

MACRO CHANGES TO THE ACT-A

A briefing by the ACT-A Civil Society and Community Representatives

This briefing has been put together by the civil society and community representatives of the ACT-A. It sets out the key macro changes that we feel need to be actioned for the ACT-A to play a legitimate, relevant and effective role in a sustainable response to COVID-19.

WACI Health, STOPAIDS and the Global Fund Advocates Network (GFAN) co-lead the [Platform for ACT-A Civil Society and Community Representatives](#). The Platform supports the representatives' involvement in the ACT-A and facilitates engagement with broader civil society and communities interested in the work of ACT-A.

A BROADER AND LONG-TERM STRATEGY FOR THE ACT-A

The ACT-A must have a broader, longer term and more ambitious strategy in order for it to play an effective role in a sustainable response to COVID-19

ACT-A is currently focused only on the acute phase of the pandemic and on reducing hospitalization, severe disease and deaths, but lacks a dynamic perspective as the epidemic, medical technologies, and experience with effective responses evolves.

As a result, its commitment to deliver existing and new COVID-19 health technologies has so far been limited. For example, ACT-A leadership anticipated that the COVAX Facility and Advance Market Commitment would at most meet 20% of need in LMICs. Similarly, the goal for therapeutics was only 265 million treatments and the goal for diagnostics was only 500 million tests (one test per year for less than 10% of LMIC population). ACT-A has previously rationalized its limited aspirations and durations on the expectation that normal market activity will meet LMIC needs after the acute phase. At this point, even these goals are ephemeral, as the ACT-A has a \$28 billion resource shortfall that is especially severe for diagnostics and therapeutics.

There are a great deal of unknowns around the future of the pandemic and its long-term impacts: the durability of immunity and of vaccine, diagnostic, and therapeutic effectiveness against mutations are still uncertain; the complications of COVID and long-COVID physically and mentally are still emerging; and the scale of the fall-out for other diseases is unclear. But some things are clear: the COVID-19 medical needs of LMICs will not be met in 2021 or 2022; they will have longer mid-term need for diagnostics and therapeutics because of their delayed access to vaccines; and LMICs cannot rely on ordinary market forces to deliver sufficient quantities of well-adapted, affordable medical products to meet their needs.

Recommendations:

- For all these reasons our constituency would like to work with all ACT-A partners to develop broader and longer-term, population-based responses and interventions that can effectively

address long-lasting consequences of COVID-19 on individuals, health systems, economies and social life as well as developing the architecture to organise around global epidemic preparedness.

- We welcome the preliminary discussions within the ACT-A lead institutions around expanding and lengthening ACT-A's mandate and all three Pillars and the Health Systems Connector are working on interventions that will extend into 2022 and perhaps beyond. However, we require an open and consultative process to build on this extension to the mandate which fully involves civil society, communities and representatives from LMICs (as set out below in the section on Meaningful Participation in Decision Making).

The ACT-A must focus on facilitating a scale-up of manufacturing to meet global demand for Covid-19 tools over a longer period of time

Unfortunately, it has become increasingly clear over the last couple of months that the projected demand for COVID-19 innovations will not be met by expected ACT-A supply. Rather than dividing a small pie which will inevitably lead to rationing we need to increase the size of the pie and ensure it is equitably distributed. History shows that normal market-based approaches to priority setting, research and development, manufacturing arrangements and licensing will not be adequate to accomplish any of these needs. An effective and sustainable response to COVID-19 requires rapid scale-up of manufacturing of all COVID-19 health technologies, persistence, ironclad solidarity, and equitable access until the disease is truly defeated.

Recommendations:

- We need the pharmaceutical industry to share and collaborate; we need broad licensing of COVID-19 health technologies and deep technology transfer (sharing of patents, data and know-how) to facilitate the rapid scale up of manufacturing to the required levels.
- This can be achieved by the ACT-A introducing conditionalities to their procurement deals which include technology transfer provisions to LMICs; they must also conduct a thorough mapping of possible manufacturing facilities relating to each product.
- The ACT-A must also work in collaboration with the [COVID-19 Technology Access Pool \(C-TAP\)](#), housed at the World Health Organisation, an initiative which through the work of its implementing partners can facilitate non-exclusive licensing agreements, technology transfer and the sharing of clinical data and related research which could help with the development of future, more effective and better adapted Covid-19 tools.

ENSURING EQUITABLE ACCESS

The ACT-A must use its position to ensure that high income-countries and companies are abiding by the Fair Allocation Framework across their engagement in the ACT-A and their bilateral deals. Within this there must be a robust strategy for re-allocation of doses to achieve equitable coverage of current stock volumes.

There are already supply constraints for existing therapeutics, diagnostics and vaccines due to limited manufacturing capacity and intellectual property barriers. On top of this high-income countries have been stockpiling tests, monoclonal antibody therapies and vaccines which is causing further scarcity. In regard to the latter, the latest figures show that 75% of current vaccine doses have been rolled-out across just 10 countries whilst 130 countries have not received one single dose. If trends persist then it is likely that the majority of LMICs won't have general access to vaccines until the middle of 2023. Vaccine nationalism is driving this inequity but it's important to note that companies are also culpable; firstly, because they supply to those that present the highest purchasing power; and secondly because of their general refusal to share IP and know-how to allow the necessary scale-up in manufacturing to meet global demand.

Recommendations:

- It is imperative that the ACT-A call on countries, and companies, to abide by the WHO's Fair Allocation Framework to ensure all countries get fair access to the tools they need to end the pandemic for their citizens and the rest of the world. With the emergence of new variants, it is truer than ever that the virus uncontrolled anywhere is the virus uncontrolled everywhere. The Fair Allocation Framework, if implemented correctly, provides us with a human rights-driven approach to addressing global health inequalities and discriminatory practices.
- We also call for the ACT-A to build in open licensing, technology transfer, and mappings of potential manufacturing capacity in high, middle- and low-income countries into every procurement deal. Without these conditions included within deals we will be dependent on the good-will of every pharmaceutical company to voluntarily license their products in the hope that collectively this will help us meet global supply. Not only is this a highly unlikely eventuality, it is the norm for voluntary licenses to be issued on the basis that they restrict access in certain territories and are therefore criticised for not being a comprehensive approach to achieving adequate or equitable access.

Funding for the ACT-A must help steer it into playing a more effective role to help ensure an equitable and sustainable response to COVID-19

The ACT-A cannot be a simple partnership to identify promising health technologies, enter into advance marketing commitments and capacity reservations, disburse seed funds and set out production timelines, this approach will not lead to adequate, timely or equitable access to COVID-19 tools.

Making financial contributions should mean that funders are able to see the value of their investment over-time i.e that their money is being spent in a way that is safeguarding us against the future. This is all the more important in light of the continuous demand for tools beyond the acute pandemic period; the need to adapt and increase the efficacy of existing tools; and the need to respond to the unknown impacts of COVID-19 on individuals (both mental and physical), health systems and economies more broadly.

Recommendations:

- Funders have the power to steer the ACT-A towards these ends by attaching conditions to their funding which state that:
 - All procurement contracts need to be fully transparent and open to thorough scrutiny, they also need to include stipulations around sharing data, open licensing and deep technology transfer. All of this can be achieved through working with the C-TAP.
- ACT-A and other global health institutions including the WHO need to identify the full resource needs of LMICs to procure and administer tests, medicines, and vaccines until the pandemic is under full control. The likely resource needs are in the tens of billions of dollars and probably over a hundred billion dollars. Although donor countries have been reluctant to fund even the initial \$38 billion resource need projected by ACT-A, they need to understand real resource needs that are far greater than the proportion set aside by the World Bank, the \$10 billion raised by ACT-A for its early work, and limited other funds made available through concessional loans or otherwise.

FULL TRANSPARENCY AND ACCOUNTABILITY

Going forward ACT-A partners must be fully transparent, accountable and responsible for ensuring and enforcing transparency compliance throughout the whole ACT-A processes and collaborations which are established.

Full transparency should be at the core of the ACT-A and effective accountability mechanisms.

Recommendations:

To achieve this the following principles must be adhered to:

- **Transparent priority setting:** Funding decisions on the selection of tools and interventions that are the most appropriate and effective in widely different settings and different countries must

be transparent, free from conflict of interest and whenever possible, based on scientific evidence. A transparent process to prioritize the candidates with best efficacy and safety profile, as well as the ability to scale up manufacturing, should be established. Civil society and community representatives must be supported to meaningfully participate in this decision making process.

- **Transparent access policies and practices:** All partners must publish their global access policies and the detailed access practices implemented. Access policies and practices need to respond to the principles of fair and equitable global access and address all phases from early stages of R&D to deployment and procurement.
- **Transparent agreements with third parties:** The publication of every agreement between implementing partners, such as research institutes and consortia and private companies, must be a standard operating procedure for all organisations.
- **Transparent R&D and delivery:** The life sciences sector, including the pharmaceutical, medical devices industry and research institutions, must comply with full transparency on the development and deployment of COVID-19-related health products. This includes full transparency of: cost of R&D and manufacturing, public investment contributions and other forms of public support, know-how, clinical trials data and results, manufacturing capacity and selection of production facilities, patent applications and real price (without rebates) of all diagnostics, vaccines and therapeutics.
- **Transparency of conflicts of interest:** For the ACT-A to maintain its legitimacy and a balance between the positions and power dynamics of the partners involved, it must be mandatory that all representatives declare conflicts of interest in relation to their work within the ACT-A.
 - This is not just the responsibility of the private sector. All the global health agencies involved in the ACT-A work, to some extent, with the pharmaceutical industry and some even have shares in pharmaceutical companies; it is right that there is full transparency around these relationships, and they are put on the table.
- **Independent evaluation:** The ACT-A must be subject to regular evaluations by an independent body to assess its commitments to transparency, accountability, and meaningful engagement of civil society and community actors, alongside a robust analysis of its impact in the equitable and timely distribution of COVID-19 health technologies. This evaluation must be publicly available and accessible to facilitate public scrutiny.

MEANINGFUL PARTICIPATION IN DECISION MAKING

Governments, generic pharmaceutical companies, scientists and academics from Low- and Middle-Income Countries must be meaningfully involved in decision making in the ACT-A from priority setting to delivery

The participation of LMIC governments are under-represented in the current ACT-A governance structure and this lack of inclusion threatens the legitimacy and effectiveness of the ACT-A. In the absence of this kind of country participation, there is a risk that top-down decisions will be ill-conceived, difficult to implement and have questionable relevance. The involvement of generic pharmaceutical manufacturers and academia from LMICs is also essential so that localized tools and solutions can be developed.

Recommendations:

- Just as governments, pharmaceutical companies, scientists and academics from HICs are consulted, representatives from the same groups within LMICs must also be fully consulted on the decisions regarding up-stream priority setting through to the delivery of products in order to be able to plan a national strategy to support their disbursement and uptake.

Representatives from civil society organisations and communities must be meaningfully involved in decision making in the ACT-A from priority setting to delivery

Representatives from CSOs and communities are critical intellectual partners which must also have a seat at the table when these initial decisions are being made. Side-lining CSOs and communities ignores the strength they have at national, regional and international levels in all areas of health which will have a positive impact on the ACT-A in terms of supporting its decision making, service delivery and governance as well as ensuring it is fully funded. Civil society is already playing an important role conducting advocacy with country governments to get them to commit more resources and engage fully in developing use cases for diagnostics and therapeutics and understand demand and they should be funded for this work.

Involvement of these actors in the governance of ACT-A can't be an afterthought or a tokenistic gesture. The legitimacy and effectiveness of the ACT-A rest upon their meaningful involvement in decision making at every stage. We request that you take the following preliminary steps to help pave the way for our constituencies to be able to play an active role in shaping the work of the ACT-A:

- A detailed map of the current decision-making pathways, governance oversight and processes of consultation from priority setting, resource allocation through to procurement and deployment.
- Full disclosure and statements of conflicts of interest of all ACT-A partners at every meeting.
- Periodical, independent evaluations of the ACT-A to identify what lessons can be learned about the external, strategic, and operational factors shaping the elaboration, implementation and impact of ACT-A's various initiatives. A clear commitment to independent evaluation also contributes to ACT-A's good governance, assuring stakeholder accountability.
- Stronger and regular public communication of the work of the ACT-A via an effective communications strategy which is adapted for different stakeholders in different geographies.