

## **Comments on the working draft of a WHO convention, agreement or other international instrument on pandemic prevention, preparedness and response (the WHO CAII), for the consideration of the Intergovernmental Negotiating Body (INB) at its second meeting**

**July 2022**

### **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. In response to the COVID-19 pandemic DNDi 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 and launched [ANTICOV](#), a multi-country, adaptive platform trial conducted in 13 African countries with to identify treatments for mild-to-moderate COVID-19 outpatients. We collaborated with the Therapeutics Pillar of the Access to COVID-19 Tools Accelerator (ACT-A) as well as various research consortia, and now lead the global, not-for-profit, open science consortium, [COVID Moonshot](#) 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.

DNDi welcomes the opportunity to respond in these discussions and commends the INB on its collaborative approach thus far. As a not-for-profit research and development (R&D) organization, DNDi focuses these comments on how the instrument can best ensure innovation of and equitable access to the health tools necessary to alleviate suffering and reduce illness and death from future pandemics and other critically important health threats.

### **Comments on the Objectives and Scope of WHO CAII**

#### **Objectives**

- DNDi support the broad objectives contained in this draft and in particular welcome the inclusion of the objective of ‘ensuring availability and equitable access to affordable medical and other pandemic response products. Addressing these inequities should be a central objective of the WHO CAII.
- However, to be able to have access to needed diagnostic, therapeutic, or preventive health tools or technologies those tools first need to be developed. Therefore, objective 3 should be expanded to include the discovery and development of health products and should therefore read: *‘Ensure the [add **discovery and development of**], availability and equitable access to affordable medical and other pandemic response products.’*

#### **Scope**

- DNDi agree that the scope of the WHO CAII should cover pandemic prevention, preparedness, and response and to the extent possible, recovery.

- The definition of a ‘pandemic’ should avoid a narrowly defined focus solely on those diseases or pathogens thought to be a security threat in high-income countries (HICs).
- The scope must also include existing epidemics, pandemic-prone, and climate sensitive diseases.
- DNDi welcome antimicrobial resistance (AMR) mentioned throughout the current draft and wish to reiterate that a One Health approach is critical.
- A broad scope is needed to ensure that the infrastructure and architecture put in place can be flexible enough to operate throughout the ‘peaks and troughs’ of a pandemic to break the cycle of panic and neglect.
- Much of the infrastructure that is needed to ensure timely development and delivery of medical countermeasures for pandemics – including for surveillance, research, clinical trials, manufacturing, regulatory systems, health services, etc. – must be ‘kept warm’ and robustly supported and strengthened during inter-crisis times both to deliver necessary services for communities and to prepare for and respond to pandemics.

## Comments on Specific Provisions/Areas/Elements

- In order to address the objectives outlined, DNDi welcomes the **importance given to R&D** as a specific provision within the working draft.
- However, as currently written, the WHO CAII does not acknowledge the link between R&D and access to end products and so does not provide the necessary framework to ensure end-to-end R&D in a manner that builds in equity and access at the core of the R&D process from bench to bedside.
- In particular, it does not recognize the need to ensure links between different R&D stages in order to ensure development and equitable access to the fruits of innovation. One important element that is missing is measures that embed the principles of access, affordability, and equity into the R&D process itself, including by articulating specific globally agreed norms, and acknowledging the critical role that governments can play in ensuring their public investments in R&D are designed to deliver equitable access. See Annex for examples of critical ‘hand-off’ points throughout the R&D process where commercial and policy decisions can determine access.
- Several, but not all, components for end-to-end R&D are included in the text, but not in an order that would allow efficient negotiation of measures to ensure discovery and development of tools that lead to affordable and equitable access.

We propose two potential options for how to re-structure and strengthen this section so that it more cohesively addresses the full range of core sub-elements that should come under the general heading of R&D:

### Option 1: Create one over-arching chapter on innovation/R&D

- This would include the relevant parts of other sections in Part V – including within specific provisions 1, 2, 3, 4 and 10 – as well as the transversal issues linked to governance and financing that intersect with the R&D language. This would cover measures from bench to bedside to address priority setting, surveillance, genome-sharing and sequencing, process of discovery and development, clinical trials, regulatory policies, manufacturing and local production and equitable allocation.
- Currently, measures to address similar topics are covered under different sections. For example (not an exhaustive list), issues addressing regulatory policies are covered both under *Achieving equity 1.b*

and *R&D 11.c* and measures addressing equitable allocation are featured in *Global supply chains and logistics 10.c* as well as *Equity 1.e*. Grouping the measures by relevant R&D stage may be a more efficient way to negotiate the content.

**Option 2: Move the specific provision on R&D further up in Part V and more closely link it with each of other provisions including:** (1) Equity, (2) Fair, equitable and timely access, and benefit sharing, (3) Strengthening and sustaining health systems' resilience and capacities, and (4) Local production and transfer of technology and know-how.

#### **Additional elements:**

Whatever option the WHO CAI takes there are additional elements that are needed and therefore the specific provision on R&D should also include:

- **Priority setting:** Measures to facilitate global, regional, and national R&D processes that prioritize those areas most likely to be neglected by the market.
- **Open innovation:**
  - Measures that explicitly encourage open innovation, in particular early discovery of tools with the broadest possible spectrum of activity that can be ready to be rapidly moved into clinical trials when a pandemic hits.
  - Measures to ensure coordination and collaboration, including open sharing of research knowledge and data, to avoid duplication and fragmentation of research efforts and to inform clinical guideline development and clinical practice.
- **Clinical trials:** Measures to support clinical trial networks and infrastructure, especially those based in and led by low- and middle-income countries.
- **Link R&D with access:** Measures to embed the principles of access, affordability, and equity into the R&D process itself, including by articulating specific globally agreed norms and binding rules and acknowledging the critical role that governments can play in ensuring their public investments in R&D are designed to deliver equitable access (including but not limited to IP and technology transfer policies)
- **Intellectual property:** Currently, IP is highlighted in the preamble but measures to address IP are not specifically mentioned within the provisions.

#### **Financing:**

- Sustainable and predictable financing of end-to-end preparatory as well as crisis R&D is currently not explicitly referenced in the draft. The draft only includes reference to R&D in the context of a pandemic and surge capacity. Whilst this is important there should be recognition of the need for end-to-end financing for preparatory R&D as well as for response. 14a needs to be amended to reflect this. This should include mechanisms for financing increased surveillance, clinical trial, manufacturing, and regulatory capacity which strengthens infrastructure to address both pandemic and existing health priorities.

#### **Governance:**

- Public responsibility from all governments and equal participation in overall governance must also apply 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. Measures included in 5d including the recognition of specific needs of vulnerable populations, indigenous populations, as well as promoting equitable gender, geographical and socioeconomic status representation should also be reflected within R&D sections.

## Comments on Institutional arrangements and linkages with other processes

- The WHO CAII will be emerging in a broader context and as part of a major re-shaping of the global pandemic preparedness and response architecture. For example, it will be emerging alongside a new G20-supported, World Bank-hosted Financial Intermediary Fund (FIF) for Pandemic Prevention, Preparedness and Response.
- To ensure policy alignment and coherence between the various other critical initiatives and mechanisms that are emerging it is important that the WHO CAII both provide an overarching framework for, and 'connect the dots' between, these various initiatives.

## Annex A: Critical 'hand-off' points throughout the R&D process where commercial and policy decisions can determine access

**Figure 2: Critical 'hand-off' points throughout the R&D process where commercial and policy decisions can determine access**

