DNDi
Drugs for Neglected Diseases *initiative*

# Ensuring innovation and equitable access to health tools:

# Initial comments on the Intergovernmental Negotiating Body (INB) deliberations to draft and negotiate a convention, agreement, or other international instrument to strengthen pandemic prevention, preparedness and response

## April 2022

### Introduction

The Drugs for Neglected Diseases *initiative* (DNDi) welcomes the opportunity to provide comments on the substantive elements of a convention, agreement, or other international instrument to strengthen pandemic prevention, preparedness, and response. In our view, it is essential that national, regional, and global coordination of research and development (R&D) be included as a substantive element of any instrument.

Our comments are rooted directly in our firsthand experience as an R&D organization undertaking research in the public interest, while seeking to secure globally equitable access to the fruits of innovation. We therefore focus on how an international instrument can best ensure investment in discovery and development of -- and equitable access to -- essential health tools as global public goods, providing suggestions for specific issues that should be included under the four strategic pillars contained in the Intergovernmental Negotiating Body INB questionnaire.

Looking ahead, DNDi would be pleased to offer more in-depth insights from our experience and support a dedicated meeting, 'deep dive,' or continuing dialogue on these topics.

### DNDi and COVID-19

The Drugs for Neglected Diseases *initiative* (DND*i*) is an international not-for-profit R&D organisation that discovers, develops, and delivers new treatments for neglected patients. Since its creation in 2003, DND*i* 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 DND*i* has:

- Established the COVID-19 Clinical Research Coalition, with members from nearly 100 countries, to accelerate research specific to the needs of people and health systems in low- and middle-income countries.
- Launched ANTICOV, a multi-country, adaptive platform trial in 13 African countries to identify treatment options for mild-to-moderate COVID-19 outpatients, with plans to extend this study in India and Brazil in 2022.
- Collaborated with the Therapeutics Pillar of the Access to COVID-19 Tools Accelerator (ACT-A) as well as various research consortia, and now leads a global consortium known as the COVID Moonshot, 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.
- Conducted policy research, analysis, and advocacy, including publishing a key policy report – *Another triumph of science but defeat for access?* – 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 future pandemics.

## Central objective of a pandemic instrument: equity

DNDi welcomes the prioritization of equity as a strategic pillar within the Working Group on Strengthening WHO Preparedness and Response to Health Emergencies (WGPR) and the INB and notes the many reports, including the interim report of the WGPR to the 150th Executive Board, that rightly identify equity (or the lack thereof) as being at the core of the breakdown of the current response to COVID-19, in particular as it relates to incentivizing innovation and ensuring equitable access to essential health tools and technologies.

Without a more dramatic shift in approach, there will continue to be a struggle for access to new treatments, tests, vaccines, and other health tools – disease by disease, product by product, country by country, company by company.

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 in low- and middle-income countries (LMICs); the serious power imbalances that determine who has a seat at the R&D 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, intellectual property, technology and equitable access to any new health tools developed. Addressing these inequities should therefore be a central objective of the pandemic instrument.

## Substantive elements of a pandemic instrument

To tackle the inequities outlined above, **the pandemic instrument should ensure national, regional and global coordination of R&D as a substantive element**. The scope should include medicines, diagnostics, and vaccines – not only for pandemics but also existing epidemics, AMR, and pandemic-prone and climate-sensitive neglected diseases.

To deliver on this, the four strategic pillars must encompass the following main elements:

- **Equity: Globally agreed norms and binding rules across the innovation lifecycle - including transparency and open sharing of data, knowledge, intellectual property (IP), and technology and equitable allocation of health tools.**

A pandemic instrument must address the need for globally agreed rules that will guarantee open sharing of research data and knowledge and robust transfer of technology. This includes clear norms to ensure essential health tools and technologies are free of IP or other restrictions, which can obstruct research and large-scale production These may include non-enforcement of existing IP, non-exclusive licensing globally through mechanisms such as the WHO COVID-19 Technology Access Pool (C-TAP), formal waiver of IP

during a pandemic and the use of TRIPS flexibilities and other legal mechanisms to ensure access. The instrument should facilitate increased national, sub-regional, and regional manufacturing capacity (see below for more). Once new health tools are developed, they will need to be equitably allocated both between wealthier and poorer countries, and within countries. Allocation frameworks need to be agreed upfront and ensure that the most vulnerable and those at highest risk are prioritized. The pricing of these tools must be as close as possible to what it costs to make them, so that they are affordable for health systems, and free to those most in need. These norms and rules should accelerate the R&D process and ensure the benefits of scientific progress will be more equitably shared, regardless of where they are discovered, developed or produced.

- **Leadership and governance: National, regional and global coordination of R&D with a governance architecture that ensures public leadership and greater parity between the 'global south' and the 'global north.'**

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 the global south. Public responsibility from all governments and equal participation in overall governance will be essential for a new pandemic instrument – including when it comes to R&D priority setting, decision-making, and resource allocation. There must be clear mechanisms for civil society and communities as well as public health and scientific experts to engage generally with the process, but also formally within the governance set-up. In addition, the instrument must ensure its independence from potential conflicts of interest with the private sector. A more distributed, decentralized, and democratic approach to the production of knowledge and innovation should facilitate R&D, manufacturing, and regulatory capacity through regional and national networks and hubs, not only through donor-driven global mechanisms, and re-balance decision-making power between public and private actors and between the 'global south' and the 'global north.'

- **Systems and tools: Increased surveillance, R&D, manufacturing, and regulatory capacity as part of broader efforts to strengthen health systems.**

The instrument should ensure that WHO is sufficiently empowered to play a strong normative role in helping define a priority pandemics research agenda and coordinating research as part of the R&D Blueprint, to speed innovation and avoid duplication and fragmentation of data, as happened for COVID-19.
The instrument should

- facilitate global, regional, and national R&D processes that prioritize those areas most likely to be neglected by the market;
- promote open sharing of data, particularly to inform clinical guideline development and clinical practice;
- support clinical trial networks, especially those based in and led by low and middle income countries.
- collaborate on regulatory and safety monitoring, with a special focus on strengthening existing regulatory capacity and supporting collaborative and regional approaches;
- encourage open innovation, in particular early discovery for tools with the broadest possible spectrum of activity that can be ready to be rapidly moved into clinical trials, 'phase II-ready', when a pandemic hits.

- ensure rapid, regular and timely sharing of pathogen genomic sequences and related benefit sharing, including for the development and use of diagnostics, vaccines and therapeutics.

- **Financing: Sustainable and predictable financing of end-to-end R&D, that support open, collaborative approaches to discovery and development, with clear priority given to areas most likely to be neglected by the market.**

Financing must avoid a narrowly defined focus only concerned with 'security threats' in high-income countries 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 and innovation and manufacturing capacity is left idle. Financing must support R&D from 'bench to bedside' and ensure that unmet needs are prioritized, that there are adequate resources dedicated to developing and advancing medical technologies through the entire R&D pipeline, including mechanisms for rapid mobilization of at-risk public investments.

Financing conditions should ensure that such products are developed as global public goods and adapted to the different contexts and populations that require access. Financing must ensure the strengthening of health infrastructure and human resources to address both pandemics and existing health priorities, including at the primary care level, and acceleration of the discovery and development of new diagnostics, treatments, and vaccines to respond to existing and new infectious diseases.