

GHTC Medical Countermeasures Platform Priorities

Recommendations for a potential MCMs platform

Introduction

During the COVID-19 pandemic, decades of past research and development (R&D) advancements and new partnership models enabled the development of health products at record speed, yet the promise of equitable access was never realized.

Instead of global solidarity, there was slow and fragmented action, tepid leadership, geopolitical infighting, and limited community inclusion. The pandemic highlighted how the current system for the development, production, allocation, and distribution of medical countermeasures (MCMs) benefits high-income countries and leaves low- and middle-income countries (LMICs) behind. It also exposed fundamental gaps in regional technological capacity to produce and deploy innovations. Rather than a focus on equity at all stages of product development, access was left to the procurement and distribution phases. This approach resulted in products that were not suitable or tested for all settings and an unsustainable race and unpredictable funding to purchase MCMs.

As new proposals circulate for a pandemic MCMs platform as part of World Health Organization (WHO) consultations and the India G20 presidency, here are key considerations that must be included in any future framework to ensure success.

Equity

Centering Human rights and equity

There is both a need and opportunity for a new MCMs platform to break from past models and reimagine how equity can be delivered. It is imperative to learn lessons from the Access to COVID-19 Tools Accelerator (ACT-A), which regrettably excluded LMICs and civil society stakeholders in the conceptualization phase under the guise of urgency.

A future platform must from the outset be guided by the needs and priorities of all people, especially those living in LMICs. Leaders must put human rights and equity at the heart of the design and ensure a broad set of stakeholders are not just engaged in informing the process but at all levels of decision-making.

Of particular importance is establishing the right of everyone to enjoy the benefits of scientific progress and its applications (i.e., the right to science as established by the Universal Declaration of Human Rights Article 27 and International Covenant on Economic, Social and Cultural Rights Article 15), which enshrines community engagement and access to new health technologies. Governments have an obligation to make available "all the best available applications of scientific progress



necessary to enjoy the highest attainable standard of heath." In addition, the right to science establishes a duty of international cooperation to address "deep international disparities among countries in science and technology," including in pandemic contexts.

Maximizing health outcomes for all

Any new platform must ensure that new technologies are designed and/or adapted to suit the needs of those living in low-resource settings and the most vulnerable. To achieve this, stakeholders who use these tools should be engaged early in the R&D process and all populations should be represented in clinical trials, including children, pregnant people, people living with HIV, and other vulnerable populations. This patient- and human-centered approach must be explicitly integrated as a guiding principle in any future platform, with the goal to maximize health outcomes for all by prioritizing those who are most vulnerable.

Global leadership also has a responsibility to ensure that once technologies are developed, they reach all countries equitably within a defined, short time span. Allocation of MCMs in acute phases of an outbreak should be based on need, and preset procurement agreements should be put in place to prevent a repeat situation where LMICs are left without the ability to procure crucial health tools.

Governance

Putting LMICs in the driver seat

At the outset of the pandemic, the global response was top-down and donor-driven, with key decisions on financing, development, procurement, and distribution of MCMs ultimately being made by a small set of high-income country stakeholders with LMIC representation largely absent.

A future platform must redefine this power dynamic, operate on the principles of inclusivity, and be convened and designed from the outset together with LMIC regional bodies and governments. It should also concretize governance principles that guarantee meaningful representation of LMICs with clear, equitable criteria (population/demographic-defined) of inclusion at all decision-making levels and at the earliest stages, with an eye to maximizing participation.

Recognize role of regional bodies and local institutions

Any new platform must have pre-agreed coordination mechanisms outlining the specific roles and responsibilities of governments, international organizations, and civil society, as well as clearly delineating the scope of WHO's involvement. This will ensure that each engaged institution operates within its mandate and strengths.

Leaders must also recognize the importance of regional bodies and institutions and look to them to inform allocation and disease priorities and drive implementation.

End-to-End Approach

Working across the ecosystem

The platform must adopt an end-to-end approach, from basic research through manufacturing, regulatory approval, and delivery. It must work in lockstep with regulators and procurers to ensure equitable access to critical supplies and innovations during a crisis. The platform should also facilitate collaborative product registration to eliminate duplication of efforts and ensure rapid rollout and broad trust.



Ensure sustainability and financing

To avoid the fiscal constraints faced by ACT-A, the platform must be sustainably financed both to maintain operations during inter-pandemic periods and to flex up during outbreaks. In inter-pandemic times, the platform should seek to advance a library of countermeasure candidates for pathogens of pandemic potential, adopting a portfolio approach to ensure a varied pipeline that can be rapidly iterated and improved upon as pandemic arise and threats evolve. Nations must also sustainably fund the research institutions that support the platform by investing in R&D for unmet needs for existing pandemics such as tuberculosis, HIV/AIDS, and malaria.

There should also be clear mechanisms in place to provide surge financing during outbreaks to incentive at-risk R&D and manufacturing and support scale-up. To end the overreliance on funding from high-income countries or private capital, leaders must advance sustainable funding plans, such as leveraging the Global Public Investment model.

Regional & Local Capacity

Strengthening local capacity

During the pandemic, the acute concentration of R&D and manufacturing capacity in just a few countries restricted the supply and timely delivery of essential medical products, particularly to LMICs.

Any new mechanism must support the establishment of regional and sub-regional R&D hubs, bolstering existing R&D capacities and research institutions. Leaders should expand distributed manufacturing capacity across regions, especially in LMICs, with the right to adapt technologies and use them for other purposes. Finally, the platform should

strengthen clinical trial infrastructure and ensure that Good Participatory Practice principles are employed.

Knowledge and know-how sharing

The platform should work with a variety of relevant stakeholders, such as the Medicines Patent Pool, to accelerate licensing and technology transfer. Regional and sub-regional R&D and manufacturing hubs must work as a network underpinned by the principles of collective intelligence and knowledge and technology sharing. They must be able to work with new technologies, share knowledge and knowhow, and adapt technologies to emerging local health threats.

Accountability

Prior mechanisms stood up during the COVID-19 pandemic lacked robust monitoring, evaluation, and accountability structures, and it proved challenging for stakeholders to understand the progress of tools from production to patients.

Any new platform must correct for that to ensure the financing, manufacturing, supply, and delivery of MCMs can be accurately tracked. It should also establish clear and transparent performance indicators, evaluation metrics, and reporting mechanisms. This will promote accountability and provide key national decisionmakers and stakeholders a line of sight on what's coming through the R&D and delivery pipeline, enabling better prioritization, health system responsiveness, and needs-based approaches.