

## **DNDi comments on Proposal for the WHO Pandemic Agreement**

### **Recommendations for Article 9: Research and Development – April 2024**

*The Drugs for Neglected Diseases initiative (DNDi) is a not-for-profit research and development (R&D) organization, in official relations with the WHO, 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, Médecins Sans Frontières (MSF), and WHO TDR, 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. Furthermore, DNDi, in partnership with the World Health Organization (WHO), jointly established the Global Antibiotic Research and Development Partnership (GARDP), now an independent organization playing an essential role in its work with Member States to deliver on the Global Action Plan on Antimicrobial Resistance. DNDi is also a member of the Global Accelerator for Pediatric Formulations Network (GAP-f), which promotes innovation of and access to quality, safe, efficacious, and affordable medicines for children.*

**This briefing sets out DNDi’s comments and recommendations for the Proposal for the WHO Pandemic Agreement circulated by the INB Bureau on April 18.** A textual comparison of the Proposal text and the previous negotiating text (March 2024) for Article 9 on research and development is presented on Page 6.

### **Summary of key points**

#### **1. Art 9.4 Conditions on public funding**

- We welcome the retention and strengthening of the previous provision 9.6 (now 9.4) on conditions on public funding of R&D.
- It is positive that the new text contains a clear obligation, to ‘ensure’, the inclusion of conditions in public-funding R&D agreements and clarifies that this obligation applies to both preparation and response by deleting language limiting its application to ‘during public health emergencies of international concern and pandemics’.
- However, the obligation on conditions is now reduced and qualified ‘as appropriate’ rather than a straightforward obligation. This qualifier should be removed.
- While listing the specific types of conditions that may be applied continues to be a positive advancement, these are not mandatory and should be obligatory.
- While the inclusion in 9.4(ii) of conditions on affordable pricing is positive, this could be further clarified by changing ‘policies’ to ‘commitments’.
- One critical condition is missing: the retention of rights by funders.
- The definition of funding types should be expanded. Obligations should apply to licensing of government-owned technology as well as public-funding R&D agreements.
- The term ‘government funding’ should be changed to ‘public funding’.

- The obligation to publish terms of public-funding R&D agreements is limited to the publication of ‘*relevant*’ terms. This limitation should be removed.
- We welcome the deletion of the limitations on the obligation to publish terms and conditions of public-funding R&D agreements ‘during a pandemic emergency’. These edits should be retained.
- Ensure retention of conditions on all aspects of the end-to-end development, production, and supply of pandemic-related products and ensure the effectiveness of the scope of conditions and how they will be triggered throughout Articles 9, 11, 12 and 13.

**2. Clinical trials: The new text fails to reinstate key provisions on clinical trials, including access to comparator health tools and post-clinical trial access.**

**3. Conditions on public funding should apply end to end.** References to conditions which were reflected in various articles of the previous draft (9.6a, 11.1c, 13bis) have been weakened or deleted:

- The obligation in art 11.1c to make available **licenses**, on a non-exclusive, for government-owned pandemic-related products has been moved and reduced to licensing on mutually agreed terms in the new art 11.a.
- The obligation in art 13bis2 to include **provisions in government-funded purchase agreements** for pandemic-related products has been deleted.

**4. Art 9.1, states that Parties shall collaborate to strengthen R&D; however, the new text in art 9.2 omits the breadth of knowledge and the areas in which researchers should participate by attempting to synthesize elements of these provisions, including:**

- Equitable access to research knowledge, evidence synthesis, knowledge translation, and evidence-based communication tools, strategies and partnerships;
- Innovative research and development, including community-led and cross-sector collaboration;
- Access for scientists and researchers, particularly from developing countries, to relevant international scientific research programmes, projects, and partnerships; and
- The sharing of information on national research agendas, capacity-building activities, and research and development priorities during pandemic emergencies.

## Comments and analysis on Article 9

### 1. Art 9.4 Conditions on public funding

**We welcome the retention and strengthening of the previous provision 9.6 (now 9.4) on conditions on public funding:**

- The new text strengthens the provision** through a clear obligation to ‘ensure’ the inclusion of conditions in public-funding R&D agreements for development of pandemic-related health products. These edits should be retained.
- The new wording also makes it clear that the provision applies to both preparation and response.** We welcome the drafting of the current text and the deletion of the language from the previous text which limited the provision to promote equitable access ‘during public health emergencies of international concern and pandemics’, reducing ambiguity and making clearer that the provision applies to both preparedness and response, including the development of and access to new health tools – a key element of preparedness. This reflects the reality of how R&D is practically conducted, with different funders within and across countries/regions funding different R&D stages.

- iii. **The obligation on conditions is limited to ‘include, as appropriate, provisions’ rather than a straightforward obligation.** The reference to ‘as appropriate’ opens the possibility that conditions will be included only if deemed appropriate and could lead to ambiguity and a lack of consistency in interpretation and implementation. This phrase should be removed to clarify that conditions that promote timely and equitable access should be included in **all public R&D finding agreements**. The addition of ‘as appropriate’ is unnecessary and confuses two things: 1) the obligation in the Agreement, which should apply to all public R&D agreements; and 2) the implementation of this obligation at the national or regional level, where the appropriate provisions for the actual R&D stage and type of agreement should be included.
- iv. **While the list specifying the of types of conditions is a positive advancement, these are not mandatory and should be obligatory:** art 9.4 includes a list of what conditions may be included, such as those on licensing, affordable pricing policies, technology transfer, publication, and allocation. This is important, as lack of agreement on the nature of required conditions will create incoherence between funders, leaving potential gaps and limitations in implementation to ensure acceleration of research, development, and access. However, the conditions are not obligatory, as indicated by ‘may include’. **The types of conditions to be included should be made mandatory.** While the specific way in which these obligations will be implemented will depend on the stage of research being funded and guided by domestic implementation of the WHO CA+, there are key elements which should be included in order to align expectations and guidance to State Parties for implementation on baseline terms, with backstop powers if those terms are not adhered to.
- v. **While the inclusion in 9.4(ii) of conditions on affordable pricing is positive, this could be further clarified by changing ‘policies’ to ‘commitments’** to make clear that this is intended to be a specific commitment that the products developed with public funding will be affordable, rather than an outline only of policies to do so, which may or may not be applied.
- vi. **One critical condition – the retention of rights by funders – is missing.** To ensure that the public funder secures the right to act (whether secured through retaining direct ownership of key knowledge or the ability to have a license back) if there is inadequate performance by the funding recipient, or an inability to abide by the terms set to ensure affordable access. Member States need the ability to take action via this backstop power to ensure that the development can continue or that affordable and equitable access can be ensured. **Without retaining these rights in the first place, this will not be possible.**
- vii. **The definition of funding types should be expanded. Obligations should apply to licensing of government-owned technology as well as public-funding R&D agreements.** In addition to directly funding R&D, governments also license technology that they own and therefore have the potential to include access conditions in these agreements, as well as conditions that give them the rights to take control if access conditions are not met or if certain triggers are reached (for example, during an emergency).
- viii. **The term ‘government funding’ should be changed to ‘public funding’.** The term public funding is clearer because there could be instances where there is no direct government funding but where public funds are used. For example, via public research institutions and not directly via a government department.
- ix. **We welcome the retention of the previous provision 9.6b (now included in 9.4) on the obligation to publish the terms of government-funded research and development agreements, however the obligation is reduced to ‘relevant terms’** rather than a straightforward obligation to share the terms. This leaves the definition of ‘relevant terms’ open to interpretation by and at the discretion of

individual Parties, risking minimal or inconsistent publication, limiting accountability to the commitments, and undermining the purpose and utility of this obligation.

- x. **We welcome the scope expansion of the obligation to publish terms of public funding agreements to ensure preparedness.** In the previous version of the text, the provision's scope was narrowed to apply only 'during a pandemic emergency'.

## **2. Ensure conditions apply on all aspects of the end-to-end development, production, and supply of products and address the effectiveness of the scope of conditions and how they will be triggered throughout Articles 9, 11, 12 and 13.**

Conditions on public funding should apply end to end, not just for the development stage but also in licensing agreements for production of government-owned technologies and procurement contracts for end products. This is not the case in the new text. References to conditions which were reflected in various articles of the previous draft (9.6a, 11.1c, 13bis) have been weakened or deleted:

- The obligation in art 11.1c to 'make available licenses, on a non-exclusive, worldwide and transparent basis and for the benefit of developing countries, for government-owned pandemic-related products' has been moved and reduced to licensing on mutually agreed terms in the new art 11.a 'promote and otherwise facilitate or incentivize the transfer of technology and know-how for pandemic-related health products, in particular for the benefit of developing countries and for technologies that have received public funding for their development, through a variety of measures such as licensing, on mutually agreed terms'.
- The obligation in art 13bis2 to 'include provisions in government-funded purchase agreements for pandemic-related products that promote timely and equitable global access to such products' has been deleted.

These obligations should be reinstated and remain throughout the development and access continuum. This is important because each addresses different activities at different stages; inclusion in one stage does not negate the need for inclusion in another. For example, the need to include such provisions for the development of new health tools in R&D funding agreements in new art 9.4 does not replace the need to include a reference to conditions on technology transfer, licensing, and affordability to support production, procurement, and supply of successfully developed health tools.

The linkages and coherence between Articles 9, 10 and 11 need to be clearly considered and referenced in the text to support efficient and effective implementation by the Parties.

## **3. Clinical trials: Art 9.3 has deleted the majority of clinical trial provisions. Key provisions should be reinstated.**

We also share concerns over the deletion of significant portions of the previous version of the text in Article 9.3. Only the general provision to strengthen coordination by developing and sustaining clinical trial capacities and networks, and facilitating the rapid reporting of clinical trial data has remained (new art 9.3).

Key elements should be reinstated, and at a minimum include important provisions such as:

- **Reinstate old art 9.3(d) ii post-trial access:** Given that patients and affected communities play critical roles in contributing to clinical research, it is important to ensure the sharing of the research outputs and post-trial access to medical products.

- **Reinstate old art 9.3(h) Access to comparator products needed for clinical trials:** Originator companies have declined to provide access to relevant drugs for research purposes, for example for use in combination studies in low- and middle-income countries. Critically important public health research questions must be answered quickly during a pandemic, especially to determine optimal use of drugs, diagnostics, and vaccines in resource-limited settings. Covid-19 also highlighted barriers faced by generics and biosimilars companies in accessing originator products for reference products needed to conduct the necessary bioequivalence studies for regulatory approval, resulting in unnecessary delays and costs. The provisions for access to comparator drugs, tests, vaccines, or assays needed for clinical trials to develop or compare technologies should be reinstated.

#### **4. Provision to strengthen R&D Art 9.1**

**The obligation to collaborate to strengthen R&D is retained in the new art 9.1; however, the new text in art 9.2 omits the breadth of knowledge and the areas in which researchers should participate by attempting to synthesize elements of these provisions, including:**

- Equitable access to research knowledge, evidence synthesis, knowledge translation and evidence-based communication tools, strategies, and partnerships;
- Innovative research and development, including community-led and cross-sector collaboration;
- Access for scientists and researchers, particularly from developing countries, to relevant international scientific research programmes, projects, and partnerships; and
- The sharing of information on national research agendas, capacity-building activities, and research and development priorities during pandemic emergencies.

## Textual comparison: REVISED Draft of the negotiating text of the WHO Pandemic Agreement (March 2024) vs Proposal for the WHO Pandemic Agreement (April 2024)

### Art 9. Research and development

1. The Parties shall cooperate to build, strengthen and sustain ~~national, regional and international~~ **geographically diverse** capacities and institutions for research and development, particularly in developing countries, **based on a shared agenda**, [and shall promote scientific collaboration for the rapid sharing of information and access to research results and outcomes, including through open science approaches] ~~(reordered)~~. , **especially during pandemics**
2. To this end, the Parties shall promote, ~~within means and resources at their disposal~~:
  - a. ~~sustained investment in research and development for public health priorities, including for pandemic-related products, and support for research institutions and networks that can rapidly adapt and respond to research and development needs in the event of a pandemic emergency~~
  - b. ~~technology co-creation and joint venture initiatives that engage the participation of, and international collaboration among, scientists and/or research centres, particularly from developing countries, including from the public and, as appropriate, private sector; actively engaging the participation of scientists and/or research centres from developing countries.~~
  - c. ~~innovative research and development, including community-led and cross-sector collaboration, for addressing pathogens with pandemic potential;~~
  - d. ~~equitable access to research knowledge, evidence synthesis, knowledge translation and evidence-based communication tools, strategies and partnerships, relating to pandemic prevention, preparedness and response;~~
  - e. ~~capacity-building programmes, projects and partnerships, and substantial and sustained support for all phases of research and development, including basic and applied research, such as early-stage research, product discovery, pre-clinical and translational research;~~
  - f. ~~international collaboration and coordination, including with the private sector, to set common objectives, research goals and priorities, to develop pandemic-related products for diverse populations and settings, with a central role for WHO;~~
  - g. ~~access for scientists and researchers, particularly from developing countries, to relevant international scientific research programmes, projects and partnerships, including those referred to in this Article, as well as scientific publications;~~
  - h. ~~the sharing of information on national research agendas, capacity-building activities, and research and development priorities during pandemic emergencies; and~~
  - i. ~~research on the causes and effects of pandemics, on their prevention and management, including: (1) the epidemiology of emerging diseases, factors driving disease spillover or emergence, and behavioural science; (2) public health and social interventions used to control pandemics and their effect on the spread of disease and the burden imposed by these measures on society, including its economic cost; and (3) relevant health products, with the aim of promoting equitable access, including their timely availability, affordability and quality.~~
  - j. ~~(new d) participation of relevant stakeholders, consistent with applicable biosafety and biosecurity obligations, laws, regulations and guidance, to accelerate innovative research and development.~~

3. The Parties shall, in accordance with national circumstances and mindful of relevant international standards **and obligations**, take steps to strengthen international coordination and collaboration to support well-designed and well-implemented clinical trials, by developing, strengthening and sustaining clinical trial capacities and research networks at the national, regional and international levels, **and facilitating the rapid reporting and interpretation of data from such trials.**

~~4. The Parties shall 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 trial guidelines, including during a pandemic. Moved to paragraph 3.~~

~~5. Each Party shall, in accordance with national law, support the transparent and public sharing of research inputs and outputs from research and development of government-funded pandemic-related products, including scientific publications with data shared and stored securely.~~

~~6. (New 4) Each Party shall develop national policies to: ensure that~~

~~(a) include provisions in government-funded research and development agreements for the development of pandemic-related health products include, as appropriate, provisions that promote timely and equitable global access to such products and shall publish the relevant terms. during public health emergencies of international concern and pandemics.~~ Such provisions may include: (i) licensing and/or sublicensing, preferably on a non-exclusive basis; (ii) affordable pricing policies; (iii) technology transfer on **voluntary mutually agreed** terms; (iv) publication of relevant information on research inputs and outputs; and/or (v) adherence to product allocation frameworks adopted by WHO; **and**

~~(b) publish relevant terms of government-funded research and development agreements promoting equitable and timely access to such products during a pandemic emergency. (moved to previous 6.a)~~