Platform for ACT-A Civil Society and Community Representatives: Initial Assessment of Paper 1: Assessment of gaps and needs relevant for a future medical countermeasures (MCM) platform

Do the identified gaps in this document cover the major response needs for a pandemic crisis or crisis of pandemic potential? Which needs should be addressed by global vs regional vs national mechanisms? Existing mechanisms or new ones?

With respect to supporting R&D and tracking the countermeasure pipeline, the starting point should be that the research agenda is grounded in the needs of communities with lived experience of the (new) pandemic. This may be people living with the (new) condition, their loved ones and those bereaved - as well as people who do not recover. Research investments and protocols need to be based on direct understanding of their realities and assessment of how products will be used as well as presumed needs - not purely on public health models focused on prevention. There should be a specific focus on the need to develop countermeasures that are well adapted to use in resource poor settings, e.g., oral or nasal spray administration, heat-stable, and at the community level, e.g. self-tests and multiplex testing platforms. There should be an emphasis on countermeasures that are affordable and easy to administer/use, safe and effective, and targeted to the specificities of the new pandemic (which may be sexually transmitted, blood borne, respiratory, or otherwise). In addition, R&D for neglected diseases should be constant and draw on public funding to develop countermeasures regardless of profitability.

There is virtually no discussion of clinical trials in the paper. It is crucial that such a platform draws on lessons learned from the novel trial protocols developed in the early days of the AIDS epidemic which led to high quality results and early release of effective products which reduced mortality and improved quality of life dramatically. Novel clinical trial protocols must: be ethical and employ good participatory practice; be well-powered to produce clinical guidance; involve comparison between competing products (or “standard of care”) for safety, efficacy, acceptability and ease of use, especially in resource poor settings; should support identification of therapeutic regimens; and involve post approval/after-studies (with investments from companies profiting from the products) to detect longer-term safety and efficacy. In addition, clinical trials should be inclusive of populations (with protocols and recruitment modified as needed) to include girls, women, and pregnant people, elders, children and adolescents, people with common comorbid conditions, people with diverse abilities, people from diverse racial and ethnic communities. Clinical trials should include studies in diverse regions and settings and build sustainable platforms for future clinical trials alongside quality care. All clinical trial results should be transparently reported and should engage in an ethical way with trial participants including sharing information with participants at the same time as public release. Communities of people most affected by the pandemic should be supported to develop treatment and trial literacy, with proactive efforts and funding provided by the global health system and companies to ensure high quality education and support for meaningful engagement. WHO, CDC Africa and other normative regional and global bodies have a responsibility to support community

education and to cascade reliable and accurate information and guidelines rapidly for health care providers as well as the communities they serve.

In addition, it is absolutely essential that intellectual property barriers be addressed and that there are strong incentives for technology transfer to developing country producers. The countermeasures platform should explicitly support the adoption of IP waivers at the international, regional, and national level and full adoption, use, and protection of TRIPS flexibilities, including compulsory and government use licenses. Voluntary licenses may have a role to play and companies should be encouraged to pool knowledge for open science and open source research. Companies should also be encouraged and incentivized to enter into voluntary licenses/tech transfer agreements with the Medicines Patent Pool and the COVID-19 Technology Access Pool or its successor. Companies should also share knowledge, intellectual property, know-how, and data with entities like the mRNA Vaccine Technology Transfer Hub. Public and charitable R&D funding agreements should come with conditionalities on licensing/tech transfer, affordable pricing, and equitable distribution.

The Paper does not address the transparency challenges that negatively impacted COVID response and the work of ACT-A. For example, there was little publicly available forecasting of biopharmaceutical manufacturing capacity or of the strengthening necessary for facilities with near capacity to be able to manufacture countermeasures. Much worse, ACT-A and even States succumbed to industry demands that discussions/negotiation be subject to non-disclosure agreements and that price points for countermeasures, advance purchase commitments and options, and actual purchases and distribution not be publicly disclosed. In the case of an emergency situation, such as the public procurement of vaccines for a future pathogen, the public ought to be informed how large sums of public money are spent in terms of the per dose prices of each vaccine. This will provide complete transparency to taxpayers and will also help ensure fairness in negotiations between companies, a Countermeasures Platform and other countries (e.g. low- and middle-income countries to prevent them being overcharged). This information is needed for public accountability but also for mounting an equitable response. Any new platform should adopt a general principle of transparency in negotiations and agreements, including price, quantity, and delivery terms. In addition, the Platform should also seek disclosure of public and charitable R&D funding to companies, private investments in R&D, costs of production, and production schedules. Voluntary licenses and contract manufacturing agreements should also be transparent. The growing consensus that all clinical results and data be disclosed must be operationalized with respect to pandemic/infectious disease countermeasures. By securing greater transparency on public R&D funding for countermeasures, purchasers would be better equipped in negotiations with manufacturers for countermeasures that involved substantial public funding for development and production, to ensure more affordable prices and provisions enabling for the transfer of technology to other manufacturers, particularly those in the global south. To avoid corporate capture of decision making on access to countermeasures, future preliminary negotiations held between purchasers and pharmaceutical companies before contracts are signed should be conducted in a fully open and transparent manner and using established processes rather than informal channels. In

addition, there should be transparency of patent landscapes and regulatory filings and status for all countermeasure medical products.

The existing processes for developing countermeasure use cases and guidance are too slow and laborious in terms of both WHO use-case and guideline development and country adoption of guidance. It is not acceptable that guidance was developed allowing diagnostics and therapeutics many months faster in HICs than in LMICs throughout the COVID-19 pandemic.

Similarly, although the Paper does mention the need to harmonize and accelerate emergency use authorizations and regulatory approvals, the Platform will need to specifically focus on strengthening, capacitating, and accelerating WHO prequalification and the WHO collaborative registration process. However, better global, regional, and national mechanisms for accelerating emergency use authorizations/listings and regulatory approvals will be insufficient if biopharmaceutical companies do not recognize and implement a duty to register the countermeasures as quickly and broadly in LMICs as they do in HICs. To continue to leave even the possibility of national access to the motivations of commercial entities is intolerable. The failure to recognize the synergies between testing and treatment and to quickly promote and implement test-and-treat strategies must be redressed with urgency in the proposed Platform. Testing needs to be understood as a gateway to quality care, services and treatment, not merely as “screening”. Informed consent to non-coercive testing, and clarity about the impact of diagnosis, needs to be built into these models.

There needs to be much greater attention to demand creation, countermeasure/health literacy, and community based service delivery. In addition, there needs to be greater support for community-based and self-testing which relies on community mobilization, community-based education and awareness building.

The focus of the Platform cannot just be on the acute phase of a pandemic and on those populations that are most vulnerable especially in the initial stages of an outbreak. Priority should certainly be given to protecting and treating health care workers and other key workers, including community health workers and educators, who are likely to be extremely vulnerable (due to multiple exposures) and where, in most contexts, there will be additional gendered vulnerabilities, since women often occupy the front line roles which place people at greatest risk, and frequently have the least power to demand and access quality protective equipment.

As well as paying attention to those individuals and communities most vulnerable to acquiring the new condition, and at highest risk of disease progression, morbidity, and mortality, controlling a pandemic requires implementation of effective, human rights-based public health measures to reach all people vulnerable to the pandemic and equitable distribution of quality and reliable medical countermeasures to all.

Attention to the potential long term impact on those who experience early exposure and illness is important, and requires investment in well designed longitudinal trials in order to document and understand natural history and disease progression. In the case of COVID-19, despite early

alerts and concerns being raised, insufficient attention has been paid to gathering data on the long term impact of the condition, and conducting the necessary research not only on the scale and severity of illness and the range of long-lasting health effects (such as Long COVID/Post Acute COVID Syndrome) and putting in place the treatments, rehabilitation and service required after acute infection.

From the beginning of the pandemic response, the Platform must pay attention to the need to monitor and assess these risks, to gather data and deliver the treatment and support needed by people who experience long term effects.

What principles should guide an MCM Platform?

Human Rights. Preparation for and response to future pandemics must be grounded in human rights principles, including the human rights to health, to bodily integrity, to countermeasures, and to the benefits of scientific progress and its applications.

Shared Global Risks & Equity. Additionally, the governance of such platforms should be underpinned by a common principle of shared global risks of pandemic threats and the imperative of shared responsibility to manage them. The structures to coordinate global MCM platforms should have predetermined convening stipulations with clear, equitable criteria (population/demographic defined) of inclusion. Medical countermeasures should be developed to the extent possible before the pandemic strikes and rational stockpiles of PPE and other countermeasures should be maintained even in the interpandemic phase. Intellectual property barriers must be avoided or overcome and technology transfer must quickly occur to allow maximum production of needed countermeasures. Those countermeasures must be affordably priced, and the distribution/allocation system must achieve equitable distribution to all in need everywhere. The suggestion that there should be special provision for health care workers and conflict areas and areas of humanitarian concern in regards to access to countermeasures is certainly true, but there is no excuse that equity should not include all.

LMIC Expertise. The ACT-Accelerator insufficiently incorporated LMIC expertise, which resulted in the distortion of priorities and poorly-contextualised responses. One idea is that an LMIC Council, consisting of experts with LMIC passports, including people with direct lived experience of the new pandemic, as well as community mobilisation experts, laboratory specialists, infectious diseases epidemiologists, supply chain and logistics specialists, exist as part of a structure through which decision points should be channeled.

Civil society and communities as decision-makers. Civil society and communities need to be meaningfully and formally engaged in the decision making and oversight structures of any medical countermeasures platform. This includes reserved seats in any governance structure with equal decision-making and involvement from the beginning as co-creators of any new platform. This also means genuine power sharing using models of resourcing those communities most affected by the new pandemic that do not yet have the resources and

infrastructure to organize and share information and participate correctly. The innovative power sharing governance models of existing global health bodies (e.g. the Global Fund) provide a model for building capacity and facilitating meaningful engagement in governance structures.

Gender-Inclusive. It is important that the MCM platform ensures a gender-inclusive (and intersectional) approach to all Platform activities at the outset. This should build on the development of useful tools such as the vaccine deployment gender checklist, which recommends, inter alia: gender-disaggregated and age-disaggregated data on pre- and post-market trials of vaccines, treatments and other medical product;. an essential requirement for expedited regulatory approval, remuneration of the work and time of women healthcare workers and volunteers; and differentiated vaccine delivery strategies to effectively reach women, men, and transgender and gender-diverse people,

What are the incentives for different countries to be part of a regional and/or global MCM platform? What are the incentives for global health agencies, regional organizations, industry and others to join or collaborate with such a platform?

Infectious disease pandemics provide their own internal justification for participation and pragmatic solidarity. Pandemic spread and pathogens mutate. Failure to control a pandemic through nationalistic responses, export controls, stockpiling, etc., exacerbate and extend pandemics and provide a continuing breeding ground for more infectious and more virulent mutations. It is simply not in the best interest of any country to act on me first/me only assumptions.

All global and regional organisations have a strong incentive and obligation to collaborate through such a MCM platform to ensure greater co-ordination and identify efficiencies. Any new MCM Platform must actively bring in all relevant global and regional bodies who can or are playing a key role in preparing for or addressing a pandemic. To support full and effective engagement of all participating organisations, it will be critical that there is a strong strategic distribution of funding to each organisation based on a collectively agreed spread of resourcing needs.

It is unclear whether civil society and communities are covered under the ‘others’ category in the second question. It is notable that this is a major stakeholder group that is not specifically mentioned in these two questions. Including civil society and communities most affected by pandemics is critical to ensure that a new MCM platform has a strong focus on equity and reaching the most affected and marginalised. The involvement of civil society and communities however cannot be taken for granted - incentives to civil society and communities involvement include: representation at all levels of decision-making; timely sharing of documentation to ensure opportunity for consultation; and funding provision to facilitate representative participation and co-ordination of any civil society support body;.

How can we, more meaningfully, include relevant informed and legitimate participation by a wider range of critical stakeholders? How should regional bodies be included?

Any new mechanism should be guided by the principle of co-creation and co-ownership with equitable resource sharing among participants. It remains true that parties and people are more likely to act in unison to achieve common goals if they have been involved from the start in creating structures and governance mechanisms, articulating/deciding goals, strategies, and priorities, and implementing relevant responses. There is a difference between being on a football/soccer team, being a fan in the stands, listening to a game on the radio, or reading about a result in a paper. Many stakeholders in the ACT-Accelerator were relegated to the 'reading the paper' role with all the disinterest and disillusion attendant thereto. Those who were most directly affected (including communities living with Long COVID), couldn't even buy the paper as they had no resources.

In the case of civil society and communities, there are several steps to help ensure relevant, informed, legitimate and (we would add) meaningful participation. The following steps are being developed by civil society and communities into a set of principles for meaningful participation and are regularly discussed with ACT-A Lead agencies:

1. Governance structures must ensure equal representation of all those engaged in achieving the goals of the institution – recognising a mix of factors such as financial and programmatic contributions, programmatic and policy expertise, level of affectedness by the issue.
2. Civil society and communities must be meaningfully involved and enabled to effectively represent their constituencies in the development and governance at every level of the governing body with a permanent role and equal voting.
3. The identification of and work of the representatives should be supported by a funded civil society support mechanism.
4. The central co-ordination hub and/or lead agencies should provide adequate resourcing to facilitate the participation of civil society and community representation and for a civil society and community body to effectively convene the representatives and to facilitate the updating of and input of broader community and civil society voices.
5. All recognized stakeholder groups should be able to choose their own representatives for any public governing body. For civil society and communities this means that the selection process for representatives must be designed and led by civil society and communities themselves.
6. Civil society and community representation in the governing body should reflect their expertise, experience and diversity. Each civil society or community representative should also seek to understand and represent the perspectives and priorities of the group they have been chosen to represent. However, this is difficult to do consistently without the provision of financial support to representatives and the help of a funded civil society support mechanism.
7. The governance / co-ordination body should develop and publish a detailed map of the decision-making pathways, governance oversight and processes of consultation from priority setting, resource allocation through to procurement and deployment. As relevant, there should also be detailed maps of each component of the Platform including a clear and transparent overview of relevant working groups (and other informal groups), who is

coordinating each workstream and who is invited to participate in these groups. One example is ‘COVAX: The Vaccines Pillar of the Access to COVID-19 Tools (ACT) Accelerator: Structure and Principles’.

8. Ensure civil society and community representatives are invited to participate in each working group and that they are given an equal voice to other members and are listened to. By ensuring civil society and community organisations with technical expertise and local partnerships are fully engaged and supported to facilitate an equitable response to the pandemic in question, the Platform can get ahead of equity gaps (e.g., gender, income, access).
9. Ensure each structure component (or the agency responsible for leading the component) should have a staff member who has named job responsibility for ensuring meaningful involvement of and engagement with civil society and community representatives.
10. Civil society and community representatives should be invited to co-develop strategic priorities with lead agencies. All stakeholders should share exploratory ideas, new initiatives, analytical work, and project plans in advance - preferably at the conceptual stage to identify intended impact and outcomes through Terms of Reference - with enough time for meaningful review, consultation, and response from civil society and community representatives. Civil society and community representatives should be notified well in advance of when they will receive documents for feedback with a clear deadline that allows enough time to consult with broader civil society and communities. Where information is to be embargoed, a clear communication should be provided including reason and for how long.