



Drugs for Neglected Diseases *initiative*

## **Input, Suggestions, and Feedback from the Drugs for Neglected Diseases *initiative* on the Proposed Financial Intermediary Fund for Pandemic Prevention, Preparedness, and Response**

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### Introduction

The Drugs for Neglected Diseases *initiative* ([DNDi](#)) is a not-for-profit research and development (R&D) organisation that discovers, develops, and delivers new treatments for neglected patients. Since its creation in 2003, DNDi has developed nine new and improved treatments for six deadly diseases that have reached millions of people and has dozens of potential new drugs in our pipeline for neglected populations.

In response to the COVID-19 pandemic DNDi:

1. Established the [COVID-19 Clinical Research Coalition](#) which now includes more than 900 scientific organizations and individual members from nearly 90 countries to accelerate research specific to the needs of people and health systems in low- and middle-income countries.
2. Launched [ANTICOV](#), a multi-country, adaptive platform trial conducted in 13 African countries with to identify treatments for mild-to-moderate COVID-19 outpatients, with plans to extend this study in India and Brazil in 2022.
3. Collaborated with various research consortia, and now lead the global, not-for-profit, open science consortium, [COVID Moonshot](#), and its new [Artificial Intelligence-driven Structure-enabled Antiviral Platform](#) (ASAP), to identify novel, early-stage discovery projects to contribute to building the pipeline for new, accessible treatments for Covid-19, other coronaviruses, and other pathogens of pandemic potential.
4. Conducted policy research, analysis, and advocacy, including publishing an [August 2021 Policy Report](#), to increase attention to the need for innovation of and equitable access to therapeutics, in addition to vaccines and other health technologies, for COVID-19 and for future pandemics.

DNDi welcomes the establishment of a proposed Financial Intermediary Fund for Pandemic Prevention, Preparedness and Response (FIF). The FIF could play a critically important role in ensuring that pandemic prevention, preparedness, and response is sustainably financed, leading to improved health security, solidarity, and outcomes at global, regional, and national levels.

The lack of equity in nearly all aspects of the global response to COVID-19 led to a devastating breakdown in the current pandemic response, in particular as relates to incentivizing innovation and ensuring equitable access to essential health tools and technologies.

Although science has delivered remarkable and lifesaving innovations at unprecedented speed, the response to COVID-19 has thrown into sharp relief the limited commitment of global health funders and actors to prioritizing and financing research and service delivery in low- and middle-income countries (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 globally agreed rules to ensure open sharing of knowledge, data, intellectual property, and technology and equitable access to any new health tools developed.

We strongly recommend that the World Bank Group and all other actors involved in the establishment of the FIF take into account both the positive and negative lessons learned from the COVID-19 response while designing the FIF. Our comments are limited to those related to the focus of FIF financing and governance.

## Focus of FIF Financing

Sustainable and predictable financing is essential for a successful FIF and we agree that it must be additive and complementary in relation to other existing and future bilateral and multilateral financing mechanisms in global health; catalytic; flexible and geared toward coordination versus fragmentation; and inclusive.

### **Embedding equity and innovation into development, procurement, and deployment of health tools**

The White Paper currently suggests that the FIF will include a focus on increasing ‘capacity for coordinated development, procurement and deployment of countermeasures and essential medical supplies.’ DNDi strongly supports this focus and recommends that the FIF more explicitly articulates that R&D of new health tools and technologies will be supported, with clear priority given to open, collaborative approaches and areas most likely to be neglected by the market. Sustained, proactive investments in research, development, and delivery of medical countermeasures are critical to responding effectively to the medical needs of the most vulnerable and avoiding the equity failures we have seen in the COVID-19 response.

Any pandemic financing mechanism must address the need for globally agreed rules that will guarantee equitable access to new health tools and technologies. As such, financing should be conditioned upon ensuring that such products are:

- Developed as global public goods according to a clear public health-driven priority research agenda, with requirements for open sharing of research data and knowledge and robust transfer of technology and with preference for tools with the broadest possible spectrum of activity that can be rapidly moved into clinical trials when a pandemic hits;
- Manufactured at sufficient scale across multiple geographies to meet global needs;
- Procured with an explicit pharmaceutical policy in place to ensure intellectual property (IP) or other restrictions on access to data do not constitute a barrier to research, production, or equitable access to affordable, quality-assured generics or biosimilars (this policy should support non-enforcement of existing IP, non-exclusive licensing globally, a formal waiver of IP during a pandemic, and the use of TRIPS flexibilities and other legal mechanisms to ensure access);
- Approved within a regulatory system that is better adapted to today’s needs, including adoption of a World Health Organization (WHO) ‘maturity level’ approach in terms of regulatory approvals and support for collaborative and regional approaches, such as the

African Vaccine Regulatory Forum (AVAREF) and the future African Medicines Agency (AMA), rather than over-relying on 'stringent regulatory authorities,' which can impact timely access to essential health commodities;

- Priced as close as possible to cost of production plus a reasonable and sustainable margin so that they are affordable for health systems and free to those most in need;
- Equitably allocated between both wealthier and poorer countries, and within countries, which will require that allocation frameworks (e.g. those developed by WHO) be agreed upon upfront and ensure that the most vulnerable and those at highest risk are prioritized.

These norms and rules should accelerate the innovation process, safeguard transparency, and ensure the benefits of scientific progress are more equitably shared, regardless of where they are discovered, developed or produced.

If any funding is provided to the private sector, the need for funding conditions is all the more important, as are assurances that funds will be directed to areas most likely to be neglected by the commercial sector, linked to a public health-driven priority research agenda, and developed in partnership with not-for-profit groups that have a solid track record of partnering with the both the public and private sectors and developing and delivering health tools that are affordable and accessible for all.

### **Scope**

In terms of scope, the FIF should avoid a narrowly defined focus only concerned with 'security threats' in 'pandemics' that affect high-income countries. This means the FIF should include existing epidemics, the 'silent pandemic' of antimicrobial resistance (AMR), and other pandemic-prone and climate sensitive diseases, including many neglected tropical diseases (NTDs) and emerging infectious disease threats.

An appropriately broad scope will help ensure a disruption in 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 – leading to innovation and manufacturing capacity being left idle.

The FIF should therefore include mechanisms for funding national, sub-regional and regional surveillance, manufacturing, and clinical trial platforms during 'non-pandemic', inter-crisis times – particularly those based in and led by LMICs – and facilitate rapid mobilization of at-risk public investments during a pandemic. The FIF should also support the mutualization of these resources, where appropriate, so that they can be optimized and used for existing public health priorities. This should include financing for strengthening of health infrastructure, human resources for health, and service delivery to address pandemics, existing epidemics, and pandemic-prone diseases at all levels of the health system, including at the primary care level.

The FIF must complement and ensure better linkages and coordination between existing and future financing mechanisms and frameworks so as to avoid duplication or competition.

## Governance

### Equitable Governance

The power imbalances laid bare during COVID-19 have made clear that the current global health architecture persistently fails to answer to the needs of communities and countries in LMICs. Public responsibility from all governments and equal participation in overall governance – including priority setting, decision-making, and resource allocation – will be essential for the very legitimacy of any new financing mechanism.

The governance architecture of the FIF must be grounded in equity and inclusion and ensure greater parity, with governments of LMICs having equal rights in the governing body. The priorities, populations at highest risk, programmatic approaches, and innovations developed in high-income countries (HICs) and LMICs may vary and only a more equitable governance arrangement can assure programs are truly country-driven and that resources are directed to interventions that address countries' most pressing unmet needs rather than the priorities *du jour* of donor countries.

In addition, there must be clear mechanisms for civil society and affected communities to participate fully in shaping the FIF's priorities and to have voting rights, and not simply as observers. It is unnecessary to pit 'inclusivity' against 'efficiency,' as is done in the White Paper. This is a false dichotomy and both can be achieved with a more equitable governance set-up. In addition, the FIF must ensure its independence from potential conflicts of interest with the private sector.

### Normative Role of WHO

Finally, the FIF should ensure that WHO is sufficiently empowered to play a strong normative role. This may include having a seat on the board (potentially as observers), leading relevant expert advisory bodies in order to guide technical decision-making, and creating an enabling environment, which supports the FIF objectives, supporter stronger coordination of global, regional, and national processes, and accelerates the development of new diagnostics, treatments, vaccines, and other health tools in a manner that prioritizes equitable access.

This enabling environment in which WHO should play a leading role must include:

- Definition of a priority research agenda and coordination of research efforts as part of the R&D Blueprint to avoid duplication and fragmentation;
- Promotion of open sharing of data, particularly to inform clinical guideline development and clinical practice in real-time;
- Support for surveillance capacity, manufacturing hubs, and clinical trial networks, especially those based in and led by LMICs;
- Collaboration on regulatory and safety monitoring, with a special focus on strengthening existing regulatory capacity and supporting collaborative and regional approaches.