ADDENDUM

External Evaluation of the ACT-Accelerator:

ACT-A Agency & Partner comments

18 October 2022

This is an addendum to the full report on the External Evaluation of the ACT-Accelerator which can be accessed here: https://www.act-a.org/evaluation

ACT-A Agency comments

CEPI

<u>High level response to ACT-A Evaluation:</u> If we are to build a system able to meet the demands of the continuing as well as future pandemics it's vital that we are able to learn the lessons of the last 2.5 years. Collectively we must build on what worked as well as 'course correct' where needed. Doing this successfully requires internal reflection (COVAX partners recently published an internal COVAX lessons learned report) and external and independent scrutiny. That external evaluation must be rigorous, and informed by evidence with a clear understanding of the contexts and global dynamics within which the response operated. It must also seek to identify areas where there was an absence of quantifiable action, or a mistaken analysis of the available options. This is a harder task, but failure to take this into account will inevitably lead to an imbalanced assessment that scrutinizes and critiques the action taken and will miss much of what needs to be addressed in the future. With that in mind we want to note some thoughts regarding the process and conclusions of the evaluation of ACT-A commissioned by the ACT-A Facilitation Council:

1: The evaluation process, methods and strength of evidence were sub-optimal and as such, some conclusions are not informed by a strong evidence-base:

- The Terms of Reference were set to focus on ACT-A's role, scope, mandate and overall contributions. However, a large amount of the report focuses more on the work of the Pillars (with a heavily weighted emphasis on COVAX). This being noted:
    - A greater level of engagement with the COVAX Pillar, including the Co-Chairs, would have provided a stronger base for the analysis of COVAX's work
    - The report does not offer a full appraisal of ACT-A in some areas
- The report does not show the strength of evidence to support key findings and conclusions, and in parts, appears to be more of a summary of survey responses and key informant perspectives, rather than presenting strong analysis, evidence base, and triangulation to lead to action points and key lessons learned. An example of this is:
    - The report states COVAX sought to be *the* purchasing agent for the world. The June 2020 Investment case stated COVAX "Created a Global COVID-19 Vaccine Facility through which countries can work together to share risk by accessing a wide portfolio of vaccine candidates. At the same time, countries can optimize their chances of accessing the number of doses they need, whether by financing procurement themselves or through official development assistance"

2: There are results that are misattributed to ACT-A, and in a number of places there is a conflation and confusion of ACT-A with the pillars and agencies and vice versa.

- There are instances where the findings misattribute results of the COVAX Pillar to ACT-A itself. This is most notably the case for findings related to resource mobilization.

3. In reflecting on COVAX's work it is critical that the operating environment within which decisions were made, and the inherent uncertainty of how COVID-19 would evolve when those decisions were made, is taken into account. Two examples of this are noted:

- The report says COVAX should not have been so ambitious. COVAX's focus was on achieving equity, and while targets were not achieved in full, we believe that trying to achieve equitable outcomes was the right approach, and smaller targets would have rightly been criticized for fairly to understand the scale of the problem and not been seen as a real contribution
- A "key lesson learnt" is according to the report that "For future pandemic response, there should be a more targeted approach on the lowest-income economies. The added value of the self-financing arm of the COVAX Facility is questionable." While we appreciate some comments regarding the self-financing model, this does not necessarily mean that for any future pandemic response, the response should automatically be more targeted. The self-financing participant component of the COVAX model was proposed when it was unclear which if any vaccines would be successful and when. To this end, it offered countries an option beyond any direct national efforts and which may have offered access to additional vaccines if only some were successful. Each pandemic is unique in nature in terms of epidemiology and any consideration of future participation would need to be responsive to the trajectory of that pandemic.

FIND's response to External Evaluation of the Access To COVID-19 Tools Accelerator (ACT-A)
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The Diagnostics Pillar is co-convened by FIND and the Global Fund, with WHO leading on regulatory, policy, product procurement and allocation. The Diagnostics Pillar works alongside 50 global health partners to scale-up equitable access to COVID-19 diagnostic tools and resources.

As co-convener of the Diagnostic's Pillar, FIND applauds the efforts by the Facilitation Council co-chairs Norway and South Africa for undertaking this evaluation exercise for ACT-A. We value many of the recommendations in the report, and especially want to reinforce the Key Findings on the ACT-A Operating Model, notably Finding 8 which states "LIC and LMIC governments were insufficiently included in ACT-A's model, resulting in a lack of ownership and affecting the delivery of COVID-19 tools." We recognize this challenge and its effects on diagnostics and are actively working within and across the ACT-A pillars to support countries on a scale and sustainability plan for COVID-19 diagnostics.

In addition, in our view, we strongly feel that the evaluation report disproportionately focuses on vaccines and thereby misses some key points about testing and diagnostics broadly. We would be disappointed to see the disproportionate focus on vaccines that have often hampered the global COVID-19 response be made worse by the ACT-A evaluation report, in failing to highlight that the issue of regional manufacturing capacity is as critical for diagnostics as it is for vaccines.

Specifically, we want to highlight the need for local/regional manufacturing capacity to be significantly expanded and supported by global funders moving forward for not only vaccines but also for diagnostics. The issues around the global supply chain for diagnostics, and the limited diagnostic manufacturing capacity across all LMIC regions, are dire and especially critical for future pandemic preparedness. The lack of diagnostics manufacturing capacity in South America, in Africa, and in much of Asia will greatly hamper the ability to monitor and detect pathogens of concern in the future as they emerge in initial, localized outbreaks. Routine use of locally produced diagnostic tests will be essential to surveillance and will drive vaccination strategies for pandemic threats moving forward.

Gavi Response to ACT-A Evaluation:

We welcome the many evaluations currently underway on ACT-A, COVAX, and the global response to COVID-19 more broadly. As the world seeks to better prepare for the next pandemic, it is critical that key learnings from the COVID-19 response are captured and implemented. Given the importance of this task, it is critical that evaluations are rigorous, informed by evidence with a clear understanding of the contexts and global dynamics within which we are operating.

On that note, and as the administrator of the COVAX Facility, in response to the evaluation of ACT-A commissioned by the ACT-A Facilitation Council, we have concerns with the evaluation process and conclusions:

1: The evaluation does not deliver a robust evaluation of ACT-A and rather focused more on the work of the Pillars (and COVAX in particular). The TORs for this evaluation are intended to focus on the role, scope, mandate and overall contributions of ACT-A. However, the actual findings and content focused more on the work of the Pillars as opposed to what ACT-A as the connector did or did not achieve (including the Facilitation Council, the manufacturing taskforce, the mRNA transfer hub, CSO coordination, etc). The report focuses more on the vaccine pillar (COVAX) compared to the therapeutics pillar, diagnostics pillar, the HSRC and the ACT-A itself as a coordination mechanism, and as such, does not offer the valuable, comprehensive, and critical appraisal of ACT-A that was expected per the TORs. Furthermore, given limited engagement with the COVAX Pillar in the evaluation itself, it does not present a sufficiently nuanced understanding of our work.

2: There are results that are misattributed to ACT-A. There are instances where the findings misattribute results of the COVAX Pillar to ACT-A itself. This is most notably the case for findings related to resource mobilization. While ACT-A did raise funding across other pillars, the funds mobilized for COVAX were almost entirely mobilized by the agencies themselves. This critique is linked to the first point – a more thoughtful unpacking of attribution and contribution, supported by robust analyses, is needed.

3: The evaluation process, methods and strength of evidence were sub-optimal and as such, some conclusions are not informed by a strong evidence-base. The approach taken and methods employed diverge from standard evaluation good practice (e.g.: UNEG Norms and Standards for Evaluation), particularly with respect to quality assurance and lack of strong evidence to support findings and recommendations. The report lacks any assessment of the strength of evidence to support key findings and conclusions, and in parts, appears to be more of a summary of survey responses and key informant perspectives, rather than presenting strong analysis, evidence base, and triangulation to lead to action points and key lessons learned. The UNEG's Standard 4.10 is relevant in this respect "Recommendations should be firmly based on evidence and analysis (not be opinion based)." We share a number of examples to illustrate our point:

- The action point to "Use ACT-A's coordinated resource mobilization model" would have benefited from a more robust exploration of the direct contributions and value-add of the ACT-A compared to the efforts of discrete agencies and pillars.
- The report highlights the success of CoVDP as an interagency model for delivery that provided concerted and operational country support, with an action point to set-up a similar

model led by an operational agency in the future. The analysis supporting this action point could have benefited from considerably more analysis on how CoVDP works and what it has achieved. The CoVDP focused primarily on an important subset of 34 countries (those with lowest coverage). Any future models of delivery support would likely need to consider a broader groups of countries: COVAX delivered to 146 countries; 92 of which were AMC low and lower middle-income countries, and WHO and UNICEF have broader mandates serving all Member States. Drawing lessons from the model of leveraged funding, technical assistance and political engagement and advocacy could inform future architecture and planning. In addition, the evaluation could have better dissected the specific contributions of the core agencies, including the work of the Country Readiness and Delivery working group – ancestor to CoVDP – that among other contributions, 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.

- The report states that there "is a need to invest in health systems" and has a key finding that "Strengthening country health systems, and especially primary health care systems, during "peace time" is a key imperative". While we strongly agree with the need to strengthen primary healthcare systems and country-level systems more broadly, these findings are not supported by analyses or evidence-based recommendations that could enable decisions to be taken as to which aspects should be prioritized from a pandemic preparedness perspective. As such, the utility of these high-level findings is limited.
- A key learning from the report is that "For future pandemic response, there should be a more targeted approach on the lowest-income economies. The added value of the self-financing arm of the COVAX Facility is questionable." While we can appreciate some of the perspectives reflected in the report pertaining to the self-financing model, this does not necessarily mean that for any future pandemic response, the response should automatically be more targeted. There is no accompanying analysis of key assumptions made, trade-offs debated nor flexibilities extended through the SFP model and no solid evidence or cost-benefit analysis behind the recommendation to make any future response targeted on lowest-income economies. Furthermore, each pandemic is unique in nature in terms of epidemiology and any consideration of future participation would need to be responsive to the trajectory of that pandemic.

Global Fund's response to External Evaluation of the Access To COVID-19 Tools Accelerator (ACT-A)

18 October 2022

Overall Comments and Reflections:

As a founding member of ACT-A and co-leader of the Diagnostics and Therapeutics pillars and of the Health Systems and Response Connector, the Global Fund has been an integral part of the groundbreaking coordination platform to collectively respond to the COVID-19 pandemic. Coronavirus will not be the last pandemic in our lifetime, and it is critical to look at lessons learned as we prepare for the next deadly pathogen. The Global Fund commends the Facilitation Council Co-Chairs Norway and South Africa for commissioning such an important evaluation of ACT-A.

In view of the usefulness such an important evaluation might have had, the Global Fund is disappointed that it was conducted in such a flawed and inadequate manner, largely reliant on an unscientific opinion survey and selective use of interview responses, devoid of rigorous analysis and ignoring other relevant sources of information. We believe that the evaluation draws conclusions that are not based on an exhaustive evidence base and rigorous methods, hence misinterpreting the complex reality. Considering the interest in the innovative coordination model, particularly now that the future pandemic preparedness and response architecture is being discussed in many fora, it is vital that such an evaluation gives a truthful and nuanced picture of ACT-A's achievements and challenges. As this evaluation could be used as an important building block for future collective pandemic response, we must ensure that the foundation of future pandemic response is rock solid. To this extent, we would like to bring to your attention the following observations:

The evaluation methodology is inadequate

- Considering the ambitious scope of the evaluation, a more rigorous evidence base would have been needed to form a credible interpretation of ACT-A's impact and role in the pandemic response. The evaluation findings rely largely on survey results or interviews that failed to be analyzed against the large amount of existing research on the topic. More specifically, here are some of the issues with the methodology:
    - Quoting percentages of unweighted survey responses only makes sense when there is some clear logic to the survey sample – e.g., it is random, comprehensive, or drawn from a reasonable sample of a representative population. Otherwise, it simply reflects the biases of those devising the interview sample. There are 9 WHO respondents to the survey, 1 from the Global Fund. For most ACT-A agencies only one person was interviewed.
    - References to opinions garnered from interviews appear to have been highly selective. The report gives weight to some opinions that are factually incorrect (e.g., the constraints on diagnostic deployment through the Global Fund), while ignoring

completely some of the main points made by other interviewees, including from the Global Fund.

- ACT-A partner agencies themselves have significant data available. The evaluators did not request data from the Global Fund, and almost none of the publicly available data was used, according to the references quoted in the report.
- Agencies were not given an opportunity to provide feedback on the results before they were published on the 10th of October 2022, contrary to standard practice for evaluations of this kind.
- The evaluation draws on data from the early phase of the pandemic for its conclusions. There is an absence of data and evidence from 2021 and early 2022, when significant progress was made on Diagnostics and Therapeutics. Once these pillars were better funded and through Global Fund grants, there was a rapid scale up on access to diagnostics and therapeutics, including oxygen. For example, the only documentation referenced for the Global Fund is an audit of the Global Fund's Covid-19 Response Mechanism (C19RM) in 2020. This ignores the adjustments incorporated into C19RM 2021, bringing about important adjustments in 2021 and 2022, e.g., providing oxygen Pressure Swing Adsorption plants and funding in-country laboratory capacity.

<u>Many of the conclusions and interpretations of the Evaluation are flawed</u>

- The evaluation would have likely drawn different conclusions if more of the available research had been taken into consideration, and if the unique and complex dynamics of ACT-A and its external landscape had been interpreted more rigorously. There are errors of omission that relate directly to the main findings and recommendations of the report. There is a clear impression that the report was written to support existing beliefs about funding and recommendations, rather than as an objective evaluation of the facts. More specifically, some of the incorrect findings and interpretations include:
  - The evaluation does not fully appreciate that ACT-A was a best effort by several global health agencies to respond collectively to a pandemic involving a new pathogen with many unknowns. The field developed very rapidly, and ACT-A had to respond in real time to a fast-moving situation with unprecedented global implications. Also ACT-A was intentionally designed to coordinate the existing institutions but not replace them, therefore many of the existing governance models, oversight and engagement of LMICs and civil society in place in the agencies served the ACTA-A Covid response as well.
  - Therefore, concluding that ACT-A had challenges with accountability and transparency and that there was only limited involvement of civil society and LMICs is misleading. Some 60% of all funding through three of the four ACT-A pillars was channelled through the Global Fund's COVID-19 Response Mechanism (C19RM). This mechanism was designed with the active involvement of implementer countries (i.e., LMICs), civil society and other partners. Every C19RM funding proposal was developed by in-country partners and involved explicit prioritisation across the three pillars. Every award decision went through a consultative process involving all ACT-A partners, including civil society. Oversight and accountability have been secured through the Global Fund's established partner mechanisms, which give implementer

countries and civil society far greater power than in any other major grant-making organisation in global health. The evaluation does not mention this reality. The report "finds" that ACT-A needed greater involvement of LMICs, more cross-pillar coordination and stronger accountability mechanisms, without considering whether these arrangements provided exactly that. In fact, the evaluation makes only one specific reference to C19RM - and that one misleading and based on an outdated evaluation of the response mechanism.

- Concluding that the Vaccine pillar fundraising was the most successful fails to take into consideration the fact that early ACT-A external communication and outreach and initial donor interest was strongly focused on vaccines. There was little advocacy for a more comprehensive and broader public health response. It was the rigorous work of the other pillars and improvement of wider ACT-A messaging that prompted a more comprehensive pandemic response, including funding beyond vaccines.
- The evaluation's conclusions on diagnostics are incomplete and unnecessarily negative. Diagnostics was the first pillar to deliver health products to countries. It was the first to adopt an equitable allocation model, as well as first to engage civil society. Equally, the pillar attempted to give significant leadership roles to LMIC representatives; this was a challenging process as the most relevant people were needed at national level to respond to the pandemic and had little badnwidth to engage globally. The report fails to reflect these facts.
- On resource mobilisation, while the Global Fund agrees that "the joint strategy and budget, alignment of agencies, and provision of investment case materials to donors were critical success factors in mobilising resources" (P39), we do not agree with the conclusions on the fair share model. The fair-share approach did not significantly contribute to fundraising for diagnostics, therapeutics, and health systems, but provided a funding ceiling for some of the more generous donors.

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

Overall Comments and Reflections, October 18, 2022

Unitaid welcomes the commission of the External Evaluation of the Access To COVID-19 Tools Accelerator (ACT-A) 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. However, we have serious concerns about the quality and relevance of the evaluation's data collection methodology as well as its key findings.

As explained in the separately submitted commentary detailing factual inaccuracies or incomplete sections of the report (particularly for section 4.2: *Performance of ACT-A Tx Pillar)*, we perceive significant flaws in the methodology of the External Evaluation and in the resulting conclusions. These methodological weaknesses severely limit the opportunity to draw relevant lessons from our experience over the past two and a half years. 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.

Overall, the report misses an excellent opportunity to inform our collective thinking on how to respond to global health emergencies going forward. Unitaid, as the co-lead of the ACT-A Therapeutics (Tx) Pillar, believes it is critical to look at learnings from the COVID-19 response to inform future pandemic preparedness and response efforts. We take this opportunity to share key learnings from the Tx Pillar below, with a focus on actions to enhance and accelerate equitable global access to medical countermeasures (MCMs), in particular for low- and middle-income countries (LMICs).

The highly uncertain and changing contexts of a pandemic require conscious prioritization to make coherent and robust decisions. COVID-19 has shown us that at the start of a pandemic, evidence for decision-making is scarce and that the context and resulting information changes rapidly. With COVID-19, we saw rapid changes in disease epidemiology, the emergence of variants of concern and evolution in disease severity, and the emergence of Post COVID condition. In addition, context and landscape were quickly evolving with the fast approval of vaccines, variable vaccination and

diagnostics rates, and a complex therapeutic pipeline. In this highly uncertain and fast evolving context, investment decisions needed to be made quickly, whether related to R&D, market preparedness, or product deployment at the country level.
Going forward, it is crucial for pandemic PPR efforts to adequately factor in this uncertainty, in particular by:

- **maintaining a flexible strategy and robust decision-making processes.** It is crucial to maintain a flexible strategy that can be rapidly adjusted in light of new information. In addition, given the lack of reliable forecasts of pandemic evolution, adopting a scenario planning approach to prepare for several possible futures is key to ensuring markets and countries can timely respond. As significant investments need to be made while evidence has not yet been fully acquired, it is important to establish robust risk management policies, and efficient communication between partner organizations, donors, and key stakeholders.
- **ensuring early and adequate availability of funding to build and maintain the capacity to produce and potentially deliver treatments**. As disease trajectory and epidemiology are highly unpredictable, we should overprepare by identifying "no-regret" moves to incentivize the research, development, and manufacturing of adequate and adapted therapeutics in sufficient capacity for the expected need, even at the risk of the pandemic course eventually negating the need to deploy the therapeutics according to initial assumptions.
- **having a cohesive strategy across the different medical countermeasures (e.g., vaccines, diagnostics, and therapeutics).** The availability and effectiveness of each medical countermeasure directly impact the others. Building a strong and coordinated response across MCMs is crucial to enable countries to have successful, comprehensive responses to health threats. More strategic, predictable, and integrated financing across MCMs is required.

In future pandemic responses, global therapeutics R&D efforts should more urgently prioritize the specific needs of low- and middle-income countries (LMICs).

The ACT-A Therapeutics Pillar's R&D mandate has been to transform global R&D developments into accelerated and equitable access to therapeutics, connecting the pipeline with rapid uptake by LMICs in particular. However, global R&D efforts faced setbacks and as a result the pipeline of novel therapeutics against SARS-CoV2 was significantly delayed; widely deployable therapeutics, such as oral antivirals, only became available at the end of 2021.
Going forward, it will be key to establish and coordinate trial platforms with wide geographical coverage, including LMICs, in order to accelerate the identification and adaptation of tools in rapidly evolving pandemics. Attention should be made to simpler treatment regimens and therapeutics that are safe and effective for broader patient populations, and to combination therapies as relevant. It is essential that the advancements achieved during COVID-19 are leveraged and expanded to prepare and respond to other pathogens of pandemic potential.

Equitable access to therapeutics including LMICs should be prioritized early in the industry response.

Industry, governments, and global health stakeholders will need to align on robust access policies earlier in a pandemic. These access strategies must address the specific access challenges that occur in pandemic contexts, such as limited demand visibility. In particular, it will be crucial to:

- ensure that affordable, quality-assured therapeutics are available in sufficient quantities as soon as possible by (i) facilitating early commitments for novel therapeutics for broad and sustainable access plans; (ii) granting low- and middle-income countries rapid and equitable access to originator therapeutics as a bridge until generics are widely available, and (iii) engaging with manufacturers of generic therapeutics early on to accelerate access plans, particularly for licensing and product development;

- ensure access policies, including voluntary licenses for generic manufacturing, cover the broadest geographical scope possible, including upper-middle-income countries, and support the diversification of the supplier base;
- continue efforts to diversify therapeutic manufacturing capacity, particularly by building manufacturing capacity in LMICs, to help strengthen regional health security and pandemic preparedness;
- provide visibility on product pipeline, supply timelines, and price transparency to decision-makers and communities at country level, as key to facilitating countries' demand decisions and response planning, already hampered by the constantly evolving nature of a pandemic.

Expanding and maintaining a sustainable and affordable supply of oxygen in LMICs should be a cornerstone of future PPR efforts, in view of broad public health needs and potential future respiratory pandemic-prone pathogens.

As the External evaluation indicates, the ACT-A partnership has been able to rapidly mobilize funding and catalyze urgent and major changes to the oxygen landscape; oxygen is a critical health tool that has been subject to significant access and market barriers in most LMICs. Through ACT-A, available financing and strategic planning coupled with large procurement efforts have delivered oxygen equipment at unprecedented levels. The partnership has helped shape the oxygen market by engaging with industrial, multilateral, and government partners to secure commitments to i) improve liquid oxygen manufacturing capacity and supply chains in LMICs and ii) agree to price reductions for bulk liquid oxygen and filled cylinders to meet demand surges. In addition, the ACT-A partnership supported countries to evaluate their oxygen needs and promote the rapid uptake of this life-saving tool. Resulting solutions and interventions were directly informed by the countries' expressed needs and priorities. LMICs are now prioritizing oxygen, with the support of the Tx Pillar's Oxygen Emergency Taskforce, which directly helped 21 countries to assess oxygen needs & access available funding. Going forward, it will be crucial to build on the learnings from the Oxygen Emergency Taskforce's work and to sustain its achievements. To this end, discussions are underway on how to transition the Taskforce to a Global Oxygen Alliance in order to maintain the momentum of expanding equitable oxygen access, through strategic alignment and collaboration across all key stakeholders.

For faster and broader therapeutics adoption at country level, early investments in country preparedness and meaningful engagement with country stakeholders at each step of the pandemic response are key.

It is crucial to support early investments to equip countries to cope with different epidemiological scenarios and to adapt to evolving landscapes. In alignment with Dx and Vx deployment, support should be provided to i) identify simplified models of care (including T&T), ii) achieve an enabling environment for product roll-out (mapping and anticipating health system prerequisites for effective use by target population of a given product, identifying regulatory pathways and procurement and supply chain), iii) support treatment literacy and demand creation, and iv) support planning for full scale-up if epidemiologic need persists.

In addition, meaningful engagement with country partners and decision-making bodies at the country level – including governments, communities, and civil society – should happen at each stage of the response process, from R&D to planning for procurement and delivery. Information sharing is pivotal to meaningful and timely strategic planning and implementation. Continuous communication with LMICs on the available and upcoming Tx products (and likely cost-effectiveness and available funding sources) is critical, as demand can be limited or delayed in part due to the complexities of navigating fast evolving product and funding landscape.

To close the therapeutics equity gap when addressing future pandemics, we need a new model of collaboration across key stakeholders, including industry, to set far higher standards for access and speed of response despite pandemic-related uncertainties. Such a model would seek to enhance the coherence of collective strategy setting and decision-making, across key stakeholders at global and country levels, and the ability to adapt rapidly to new information.

In addition, it will be crucial to create a continuum between pandemic preparedness and response, supporting preparedness initiatives that enable a rapid and robust strong response when the next pandemic occurs. This implies ensuring that global R&D efforts factor in the needs of LMICs at the beginning of the research and development process and focusing on building resilient markets and resilient country capacity to quickly adopt and deploy new products, despite uncertainty on how the pandemic burden will evolve over time. By building access, market, and country capacities early on in the pandemic prevention, preparedness, and response (PPR) cycle, we can accelerate the implementation and uptake of optimal solutions for populations in need, including those in low- and middle-income countries (LMICs).

World Health Organization (WHO) response to the External Evaluation of the Access to COVID-19 Tools Accelerator (ACT-A)

18 October 2022

WHO appreciates the broad range of views on the ACT-Accelerator (ACT-A) setup, operations and results that are captured in the External Evaluation, which was commissioned by the ACT-A Facilitation Council. Of particular value in this report are the perspectives expressed by a number of countries in Africa, South America and Asia that used ACT-A processes and services during the pandemic, but whose voices have not always been heard in such reviews.

While acknowledging the limitations that have been cited by the authors and other commentators, this report does provide important perspectives that add to the growing number of evaluations, reports, reviews and recommendations that aim to inform the establishment of a stronger countermeasures platform. Collectively, this work will help shape efforts to build on the experience of ACT-A and other instruments and initiatives (e.g. the Pandemic Influenza Preparedness (PIP) Framework, the '100 Day Mission') to ensure the world can rely on a more robust platform for accelerating the development, and equitable allocation and delivery of countermeasures in future pandemics.

Of particular note in this report is the strong, majority position of survey respondents that the innovative and collaborative ACT-A arrangement was the right approach for accelerating access to COVID-19 countermeasures at a time when the global community needed to act quickly and decisively to combat a poorly understood threat. The report also documents important results that were achieved through the ACT-A approach, including the unprecedented speed of its core agencies in delivering vaccines and diagnostics to the lowest income countries, as compared to previous pandemics, and in driving crucial market interventions that substantially reduced prices and enhanced access to diagnostics, oxygen and antivirals at a critical time. The counterfactual is that in the absence of ACT-A, equity in access to countermeasures would have been much worse.

WHO concurs with the challenges identified in the areas of the Health Systems Connector (vs. the HSRC) and the quality assurance of rapid diagnostics. With respect to the former, this lesson was learned and corrected in the course of ACT-A, with the Connector being substantially revamped and relaunched in 2021 (a point that is not fully reflected in the report). Addressing gaps in WHO's capacity to assess the very high volume of diagnostics submissions during the course of the pandemic was inherently more challenging and signals the vital need for additional financing and personnel for this area, adjustments to the assessment process for emergency situations, and greater support from collaborating agencies.

The report also reinforces previously identified shortcomings in the ACT-A operating model that were largely the result of the urgency and speed with which ACT-A had to be established.

These findings support the existing consensus on the vital need to ensure the future countermeasures platform is more inclusive, has greater transparency in its operations and establishes robust mechanisms for collective accountability. The report particularly highlights the need to completely rethink and rework key processes with low- and lower-middle income countries to ensure their full and meaningful engagement. An important omission in this evaluation is an assessment of the role and impact of industry in ACT-A through its participation in the Facilitation Council, Principals Group and some Pillars, and the degree to which this did or did not facilitate the coalition's core objective of ensuring equitable access to vaccines, tests and treatments in real time.

In formulating other recommendations on the way forward, however, the report seems to have based some important conclusions on incomplete information or a misunderstanding of key aspects of the ACT-A collaboration. This appears to be the case in areas such as how targets for product volumes were established, the original ambition for the COVAX Facility, the nature of the COVID Vaccines Delivery Platform (CoVDP) and its mode of operations, and the key role of individual ACT-A agencies in resource mobilization. Most importantly, and contrary to the data presented, the report could inadvertently lead readers to conclude that creating a more robust countermeasures platform is best achieved by starting from scratch, rather than building on the considerable, documented strengths of the ACT-A collaboration and its three product pillars. The framing of an important survey question(s) may have contributed to this perspective. From a pragmatic perspective, it would seem more advantageous to harness and build on the substantial experience that international health agencies and partners have gained through their work in ACT-A, while also addressing the shortcomings of this model.

Notwithstanding these issues, the perspectives captured in this report strongly reinforce the need for an inclusive, robust process that engages countries, relevant international health agencies and organizations, civil society and community organizations, donors, industry and other stakeholders, to co-create a countermeasures platform that is anchored in the principles of speed and equity. This process will need to be informed by all such reviews and experience to optimize upstream operations (e.g. R&D, market shaping), downstream work (e.g. procurement, delivery), collective accountability and financing. WHO will take such a process forward with partners and stakeholders and with urgency, because, as the evaluation report again emphasizes, this cannot wait for the next pandemic.

WHO is deeply grateful for the extraordinary role that Norway and South Africa have played in co-chairing the ACT-A Facilitation Council throughout these turbulent times, and for commissioning this External Evaluation that is an important contribution to our collective efforts to build a safer, fairer world, together.

ACT-A Partner comments

CoVDP comment on the ACT-A evaluation

19 October 2022

The evaluation should recognize that countries and regional institutions drove much of the increase in COVID-19 vaccination coverage. Building on that work, the COVID-19 Vaccine Delivery Partnership (CoVDP) did play a role in catalyzing support in 23 of the 34 countries to date working with partners. 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. The language pertaining to this should be more nuanced. Also important to note 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.

Where the CoVDP model is highlighted as a success, the report would have benefited from analysis on what made this successful. CoVDP provided political advocacy and engagement, leveraged funding from core partners (WHO, UNICEF and Gavi) through an accelerated process and lined up technical assistance (including some that it fielded). Drawing lessons from this model of leveraged funding, technical assistance and political engagement and advocacy could inform future architecture and planning. A key enabling factor was that partners came together around the principle of the One Team, One Plan and One Budget to ensure alignment of the support provided around government ownership.

In addition, the evaluation should highlight the specific contributions of the core agencies, including the work of the Country Readiness and Delivery working group – precursor 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.

We would also like to provide two points to contextualize our comments.

1. 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 that what is effective is putting the country at the center and lining up regional and global support in a manner that gets the best capacity available and reduces transaction costs, while respecting the principle of subsidiarity. The principles of the International Health Regulations (IHR) and the declaration of a Public Health Emergency of International Concern (PHEIC) are already based on this approach.
2. 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.

PLATFORM FOR ACT-A
CIVIL SOCIETY AND COMMUNITY REPRESENTATIVES

Statement on the External Evaluation of the Access To COVID-19 Tools Accelerator (ACT-A) - 11 October 2022

In July 2022 the ACT-A Facilitation Council commissioned an external evaluation of ACT-A to identify lessons learnt that will be of use in establishing a better global pandemic preparedness and response system. An Evaluation Reference Group was established to oversee the evaluation including 4 civil society and community representatives. The term of reference of the evaluation set out 6 key areas to evaluate the role of ACT-A, its mandate, set-up and structure, achievement of its objectives and commitments, resource mobilisation and financing, gaps and missed opportunities, and way forward. This evaluation was not designed as an impact evaluation of the global response to the Covid-19 pandemic, nor was it intended to describe in detail all activities carried out by ACT-A.

The external evaluation (published on 11 October 2022) was conducted by Open Consultants, who executed the report in line with the Terms of Reference (ToR) with efforts to ensure the civil society and community representatives to ACT-A were consulted through interviews, focus groups and written submissions. In addition civil society and community representatives prepared briefings on key lessons in our engagement with ACT-A.

Throughout ACT-A, civil society and community representatives have highlighted a number of key areas outlined in the report. This includes LIC and LMIC governments being insufficiently included in ACT-A's model (resulting in a lack of ownership and affecting the delivery of COVID-19 tools), and accountability and transparency not sufficiently promoted by the ACT-A model. The report acknowledges that access to certain diagnostic types was delayed due to late WHO clearance (especially for self-tests) and that strengthening WHO's prequalification is required. Key informants highlighted that a test-to-treat strategy should have been prioritised earlier in the work of ACT-A, a key priority raised by civil society and community representatives. Additionally, the report highlights that the Health Systems and Response Connector (HSRC) missed strong political drive, ambition and support and was largely disconnected from the other pillars and poorly focused, with the weakest performance and funding.

As highlighted in the report, **ACT-A's informal coordination model is insufficient for future pandemic response. A different design will be needed to address future pandemics.** As the lessons learnt highlighted in the report are considered, and we look to future pandemic prevention, preparedness and response mechanisms, we must ensure any new mechanisms include:

Equal intellectual partnership of LMICs
The representation and leadership of low and middle income countries (LMICs), including technical experts with LMIC passports, must be prioritised across the entire pandemic preparedness and response spectrum, particularly in global leadership. As noted in the evaluation, a forum of G20 countries only will be insufficient. Partnership must also include the framework design, implementation and priority setting of pandemic preparedness mechanisms with equal intellectual partnership of expertise, as well as formal representation in

decision-making and governance (with a clear structure for accountability and decision making in place at the onset and clearly communicated to all stakeholders).

Co-creation with civil society and communities

Civil society and communities are recognised across most global health bodies as critical partners in the global health architecture and must be formally represented in governance and decision-making processes as well as technical areas of work. This includes permanent representation of civil society and community constituencies in the governance structures, provision of voting rights and funding to constituencies to support engagement with broader civil society and communities. In order to ensure an inclusive governance and decision-making process, governments and organisations must co-develop the operations and governance of new mechanisms with a broad range of actors, including civil society and communities.

A new intellectual property order

A new intellectual property order must be put in place, ensuring that: (1) pandemic research and product development follow open science principles and focuses on medical countermeasures well adapted for use and affordability in low resourced settings; (2) public, charitable, and multilateral funding of research and development be conditioned on licensing and technology sharing and on commitment to market broadly in LMICs; (3) Intellectual property barriers arising from patents, trade secrets, copyright, and industrial design be waived or eliminated in the TRIPS Agreement, free trade and investment agreements, and national legislation with respect to pandemic countermeasures so as to allow quicker and expanded supply, more affordable pricing, and truly equitable distribution; and (4) regional production and pooled purchasing power be developed and used to more equitably distribute biopharmaceutical manufacturing capacity and to more equitably, affordably, and efficiently source medical countermeasures.

A central role for health systems and response

New mechanisms must center and prioritise the building of resilient and equitable health systems with a view toward universal health coverage, including community health systems and primary health care approaches as foundational to the success of any future mechanism. This goes beyond the role of the new Financial Intermediary Fund on PPR. Such systems should build stronger support for rights-based, equity-centred adoption and roll-out of novel treatments, alongside timely guidance (regulatory and clinical) and strengthened systems for technology transfer and co-creation. There are a number of key health system gaps made worse in pandemics, including insufficiently supported, trained, and well remunerated health workforce and disrupted essential health services. Addressing these gaps must be part of long term and sustainable interventions even in “interpandemic” times. But they must also be prioritised as an early focus during pandemics to prevent the stalling and devastating impact on other essential health services, and disease programs and health interventions as seen with the COVID-19 impact on HIV, TB, sexual reproductive and health, malaria, maternal and child health, routine immunization among others. HSRC country coordination teams that can support robust prevention, preparedness, response, and recovery needs are key. These teams must be operational before, in between, and during pandemics so that: robust and sustainable surveillance systems are in place longitudinally; gaps in workforce, services, and supplies are known and addressed before emergencies occur; and pandemic preparedness is incorporated into routine health systems strengthening.

Future of ACT-A

In addition to informing new PPR mechanisms, the ongoing development of the ACT-A transition plan must draw from the key lessons highlighted in the report to ensure it's ongoing ability to support country need and demand, while maintaining capacity to manage subsequent waves of COVID-19, if and when new variants emerge.

And though not intended for the scope of this review, assessing the impact of ACT-A is still essential. The ongoing evaluation processes across ACT-A must include assessments of all pillars, on how they delivered on their objectives within the strategic period (October 2021-September 2022), addressed growing inequities in access to COVID-19 tools and to what extent interventions were aligned to the needs of low and middle income countries and particularly the most vulnerable and marginalised. For example, we must be able to fully understand how and why vaccine deployments were returned and why donors were so disinterested in funding self-testing for LMICs but were more focused on surveillance which is arguably an intervention that is more beneficial to the interests of high income countries.

International Federation of Pharmaceutical Manufacturers & Associations

IFPMA

IFPMA Response to the release of the ACT-A Evaluation report

The International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) was a founding member of ACT-A when it was launched in April 2020. We welcomed the vision of the ACT-A to involve the private sector, including the innovative biopharmaceutical industry, to join this unique global collaboration set up in the wake of the pandemic to accelerate development, production, and equitable access to COVID-19 tests, treatments, and vaccines.

After two intensive years of collective response to the pandemic, we welcomed the opportunity to contribute to the consultation process (including the survey and interview with Thomas Cueni, Director General of IFPMA), which has resulted in the ACT-A Evaluation Report. We appreciate having the opportunity to provide comments on the report.

We were pleased to see the report flag a number of key elements that we considered either instrumental to ACT-A's success, or detrimental to delivering on its mission, such as the lack of available funding for procurement at the onset of the pandemic, insufficient country readiness, the need to invest in health system strengthening and the importance of open trade. In general, we would like to indicate that we had been expecting the report to be a robust analysis providing evidence-based recommendations. As it currently stands, we feel it has been limited to a summary of the different views shared by participants contributing to the survey and interviews

We would like to share several key concerns:

First, the report failed to evaluate robustly ACT-A's performance *per se* (separately from the performance of the different pillars). The report should have analyzed ACT-A's governance mechanism and how it contributes or not to its success. The report was a missed opportunity to underscore what the real-life experience of the COVID-19 pandemic response has shown - namely that a multistakeholder partnership which includes industry, public agencies, multilateral organizations, financial institutions, governments, civil society, and philanthropic organizations is the only viable solution to managing pandemic crises. While this was the basis upon which ACT-A was set up, regrettably over the past two years, engagement with the private sector has been uneven across the different ACT-A pillars. While COVAX's approach was inclusive and manufacturers (IFPMA, as well as developing countries vaccine manufacturers/DCVMN) had opportunities to share their expertise, the same could not be said for the therapeutics pillar. To the extent that we resorted to publishing an Open Letter on ACT-A Therapeutics and Ongoing Roadblocks to Enhancing Access[1]. We believe the report should have underscored the inclusiveness principle needs to be built into inter-pandemic governance mechanisms.

Second, we were surprised that the report failed to mention the key role the biopharmaceutical industry played in delivering on ACT-A's mission, in particular with respect to the acceleration of development and production of COVID-19 tests, treatments, and vaccines. In just two years, the innovative pharmaceutical industry has developed COVID-19 vaccines and treatments at record

[1] Open Letter on ACT-A Therapeutics and Ongoing Roadblocks to Enhancing Access - IFPMA

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speed and in historic quantities, with 47 vaccines authorized or approved by at least one country, 36 approved therapeutics worldwide, 381 manufacturing deals for COVID-19 vaccines with a total of 15 billion vaccines produced, 148 manufacturing deals for therapeutics. To the extent that supply very swiftly was able to outstrip demand[2].

Third, the report presents technology transfer as an underused solution in the COVID-19 response. It fails to acknowledge the unprecedented effort of the biopharmaceutical industry to facilitate access, including through voluntary agreements, many of which featured technology transfer (approx. 88%). In just the first year of COVID-19 vaccines, there were more than 300 manufacturing and production deals around the globe, the vast majority of which (approx. 75%) involve some sort of licensing and transfer of technology, and at least 30 of them on mRNA vaccines. Furthermore, while the report largely relays calls for even greater levels of COVID-19 technology transfer, particularly for low-income countries, it does not provide a robust analysis of its likelihood for success and impact. While addressing COVID-19 in these countries is critically important, there are many complex factors that must be addressed to ensure the safe, high-quality production of these vaccines, including those related to site selection and capabilities, national regulations and licensure requirements, and workforce skills. With regards to therapeutics, our member companies have signed voluntary license agreements (bilaterally and through Medicines Patent Pool) along with enabling the transfer of technology to scale up sublicensees' manufacturing capabilities. Our member companies have also engaged with ACT-A's procurement partners to put in place timely supply agreements for several million treatment courses to reach LMICs, while also submitting for emergency and full regulatory approvals and WHO pre-qualification in record time. In amongst all this, our companies continue to adhere to tiered pricing as a guiding principle for access.

Despite these efforts, we remain concerned that COVID-19 vaccines and treatments are still not reaching those who need them in a timely and efficient manner due to a number of issues, several of which rest with ACT-A. We believe that the world should aim to do better in the future – by preparing to respond faster and more equitably. No one stakeholder alone can fully address such issues, and we are committed to collaborating with all relevant actors.

In July 2022 the biopharmaceutical industry launched the "Berlin Declaration – biopharmaceutical industry vision for equitable access in pandemics" which presents global leaders with a proposal that could help ensure the supply of pandemic vaccines, treatments and diagnostics are delivered as early as possible in future pandemics to those who need them most. The declaration is an acknowledgement that while innovation and manufacturing scaling-up succeeded in an unprecedented manner during COVID-19, efforts to achieve equitable access were not fully realized. The absence of an adequate financing mechanism upfront and a lack of country readiness played an important role in inhibiting equitable and timely access to vaccines. In line with the Declaration, the IFPMA is calling for discussions with G7, G20, multilateral organizations and other decision-makers

[2] As COVID-19 vaccine output estimated to reach over 12 billion by year end and 24 billion by mid-2022, innovative vaccine manufacturers renew commitment to support G20 efforts to address remaining barriers to equitable access - IFPMA

involved in pandemic preparedness to explore how industry's offer to prioritize and reserve an allocation of real-time production for distribution to priority populations in lower-income countries would contribute towards the holistic and equitable solution the world needs.

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