the timely utilization of funds”.*
- Global Fund response: This was not the major conclusion of the audit. The Office of Inspector General’s 2021 audit noted the significant achievements of C19RM 2021, stating that C19RM was fast and effective, and that its design was robust and inclusive and clearly linked to the Global Fund’s strategic objectives. Looking only at the 2020 audit report also ignores the adjustments incorporated into C19RM 2021.

# ACT-A External Evaluation report – Response submitted by Unitaid as co-lead of the Therapeutics Pillar

18 October 2022

**Objective of this submission:** Highlight sections of the ACT-A External Evaluation that are inaccurate or incomplete, providing facts that contextualize the evaluation findings with regards to the Therapeutics Pillar.

While Unitaid welcomes the commission of the ACT-A external evaluation by the Facilitation Council Co-Chairs, Norway, and South Africa, with a primary objective *“to identify lessons for future pandemic preparedness and response to enhance equitable global access to medical countermeasures”*, we have serious concerns about the quality and relevance of the evaluation’s data collection methodology as well as its key findings. These concerns are broadly in two areas:

- The evaluation process did not gather comprehensive evidence, nor did it differentiate between evidence-based findings versus opinion-based hypotheses. For example, the evaluation team did not adequately investigate stakeholder survey findings to assess the extent to which they were based on facts or reasonable underlying assumptions. In addition, it is concerning that the evaluation’s analysis incorporates only a small fraction of the available documented evidence. In fact, ACT-A partners have generated a large volume of evidence over the past two years, much of which is widely available. Unfortunately, ACT-A partners were not offered the opportunity to provide said documentation or clarifications.
- Our underlying understanding of COVID-19, and the surrounding context of the pandemic, changed rapidly over time. A strong evaluation should account for those changes when generating findings and implications. This report doesn’t do that – for example, a backward-looking description of the dynamic context is absent.

These methodological weaknesses severely limit the opportunity to draw relevant lessons from our experience over the past two and a half years. Overall, the report misses an excellent opportunity to inform our collective thinking on how to respond to global health emergencies going forward.

The below table provides further details on the statements that may warrant further clarification in the report itself, particularly for section 4.2: *Performance of ACT-A Tx Pillar*.

**Upstream Performance**, Key finding:

**The Therapeutics Pillar was held back by complex science, as well as by insufficient coordination across the various players and limited funding.**

	<b>Tx Pillar clarification</b>
<b>Drugs for acute viral infections are complex to develop and there are only few such treatments, except for influenza. The science itself is difficult.</b>	<ul style="list-style-type: none"><li>• ACT-A Therapeutics Pillar was set to <b>transform R&amp;D outcomes into accelerated and equitable access to therapeutics</b> for all countries, particularly LMICs, <b>connecting the pipeline with rapid uptake by countries.</b></li><li>• While it is true the science behind novel antiviral medicines is difficult as the report acknowledges, the lack of early funding to support global R&amp;D efforts (as was the case for vaccines) was a major challenge delaying the pipeline of novel treatments against SARS-CoV2. In addition, a focus on R&amp;D for products responding to Target Product Profiles adapted to the needs of LMICs was not consistent.</li></ul>
<p><b>Many key informants also commented that the pillar was a rather loose alliance.</b></p> <p>Compared to the Vaccines pillar, it was comprised of agencies with less experience and capacity in this area.</p> <p>There was insufficient leadership, and coordination between the working groups was considered to be incohesive, with individual members being unaware of the work done by other working groups and/or other stakeholders outside the pillar.</p> <p>Overall, it appeared to be multiple organizations working in a siloed rather than a coordinated manner.</p>	<ul style="list-style-type: none"><li>• The Tx pillar partnership brought together partners with demonstrated expertise across the value chain (end-to-end approach), with lead agencies for each key area working in close coordination with others.</li><li>• Multiple channels of coordination and communication across the Tx pillar workstreams were set up, with the extended network Tx Pillar partnership (i.e. including Industry representatives, civil society, communities, implementing partners, countries representatives, research organizations, etc.), and with varying degrees of cadence for meetings in line with the evolution of the response.</li><li>• <b>Detailed information and documentation about membership, structure and ways of working and coordinating for each working stream of the Tx Pillar, and across workstreams, are available upon request.</b></li></ul>
<p>For example, key informants reported that the participating agencies pursued a range of options – repurposed drugs (short term), monoclonal antibodies (medium term), and antiviral drugs – but that there was no coordinated and prioritized approach.</p>	<ul style="list-style-type: none"><li>• As stated above, and given the challenges of developing therapeutics that target viral infections and the urgency to identify products that could be quickly scaled-up, the clinical trials pipeline included both repurposed and novel candidates, whether small molecules and biologics, whether supported by industry, academia or research institutions; ACT-A Tx Pillar funded-trials mainly focused on small molecules.</li><li>• Tx Pillar agencies aligned on a clear prioritization pathway of the most promising candidates in the pipeline, that were to be considered for potential market interventions supported by ACT-A. The prioritization criteria was applied to all promising products for both outpatient and inpatient use, taking into account the potential health impact of candidates in the pipeline (data on clinical efficacy from preliminary evidence to results of actionable trials, safety, DDis, and administration form) as well as the potential to be delivered at scale in LMICs should they become WHO-recommended (manufacturing complexity, intellectual property, pricing, regulatory, and administration and conditions that could restrict their use in LMICs).</li><li>• <b>The prioritization list</b> (regularly reviewed) was then transmitted to all ACT-A Tx agencies to begin exploratory work by the Market Preparedness (WS2) and the Procurement and Allocation (WS3)</li></ul>



	<p>workstreams, and Country-supported streams, to minimize timelines for deployment at country level if and when products were recommended by WHO.</p> <ul style="list-style-type: none"> <li>• <b>Slide deck explaining defined criteria and scoring system for the prioritization matrix, presented at multiple meetings of the ACT-A Tx Pillar, is available upon request.</b></li> <li>• In conjunction with oxygen and adjuvant medicines, the Tx Pillar addressed the potential access barriers, and procurement and delivery of both inpatient and outpatient treatments, as new products were recommended by WHO: <ul style="list-style-type: none"> <li>○ While most of the products initially recommended for use in COVID-19 did not address the viral infection itself but its consequences (severe and critical COVID-19 cases), at the end of 2021 novel oral antivirals (more adapted for outpatient care and scaled use in LMICs than injectables) entered the market, and have since then been WHO-recommended for people at high risk of severe COVID-19; these novel oral antivirals are currently available via ACT-A channels for procurement and deployment at the country level.</li> <li>○ In addition, the Tx Pillar considered multiple other candidates that were promising in early stages of their preclinical or clinical evaluation. However, either these were eventually not recommended for use by WHO (as was the case with multiple repurposed products given the evidence gathered from clinical trials), or the WHO recommendation changed based on the evolution of the pandemic with new variants (as is the case for several monoclonal antibodies) or on the emergence of new clinical evidence. <b>For further information, WHO, Therapeutics and COVID-19: living guideline could be consulted.</b></li> </ul> </li> </ul>
<p><b>Clinical trials were conducted in a “wild west” style.</b> Key informants reported that it took a long time to standardize clinical trial protocols, which resulted in a fragmented and often low-quality evidence basis for treatments. The concept of having a Solidarity Trial was perceived as useful, but it would have benefitted from earlier guidance and sharing of protocols. Overall, it was not seen as a success.</p>	<ul style="list-style-type: none"> <li>• The number of low-quality clinical trials was high, and the international community has acquired important lessons in this regard.</li> <li>• Importantly, gathering evidence was further complicated by the variability of the epidemiologic situation, with different areas of the world affected at different times, corroborating the need to have coordinated platforms for R&amp;D established in all geographic areas to ensure both i) speedy recruitment and evidence gathering, and ii) valuable information for the use of the products in LMICs.</li> <li>• In addition to WHO-supported SOLIDARITY, there were hundreds of clinical trials carried out worldwide, with only a few funded by ACT-A partners (namely Bill and Melinda Gates Foundation, Wellcome, and Unitaid). These studies were designed to provide conclusive evidence for guidance and policy development, in coordination with other partners and WHO. These efforts were possible as Tx Pillar partners were able to: <ul style="list-style-type: none"> <li>○ Provide quick, flexible, and targeted funding, including the trial that led to the recommendation of corticoids (inc. dexamethasone) for treating severe COVID-19.</li> <li>○ Support the development of clinical trial platforms in the global south, including ANTICOV, collecting evidence in populations living in LMICs to fill in the gap of outpatient treatment adapted to LMICs to prevent the need for hospitalization (noting that most trials at the initial stages of the pandemic were otherwise focused on severe/critical, hospitalized, patients).</li> </ul> </li> </ul>

<p><b>While IP waivers for COVID-19 vaccines were frequently discussed, some stakeholders argued that the Therapeutics pillar could have done much more on technology transfer as there are only a few manufacturers, making the market situation difficult, for example compared to the vaccines market.</b></p>	<ul style="list-style-type: none"> <li>• Technology transfer remains an important element in ensuring prompt and sustainable access pathways, and it is key that manufacturers and developers of originator products (small molecules and biologics) offer this possibility. However, although such a possibility is included in the MPP licensing of the novel antivirals, no generic company has opted for acquiring the technology transfer package for these products as, presumably, it has not been needed.</li> <li>• As things stand today, for currently recommended products, and with the decline in severity and the number of cases, the statement on the number of manufacturers being limited to a few, <i>“making the market situation difficult,”</i> should be reviewed as current demand (and demand expected in near future) is very limited.</li> <li>• The Tx pillar and partners have taken all necessary steps to ensure sufficient capacity to manufacture those products to meet a potential increase in demand (e.g. in case of surges) that might exceed current availability levels: <ul style="list-style-type: none"> <li>○ In October 2021, MPP signed a license agreement with Merck Sharp &amp; Dohme to facilitate broad and affordable access to molnupiravir, and in November 2021 a similar agreement was signed with Pfizer for nirmatrelvir + ritonavir. Sublicensing agreements have since been signed with <b>23 generic manufacturers</b> in 10 countries for molnupiravir and <b>38 manufacturers</b> in 13 countries for nirmatrelvir+ritonavir. <b>In total, if development and production were to be fully implemented, collectively they could provide up to 125 million treatment courses (5 billion doses) for molnupiravir and 400 million treatment courses (8 billion doses) for nirmatrelvir/ritonavir.</b></li> <li>○ Generic companies are now in the product development stage, with frontrunner products already under assessment by the WHO PQP. One generic product of molnupiravir already prequalified, and prequalification of generics of nirmatrelvir/ritonavir is expected before the end of 2022.</li> <li>○ The key element that now warrants further attention is the support to maintain a resilient market that could meet the expected level of production in case of need, with the persisting uncertainty on the size of such potential need.</li> </ul> </li> </ul>
<p>Downstream Performance, Key finding:  <b>The Therapeutics pillar failed to achieve its original delivery targets, and there remain challenges with the delivery of therapeutics.</b></p>	
<p><b>The original objective of the pillar was to deliver 245 million treatment courses to low- and middle-income countries in 2021.</b>  However, the “ACT-Accelerator Prioritized Strategy &amp; Budget for 2021” changed the target to “promote successful uptake of medical oxygen and corticosteroids for up to 12 million severe and critical patients and introduce new COVID-19 therapies for up to 100 million treatment courses across all use cases.”</p>	<ul style="list-style-type: none"> <li>• <b>The initial delivery targets were a projection based on the best available information at the time and are not relevant in a rapidly evolving pandemic context.</b> The need and demand for potential treatments have radically decreased due to the evolution of variants, in particular Omicron, the narrowing of the target population (e.g., current antivirals only recommended for the mild-moderate patients at highest risk of hospitalization and severe disease), the vaccine coverage and the acquired natural immunity.</li> <li>• In addition, outpatient therapeutics only became available in 2022, significantly impacting delivery plans:</li> </ul>

	<ul style="list-style-type: none"> <li>○ March 2022: molnupiravir recommended by WHO Guidelines</li> <li>○ April 2022: nirmatrelvir/ ritonavir recommended by WHO Guidelines</li> <li>● Access agreement negotiations with originator manufacturers were difficult and lengthy, hampering the roll-out of therapeutics to LMICs. e.g., Pfizer-Global Fund agreement on Paxlovid access only finalized on Sept 2022.</li> <li>● Lack of transparent pricing and terms, limited supply of current antivirals and challenges in reaching target patient populations within the treatment window (among other product-related constraints), create a complex environment for implementation and demand.</li> <li>● As demand declines in view of epidemiologic changes, it is important to reiterate that an overall supply capacity has been achieved for molnupiravir and nirmatrelvir/r (with the diversification of manufacturer supply base among sublicensees) that could meet those initial treatment targets in case of need.</li> </ul>
<p><b>There was a strong focus on upstream activities, and that no agency focused on delivery aspects.</b></p> <p>The “Test &amp; Treat” strategy should have been prioritized earlier in the process, at the latest when it became clear that vaccines did not prevent transmission as initially expected.</p>	<ul style="list-style-type: none"> <li>● In April 2020, Unitaid, in collaboration with FIND (from Dx pillar), launched an RFP to invest US\$ 50 million to support countries preparing for introduction of COVID-19 test and treat solutions, <b><u>before any outpatient treatments that could be rolled out at country level in a T&amp;T strategy were available</u></b>, to enable and accelerate scaled-up use in anticipation of future therapeutics being recommended.</li> </ul> <p>In addition, in January 2022 FIND and Unitaid, launched an advocacy RFP to select the services of organizations with a proven record of advocacy and awareness-raising in healthcare in low- and middle-income countries, to implement projects to increase access and uptake to COVID-19 testing and therapeutics.</p> <ul style="list-style-type: none"> <li>● In Q1 2022, the ACT-A Tx Pillar re-organized its activities in line with its renewed focus on downstream activities and further enhancing country preparedness. In May 2022, the Global Fund joined Unitaid and Wellcome as a co-convenor of the ACT-A Tx Pillar, reflecting the increased focus on downstream activities. More partners have also committed additional funds (over \$125M) in COVID-19 Test-and-Treat programs, and a Coordination T&amp;T working group (led by Unitaid and Global Fund) was established in June 2022.</li> </ul>

**World Health Organization (WHO) requests for correction of errors in the  
External Evaluation of the Access to COVID-19 Tools Accelerator (ACT-A)  
18 October 2022**

This document contains two sections: 1) correction of errors and 2) contextual comments and edits for authors to consider for improving the accuracy of the report

**1. Factual errors:**

- i. P13: Prequalification: the delay in EUL of the self-tests was dependent on development of the related policy and hence the delay in inclusion in their eligibility for EUL evaluation. Once the policy was in place and application submitted, they were promptly reviewed by PQ and listed.
- ii. P14: WHO mRNA hub and spokes go beyond Africa (in the text it only references Africa), including LATAM and Asia. Full list here:  
<https://www.who.int/initiatives/the-mrna-vaccine-technology-transfer-hub/recipient-of-mrna-technology-from-the-who-mrna-technology-transfer-hub>
- iii. P25: Title refers to Scope of ACT-A pillars but 6 of 7 paragraphs are exclusively about Vaccines Pillar and 1 paragraph includes reference to diagnostics and therapeutics pillar but is primarily about COVAX. The title is misleading.
- iv. P45: WHO alone did not develop the standardized indemnification and liability system. Ultimately the I & L was part of the Gavi contracts with manufacturers.
- v. P45, 2<sup>nd</sup> paragraph: It says *“Due to this system, countries did not have to sign individual agreements with vaccine manufacturers”* Countries did have to sign I&L with manufacturers, however “what” they had to sign was important as COVAX effectively negotiated the “what” on the countries behalf, recognizing that individual countries (in most instances) would not have had the leverage with the manufacturers. COVAX also standardized the I&L that manufacturers asked for - otherwise we were very likely to have seen different requirements from each manufacturer. Additionally, the above made it more time efficient for countries and manufacturers by removing one negotiation that would otherwise have had to occur. This was one hurdle identified ( learned ) from the previous experiences.
- vi. P46, 1<sup>st</sup> para: COVAX manufacturing Task Force also resulted in the WHO mRNA hubs, which is arguably one of the most important outcomes of the TF
- vii. P48, last Key finding: *“substantial vaccine inequities persist globally.”* They probably mean substantial VACCINATION inequities persist globally”. It is inequity in coverage that now exists not inequity in vaccine.
- viii. P49, last paragraph, first line: same issue on the use of the term “vaccine inequity” vs. “vaccination inequity” or ‘vaccination coverage inequity”
- ix. P49, last sentence: It is not accurate to say COVAX never formally adopted the 70% goal. It recognized the WHO strategy and goals based on WHO's technical lead role in setting global targets and expressed that it was contributing to the goal. COVAX did acknowledge the goal, and as WHO was a core partner in COVAX it was responsible for setting those strategies and goals. The WHO targets were included in the ACT-A Strategic Plan and budget, Oct 2021.

- x. P50, first sentence of paragraph: It should be more specific to say “while delivery FUNDING FOR COUNTRIES was initially .....”. Also when referring to HSC, it was the World Bank loans specifically that were expected to pay for the delivery funding.
- xi. P50, last paragraph: The description of CoVDP is not accurate. First sentence and later in the paragraph. This has previously been pointed out in Ted’s feedback.
- xii. P53, 1<sup>st</sup> paragraph: The report says, “agencies with less experience”, it would be important to clarify which of the agencies had less experience? Global Fund, Unitaaid, WHO or WT?
- xiii. P53, 2<sup>nd</sup> paragraph: Despite what was reported by respondents, tech transfer of Therapeutics was a success with fast entrants of generic products.
- xiv. P53, 2<sup>nd</sup> paragraph: Recommend mentioning MPP also have generic licencing agreement with Merck and Shionogi in addition to the one with Pfizer, which was noted.
- xv. P54: The report notes that key informants said that Test & Treat should have been prioritized earlier in the process when it became clear that vaccines did not prevent transmission, however the roll out of Test & Treat would still be needed even with more effective vaccines as a combination of all medical countermeasures are necessary to end the pandemic.
- xvi. P55: ACT-A O2 Taskforce in no longer chaired by Unitaaid and Wellcome Trust. Update report to say that it *was* chaired by Unitaaid and Wellcome Trust. It is currently only chaired by Unitaaid.
- xvii. P60: HSC was led by Global Fund WHO and WB, not only WHO and WB.

1. **Contextual comments and edits for authors to consider for improving the accuracy of the report**

- a. **General comments and edits:** There are a number of key issues with the report, whereupon resolving them would significantly enhance its quality, clarity, credibility as well as the articulation of specific lessons adjusted to the context and goals of the ACT-A to guide future refinements and development.
  - i. Consider adding context paragraphs to the executive summary, for example, noting that ACT-A’s creation was in response to emergency needs of countries (particularly LMIC) to obtain critical medical countermeasures – diagnostics, vaccines and therapeutics, during a pandemic where every second counted.
  - ii. Reflect on the evolving goals and/or institutional design of ACT-A to contextualize the findings (ie entire inception and evolution was over a 24 month period—starting from scratch).
  - iii. Capture more lessons and practice on the organizational and institutional model, dynamics, mechanisms, processes, performance, ability to apply mid-course corrections, etc.
  - iv. Recommend including some description of the broader historical and geopolitical contexts surrounding R&D/manufacturing/supply chain for MCMs – critical not only for ACT-A but for any future entity/mechanism.

- v. Include (in an annex or otherwise) the key roles/mandates of existing institutions, and the multi-decade nature of the issues without progress. This is especially important given that a fundamental assumption of the ACT-A was to rely on those institutions and their various comparative advantages.
- vi. There is no articulation of the limitations of the design and rollout of ACT-A that are necessary to enable the conduct of an evaluation. For example, an evaluation needs to begin by looking at the stated goals of the entity – are their clearly articulated objective statements, a Theory of Change (ToC) or similar, a monitoring and evaluation framework? If not, this needs to be stated up front in the evaluation; and for the evaluators to create a ToC for the evaluation (which was absent).
- vii. State up front if it is a formative or impact evaluation (or both). It was noted that statements in the report reflect impact, e.g. “failure” yet the report is not as far as we can tell an impact evaluation
- viii. Suggest avoid language as “failure” given the lack of stated benchmarks to define or measure this.
- ix. Within the executive summary, to consistently use the same framing of categories of questions (which change several times)..
- x. Provide information on response rate for the survey (including what the denominator was)
- xi. Consider including mention of GPMB reports and its commissioned reports (including from the Wellcome Trust on R&D); WHO SPRP, IHR or R&D Blueprint as contributing coordination mechanisms that could contribute to a past or future Act-A.
- xii. Consider including analysis of the dynamics underpinning the functioning of an informal partnership.
- xiii. Mention the short country case studies earlier in the report so the reader is aware they are coming. Consider labeling the last pages of the report as “recommendations”
- xiv. There should be a better bridge between analysis and recommendations, e.g launch of AMC as a recommendation with very formal governance vis a vis, building on ACT-A learning from COVID to create a permanent medical countermeasures platform. The analysis to make that recommendations should be more fleshed out and based on more analytics.
- xv. Consider using more neutral and less opinionated language, e.g., p. 28 “The survey provides a remarkable finding in this regard”
- xvi. This report does not recognize the challenge or description of meaningful engagement of LMICs in leading roles. Several LMICs were invited to hold leading roles in the Facilitation Council and its working groups, but for workload reasons, they were not able to participate as much as one could have expected. This is a challenge that should be recognized and addressed.
- xvii. The report does not recognize LMICs which played a key role in ACT-A, such as South Africa, India and Indonesia which championed ACT-A and were active in the Council and its working groups.

- xviii. The evaluation does not mention what could be seen as a significant challenge of ACT-A: limited access to data and actual impact at the country level.
- xix. P59: HSCs main role was to coordinate the cross-cutting systems work that otherwise multiple pillars would be working on in silos. It was also supposed to address HS issues that no one pillar could address (eg waste management). The description is not clear.

**b. Vaccines:**

- i. P46, 2<sup>nd</sup> para: The statement says that CSOs criticized COVAX partners for not showing support to the TRIPS waiver, that may be true that CSOs says that, but the report should correct the fact that WHO was a strong supporter of TRIPS waiver. The report should not leave inaccurate perceptions out there unaddressed. Reference: <https://www.who.int/director-general/speeches/detail/who-director-general-s-opening-remarks-at-the-covid-19-media-briefing--14-june-2022>
- ii. P46, 4.1.2 Key finding: it is true the COVAX did not deploy the SFP doses envisioned, but those were projections of what the SFP would request. COVAX was providing what SFPs requested so it seems odd to say that COVAX fell short of the target since the ultimate demand from SFPs was not in its control.
- iii. P46, 4.1.2/second last paragraph: “arguing that COVAX largely failed.” The report is providing the results of respondent’s perceptions of COVAX, the structure of the report comingles factual data with survey results of perception and does not adequately signal the subjective nature of the survey. What is not said here is that by the measure of equity in supply over the course of 2021, or vaccination coverage in 2022, the regional mechanisms also failed. So, the question is not addressed whether COVAX ‘failed’ because of externalities or because of things in the control of COVAX.
- iv. P47, 2<sup>nd</sup> last paragraph: It might be clearer to the reader to know that the target for self-financing participants was not reached because they chose not to use the mechanism in the magnitude that was planned for. It was not that COVAX did not fulfill its commitments that the SFPs asked for.
- v. P48, 1<sup>st</sup> para: On donations, it is important to clarify that there was not reluctance to take donations, but rather it was unclear that donations would become so important, that it required a set of principles and mechanism during the operation. Formal discussion with member states started in late 2020, before there were doses available.

**c. Regulatory and PQ:**

- i. P57: For SARS-CoV-2 IVDs, a total of 32 tests were listed and over 90 applications were evaluated and rejected because they were found inadequate (poor validation and QMS). Of the 32 listed tests, only few were actually authorized and purchased at the national level. Reasons for this ranged from limited efforts to facilitated their national authorization compared to that put in for vaccines, weak national IVD regulatory systems, unharmonized global and regional IVD regulatory requirements and processes and limited funding for procurement of tests. This could be further elaborated in the report.

**d. Diagnostics:**



- i. Page 21 and page 34: There seems to be lack of acknowledgement of the COVID-19 Supply Chain System (CSCS) -- overview can be found [here](#); both Diagnostics and Biomed Consortia are still ongoing. Data from all partners in each consortia is shared and collated by WHO and there has been consensus that this is a critical role played by WHO. Because of the informal nature of the systems established during this response appropriate data sharing agreements are still being put in place and therefore though these procurement data are summarized on dashboards their access is still by permission only and are not public.
- ii. There are 4 main aspects of the Dx pillar that are highlighted as having contributed to the perception that there was an insufficient focus on delivery of tests including: overall funding, GF ability to procure, delivery challenges and normative guidance but the landscape is much more complex than just four issues and includes country engagement, cost of tests, supply constraint /scarcity of tests (in the beginning), rationale for testing, community engagement, etc.
- iii. Page 57: this maybe a misunderstanding of the procurement landscape. Global Fund needed to indeed to reorient their procurement systems to incorporate COVID-19 having only included HIV, TB and Malaria before. Understanding this would be the case, and take some time, the UN agencies (specifically WHO and Unicef in particular) led early procurements. Whereas Global Fund procured roughly 6 million tests in 2020, this then greatly increased to 53 million tests in 2021; On the other hand UN agencies procured nearly 38 million tests in 2020 and 46 million in 2021.

**e. Therapeutics:**

- i. Page 10: *The Therapeutics pillar failed to achieve its original delivery targets and there remain challenges with delivery of therapeutics.* This statement is misleading. Consider “Estimates for therapeutics were highly subject to change. The outcomes of trials and treatment guidelines showed lower need than population-based targets that were developed in advance of release to markets of Tx products.” Background: Targets for therapeutics would normally be based on estimates of patients over time for whom the treatment would be effective. It doesn’t work to use a percent coverage of population, as the case of vaccines. Given that original targets were broad estimates developed prior to conclusion of trials and treatment guidelines, it would be assumed that they were illustrative and subject to change so perhaps failure to deliver to those targets is a misleading statement. Given that the final outcome of clinical trials showed efficacy in only a subset of patients, it would be irresponsible to drive towards the original estimates. One extreme delay in delivery was caused by a manufacturer. This was common knowledge, including media level information.
- ii. Page 10. *Agencies found it challenging to rapidly disburse funding.* A point to consider adding: “Decentralized funding, in particular, created complications for countries and WHO received reports of countries that did not receive funding in time for commodities. The pillar was under-funded and procurement of antivirals was dependent on each country to mobilize a donor source to cover the costs, resulting in lower uptake due to high prices. ”
- iii. Page 12. *We suggest a “club of buyers” Consider: “Coordinated procurement has benefits and is a complex area. One of the key factors to moving towards stronger coordination would be a strategy that includes specialized technical*



capacities, such as regulation, mediation and others.” Background: We know that stakeholders often suggest pooled or coordinated procurement. It is a complex space that is generally poorly understood, particularly in managing conflicts of interest, variability in specialized technical competencies and legal agreements.

- iv. Page 13. *Indemnification and no-fault compensation mechanisms* Consider: “It will be important to have mechanisms that support all novel products, not just vaccines, and that the coverage is linked to the product and not to the delivery channel.” It is just an unrealistic suggestion that has better options. Including CSOs and NGOs in indemnification language is a non-starter for most companies. The easiest option here is to make the link to the product stronger, not add a catch-all clause that no one will accept.
- v. Page 39 Resource mobilization model. Consider adding “While resource mobilization was rapid, there were multiple approaches that included decentralized, country-driven requests. The latter were particularly slow to process and WHO received complaints from countries that were not able to access funds for therapeutic products.”
- vi. Page 53. *The “wild west”* approach of clinical trials is an unusual statement. Having multiple products in a pipeline was largely a positive area and given that trials were often run by private sector or other parties, it would be expected that the pillar would have limited control. Even with the common protocol approach.
- vii. Page 53: Report fails to mention delivery of significant quantities of tocilizumab and pre-market demand generation and allocation of the antivirals. WHO received comments from countries that lack of financing inhibited uptake. On the test and treat strategy, the original strategy did not include sufficient guidance for countries in possible approaches.
- viii. External factors, page 67: Consider mentioning that while vaccine manufacturers are accustomed to working with multi-lateral agencies, many of the Tx manufacturers were not. In some instances, commitments and good faith were easily achieved, but this was not universal for the Tx products. There were multiple situations where commitments from industry members were made and repeatedly reneged and in others, companies refused to cooperate at all.

**f. Resource mobilization and financing:**

- i. Section 3: The message on the vaccine pillar getting most of the funds could be put in perspective. Most agencies actually received much more funding through ACT-A (up to 8 time more) than they did in normal times. It is true that agencies with existing teams and processes to manage large amounts of funding did receive more contributions in value, as one could have expected, but compared to their usual level of fundraising, they did not necessary received more than smaller agencies in proportion.

**g. Humanitarian issues, including the buffer**

- i. Page 13, *Indemnification and no-fault compensation mechanisms*: I&L issues for the humanitarian buffer for NGOs was indeed an issues and require, however UN Agencies also struggled to be an applicant due to drawn out contract negotiations, (including issues around I&L) which was not resolved until Q2 2022. I&L issues for all the different types of humanitarian actors need to be

addressed prior to any pandemic. They should not be resolved during the pandemic, see below for more detail.

- ii. Page 46, second to last paragraph: For countries facing humanitarian crises by end of 2021, LICs have higher number of people affected by humanitarian crisis and in need for additional humanitarian assistance, downstream challenges faced by LICs perpetuated this inequity.
- iii. Page 50: It could be contextualized that 22 of the 34 priority countries were facing humanitarian crises as defined in the UN Global Humanitarian Overview <https://hum-insight.info/>
- iv. Page 51: vaccination in humanitarian settings: 30 countries have Humanitarian Response Plan, with a total population of 1.2B. Most areas sub-nationally have humanitarian partners delivering health services, and coordinating through the health cluster yet still countries with highest humanitarian need have the lowest vaccination coverage, this is mirrored at subnational level where areas with high humanitarian need have the lowest coverage. CoVDP is strengthening leveraging humanitarian partners, and humanitarian platforms such as health cluster, HCT, to increase reach, however they have yet to address equity gaps within countries.
- v. P51, key Finding paragraph: It was not noted that the Humanitarian Buffer was a means of last resort when country programs could not provide doses to humanitarian settings. Also, the IASC was the means to allocate the doses that were set aside for the Humanitarian Buffer.
- vi. Section 4.7: There is not a strong representation / inclusion of countries facing humanitarian crises.

CoVDP detailed comments and corrections for ACT-A evaluation  
19 October 2022

**Factual inaccuracies:**

- **In simplifying the analysis, too much success is attributed to CoVDP:** CoVDP did play a key role to catalyze support in 23 of the 34 countries (to date), but several countries such as Uganda, Cote d'Ivoire and Zambia moved forward without the need for dedicated CoVDP support leveraging existing in-country expertise and additional support provided through the UNICEF and WHO regional offices. In two cases, our engagement has not yielded the desired results (Senegal, Gabon). A more nuanced language is needed. Also important to note, as discussed, was that new actors supported delivery such as Africa CDC. While it was not in the scope of the evaluation to look beyond ACT-A, it is important to acknowledge the role that regional institutions played and to put countries at the center of the progress achieved with the support of their partners.

In sum, the report highlights the success of CoVDP as an interagency model for delivery that provided concerted and operational country support to up to 34 countries but could have benefitted from more analysis on how this was achieved. Drawing lessons from the models of leveraged funding, technical assistance and political engagement and advocacy could inform future architecture and planning.

In addition, the evaluation should highlight the specific contributions of the core agencies, including the work of the Country Readiness and Delivery working group – ancestor to CoVDP – that ensured that all countries have national vaccination and deployment plans and assessed their readiness to introduce vaccines using tools such as VIRAT. This group also set the foundation for coordination of partners and donors, data monitoring, development of technical guidance tools and global training initiatives, some of which ran across the 92 AMC countries.

- **CoVDP has not provided funding,** instead CoVDP is leveraging funding available within the institutions (GAVI, WHO and UNICEF). CoVDP does not have funding, nor was funding centralized. Instead CoVDP worked with its core partners (WHO, UNICEF and GAVI) to align around funding requests and to then leverage the funds that are already within these institutions and to disburse these quickly, e.g. providing urgent funding for a country to operationalize an upcoming nationwide vaccination campaign. The report should therefore say that “CoVDP has established processes that allow for the alignment of urgent funding needs and enable the quick disbursement of funds mobilized by GAVI, WHO and UNICEF”.
- **Focus on high-level coverage:** CoVDP has since inception focused to support countries achieve their national coverage targets with a focus on high priority groups (on the way to global targets) – which is more deliberate and targeted than ‘high level coverage’. We suggest to change the wording from ‘high level coverage’ towards ‘support countries achieve their national coverage targets with a focus on high priority groups (on the way to global targets)’. We were given a specific mandate and focused on that.

**Contextual issues to take into further account:**

- One of the questions asked in the survey is whether in future pandemics functions should be performed primarily at the global or regional level. We understand the intent of the question but the experience of other emergencies and health emergency responses is putting country at the center and lining up regional and global support in a manner that gets

the best capacity available and reducing transaction costs while respecting the principle of subsidiarity. The principles of the IHR and the declaration of a PHEIC are already based on this approach.

- There were not sufficient vaccines available when low and lower-middle income countries needed them in mid-2021. High income countries had access to vaccines but were focused on domestic needs. Omicron subsequently changed the risk perception of COVID-19. Since vaccines became more widely available, low and lower-middle income countries in particular have been in the lead in achieving progress on COVID-19 vaccination coverage in a context of competing health and economic priorities, humanitarian crises and stretched health systems.