



Drugs for Neglected Diseases initiative (DNDi)

Submission in Response to Department of Health and Human Services (HHS) Notice and Request for Comments on the Implications of Access and Benefit Sharing (ABS) Commitments/Regimes and Other Proposed Commitments Being Considered Under a WHO Convention, Agreement or Other International Instrument on Pandemic Prevention, Preparedness and Response

January 2024

The Drugs for Neglected Diseases initiative (DNDi) is a not-for-profit research and development (R&D) organization that discovers, develops, and delivers new treatments for neglected patients. Since our creation in 2003 by public research institutions in Brazil, France, India, Kenya, and Malaysia and Médecins Sans Frontières (MSF), we have developed 13 new and improved treatments for six deadly diseases that have reached millions of people utilizing an alternative, collaborative, not-for-profit R&D model.

We focus these comments on areas where the World Health Organization convention, agreement or other international instrument on pandemic prevention, preparedness, and response (WHO CA+) negotiation text could be strengthened and made more specific to ensure innovation and equitable access to health tools, with a particular focus on conditions on public financing of research and development (R&D).

General comments

In accordance/consistent with national laws: Throughout the Negotiating Text, there are increasing references to ‘in accordance/consistent with national laws’ prefacing many provisions. This raises questions as to what the accord seeks to change, and could reduce the effectiveness, impact, and legitimacy of the WHO CA+ and is a concerning trend.

Significant public financing/considering the extent of public funding: When public funding is referenced, it is often preceded with a qualifier such as ‘significant public financing’ or ‘considering the extent of public funding.’ We do not think this additional qualifier is helpful as its meaning will be open to interpretation. Additionally, obligations can be attached to funding regardless of how much of the

overall project a given funder is funding, as in the case of the US National Institutes of Health (NIH) Policy for Data Management and Sharing (DMS, 2023¹). We suggest deleting references to ‘significant’ whenever they appear next to public funding (throughout articles 9-14).

Below are comments and analysis on various Articles, which are complemented by drafting suggestions on the Negotiating Text in the second part of this document.

Recommendations for Article 9: Research and Development

For ease of reference see Annex 1 for the full text of Article 9 in the Negotiating Text (October 2023) with DNDi drafting comments embedded.

The chapeaux provision (9.1²) should make clearer the purpose and relevance of R&D provisions across entirety of prevention, preparedness, and response continuum

This will enable an interpretation of the resulting Article 9 provisions to ensure obligations are also preventing and preparing for pandemics, in addition to responding when a pandemic hits. R&D activities are critical to pandemic preparedness. For example, being prepared will require early-stage research to work on as many different potential treatments and vaccines as possible, targeting different types of diseases and pathogens of pandemic potential. However, as it is not known what a future pandemic will look like, many products will have to be paused at certain stages of development, so they are on the shelf ready to go for further clinical development in the event of a future pandemic.

Ideally, these products would complete phase 1 studies so that they are ‘phase 2-ready’. This is why it is important to ensure that any R&D investments and activities are both *sustained* across R&D stages and *sustainable* during both ‘peak’ pandemic and ‘through’ non-pandemic periods. The aim of Article 9 provisions should explicitly include all aspects of PPR.

DRAFTING SUGGESTION 9.1:

1. [ADD With the aim of preventing, being prepared for, and responding to outbreaks caused by pathogens with pandemic potential, t]he Parties shall cooperate to build strengthen and sustain geographically diverse capacities and institutions for research and development, particularly in developing countries, [ADD including sustained efforts between pandemic emergencies] and shall promote research collaboration and access to research through open science approaches

¹“The DMS Policy applies to all research, funded or conducted in whole or in part by NIH, that results in the generation of scientific data. This includes research funded or conducted by extramural grants, contracts, Intramural Research Projects, or other funding agreements regardless of NIH funding level or funding mechanism” NOT-OD-21-013: Final NIH Policy for Data Management and Sharing.

² 9.1 The Parties shall cooperate to build strengthen and sustain geographically diverse capacities and institutions for research and development, particularly in developing countries, and shall promote research collaboration and access to research through open science approaches for rapid sharing of information and results.

for rapid sharing of information and results, [ADD to reduce the time and cost of further development, and reduce risk of inequitable access to resulting product, during a pandemic]

Reinstate conditions on public funding of R&D

It is very concerning that a specific obligation to attach access conditions to public funding has not been reinstated in the Negotiating Text. A specific obligation was present in the zero draft, and its inclusion in INB7 as a starting point for negotiations has support from a wide range of Member States, including during the informal meetings. It is one of the few specific mechanisms to operationalize equity and should be reinstated.

Member States have agreed that operationalizing equity is central to WHO CA+. Attaching equitable access conditions on public funding is a concrete mechanism to do so, where Member States can use their leverage as R&D funders to operationalize equity at all stages of product development. Failure to ensure that Member States can negotiate these provisions removes one of the few specific equity obligations originally contained in the draft and undermines the stated commitment to equity.

A provision must be added that requires clear and transparent terms and conditions on public funding of R&D that ensures open collaboration to accelerate research as well as the affordability, availability, and equitable allocation of essential health tools.

Attaching conditions is not a novel concept, but it is not yet universally applied. The U.S. government systematically reserves rights in its R&D funding and licensing agreements and includes conditions on its licensees to address public access to the resulting medical products. Historically, the U.S. has only rarely enforced its rights, but [several recent announcements](#) indicate a greater willingness to do so.

As an organization that conducts R&D in the public interest, DNDi has experience working with different funders at different stages of the R&D process to successfully apply access conditions throughout to enable and accelerate the development of health tools and to ensure those tools are available and affordable for who need them. We also know from experience what is at risk when no such safeguards are in place. COVID-19 demonstrated that if Member States wait until a treatment is developed then they have limited leverage and options to ensure equitable access.

Conditions applied at an earlier stage provide Member States with the ability to address potential barriers to development and equitable access and provide clarity to all R&D stakeholders on what is expected in return for public investment. There can be baseline requirements during inter-crisis periods and others triggered by specific events, e.g., when a public health emergency of international concern (PHEIC) is declared.

These conditions could include specific provisions on, for example, affordability; management of intellectual property and licensing strategies that will encourage open innovation, knowledge-sharing; and transfer of technologies and know-how that will allow distributed manufacturing to ensure supply autonomy in different regions of the world.

Additionally, these terms and conditions should ensure transparency and open sharing of knowledge, including research inputs (e.g., specimens, samples, compound libraries, and datasets with appropriate data protections), processes (e.g., protocols, clinical trial designs, and R&D costs), and outputs (e.g., study data and clinical trial results – shared openly, including through open-access publications). Applying such terms and conditions to public (and philanthropic) R&D funding is critical to enabling continuity of research, avoiding duplication, and ensuring that fruits of research reach those in need.

It is important that the list of areas is expanded to include an ability for funders to retain the rights to their funded developments as the U.S. government does in its R&D funding and licensing agreements. State Parties can and should secure rights on outcomes of research they fund to have the ability to use, license, or assign those rights, if needed, to ensure the development and equitable access to health technologies.

DRAFTING SUGGESTIONS

The Negotiating Text, based on the Bureau draft, combines and conflates two provisions in the Zero Draft one to include conditions on public funding³ and a Member State proposal on publication of contract terms, into one obligation to publish terms of funding agreements.

An obligation to only publish contract terms, which we support as a separate obligation, does not ensure that public R&D funders attach pro-access conditions to their funding in the first place, nor ensure that recipients of funding enact pro-access activities. Both obligations are needed - transparency and conditions - to not only ensure the fast and efficient development of health tools, but also ensure equitable access.

These two provisions should be separated back out and at a minimum the obligation to include conditions on public funding specifically reinstated as per the Zero Draft, as supported by many Member States in their proposals.

Our primary drafting proposal below is to add a new provision 9.5 on attaching conditions. This is in addition to the provision on publication of contract terms (which DNDi supports, and which should remain as 9.4).

DRAFTING SUGGESTION 9.5:

[NEW 5 Each Party, with a view to promoting greater sharing of knowledge, efficiency of R&D, and equitable access to health tools, when providing public funding for R&D for pandemic prevention, preparedness, response and recovery of health systems, shall include provisions promoting global access and efficient development in publicly funded R&D agreements and in licensing of government owned technology for pandemic-related products, including:

³ Zero Draft 9.2b - (b) endeavour to include terms and conditions on prices of products, allocation, data sharing and transfer of technology, as appropriate, and publication of contract terms; 9.2e - (e) establish appropriate conditions for publicly funded research and development, including on distributed manufacturing, licensing, technology transfer and pricing policies

- i. affordable pricing of end products or pricing policies for end products;
- ii. licensing and sublicensing of innovations, including non-exclusive licenses for development, manufacturing and distribution, especially in developing countries;
- iii. publication of information on research inputs⁴, processes⁵, and outputs⁶;
- iv. retention of rights by the funder, through ownership or licensing of research results, for use, licensing, or assignment, as necessary;
- v. adherence to allocation frameworks as determined by WHO; and
- vi. Other terms regarding affordable, equitable and timely access to pandemic related products at the time of a pandemic, including specific provisions on transfer of relevant technology and know-how]

Add specific provisions for early-stage research collaboration

The Negotiating Text focuses very heavily on downstream R&D – such as clinical trials. Despite Member State proposals to widen the focus to include early-stage collaboration and open science approaches, which the US government funds at levels unprecedented in the rest of the world, there are no provisions relating to early-stage R&D activities, including discovery research, where investments and collaboration are needed to ensure an end-to-end approach, and in particular as an essential part of pandemic preparedness.

DRAFTING SUGGESTION 9.3a NEW

ADD NEW 9.3a) increase pre-clinical, discovery and translational research capacity, including by investing in skilled research workforce, promoting open science approaches and strengthening coordination and collaboration.

Add provision for effective priority-setting processes (9.3a)

There is currently insufficient reference to research priority-setting processes, despite a provision on sharing of research agendas (9.3c).

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 R&D ecosystem. The right framework is needed to bring stakeholders together and provide better coordination and alignment of national, regional, and international priorities, and this must be done not only during pandemic emergencies. The WHO CA+ should ensure that WHO is sufficiently empowered to play a strong normative role in helping define a priority research agenda and in coordinating research, building on the R&D Blueprint, to speed innovation and avoid duplication and fragmentation of data, working closely with the NIH and other public sector research institutions and scientific experts.

⁴ Research inputs (including specimens, samples, compound libraires, and datasets with appropriate data protections)

⁵ Research processes (including protocols, clinical trial design, and R&D costs)

⁶ Research outputs (including clinical trial results, open access publications, and data sharing)

The current provision 9.3(c) on sharing of national research agendas is not sufficient to ensure that research priorities ensure the above and therefore a new provision is required, as suggested by Member States.

DRAFTING SUGGESTION 9.2(e):

[ADD NEW 2E international collaboration and coordination, for inclusive and transparent priority setting processes to set common objectives and research goals and priorities, to develop pandemic-related products for diverse populations and diverse settings, with a central role for WHO.]

R&D investment obligation should remain (Article 9.2a)

The obligation to invest in research and development (9.2(a)⁷) has been strengthened in the negotiating text and should remain.

The WHO CA+ must include commitments 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. 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. This is why the addition of a reference to investment linked to public health priorities should remain.

⁷ 9.2(a) sustained investment in the research and development of public health priorities, including for pandemic related products, aimed at improving equitable access to and delivery of such products, and support for national and regional research institutions that can rapidly adapt and respond to research and development needs in case of a pandemic.

Recommendations for Article 11: Transfer of technology and know-how

Obligations should be strengthened to ‘require’ and ‘as appropriate’ should be removed in relevant Articles e.g. 11.3c/3d, especially when relating to public funding

Obligations should be strengthened to ‘require’ and ‘as appropriate’ should be removed in Article 11.3c. Entities, including manufacturers, that receive public funding should be “required” rather than “encouraged”, as a condition of public funding, to grant (non-exclusive) licenses to enable co-development and transfer of technology and know-how. References to “as appropriate” should be deleted for the same reason as, upon a PHEIC declaration, it should be an automatic requirement to grant licenses of publicly funded R&D.

Obligations to support time-bound waivers of intellectual property rights should remain (11.3a)

In case of a pandemic, measures to support waivers of intellectual property rights can be critical to quickly increase manufacturing capacity and extend availability of pandemic-related products. Waivers of intellectual property rights remove infringement risks and liabilities for manufacturers which can start developing their own products without fear of consequences from IP infringement.

Obligations to require patent holders, on receipt of public funding, to grant royalty free or royalty bearing licenses to developing country manufacturers should remain (11.3b)

It is important that Article 11.5.c (the requirement to grant royalty-free or royalty-bearing licenses to developing country manufacturers) remains specifically for holders of patents that have received public financing. This obligation should be practically implemented during inter-pandemic times via conditions on public funding agreements. In case of a pandemic, other holders of patents should also be required, as appropriate, to grant non-exclusive licenses in exchange for payment of reasonable royalties.

Annex 1

For ease of reference find below the full text of Article 9 in the Negotiating Text (October 2023) with DNDi drafting comments embedded

Article 9. Research and development

1. [ADD With the aim of preventing, being prepared for, and responding to outbreaks cause by pathogens with pandemic potential, t]he Parties shall cooperate to build strengthen and sustain geographically diverse capacities and institutions for research and development, particularly in developing countries, [ADD including sustained efforts between pandemic emergencies] and shall promote research collaboration and access to research through open science approaches for rapid sharing of information and results, [ADD to reduce the time and cost of further development, and reduce risk of inequitable access to resulting product, during a pandemic]
2. To this end, the Parties shall promote:
 - a. sustained investment in the research and development of public health priorities, including for pandemic-related products, ~~aimed at improving~~ [ADD ensuring] equitable access to and delivery of such products, and support for national and regional research institutions that can rapidly adapt and respond to research and development needs in case of a pandemic;
 - b. technology co-creation and joint venture initiatives, actively engaging the participation of and collaboration between scientists and/or research centres, particularly from developing countries;
 - c. participation of relevant stakeholders, consistent with applicable biosafety and biosecurity obligations, laws, regulations and guidance, to accelerate innovative research and development, including community-led and cross-sector collaboration, for addressing emerging and re-emerging pathogens with pandemic potential; and
 - d. knowledge translation and evidence-based communication tools, strategies and partnerships relating to pandemic prevention, preparedness and response, including infodemic management, at local, national, regional and international levels.
 - e. [ADD NEW 2E international collaboration and coordination, including for inclusive and transparent priority setting processes to set common objectives and research goals and priorities, to develop pandemic-related products for diverse populations and diverse settings, with a central role for WHO.]
3. The Parties shall, in accordance with national laws and regulatory frameworks and contexts, take steps to develop and sustain, strong, resilient, and appropriately resourced, national, regional and international research capabilities. To this end, the Parties shall:

- a. **ADD NEW 9.3a) increase pre-clinical, discovery and translational research capacity, including by investing in skilled research workforce, promoting open science approaches and strengthening coordination and collaboration.**
- b. increase clinical trial capacities, including by:
 - i. building and maintaining a skilled research workforce and infrastructure, as appropriate;
 - ii. strengthening clinical trials policy frameworks, particularly in developing countries;
 - iii. investing in the infrastructure and training of clinical research networks and coordination of trials through existing, new, or expanded clinical trial networks, including in developing countries, to be prepared to provide timely and appropriate responses to pandemics; and
 - iv. identifying and researching supply chain needs to rapidly mount and scale research responses during pandemic emergencies.
- c. ensure that clinical trials have equitable representation, considering racial, ethnic and gender diversity across the lifecycle, and designed to help address geographical, socioeconomic and health disparities, to promote a better understanding of the safety and efficacy of pandemic-related products in population subgroups;
- d. promote the sharing of information on national research agendas, including research and development priorities during pandemic emergencies and capacity-building activities along with best practices on efficient and ethical clinical trials, including through the WHO Global Observatory on Health R&D;
- e. strengthen international coordination and collaboration on clinical trials, through existing or new mechanisms, to support well-designed and well-implemented trials;
- f. develop national policies to support the transparent, public sharing of clinical trial protocols and results conducted within their territories or through partnerships with other parties, such as through open-source publication, while protecting privacy and health identifiers; and
- g. support new and existing mechanisms to facilitate the rapid reporting and interpretation of data from clinical trials, to develop or modify, as necessary, relevant clinical guidelines, including during a pandemic, **[ADD and disclose disaggregated information to measure inclusiveness, for example by gender and age, to the extent possible and as appropriate, on the results of clinical research and clinical trials]. OR MAKE ADDITION A SEPARATE PROVISION 3G.**

4A – NEW PROVISION ON CONDITIONS 9.5

4. Each Party shall, in accordance with its national laws and considering the extent of public funding provided, publish the terms of government-funded research and development agreements for pandemic-related products, including information on:

- a. research inputs, processes and outputs, including scientific publications and data repositories with data shared and stored securely in alignment with Findability, Accessibility, Interoperability, and Reusability principles;
 - b. pricing of end-products, or pricing policies for end-products;
 - c. licensing to enable development, manufacturing and distribution, especially in developing countries; and
 - d. terms regarding affordable, equitable and timely access to pandemic-related products during a pandemic.
5. [NEW 5 Each Party, with a view to promoting greater sharing of knowledge, efficiency of R&D, and equitable access to health tools, when providing public funding for R&D for pandemic prevention, preparedness, response and recovery of health systems, shall include provisions promoting global access and efficient development in publicly funded R&D agreements and in licensing of government owned technology for pandemic-related products, including:
- i) affordable pricing of end products or pricing policies for end products;
 - ii) licensing and sublicensing of innovations, including non-exclusive licenses for development, manufacturing and distribution, especially in developing countries;
 - iii) publication of information on research inputs⁸, processes⁹, and outputs¹⁰;
 - iv) retention of rights by the funder, through ownership or licensing of research results, for use, licensing, or assignment, as necessary;
 - v) adherence to allocation frameworks as determined by WHO; and
 - vi) Other terms regarding affordable, equitable and timely access to pandemic related products at the time of a pandemic, including specific provisions on transfer of relevant technology and know-how.]

⁸ Research inputs (including specimens, samples, compound libraires, and datasets with appropriate data protections)

⁹ Research processes (including protocols, clinical trial design, and R&D costs)

¹⁰ Research outputs (including clinical trial results, open access publications, and data sharing)