

**Drugs for Neglected Diseases *initiative* (DNDi) submission to GPMB call for civil society input on solidarity, equity and the global response to COVID-19**  
**27 August 2021**

**About DNDi**

The Drugs for Neglected Diseases initiative (DNDi) is a not-for-profit R&D organization that discovers, develops, and delivers new treatments for neglected patients. Since our creation in 2003 by Médecins Sans Frontières (MSF) and public research institutions in Brazil, France, India, Kenya, and Malaysia, we have developed nine new and improved treatments for six deadly diseases that have reached millions of people utilizing an alternative, collaborative, not-for-profit R&D model.

In response to the COVID-19 pandemic, DNDi has:

1. Co-founded and currently hosts the COVID-19 Clinical Research Coalition, a coalition of nearly 300 individuals and more than 200 institutions from over 85 countries, primarily from LMICs, to prioritize, facilitate, and accelerate research for COVID-19 in LMICs;
2. Launched ANTICOV,<sup>3</sup> a multi-country, adaptive platform trial conducted in 13 African countries with 26 African and global partners to identify treatments for mild-to-moderate COVID-19 outpatients to prevent the need for hospitalization;
3. Joined a spontaneous, global, open drug discovery collaboration called the COVID Moonshot,<sup>4</sup> participated in Work Stream 1 of the ACT-A Therapeutics Partnership to review the best therapeutic candidates to take forward for clinical testing, and collaborated with various research consortia working to identify novel, early-stage discovery projects to contribute to building the pipeline for new treatments for COVID-19, other coronaviruses, and other pathogens of pandemic potential, including projects originating directly from the Pandemic Response Box, released in 2018 by the Medicines for Malaria Venture (MMV) and DNDi expressly for this purpose; and
4. Advocated for R&D to be driven by the public interest and for COVID-19 health tools to be developed and delivered as global public goods, with equitable access for all. DNDi was established to address a chronic challenge when it comes to meeting the R&D needs of neglected populations.

Many of the challenges that have been identified in relation to the R&D system and access to vaccines, diagnostics, and therapeutics for COVID-19 are acute examples of the chronic failures DNDi and our partners have faced, and worked to overcome, for neglected populations over the past two decades.

DNDi's submission to this consultation is based on its recent policy report - *Another triumph for science, but defeat for access?* which can be accessed here: [COVID-19 Policy Report \(dndi.org\)](https://dndi.org/COVID-19-Policy-Report)

**1. *Solidarity and the global COVID-19 response***

In many ways, the collective response to COVID-19 has been defined by failed leadership, nationalism, inequalities and obstacles to cooperation and global solidarity.

- a) How have these issues impacted low- and middle-income countries' response to the pandemic?
- b) How have the global community and the international system dealt with these issues? What have been successful elements of the global response? What have been the biggest failures?

- COVID-19 has given rise to never-before-seen levels of collaboration and rapid advances in biomedical science that have delivered life-saving technologies, particularly vaccines and diagnostics to fight COVID-19 – at breakneck speed in a way that may be transformative for other diseases.
- It has also exposed the health consequences of racial and economic disparities within and between countries. Despite the creation of COVAX, only a fraction of the more than 3.6 billion vaccines doses given globally have been in low-income countries.
- Despite the massive amounts of public funding that went into the discovery and development of vaccines, funders have failed to use their leverage to ensure contractual conditions that would facilitate the sharing of technology, data, and know-how – in order to enable greater global production capacity. Pharmaceutical companies have largely refused to non-exclusively license and share IP and know-how. Too little has been done to promote the expansion and decentralization of vaccine manufacturing capacity in Africa, Asia, and Latin America to help meet regional and global needs.
- One central lesson from the past year, it is that there is urgent ‘unfinished business’ in global health when it comes to equitable access to health tools and technologies. At almost every step when there was an opportunity to do things differently, political and commercial choices were made that further entrenched the status quo. We must learn from this lesson and course correct both for covid and for future pandemics.

#### **ACT-A**

- The main body set up to accelerate the development and delivery of COVID-19 treatments, the Therapeutics Partnership of ACT-A, has fallen short in critical ways.
- Like the vaccines and diagnostics pillars of ACT-A, the Therapeutics Partnership was an important emergency response to the pandemic. But ACT-A’s ambitions have been too modest across all three pillars. These limited ambitions have been justified by claims that ACT-A was never meant to provide a long-term solution but rather to support countries during the acute phase of the crisis, with the assumption that after this period, ‘normal market activity’ would meet the needs in LMICs.
- ACT-A is also plagued by funding shortfalls – to the tune of USD 16.8 billion across all three pillars as of June 2021. The structure that was set up relied too heavily on an outdated international aid model driven by governments and global health actors in HICs rather than a truly global approach.
- The governing bodies of ACT-A lack equal representation for policymakers, experts, and civil society from LMICs – with a resulting lack of prioritization and financing for research driven by and in LMICs. Across all its pillars, ACT-A and its participating institutions must make immediate changes to governance structures to ensure equal representation from the public sector, scientific and public health experts, and civil society from LMICs in priority-setting and decision-making.
- In addition, it has opaque priority-setting and decision-making processes driven by a handful of largely private actors – processes, for example, that determine which technologies will be developed further. And to date, ACT-A has been unable or unwilling explicitly to address the underlying structural causes of access inequities that it was ostensibly set up to overcome, such as management of IP, licensing, and technology transfer.
- In its final report, the Independent Panel on Pandemic Preparedness and Response recommended to ‘Transform the current ACT-A into a truly end-to-end platform for vaccines, diagnostics, therapeutics, and essential supplies, shifting from a model where innovation and access is left to

the market to a model aimed at delivering global public goods', including ensuring its governance bodies include representatives of countries across income levels and regions, civil society, and the private sector.

## Therapeutics

- While ensuring vaccine equity will remain the defining challenge of 2021, The development of therapeutics has been relatively neglected in the global response to COVID-19 – and with the few treatment innovations available principally in high-income countries treatments for COVID-19.
- The need for treatments at all stages of COVID-19 is more pronounced than ever given the slow pace of global vaccine roll-out and the spiraling COVID-19 crises across Africa, South Asia and Latin America. It is further compounded by the possible waning of immunity over time, uncertainty around the efficacy of vaccines for immune-compromised individuals, and, critically, the continued impact globally of new variants of concern. Yet the scientific advances for therapeutics have to date been few and far between.
- It is unclear if treatments needed for COVID-19 will come with a guarantee of affordable access, sufficient supply, and equitable allocation globally, and related commitments of adequate sharing of knowledge, data, and technology to address the scale of global needs. Unless specific contractual commitments and an array of rules and enabling policies are proactively established to ensure rapid transfer of technology, large-scale manufacturing, and equitable access, the very same challenges that have stymied equitable access to vaccines will also hinder availability, affordability, and access for future treatments
- As one of the organizations that has taken part in deliberations in the ACT-A Therapeutics Partnership, we have seen the benefits of having a process by which the latest scientific evidence from the pipeline is brought together and reviewed – and the potential to link that with strategies to ensure access. However, we have also seen the limitations of the approach and the consequences of the absence of certain voices around the table. For therapeutics, these limitations have played out in specific ways:
  - There was an insufficient focus initially on developing therapeutics for mild-to-moderate cases in outpatients, even though such treatments would be particularly useful in places with limited intensive care and hospitalization capacity.
  - There was also an over-emphasis on mAbs (arguably, to the exclusion of small molecule antivirals or repurposing candidates), despite some feasibility and price concerns and issues related to manufacturing and procurement. Significant energy within the Therapeutics Partnership was consumed, for example, by the 'agnostic capacity reservation' with Fujifilm, which aimed to ensure some mAbs manufacturing capacity was reserved for use in LMICs, even when it became clear that the anticipated supply would only meet 2-4% of the global needs. This limited any creative discussions about expanding supply through local manufacturing.
  - There were also failures to anticipate and expediently address either the need for oxygen therapy in LMICs – with little priority given to the need for oxygen until late 2020 and early 2021 – or the consequences of treating severe ventilated patients with anti-inflammatory drugs, leading to secondary infections by fungi and bacteria, such as mucormycosis (Black fungus) in India and Nepal and the subsequent need for access to antifungals, such as liposomal amphotericin B, that are unaffordable and in short supply.

## **2. *Systemic inequity in the global health emergency ecosystem***<sup>1</sup>

The COVID-19 pandemic has exposed longstanding systemic inequities in the global health emergency ecosystem and the broader international system.

- a) What are some key structural elements of the ecosystem that contributes to these inequities ?**
- b) What impact do these structural elements have on effective and equitable health emergency preparedness and response?**

- Covid has highlighted the limited commitment of global health funders and actors to prioritizing and financing research in LMICs; the serious power imbalances that determine who has a seat at the priority-setting and decision-making table in global health; and the lack of transparency and globally agreed rules to ensure open sharing of knowledge, data, and technology and equitable access to any new health tools developed.
- Renewed public leadership and international cooperation is required to correct course and move away from a business as usual ‘trickle down’ approach to global health innovation and access.
- Pandemic prevention, preparedness, and response architecture that arises out of COVID-19 will need to be re-oriented to enable the emergence of a more effective end-to-end biomedical innovation ecosystem that ensures the benefits of scientific progress will be equitably shared and considered global public goods, available to all.

## **3. *Addressing these inequities and improving the global health emergency ecosystem***

- a) How should the global health emergency ecosystem be reformed to improve equity?**
- b) What are key measures that should be implemented to ensure future global responses to health emergencies are fairer, more equitable and more effective?**

The governments and other actors that will shape these responses at the national, regional, and international level must take as a given two major points:

- First, market-based approaches alone will not be sufficient to discover, develop, and ensure access to necessary health tools. Traditional market incentives fail to respond to, prioritize, and ensure R&D investments where the need is uncertain, or demand may be low. This is a daily reality for millions of people who are affected by diseases that do not represent a lucrative market for the pharmaceutical industry, whether other pandemic threats, AMR, NTDs, or diseases that predominantly affect children. Even where innovations have been developed, companies engage in a limited ‘contract manufacturing model’ of technology transfer, in which they retain all control over IP, production, supply, and pricing.
- Second, major public and philanthropic funding for research – whether through direct R&D subsidies or pre-purchase commitments – de-risks the R&D enterprise and funders should therefore secure a public return on their public, or public interest-driven, investments. This means requiring clear and transparent terms and conditions that ensure open collaboration, affordability, availability, and

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<sup>1</sup> Here we define the ecosystem as the institutions, leadership and governance structures, mechanisms, frameworks, policies, actors and stakeholders that contribute to global health emergency preparedness and response.

equitable allocation of essential health tools and embracing and financing alternative, needs driven R&D models.

Recommendations:

1. Guarantee sustained political attention to and financing of end-to-end 'purpose-driven' innovation for all diseases and products of public health importance, with clear priority given to those populations and pathogens most likely to be neglected by the market. Such focus and financing must avoid a 'charity driven' or narrowly defined 'security threat' approach and break the 'cycle of panic and neglect' for pandemics in which there is a surge of attention and investment during a crisis followed by years (or decades) of inaction when a threat is perceived to have subsided in certain regions or globally.
2. Re-imagine global health R&D coordination, collaboration, and financing to support a more distributed, decentralized, and democratic approach to the production of knowledge and innovation as global public goods in response to pandemics and other public health priorities. Such an approach would support R&D, manufacturing, and regulatory capacity through regional and national networks and hubs, not only through donor-driven global mechanisms, and would ensure greater parity between public and private actors and between the 'global south' and the 'global north', especially when it comes to R&D priority-setting, decision making, and resource allocation.
3. Ensure there are globally agreed norms and binding rules governing R&D and equitable access to essential health tools to guarantee such tools are made available as global public goods regardless of where they are discovered, developed, or produced. R&D funders have unique leverage that is rarely exercised to enforce and coordinate the application of these rules by requiring clear and transparent terms and conditions in contractual agreements that will guarantee open sharing of research data, knowledge, and technology; sufficient production, supply, and equitable allocation of health tools; and affordability, including through pro-access management of IP rights. With renewed public leadership and new models of international cooperation focused on these goals it will be possible to achieve not only continued innovation to meet ever more pressing needs, but also equitable access to the fruits of scientific progress for all people, no matter their income or where they live.