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DNDi initial comments on WHO CA+ Bureau Draft for consideration at the INB June Drafting Group meeting

June 2023

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 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 focuses our initial comments on areas where the draft 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, and focuses on articles which are likely to be subject of negotiations in the June drafting group with the intention to highlight areas which are currently missing, or could be strengthened, in the bureau's draft.

General comments

Throughout the Bureau's text, there are increasing references to 'in accordance/consistent with national laws' prefacing many provisions, when compared to the Zero Draft. 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.

Recommendations for Article 9: Research and Development

1. Reinstate conditions on public funding of R&D (Article 9.2)

We are concerned that the Bureau Draft has removed the specific obligation to attach access conditions to public funding.

The Bureau draft seems to combine and conflate two obligations in the zero draft on including conditions on public funding[1] and a Member State proposal on publication of contract terms into a new obligation 9.2b on publishing terms of funding agreements. An obligation to publish contract terms, which we support as a separate obligation, does not ensure that public R&D funders use their leverage to attach pro-access conditions to their funding in the first place, nor ensure that recipients of funding enact pro-access activities. Both are needed - transparency and conditions - to not only ensure the fast and efficient development of health tools, but also to ensure equitable access.

These two points 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.

[1] zero draft 9.2b - endeavor to include terms and conditions, 9.2e - establishing appropriate conditions

Our drafting proposal below (adding a new provision 9.2c) takes into account the proposal to include a new obligation on publication of contract terms (which DNDi supports and should remain), but includes the the implementation of conditions which was in the Zero Draft and supported by many Member States.

In addition, we welcome the expanded list of potential areas that funding conditions could cover from the Zero Draft. However, there are areas which could be expanded and made more specific as suggested below.

DRAFTING SUGGESTION 9.2:

Article 9.2: With a view to promoting greater sharing knowledge and transparency [ADD efficiency of R&D, and equitable access to health tools], each party, when providing public funding for research and development for pandemic prevention, preparedness, response and recovery of health systems, shall, in accordance with national laws and as appropriate taking into account the extent of public funding:

a) Promote public dissemination of results of government funded research for the development of pandemic-related products, in accessible languages and formats
b) Publish terms of government funded R&D agreements for pandemic related products, as appropriate

[ADD c) include binding terms and conditions on recipients of publicly funded research and development which promote equitable access including]

i. [ADD Public dissemination and transparency of] research inputs[2], process[3], outputs[4]
ii. [ADD Affordable] pricing of end products, or pricing policies for end products
iii. Licensing, [ADD including non-exclusive licensing][5] to enable development, manufacturing and distribution, especially in developing countries, and
iv. Terms regarding affordable, equitable and timely access to pandemic related products at the time of a pandemic
v. [ADD adherence to allocation frameworks as determined by WHO when PHEIC is declared]
vi. [ADD retention of rights by the funder, through ownership or licensing of research results, for use, licensing, or assignment, as necessary, to ensure affordable, equitable, and timely access]

2. Expand R&D financing obligation (Article 9.2d)

We welcome the addition of R&D financing obligations, which were absent from the Zero Draft, but these should be strengthened.

[2] research inputs (including specimens, samples, compound libraires, and datasets with appropriate data protections)
[3] processes (including protocols, clinical trial design, and R&D costs)
[4] outputs (including clinical trial results, open access publications, and data sharing)
[5] including provisions for data sharing, technology transfer, and waiving or managing royalties as appropriate

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.

DRAFTING SUGGESTION 9.2d

Article 9.2d: Promote and prioritize investment in research and development of pandemic-related products, [ADD linked to public health priorities], [ADD both during and between pandemics] that can promote equitable access [ADD including via conditions on funding]

3. Add provision for effective priority-setting processes (9.3a]

There is currently insufficient reference to research priority-setting processes, despite an addition in the Bureau Draft (9.3a).

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 inter-pandemic times and not only just pandemic emergencies, as currently included in 9.3a. The 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.

DRAFTING SUGGESTION 9.3A:

DNDi suggest the addition of a provision under Article 9 or editing 9.3a:

[ADD Parties shall promote international cooperation in effective and transparent research priority setting processes to develop effective and appropriate health tools that meet the needs of all people, with specific consideration given to people in vulnerable situations and to historically neglected communities, with a central role for WHO.]

OR EDITING EXISTING 9.3a

9.3a: Sharing information on, [ADD and promote international cooperation in effective and transparent] [DEL research agenda, including] national, [ADD regional and international] research and development priorities, [ADD to develop effective and appropriate health tools that meet the needs of all people, with specific consideration given to people in vulnerable situations and to historically neglected communities, with a central role for WHO.] [ADD inter-crisis and] during pandemic emergencies, [DEL as appropriate.]

4. Reference to disclosing disaggregated information by gender and age has been lost and should be reinstated

The Zero Draft included an obligation to disclose disaggregated information from clinical trials by gender and age. This has been replaced with a broader equity within clinical trials point (9.10d)[6]. This is important and should remain, with the reinstatement of disaggregated data reporting obligation.

DRAFTING SUGGESTION:

REINSTATE FROM ZERO DRAFT [ADD 9.9 e) Disclose disaggregated information, for instance by gender and age, to the extent possible and as appropriate, on the results of clinical research and clinical trials relating to pandemic prevention, response and recovery]

5. Transparency obligations have been weakened

The Zero Draft included obligations to disclose information on public funding for R&D including publications and reporting of patents and obligations to mandate and encourage public and private manufacturers to disclose prices and contractual terms for public procurement. Reference to this has been deleted in the Bureau Draft and should be reinstated.

[6] 9.10d) 'Ensure that clinical trials conducted during health emergencies are equitable, address geographic, socioeconomic and health disparities and promote racial, ethnic and gender diversity for better understanding of the safety and efficacy of new vaccines and treatments in subgroups of the population.'

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Recommendations for Article 11: Co-Development and transfer of technology and know-how

1. Option 11.A should be adopted and strengthened

Option 11.A provides more specific obligations while Option 11.B provides limited obligations for State Parties, including any additional obligations that did not already exist for COVID-19.

2. Option 11A should be strengthened to include inter-pandemic obligations and obligations related to 'co-development' as referenced in Article 11 title to enable a faster and more efficient response during pandemics.

Co-development is only considered in the title of Article 11 with no associated provisions. Response to pandemics will be more efficient if pandemic-related products are co-developed and not just transferred after development to developing countries manufacturers. This means there should be mechanisms to promote the testing and validation of pandemic-related products in collaboration with developing countries developers and manufacturers (based on affordable and equitable access and benefit sharing terms) and provisions linked to Article 9 on Research and Development.

DRAFTING SUGGESTION:

11.2 The Parties, working through the Conference of the Parties, shall strengthen existing and develop innovative multilateral mechanisms, including through the pooling of knowledge, intellectual property and data, that promote [ADD collaboration and] relevant transfer of technology and know-how for [ADD co-development with, and] production of pandemic-related products, on mutually agreed terms as appropriate, to manufacturers, particularly in developing countries.

3. Obligations should be strengthened to 'require' and 'as appropriate' should be removed in Article 11.4c

Entities, including manufacturers, that receive significant 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.

DRAFTING SUGGESTION:

11.4 (c) [Encourage DEL] [ADD REQUIRE] entities, including manufacturers within their respective jurisdictions, that conduct research and development of pre-pandemic and pandemic-related products, in particular those that receive significant public financing for that purpose, to grant, on mutually agreed terms [as appropriate DEL], [ADD NON-EXCLUSIVE] licenses to manufacturers, notably from developing

countries, to use their intellectual property and other protected substances, products, technology, know-how, information and knowledge used in the process of pandemic response product research, development and production, in particular for pre-pandemic and pandemic-related products;

4. Obligations to support time-bound waivers of intellectual property rights should remain (11.5a)

In case of 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.

5. Obligations to require patent holders, on receipt of public funding, to grant royalty free or royalty bearing licenses to developing country manufacturers should remain (11.5c)

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 inter-pandemic times via conditions on public funding agreements.

In case of pandemic, other holders of patents should also be required, as appropriate, to grant non-exclusive licenses in exchange for payment of reasonable royalties.

DRAFTING SUGGESTION:

11.5c) [ADD Require, where appropriate,] [encourage DEL] all holders of patents related to the production of pandemic-related products to waive, or manage as appropriate, payment of royalties by developing country manufacturers on the use, during the pandemic, of their technology for production of pandemic-related products, and shall require, as appropriate, those that have received public financing for the development of pandemic-related products to do so, [ADD via conditions in funding agreements];

6. Obligation to prevent trade agreements from influencing State Parties' ability to implement TRIPS flexibilities should remain (11.6).

It is important that the use of TRIPS flexibilities is not hampered by bilateral or regional trade or investment agreements, whether in case of pandemics or during interpandemic times.

7. Obligation for Member States to review national laws to incorporate TRIPS Flexibilities should be included from Member State proposals

In case of pandemics, State Parties should be able to make expeditious use of TRIPS flexibilities and should have national laws which would enable them to act quickly. A new provision, based on many Member State proposals[7], should be included to obligate State Parties to review and revise national laws to ensure public health measures can be utilized in times of pandemics.

7

From consolidated proposal document Article 7.3C:
[(c) bis make the best effort to adjust their national legislation to adapt to the full utilization of flexibilities, including compulsory licensing, as contained in the Doha Declaration on the TRIPS Agreement and Public Health of 2001; and IDN]
[(c) bis shall review and amend their national legislation to adapt to the full utilization of flexibilities, including compulsory licensing, as contained in the Doha Declaration on the TRIPS Agreement and Public Health of 2001; and NAM]

[ALT 3 (C) States Parties shall provide, in their intellectual property laws and related laws and regulations, exemptions and limitations to the exclusive rights of intellectual property holders to facilitate the manufacture, export and import of the required health products, including their materials and components. AFR GROUP]

Recommendations for Article 14. Regulatory strengthening

DNDi supports the inclusion of regulatory strengthening mechanisms for PPR under a separate article, underpinning the importance of efficient regulatory approaches to ensure the timely introduction of safe medical countermeasures during a pandemic. We also support and appreciate the inclusion on requiring transparency and information availability of national/regional regulatory processes. Our recommendations focus on how the draft could be strengthened to support regulatory functions and processes.

1. Promoting joint reviews to expedite the regulatory approval process

Joint reviews of regulatory dossiers will maximize opportunities for cooperation between countries and can help optimize review timelines by allowing regulatory authorities to share data, validate findings and streamline communications with the applicant, thereby expediting market access to the health tools developed.

DRAFTING SUGGESTION ARTICLE 14.1

The Parties shall align and, where possible, harmonise technical and regulatory requirements, and procedures, [ADD] at international, regional and national levels and promote and facilitate the use of regulatory reliance, mutual recognition [ADD] and joint reviews, use common technical documents, share relevant information and assessments concerning quality, safety and efficacy of pandemic-related products, including after regulatory approvals are granted.

2. Promote filing of regulatory approvals in endemic countries

To ensure timely global access to health tools developed, manufacturers must seek regulatory approvals or authorizations beyond high-income countries, particularly in developing countries where transmission is high and clinical trials have been conducted, to ensure fair and equitable access to the fruits of research.

DRAFTING SUGGESTION ARTICLE 14.6

Each Party shall, in accordance with national laws, encourage manufacturers, as appropriate, to generate relevant data and diligently pursue regulatory authorizations and/or approvals of pandemic-related products [ADD] including priority submissions for regulatory approvals in developing countries with high transmission and which participated in clinical trials, with WHO listed authorities, regional reference authorities, other priority authorities, and WHO.

3. Expanding the role of regulatory authorities to clinical trial approvals

The role of regulatory authorities extends beyond regulatory approvals for market-ready health tools. Conduct of clinical trials requires approvals from regulatory authorities and ethics committees as well. Regulatory authorities and ethics committees, working in a coordinated way to grant approvals, especially during a public health emergency, will speed up the conduct of clinical trials.

DRAFTING SUGGESTION [NEW POINT]

[ADD] Support the coordination and cooperation of regional and national regulatory authorities and ethics committee for clinical trial approval processes and oversight.