People's Vaccine Alliance Comments on

The Zero Draft of the WHO CA+ for the Consideration of the INB

General comments

We welcome the fact that the zero draft contains key principles for achieving a better and more equitable PPR framework, addressing critical issues on access to technologies. However, the Accord language must require governments to take specific actions to ensure equity, otherwise it would be difficult to implement it in practice. It must include concrete commitments and practical mechanisms, obligations, requirements and enforceable measures, rather than being limited to promotions and encouragements.

Preamble

The Parties to this WHO CA+[1]

Between points 37 and 44, there should be an inclusion of the following:

- Recognizing that the right to health takes priority over intellectual property rights (IPRs) in the event of their conflict.
- Recognizing the provision of the Committee on Economic, Social and Cultural Rights (ESCR), which states that "intellectual property rights are not human rights, but a social product and have a social function. Thus, States parties have a duty to prevent intellectual property and patent law regimes from undermining the enjoyment of economic, social and cultural rights" (GC, No. 17, 2005, paras. 1, 2 and 35). IPRs must therefore be interpreted and applied in a way that supports the duty of States to protect.

Chapter II. Objective, guiding principles and scope.

Article 4. Guiding principles and rights

Article 4.7 - Accountability

Accountability is mentioned in several places in the text including in para 7 and Article 22. However, the measures to ensure accountability are vague and mainly focused on health systems, reviews, reports, and advice (Para 22).

The Accord should include a clear commitment to ensuring transparency and accountability in decision-making, strategies, planning, implementation, and

[1] https://apps.who.int/gb/inb/pdf_files/inb4/A_INB4_3-en.pdf

monitoring actions. Therefore, the treaty should ensure that all governments and other relevant stakeholders commit to:

1. Making public all information on decision-making processes, strategies, plans, funding, implementation, and impacts, including both positive and negative results. All such information needs to be open to public scrutiny.
2. Enabling civil society to monitor all strategies, plans, funding, and actions.
3. Ensuring the media has open access to all information related to pandemics and potential pandemics.

Articles 4.15 and 4.16 – Precautionary principle

The principle on the role of WHO needs to include that the WHO will be guided by the precautionary principle in health relevant to situations when scientific evidence on health hazards is uncertain and the stakes are high.

Article 4.8 - Common but differentiated responsibilities.

The principle of common but differentiated responsibilities (CBDR) is included in the preamble (paragraph 36) and principles (Article 4.8). However, it is not adequately reflected in the operational provisions.

The Accord should have clear provisions to define critical areas where countries with more capacity commit to helping those with inadequate capacity including:

1. Sharing technology and know-how with developers and producers in low and middle-income countries (LMICs).
2. Financing regional manufacturing capacity via commitments to regional technology and manufacturing hubs such as the WHO mRNA technology transfer hub.
3. Prioritizing funding of R&D that is collaborative between northern and southern scientists and technology developers.
4. Contributing to financing health systems for pandemic preparedness and response (PPR).
5. Contributing to financing procurement of medical countermeasures.
6. Commitment to benefit sharing.

Chapter III. Achieving equity in, for and through pandemic prevention, preparedness, response, and recovery of health systems

Article 6. – Predictable global supply chain and logistics network

Article 6.3 (b) - Map demand and manufacturing capacity:

The text covers complex issues and therefore needs clarity on the measures needed for each issue. Measures to assess and enhance manufacturing capacity in LMICs

should be spelt out. Measures for procurements should empower regional processes instead of taking decision-making and capacity to a central body.

Article 6.3 (c) – Mechanism to ensure the fair and equitable allocation of pandemic-related products.

Establishing a mechanism for ensuring equitable access to medical countermeasures is one of the key elements of the Pandemic Accord.

The mechanism should be based on the lessons learned from COVID-19 and the failure of the Access to COVID-19 Tools Accelerator (ACT-A) to achieve this target. Early in the COVID-19 pandemic (May 2020), WHO launched the Equitable Allocation Framework, which identified the priority groups for medical countermeasures. However, most countries used it at the national level, not between countries. Instead of vaccinating health workers worldwide as per the framework, rich countries vaccinated this group, while nurses in Africa were kept at the back of the queue.

The experience of COVID-19 and other pandemics illustrates that in order to ensure fair allocation, the Accord must include:

1. Obligations on all governments to abide by a fair allocation framework and implement it during pandemics.
2. Obligations that governments do not rely on voluntary actions by producers.
3. Obligations on all parties to invest in regional manufacturing capacity to ensure an adequate supply of products.

The ongoing discussions outside the INB on setting up a Medical Countermeasures Platform risk undermining the INB process by running a parallel one.

Establishing a countermeasures platform should be avoided before INB negotiations on ensuring fair access are completed.

Article 6.3 (d) – Mapping distribution

The Accord should include clear measures to enable regional hubs to have the resources and capacities necessary for a distribution centre.

Article 6. 4 – Export restrictions

Parties commit not to impose regulations that unduly interfere with the trade in, or of, pharmaceutical raw materials and ingredients.

- The commitment needs to be legally binding by including text such as - *The commitment is understood to be legally binding and to apply in all circumstances.*
- This commitment should include finished products.

Article 7. Access to technology: promoting sustainable and equitably distributed production and transfer of technology and know-how

Article 7.1 Manufacturing capacity

Diversified global manufacturing is one of the key elements to ensure equitable access to affordable medical countermeasures. However, sustainable production and supply require investing in national/regional capacity and technology transfer rather than the mere setting up of production sites of pharmaceutical companies, which will continue to determine the supply, price and allocation of medical countermeasures.

This provision should specifically contribute to increasing regional manufacturing capacities by committing the Parties to:

- sharing technology, knowledge and know-how and removing any barriers, including IP barriers, which may hinder it.
- contributing to financial investment in developing manufacturing facilities and workforce.
- promoting collaborative research between researchers and technology developers from the South and North

To ensure the sustainability of newly established facilities, the Accord should commit governments and international and regional agencies to procure medical countermeasures from the new hubs, even if at a higher price in the early stages of manufacturing, to ensure stable demand.

Article 7.2 – Multilateral mechanism for technology and know-how transfer

The Accord rightly recognizes the need to develop multilateral mechanisms for technology and know-how transfer. However, the language used in the zero draft referring to “promotion” and “mutually agreed terms” weakens the provision and may make it more difficult to apply in practice. The Accord should require governments support to technology pooling mechanisms like WHO COVID-19 Technology Access Pool (C-TAP).

The Accord should ensure strong government commitments to enforce the sharing of technology, data and know-how with potential developers and manufacturers in the South. It should specify how the transfer of technology will be facilitated by WHO and WHO Parties.

As the experience of previous and current pandemics has shown, leaving technology sharing in the hands of pharmaceutical companies does not work. Three years into the COVID-19 pandemic, only one company (AstraZeneca) has licensed production to a few companies in the South. In the case of a pandemic, fundamental decisions on production, allocation, price and the sharing of technology and knowledge cannot be left to pharmaceutical companies.

As with diversified manufacturing, this provision should focus on developing the regional and national capabilities of developing countries. If technology transfer is

limited to private sector cooperations, it will have a limited impact on equitable access – these products will still be sold by profit-driven companies to the highest bidders – as was the case during this pandemic.

The Accord should mandate governments to:

1. Prioritize funding for collaborative innovation between scientists in the Global North and South.
2. Mandating sharing of relevant medical technology in their national purchasing contracts of medical countermeasures.
3. Contributing to financing technology transfer according to countries' means.
4. Sharing technology via global pools like C-TAP.

Article 7.3 – Mechanisms for inter-pandemic times

Article 7.3, especially Article 7.3c, should include obligations and requirements for manufacturers, not just incentives and encouragement. This is based on learning from COVID-19, where voluntary mechanisms are often limited, ad hoc and late, leaving all power in the hands of the pharmaceutical companies to set the terms without transparency or accountability.

In Article 7.3a, greater emphasis should be put on WHO Parties' support for regional hubs, including the WHO mRNA hub in South Africa and similar initiatives. The Accord should require collaboration in R&D and financing of the mRNA hubs and spokes and other regional initiatives based on shared technology.

Importantly, this Article should also require multilateral initiatives that fund health technology development, such as CEPI, to prioritize financing of these hubs.

Article 7.3(c) and Article 9.2– Conditionalities on public funding

Articles 7 and 9 contain provisions to increase the sharing of knowledge, technology, and licensing intellectual property rights by attaching conditions to public funding and including appropriate contractual clauses. While these are positive measures, in most cases, the current language is inadequate and unnecessarily vague to achieve these objectives.

Article 7.3(c) discusses among other things, crucial aspects of licensing IP rights to capable manufacturers. However, the commitment of WHO Parties to only "encourage" developers and manufacturers (even if they receive "significant public financing" for R&D of medical countermeasures) to do so significantly weakens this provision and limits its impact. This provision must turn into a commitment by replacing "encourage" with "obligate" companies to share relevant information and rights if they receive public funding.

The qualifiers such as "significant" weaken this provision and make it difficult to apply and, therefore, should be deleted.

In Article 9.2, the terms “taking into account the extent of the public funding received” should be revised to leave less room for interpretation.

While Article 9.2 uses strong wording when it states that “each Party (…) shall”, the subsequent “promote” or “endeavor” used in Articles 9.2(a) and 9.2(b) would significantly weaken the impact of these provisions. Therefore, such wording should be avoided and replaced with committing language such as “guarantee”.

The Accord should develop clear guidelines on how WHO Parties could include these conditions in funding and licensing agreements.

The Accord should also ensure that countries retain the rights to/ownership of publicly (co)funded technologies and products.

Article 7.4(a) – Waivers of intellectual property rights

The current wording regarding the waiver of intellectual property rights does not provide a significant change in the status quo. Using qualifiers or other limiting language such as "appropriate" or "to the extent necessary" would make it difficult to apply this provision in practice. I should therefore be strengthened and made more specific.

The Accord should commit the Parties to waive relevant intellectual property rights in all national and multilateral agreements once a Public Health Emergency of International Concern is declared by the WHO.

The Accord should also explicitly require WHO Parties not to enforce provisions in other agreements that conflict with a Pandemic Accord’s obligation. For example, sharing technology and know-how must precede any obligations to the opposite in other agreements.

Article 7.4(b) – TRIPS flexibilities

This provision should:

1. Commit WHO Parties to prepare their national laws to use non-voluntary sharing of the rights to patents, data, know-how and biological resources needed for pandemic response.
2. Explicitly commit WHO Parties to refrain from obstructing or seeking to dissuade other countries from making full use of existing TRIPS flexibilities.

Provisions related to the management of intellectual property rights should include proposals put forward by the Africa Group to the WGIHR on Article 13a of the IHR.[2]

[2] https://www.keionline.org/38213

Article 8. – Regulatory strengthening

The current draft focuses on harmonization, and coordination and pays little attention to measures to increase regulatory capacity.

The Pandemic Accord should require:

1. Governments to reinforce the role of the WHO pre-qualification scheme, including through fully financing its operations.
2. Governments to invest in the capacity of regional and national regulatory authorities.
3. Regulatory authorities to share dossiers in a transparent manner.
4. Manufacturers to register products in all countries.
5. Government to invest in national post-regulatory processes, such as pharmacovigilance.

The accord needs to include text on clinical trials, especially the rights of participants in clinical trials.

Article 9. – Increasing research and development capacities

Article 9.2(d) raises the important issue of technology co-creation and joint venture initiatives. This provision should, however, include obligations for the Accord parties. The Accord should require:

- All countries to gradually increase their contributions to medical R&D as an agreed % of their GDP[3].
- Governments to prioritize funding for collaborative research between Southern and Northern scientists and scientific institutions.
- Governments to develop mechanisms for coordination and collaboration to increase the effectiveness of joint R&D efforts.

Article 9.3 – Transparency of information on public funding

This Article covers important provisions for improving transparency by imposing certain obligations on the Accord WHO Parties.

Article 9.3(b) should however be significantly strengthened by deleting the reference to *"times of pandemics*". Transparency of public funding must be maintained at a high level in pre-pandemic times, not just in emergencies.

The qualifier "*the extent of the public funding received*". Any public funding of R&D should be subject to strict transparency requirements.

Obligations imposed on those receiving public funding should also include disclosing R&D costs with a breakdown between public and private sources.

[3] For example, in 2017 Senator Bernie Sanders proposed a fund of 0.55% of US GDP to reward researchers and developers for medical innovation for specific health objectives.

To increase trust, accountability, equitable access and improve countries negotiating positions, transparency requirements should be enforced on prices, contractual terms, public procurement, patent information and R&D costs. They should be placed on developers and manufacturers even if they have not received public funding.

The Accord should also include additional relevant provisions on transparency adopted in the WHO resolution on “Improving the transparency of markets for medicines, vaccines, and other health products” (WHA72.8).

Include transparency on clinical trials including protocol, funding sources and amount and all results whether negative or positive or neutral.

Article 9.5. and 9.6 Indentation

The parties commit to refraining from long-term and indefinite indemnification.

Article 10. – WHO Pathogen Access and Benefit-Sharing System

The proposed framework of allocating a percentage of production to WHO is inadequate. Equitable allocation of medical countermeasures cannot be achieved by reserving a 20% of products for 80% of the world’s population.

Product allocation should be based on a therapeutic basis defined by WHO, not by countries’ ability to pay high prices.

Access and benefit-sharing system must include practical measures for sharing pathogens, data, products, and profits from their sale.

The proposed system should mandate WHO Parties to:

1. Sharing technology, knowledge and intellectual property by manufacturers accessing pathogens and data should be mandatory during a pandemic to ensure equitable access to all medical countermeasures during a pandemic as part of any legal agreements on sharing pathogens or their data. This is in addition to in-kind contributions that should be provided by manufacturers to WHO during a pandemic.
2. During the non-pandemic period, manufacturers gaining access to pathogens and data should make monetary contributions to WHO, which should be utilized by WHO for pandemic preparedness and response.
3. Overall that any access to pathogens and related genomic data should be subject to terms and conditions governing their use, including fair and equitable benefit sharing. Such a mechanism should be operationalized at the multilateral level in the WHO and should be discussed and negotiated among WHO Members

Article 16.3. – Engagement of the private sector in decision-making

In Article 16.3, WHO Parties are asked to "promote" the engagement of communities, civil society, and other nonstate groups, including the private sector, in various activities agreed on in the Accord, including its implementation.

This provision should reflect the potential commercial interest of the private sector.

Therefore, the article should require the parties to guard against commercial conflict of interest and undue influence. Transparency on conflict of interest is critical to ensure trust and effective decision-making processes.

People Vaccine Alliance
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