Platform for ACT-A Civil Society and Community Representatives: Initial Assessment of Paper 2: An end-to-end MCM ecosystem: with Vx, Dx, Tx Pillars

Scope:

Which pathogens should be addressed and which medical products should be covered? Vx, Dx, Tx only or more?

Lead Questions: Should the focus be on pandemics, pandemics & major epidemics or an even broader approach by including all infectious outbreaks with a potential to spread? Should the MCM system also cover non-pharmaceutical interventions like PPE, oxygen, and other products that also help to save lives during pandemic responses?

We think that a narrow focus on pre-defined pandemics only would be based on an assumption that it is easy to predict in advance which pathogens are more likely to be most infectious and most lethal or debilitating. Although common sense suggests that respiratory pathogens in general are more likely to be highly infectious, anticipated virulence is less predictable. In addition, many pathogens reach epidemic status, but not pandemic, and those responses would benefit greatly from developing, manufacturing, and stockpiling countermeasures for these diseases. Accordingly, we support a broader focus on infectious outbreaks with significant potential to spread.

Although it may make sense to focus stockpiling decisions on the type of countermeasure involved, including utility across multiple diseases, we think that the countermeasures included should be broad.

Who should be the primary beneficiaries?

Lead Question: Should this platform target all countries from HIC to LIC including self-financing and financially supported countries or should it be for LMICs only? The COVID-19 pandemic has shown that countries ill prepared to deal with infectious diseases, regardless of their economic standing, were hardest hit. Potential middle ground would be a focus on LMICs, but leaving the door open to all countries, based on relative needs, own capacities and impact. Another approach would be to differentiate between upstream interventions (e.g. R&D) which are relevant to all countries and downstream procurement and delivery support that could focus on LICs and LMICs.

We think the focus should be on the middle-ground, but with funding/financing principally focused on delivery of equitable access to countermeasures to LMICs. However, we also agree with the differentiation between supports for upstream interventions (R&D, innovation), but reiterate our earlier recommendation on Paper 1 that there be special attention to the development of countermeasures well adapted for use in resource-poor settings and at the community level.

Knowledge sharing and cooperation between countries of all income status should be encouraged to ensure that there is a global effort based on solidarity and sharing resources - with the actual delivery of products focused on LMICs

How much of the value chain should be covered?
Lead Questions: Should the MCM mechanism itself cover the full circle of R&D, procurement, logistics and administration or even complementary preparedness elements in "peacetimes"? Financial aspects are especially relevant here but not covered by this paper. What need for coordination across different global health efforts at the outset to avoid duplication and fragmentation?

The full "ecosystem" approach would be optimal were there to be sufficient resources, appropriate and inclusive governance, and an efficient operating model, but each of these requirements are uncertain at this time. Therefore, it would be prudent to further develop the "support the ecosystem" approach, with special attention to governance and an effective operating model, and to simultaneously plan for the Platform's expansion and transformation as sufficient and sustainable resources are secured.

More particularly, it is unclear that the Platform will attract sufficient resources to effectively cover the entire value chain. As a prime example, at-risk funding for R&D might be inadequate. Several different pandemic R&D initiatives are already being established and industry will be funding R&D according to its own priorities as well. We do think that public funding of pandemic related R&D on countermeasures is crucial. The COVID crisis illustrated two important arms of R&D funding: a) public funding must be long-term and continuous to lead to significant breakthroughs (for example, the mRNA technology used in COVID-19 vaccines was developed over twenty years) and b) a surge of public funding is necessary for the rapid development and production of products in a novel emergency situation.

COVID-19 also illuminated key gaps in the chain, including insufficient data gathering of long term as well as acute stages of the new disease, and too few, and weakly powered, long term longitudinal studies to build understanding of the long term course of the pandemic as well as innovative approaches to tackle it.

In peacetime, there needs to be direct support for establishment of countermeasure R&D and manufacturing capacity in LMIC regions, with attention to building the necessary infrastructure, human as well as physical, to scale up local production of essential products. To support this, public R&D funders should explore the model of 'delinkage' which is based on the premise that the costs and risks associated with R&D should still be rewarded, but that the incentives for R&D can be provided by means other than financial returns from charging high product prices. As R&D financing no longer relies upon monopoly-protected high prices, directionality can be set more easily according to the public health needs identified by the funding agency and there would be greater control on pricing & guaranteeing tech transfer. The delinkage model could be

incorporated into mission-oriented R&D approaches and support the delivery of current PPR initiatives like the 100 Day Mission.

Likewise, systems for allocation and procurement should be set up in advance to the degree possible. There needs to be strong global, regional, and national support for health and community system strengthening and integrated service delivery that can be further expanded and deployed when pandemics strike. This can be achieved by empowering and strengthening community and civil society to work with the state Ministry of Health or national/regional agencies, so there will be reciprocal relationships among them, including social contracting. The Ministry of Health would benefit from a less bureaucratic procedure with a feasible monitoring mechanism, and the community and civil society will be enabled to hold institutions accountable, including through well resourced community-led monitoring systems.

Options to improve equity for core functions in an MCM mechanism
Lead Questions: Which activities could significantly improve rapid and equitable access without requiring fundamental changes in areas outside the mandate of global health agencies? Which of these should be dealt with by the MCM mechanism itself? Should some or all of those issues be dealt with outside the specific mechanism, for example strengthening MCM ecosystem including through national commitments, regional approaches, and potential new WHO or other multilateral commitments? Relationship with the Pandemic Accord?

Given the existing mechanisms for R&D, production, and allocation, there would be a shortage of supply for some time after the beginning of any pandemic. Therefore the aim of any mechanism to ensure access to MCM is to maximize global production capacities by increasing such capacities in the South. This would require:

Before a pandemic:
1. An increase in funding for R&D by all countries
2. Prioritizing collaborative research
3. Global investment in regional manufacturing hubs - at all stages (inc accreditation etc)

At the early stage of a pandemic:
1. Sharing technology and knowledge with accredited Southern producers/developers
2. Issuing licenses for production and temporary waivers of intellectual property provisions
3. Surge funding for emergency development and manufacturing for Southern producers

Structure:
Scale/ Level of ambition
Lead Questions: Are we aiming at creating a full ecosystem? Or are we looking at establishing a platform/mechanism harnessing the already existing wider ecosystem, filling specific gaps with rather modest functions in „peacetimes„ to be scaled up at the outset of a pandemic? When is it

simply upstream capacity-building and when is it response? Should it be an on/off mechanism starting anew with every new crisis or a permanent structure?

Of the options listed, again it would be preferable if there were a standing, full-fledged entity, dependent on governance, resources, and operational model pre-conditions. We certainly need something that is active in "peacetime" for purposes of prevention and preparation, including but not limited to countermeasure R&D (including licensing and tech transfer re: promising countermeasures), building globally distributed clinical trial capacity, surveillance, regulatory strengthening, building community health and scientific trial literacy, stockpiling commonly needed countermeasure products (e.g., PPE), building regionally distributed manufacturing capacity, strengthening health and community systems and health workforce, and creating effective allocation/procurement/equitable distribution systems. These are all activities that will not be delivered under existing status quo procedures and cannot be created from scratch once a pandemic hits. However, some aspects are necessarily only possible when the pandemic develops - notably investing in communities directly affected by the new condition to ensure that they are able to mobilize for peer support and to generate insight and advocacy so that responses are grounded in lived experience - and these need to happen swiftly. We also need a nimble platform that can switch on to more intensive activities when pandemic/infectious disease threats are identified. At this point, efforts to overcome IP and technology transfer barriers, to scale up manufacturing, to fund countermeasures procurement and health service delivery at the community level, and to ensure equitable distribution between and within countries is essential.

How could the internal structure of a MCM platform or multiple platforms look like?
Lead Questions: What level of central governance and coordination should be put in place? Can decisions be delegated to pillars and individual agencies?

- *"Pillar model of ACT-A": decentralized system, multiple entities involved (depending on the scope/functions of the platform) work independently in their respective pillars, possibly each with a lead entity.*
- *"Centralized Model": One central coordinating entity responsible for all functions, e.g. the procurement and distribution, also directing financing and allocation processes for all countermeasures (top down).*
- *"Coordination model (ACT-A +)": Pillars work independently in their sector, but coordinated by a central technical body that keeps track of financing, allocation processes, coordinates regional platforms/components and supports streamlining political processes, also ensuring that actions undertaken by each pillar are complementary.*

We doubt that a centralized model can or would be selected by governments or that such a model would be totally consistent with fulfillment and protection of human rights or effective in delivering equitable access. The WHO should play a key role in issuing normative guidance, but States and regional institutions will need to play their parts as well. We do think that some aspects of a centralized model should be deployed so that funding to particular activities is not at the sole discretion of donors. In the COVID-19 response, we saw generally adequate (if

delayed) funding to the Vaccine Pillar of ACT-A, but totally inadequate funding of the Therapeutics, Diagnostics, and Health Systems Connector Pillars. Clearly the ACT-A centralized process did not work for Africa, and shifting more power to regional bodies would allow for more flexibility to negotiate with corporations and use of pooled procurement.

Even the Coordination Model (ACT-A + in Paper 2) is inadequate to the task because the ACT-A Pillar system allowed too much siloing. This was particularly true with the delayed recognition of the synergies between the Diagnostics and Therapeutics Pillars and the delay to exploring and implementing test-and-treat strategies, and the lack of strategic overview across the pillars that meant that some important aspects of the response were entirely missed. There was also total confusion about the remit of the Health Systems Connector and its interface with country planning, implementation, and scale-up (except with initial support for PPE). But there is also a need to identify other “cross-cutting elements” of the Platform in the ACT-A model. Issues involving better targeted R&D, rationalizing global clinical trials, addressing IP and tech transfer barriers, accelerating technical guidance, capacitating and speeding regulatory processes (including WHO prequalification and collaborative registration processes), and coordinating procurement and equitable distribution all require cross-Pillar attention as well as attention within Pillars.

One, two, many Platform(s)?

Lead Questions: Should there be one or several platforms? If more than one, e.g. at regional level, should they be coordinated and if yes, how? Separate platforms for every MCM or groups (Vx/Tx/Dx; PPE; Oxygen; etc.)? How could bilateral assistance be incorporated in a new platform?

Multiple platforms would risk fragmentation and competition instead of global cooperation and collaboration. However, there are critical roles for regional institutions, such as expanding R&D, clinical trials, and manufacturing capacity, addressing IP, tech transfer barriers, and regulatory issues, and particularly in navigating procurement and distribution. Some regional mechanisms, such as PAHO, have a long history of successful procurement of medical products, securing sustained supply and affordable prices. Regional institutions are growing and strengthening, especially in the aftermath of a largely failed global response to COVID-19. Some of the RECs (eg SADC) have a long-standing commitment to secure access to high quality affordable, and locally produced, medicines on a regional basis.Thus the task is to enlist the coordinated efforts of regional entities as the next best solution to secure equity in access and to promote decentralized power.

Separate Platforms for separate pandemics or for Pillars is a terrible idea that would increase the fragmentation and lack of a coordinated response we already experienced with siloed pillars in ACT-A. That is not to say that international efforts and institutions focused on particular aspects of the countermeasure value chain should close shop. For many of them (e.g. the Medicines Patent Pool, Unitaid, a proposed Diagnostics consortium, Global Fund, UNAIDS,

etc.), their remit is broader than pandemic-related countermeasures. Moreover, their experience, expertise, and existing partnerships should be leveraged, not dismantled.

Any mechanism or system to address MCM must ensure that all governments consider access as a global public good that benefits their own population as well and not as an act of charity.

MCM in the Global Health Architecture, Role of WHO, other stakeholders
Lead Questions: Are we looking at a "Standalone" independent mechanism/ separate entity or rather at a fully integrated department at WHO or something "in the middle"? What role for (multilateral health) stakeholders like UNICEF, GFATM, Gavi, CEPI, FIND, UNITAID or philanthropies? What do the different actors do/not do? How to ensure it builds on the strengths of different actors (MS, individual institutions/delivery partners, private sector, WHO)? How to reflect the reality of a non-centralized global health architecture?

Several of these issues are addressed in our answer to the preceding question.

In addition to its technical role, WHO has important roles and must be strengthened in terms of advocating for: (1) better targeted R&D, focusing on products well adapted for resource poor settings and community-based use; (2) more effective, inclusive and distributed clinical trials; (3) accelerated use-case and clinical guidance; (4) accelerated prequalification and collaborative registration and capacitating/strengthening national regulatory approval; and (5) quicker allocation policies.

We think that the role of industry has to be much more limited in the framework and working of any mechanism of ensuring access to MCM. The biopharmaceutical industry benefited hugely in the pandemic with respect to public financing of R&D, clinical trials, and even expanded manufacturing capacity that greatly reduced the risks of its own investments. Industry guarded its monopoly and intellectual property closely, refused to cooperate voluntarily with the WHO COVID-19 Technology Access Pool (and with the Medicines Patent Pool with respect to vaccines) and further refused to transfer its technology to independent producers, preferring instead to expand its own capacity and engage selected contract manufacturing partners. The result, for both vaccines and therapeutics, was artificially constrained supply, needlessly high prices, and grossly inequitable distribution that prioritized countermeasure supplies to HICs. Thereafter, industry largely demanded non-disclosure of price and supply agreements and unreasonable indemnification provisions that further delayed vaccine rollout. Even with respect to its activities within the ACT-Accelerator, companies insisted on confidentiality and non-transparency. Finally, as a result of their trenchant defense of IP and non-sharing of information and technological know-how, the biopharmaceutical company reaped tens of billions of dollars in profits off hundreds of billions of dollars of sales.

The industry's priority in response to future pandemics is to continue to maintain their monopoly via intellectual property exclusivities again. Therefore, they have an unavoidable conflict of interest against helping to structure a more effective and equitable response to future pandemics. The biopharmaceuticals (innovator and generic) should certainly be consulted by

the MCM mechanism but they should have no formal role in the structure or governance of MCM mechanisms.