

## **Comments on the conceptual zero draft (CZD) of the WHO CA+ for the consideration of the Intergovernmental Negotiating Body (INB) at INB3**

**November 2022**

### **Introduction**

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 12 new and improved treatments for six deadly diseases that have reached millions of people utilizing an alternative, collaborative, not-for-profit R&D model.

DNDi welcomes the efforts the Bureau have made to incorporate the proposals made by Member States and non-state actors since July via INB2, open submissions, informal focused consultations and the public hearings, in the conceptual zero draft (CZD).

These comments build on those [DNDI made as part of the open consultation](#). As a not-for-profit research and development (R&D) organization, DNDi seeks to highlight issues within the CZD that are either missing, or could be further clarified or amended in order to best ensure innovation of and equitable access to health tools, thereby strengthening the world's capacities for preventing, preparing for, responding to, and recovering from pandemics.

### **Comments on vision, objectives, scope**

#### **Vision and scope**

- The Vision's scope is currently inconsistent with the broad definition of pandemics contained in other parts of the Conceptual Zero Draft ('CZD'). It only refers to pandemics and does not include emerging and re-emerging diseases with pandemic potential and neglected tropical diseases (NTDs) (as stated in Article 8 2.iii). DNDi suggests that pandemic-prone climate-sensitive diseases, which include many NTDs, are referenced.
- The vision also limits equitable access to pandemic response products themselves rather than ensuring equitable access is embedded in all stages of prevention, preparedness and response.
- A broad definition and scope in the CZD is necessary to ensure that both preparedness for future threats, as well as response, is adequately addressed and that the infrastructure and processes put in place can be sustained throughout the peaks and troughs of acute crises and potentially address more than one threat at a time. For example, much of the infrastructure, including clinical trial infrastructure and manufacturing capacity, that is needed for timely development and delivery of health tools for pandemics must be 'kept warm', supported, and therefore utilized during inter-crisis times to prepare for and provide surge capacity to respond to pandemics.
- **Suggested Amendment:** Amend the 'Vision' to read: 'aims to protect present and future generations from pandemics, *[ADD FROM ARTICLE 8 2.iii emerging and re-emerging diseases with pandemic potential, as well as neglected tropical diseases, [DNDI suggested add: existing epidemics, climate*

*sensitive diseases*], and their devastating consequences” and ‘to ensure unhindered timely and equitable access [ADD during the discovery, development, production and supply of pandemic preparedness and response] products.

## Objectives

- The CZD has removed the reference to ‘ensuring availability and equitable access to affordable medical and other pandemic response products’, contained in the working draft objectives. It is the only objective to not remain in the CZD compared to the working draft.
- DNDi strongly believes that addressing the inequities of access to health tools should be a central objective of the WHO CA+. COVID-19 clearly showed that equitable access is the ‘unfinished business’ of global health and is imperative to ‘save lives’ as the WHO CA+ aim states. **Suggested Amendment:** Article 3 objective(s) should be amended ‘[ADD Ensuring the discovery, development, availability, and equitable access to affordable medical and other pandemic response products.]’

## Overall comments:

At each stage of the R&D process, critical decisions are made that can either facilitate or hinder availability, affordability and access and support equity. There are multiple ‘hand-off points’ across the innovation lifecycle where commercial and policy decisions can determine equitable access. These include what priorities are set and who sets them, where the research is carried out and by whom, and how each stage of the research is undertaken. What decisions get made at each stage, and who gets to make them, is key.

As currently written, the WHO CA+ does not sufficiently acknowledge the link between the different stages of R&D and access to end products and 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, and for prevention and preparedness as well as response. 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. Below are suggested areas of amendments to address this.

### I. R&D must be included in preparedness measures in addition to response in the CZD.

- Years, in some cases decades, of investment in research for coronaviruses prior to the COVID-19 pandemic enabled the development of vaccines and diagnostics for SARS-CoV-2, in particular, at unprecedented speed. This illustrates that basic research as well as R&D into specific vaccines, treatments, diagnostics and other health tools must be seen as key components of preparedness. At present the CZD places greatest focus on ‘downstream’ response measures such as manufacturing and registration. While these are necessary, they are not sufficient to ensure the end-to-end approach – from early-stage discovery research to clinical development to access and delivery of health tools post-registration - that is needed.
- For example, a critical part of preparedness includes supporting discovery research to identify promising novel antivirals with the broadest possible spectrum of activity to build the pipeline for future viral pandemics, including pathogens of pandemic potential that are unlikely to attract

commercial attention, such as viral hemorrhagic fevers. These can be ready to be rapidly moved into clinical trials, 'phase I-ready', if an outbreak occurs.

- **Suggested Amendments**

- **In the preamble**, there should be an additional bullet point recognizing the importance of R&D as preparedness. e.g. *ADD 'Recognizing the importance of research and development of health tools as a critical component of pandemic preparedness in addition to response'.*
- **In the preamble** there should be a recognition of the importance of international coordination of R&D of health tools. Inspiration could be taken from other treaties or agreements in this regard such as the Montreal Protocol 1987 and include language such as *'recognizing the importance of and promoting international cooperation in the research and development of health tools related to pandemic preparedness and response'*
- **Include measures** for early discovery and development whenever research and development is mentioned, including in Article 8. 2 (a) i-iv.
- **The title of Article 8 should be broadened.** In addition to strengthening capacity there is a need to address the limitations and gaps in the way that R&D is conducted and coordinated that were exposed during COVID-19 and is stated in 2 a(i). To better reflect the need to focus on both aspects, the title of Article 8 should be amended to read *'increase [ADD and enhance/coordinate] research and development [ADD processes] and capacities'*

## II. **Development of norms and conditions on financing for the discovery, development, and delivery of appropriate and affordable health tools is a critical component of the CZD but should include early-stage research in addition to downstream manufacturing and supply.**

- DNDi welcomes the reference to the need for and development of norms and conditions to ensure that financing of research and development for health tools results in equitable access and affordability. DNDi strongly believes this is where the WHO CA+ can add value and supports the inclusion in preamble **41 and Article 8 1 and 2 (iii)a** of the importance of publicly funded R&D and of measures to develop norms and implement conditions to ensure equitable access. These should remain and the details further developed as part of the negotiation process.
- If equity is to be ensured it is critical that 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 regardless of where they are discovered, developed, or produced. Coordination and collaboration should be maximised throughout the R&D process including early stages at each 'hand-off point' to increase efficiency and avoid duplication or waste of resources. See annex A for critical 'hand-off points' throughout the R&D process where commercial and policy decisions can determine access.
- R&D funders and purchasers have unique leverage that is rarely exercised to enforce and coordinate the application of these norms by requiring clear and transparent terms and conditions in contractual agreements. These norms should build on the principles of affordability, effectiveness, availability, efficiency and equity as agreed by Member States<sup>1</sup> and include:

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<sup>1</sup> WHO. Follow-up of the report of the Consultative Expert Working Group on Research and Development: Financing and Coordination. World Health Organization, 2016. Available at: [http://apps.who.int/gb/ebwha/pdf\\_files/WHA69/A69\\_R23-en.pdf](http://apps.who.int/gb/ebwha/pdf_files/WHA69/A69_R23-en.pdf)

- **Effective and transparent research priority setting processes** that meet the needs of all people, with specific consideration given to people in vulnerable situations and historically neglected communities.
  - **Openness, transparency, and access to knowledge, to ensure efficiency and collaboration including: open sharing of knowledge, information and research inputs** (e.g. specimens, samples, compound libraires, datasets with appropriate data protections), **processes** (e.g. protocols, clinical trial design, R&D costs) and **outputs** (e.g. clinical trial results, open access publications and data-sharing).
  - **Scientific and technological cooperation** to harness expertise within higher, middle and lower-income countries, encourage collaboration between research centers, and facilitate technology transfer.
  - **Accessibility**, meaning universal and equitable availability and affordability of health technologies for individuals and the health systems that serve them.
  - **Pro-access management of IP rights and equitable licensing** – concerning the availability, scope, and use of research tools and affordability of end products – to enable research and the fruits of innovation to be global public goods (see section III below for more detail).
  - Efficient registration and sufficient production, supply, and equitable allocation of health tools;
- Access and licensing conditions must be included as early as possible to ensure an end-to-end approach - from discovery, development, production, all the way through to registration. From DNDi's experience it is easier to address access and licensing when the product is being designed and developed than at the end. The CA+ provides the opportunity to agree upon approaches in advance and provide certainty to both countries and developers rather than seek to negotiate during a crisis.

### III. The CZD should consistently include the sharing of Intellectual Property (IP), data and knowledge throughout the draft.

- Throughout the draft there are multiple attempts to include measures relating to the sharing of IP, which will be critical to increase research and manufacturing capacity globally and contribute to more equitable access. COVID-19 has highlighted that IP barriers need to be specifically addressed in a collective and coordinated manner beyond existing agreements.
- It is important that sharing and licensing of IP particularly that which is the result of publicly funded R&D becomes the norm to contribute to the transfer and dissemination of technology and to prevent the abuse of IP rights by right holders. Voluntary licensing agreements can take multiple forms. They can relate to up-stream research collaborations, downstream development collaborations, or just manufacture and commercialization, as illustrated in the latter case by most licenses of the UNITAID Medicines Patent Pool. However, as was the case with COVID-19, where voluntary licensing agreements do not achieve global equitable access, the CA+ should also include provisions to trigger immediate sharing of relevant IP when a public health emergency of international concern (PHEIC) is declared. These may include:
  - non-enforcement of existing IP, government 'march/step in', ownership or licensing, 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.

- Sharing only IP rights (patents, trademarks, copyrights, etc) would usually not be enough to ensure efficient development of products; access to all the relevant data and know-how needed to develop and manufacture a product must also be included.
- Measures to facilitate sharing of all the relevant rights, data and knowledge are needed at all stages, not only for manufacturing and access to products, in order to avoid duplication and ensure rapid development. There will also be multiple organizations involved. For example, some preparedness tools will be 'pandemic-ready' - meaning developed to the proof of concept or early clinical trials stages and then paused to then proceed into full trials and production in the case of an outbreak or pandemic. The entity that has taken it through the proof-of-concept stage may not be the same one that then undertakes further clinical development and production.
- **Suggested amendment:**
  - Any provision on the sharing of IP and transfer of technology should also include sharing of related necessary data and know-how.
  - Measures to ensure sharing should be included in all stages of prevention, preparedness and response and in Articles 6, 7, 8 & 9 to enable links between different R&D stages in order to ensure continued development and equitable access to the fruits of innovation.
  - Similarly, any article about the participation of the private sector and technology transfer should include sharing/licensing of relevant IP, know-how and data.

#### **IV. The CZD should consistently address the needs and vulnerabilities of individuals and groups at higher risk and in vulnerable situations throughout the text.**

- DNDi welcomes the recognition under Article 4(13) of the rights of individuals and groups at higher risk and in vulnerable situations. However, addressing vulnerabilities specific to those groups must also be integrated throughout the text including in the sections relating to R&D in Art 7, 8, 9. For example, children, and especially neonates, are at particular risk of morbidity and mortality due to drug-resistant infections with 140,000 new-born deaths directly attributable to antimicrobial resistance in 2019. Specific measures to address this group should be included in Art **17 2 d**.

#### **Additional comments on specific articles:**

##### **Article 8. Increase research and development capacities**

###### **Priority setting should be included:**

- The WHO CA+ should include measures to identify R&D needs and gaps, establish clear priorities through a transparent and inclusive process, and coordinate efforts to enhance collaboration and reduce duplication. COVID-19 highlighted that coordination challenges exist across the system. Government ministries, national research institutions and international funders often have differing priorities, making research less strategic and undermining health outcomes. The right framework is needed to bring stakeholders together and provide better coordination and alignment of national, regional and international priorities. The CA+ should ensure that WHO is sufficiently empowered to

play a strong normative role in helping define a priority research agenda and coordinating research, building on the R&D Blueprint, to speed innovation and avoid duplication and fragmentation of data.

**Allocation:**

Once new health tools are developed, they will need to be equitable 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 WHO CA+ should include an agreement to abide by allocation frameworks as determined by WHO.

**Financing**

Article 8: 2a ii: DNDi welcomes the recognition that increased and sustained resources (financial and human) for R&D are needed. This point could be further strengthened to include reference to the focus of such resources prioritizing those areas most likely to be neglected by the market, and link to the previously mentioned conditionalities.

**Clinical trials**

Article 8c on clinical trials should include a reference to measures to support the coordination and cooperation of regional and national regulatory authorities and ethics committees for clinical trial approval processes and oversight. There is also a need to ensure that clinical trials include diverse populations in order to improve equity and understanding of health outcomes between populations.

**Chapter VI. Financing**

- The WHO CA+ must include measures for 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.
- R&D requires adequate, sustainable, and at-risk funding from governments, which should be available at the national, regional, and international levels, as well as mechanisms to incentivize innovation and secure access.
- 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 not only support R&D from ‘bench to bedside’ and ensure that unmet needs are prioritized, but ensure 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.
- Article 18 2c) should include a financing mechanism that is available at-risk in the event of a new outbreak, with transparent and pre-defined triggers. Such financing mechanisms must include funding for R&D and manufacturing ‘at-risk,’
- Financing conditions should ensure that such products are developed as global public goods and adapted to the different contexts and populations that require access.

- The WHO CA+ 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 [financial intermediary fund \(FIF\) for pandemic prevention, preparedness, and response \(PPR\)](#). To ensure policy alignment and coherence between the various other critical initiatives and mechanisms that are emerging it is important that the WHO CA+ 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

