

DNDi comments on Proposal for Negotiating Text
Recommendations for Article 9: Research and Development
February 2024

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 don’t think this additional qualifier is helpful as its implementation will be open to interpretation and does not provide legal clarity. Additionally, obligations *can* be attached to funding regardless of how much of the overall project a funder is funding, as in the case of the US NIH Policy for Data Management and Sharing (DMS, 2023¹). Suggest **deleting references to significant** whenever they appear next to public funding (throughout articles 9-14).

Below are specific comments and analysis on Article 9

9.1. The chapeau provision (9.1²) has been refined to make clearer that R&D provisions should apply to prevention and preparedness - and not only response to pandemics. This clarification should remain - with edits - to ensure the needed broad scope.

The clarified chapeau will ensure that the obligations in the rest of Article 9 are interpreted to be applicable to preventing and preparing for pandemics, in addition to responding to emergencies when a pandemic hits. The language in the chapeau could be further strengthened by replacing the word ‘pandemics’ with ‘outbreaks caused by pathogen of pandemic potential’ to further clarify that the scope is broader than response.

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 To prevent, prepare for and enable a rapid, effective and equitable response to pandemics, the Parties shall cooperate to build, strengthen and sustain national, regional and international capacities and institutions for research and development (R&D), particularly in developing countries, and shall promote scientific collaboration for the rapid sharing of information and access to research results, including through open science approaches

R&D activities are critical to being prepared so that health tools can then be rapidly developed to respond. For example, being prepared will require early-stage research to work on different potential treatments, antiviral families, and vaccines targeting different types of diseases and pathogens. 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 be tested in further clinical development against the specific pathogen in the event of a future pandemic. This is what is called ‘phase 2 ready’.

This is why it is important to ensure that any investments and activities both cover this early stage research and are sustainable throughout non-pandemic periods as well as when a pandemic hits and why the aim of Article 9 provisions should explicitly include all aspects of PPR and cover pathogens with pandemic potential.

Additionally, 9.1 should be expanded to make clear that the purpose of research collaboration is to share information and access to results, and also that collaboration is needed for the development of the products so that time and cost of development is reduced and access aims embedded.

9.2. 9.2 has been restructured to clearly include general R&D provisions in addition to 9.3 on clinical trials. This provides much needed clarity and additional important provisions across the R&D lifecycle and these additions should be should be retained. However the chapeau could be strengthened.

9.2 chapeau to reflect that of 9.3 with more binding obligations

It is noticeable that 9.3 on clinical trials includes binding provisions when 9.2 on research needs more broadly do not. 9.2 chapeau could mirror that of 9.3 on clinical trials to go beyond ‘promoting’.

9.2(a) The obligation to invest in research and development linked to public health priorities (9.2(a)³) 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 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 reference to investment linked to public health priorities (the creation of which is referenced in 9.2(f)) should remain.

³ 9.2(a) sustained investment in R&D for public health and clinical priorities, including for pandemic-related products, and support for research institutions and networks that can rapidly adapt and respond to R&D needs in the event of a pandemic emergency

9.2(e) The addition of a specific provision on early stage research (9.2(e)⁴) is important and should be retained.

Previous texts focused on downstream R&D – such as clinical trials and there were no provisions relating to early-stage R&D activities, including discovery research, where investments and collaboration are needed for preparation and to ensure an end-to-end approach. This addition should be retained.

9.2(f) The addition of priority setting provision (9.2(f)⁵) is important and should be retained.

Previous texts did not include any reference to priority setting. The text now includes 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 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.

The current provision 9.3(h) on sharing of national research agendas is not sufficient to ensure that research priorities ensure the above and therefore this new provision 9.2(f) is important and should be retained.

9.3. Clinical trial provisions are now more streamlined, with clear obligations and additions including on access to comparator products and post-trial access which should be retained. However, references to disclosing disaggregated data by gender and age should be reinstated.

9.3(d) ii The new provision post-trial access⁶ to products is important and should be retained.

Given that patients and affected communities play critical roles in contributing to clinical research, it is important to ensure benefit sharing of the research outputs and post-trial access to medical products.

9.3 (f) Obligations for the transparent and rapid reporting of clinical research and trial results⁷ should be retained

Transparency and timely publication of clinical trial protocols and results (both positive and negative) is critical for the harmonization of protocols/comparisons and coordination of treatment guidelines.

⁴ 9.2(e) capacity-building programmes and partnerships for R&D, including early-stage research, such as discovery, pre-clinical, and translational research;

⁵ 9.2(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 diverse settings, with a central role for WHO;

⁶ 9.3(d)ii access to safe, effective, and quality assured interventions or products developed for the population or community in which the research is carried out;

⁷ 9.3(f) developing national policies to support the transparent, public sharing of clinical trial protocols and results conducted either within their territories or through partnerships with other Parties, such as through open access publications, while protecting privacy and health identifiers

Transparency can be enhanced through requirements to include this information in publicly available registers, such as ClinicalTrials.gov (NIH) and the Pan-African clinical trial registry, and can be obligated via conditions in funding agreements.

9.3(g) Obligation for disaggregated data reporting should be reinstated.

The Zero Draft included an obligation to disclose disaggregated information from clinical trials by gender and age. This is important in order to improve equity and understanding of health outcomes between populations and could be added to 9.3(g).

9.3(h) The new provision on access to comparator products needed for clinical trials⁸ is important and should be retained.

COVID-19 has 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. Originator companies have also 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. Therefore, the provision for access to comparator drugs, tests, vaccines, or assays needed for clinical trials in order to develop or compare technologies should remain.

9.4. Restructuring provisions on sharing of research inputs, outputs, and processes from publicly funded R&D has made the article clearer and should be retained. Text edits are provided below if detailed definitions are required.

It may be helpful to provide clarity on the details of research inputs, outputs and processes. A suggestion of such could be:

- **Inputs:** including specimens, samples, compound libraires, and datasets with appropriate data protections
- **Processes:** including protocols, clinical trial design, and R&D costs
- **Outputs:** including clinical trial results, open access publications, and data sharing

9.5. The reinstatement of the provision to attach conditions on public funding of R&D is important and welcome and should be retained with additional detail.

It is promising that a specific obligation to attach access conditions to public funding has been reinstated and provides a basis for negotiations as an area of potential bridge building and consensus. A specific obligation was present in the zero draft but then removed, and its reinstatement as a starting point for

⁸ 9.3(h) promoting access to comparator products needed for clinical trials, to allow for rapid development and comparison of products and technologies.

negotiations has support from a wide range of Member States. However, more detail is needed on the scope and nature of the obligations.

General case for inclusion of conditions:

- a) **Conditions can ensure efficient development and equitable access:** Attaching conditions is not a novel concept, but it is not yet universally applied. As an organization that conducts R&D in the public interest, we have experience of working with different funders at different stages of the R&D process to successfully apply access conditions throughout so that health tools can be developed and are available and affordable for all those that 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 barriers to development and equitable access, and provide clarity to all R&D stakeholders on what is expected in return for public investment.

- b) **Aligned expectations:** The benefit of agreement in the WHO CA+ is that it provides an opportunity to ensure aligned understanding with all players involved, including industrial partners, about what access conditions mean for them and what they will need to manage in advance and doesn't take away ability to make commercial returns. Instead, it is providing certainty both to countries and to R&D players. If the funding recipient is doing what is required to ensure access and follow on innovation, then there doesn't need to be any further intervention. Conditions seek to ensure that the expectations are set up-front, and provide a backstop to enable action if those expectations are not met.

What is needed to provide clarity to the provision 9.5(a):

1. Widen the scope of the general obligation to include:

- a. **Application of conditions to the development of health tools, in addition to equitable access:** This is important to ensure that there are no roadblocks in the development of health tools in addition to ensuring access to developed health tools during health emergencies. For example, 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. Conditions can ensure that there is a way to continue research quickly or hand it over to someone else to develop it further. It is likely to be different companies or organizations involved in different stages so there must be conditions to ensure access to all the knowledge necessary to avoid duplication and ensure fast development.
- b. **Conditions are applied to funding for R&D to cover preparatory, prevention and response R&D:** Note these suggestions effectiveness depend on the definition of pandemic related products in Chapter I. This definition should remain broad to include pathogens of pandemic potential so that the scope of this article (and others) will cover funding for both preparatory, prevention and

response R&D so that practically provisions apply to R&D preparation activities. However, if the scope of the definition is reduced or specific articles are limited to pandemic and/emergency use, then the scope of Art 9 needs to be explicitly broadened to ensure that it applies to funding for preparation, prevention and response to pandemics, PHEIC, and local outbreaks of epidemic or pandemic prone diseases.

These drafting suggestions would cover the following types of funding:

- Direct PPR funding for e.g. priority pathogens of epidemic potential WHO lists or other lists;
- Direct funding for PPR disease X or broad spectrum action;
- This will not cover funding for diseases not specific to pandemics. However, if a product becomes of use in an outbreak then this will likely need public money to take it forward into more trials and therefore now comes under PPR funding;
- Any licensing out of (direct or subsequently found useful for) PPR products from public research institutions;
- Note this article could be expanded to cover funding for advanced purchase agreements and other procurement agreements if the definition was widened to include ‘public funded agreements’ and not only for ‘R&D agreements’, depending on what is covered in other articles (mainly 10, 11,13).

- 2. Increased level of detail:** The new provision provides a general obligation to include conditions, however it does not contain any specific obligations about the type or scope of conditions that are needed. Currently, the text (via 9.5b) only provides a detailed list of conditions that could be *published*, rather than what conditions should be attached in the first place. This needs to be rebalanced, as was the case in the zero draft⁹. 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 and backstop powers if those terms are not adhered to.

For example, a critical aspect is to ensure that the public funder secures the right to take action (whether that is 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 this backstop power to be able to make sure that the development can continue, or that affordable and equitable access can be ensured. Without retaining the rights in the first place this will not be possible.

⁹ ZERO DRAFT 9.2(e) establish appropriate conditions for publicly funded research and development, **including on distributed manufacturing, licensing, technology transfer and pricing policies.**

Other conditions needed include affordable pricing of products (the specific ways to do so will be agreed in each funding agreement), provisions for licensing (preferably on a non-exclusive basis), promoting tech transfer, publication of research information, adherence to allocation frameworks as determined by the WHO CA+, and other terms which are triggered in a PHEIC/pandemic such as non-exclusive licensing and specific provisions on transfer of relevant technology and know-how. Without agreement on the nature of the conditions needed there will not be coherence between funders, leaving potential gaps and limitations on implementation to ensure acceleration of research, development and access.

3. **Change government funding to public funding:** It is clearer to use the term public funding, not government funding, because there could be times where it is not direct government funding but still using public funds. For example, via public research institutions and not directly via a government department.
4. **9.5 (a) and 9.5 (b) are both necessary:** Both a separate provision on conditions and an obligation to publish contract terms (now 9.5(b)), are needed and both should be retained. Publication alone 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.