

14 FEBRUARY 2023

**PEOPLE'S
VACCINE
ALLIANCE
COMMENTS
ON THE ZERO
DRAFT OF
THE WHO
CA+**

**CHAPTER III. ACHIEVING EQUITY IN, FOR AND THROUGH PANDEMIC PREVENTION,
PREPAREDNESS, RESPONSE AND RECOVERY OF HEALTH SYSTEMS.**

ARTICLE 7.1

MANUFACTURING CAPACITY

Local manufacturing is one of the key elements to ensure more supplies of affordable access to medical countermeasures. However, this goal needs to clearly spell out specific actions committed by all governments including:

- Commitment to sharing technology and know-how
- Financial investment in developing manufacturing facilities and workforce
- Promoting collaborative research between researchers from the South and North
- Removing IP barriers to sharing technology and knowledge

In that way, governments' commitments would specifically contribute to increasing national manufacturing capacities.

To ensure the sustainability of newly established facilities, the accord should commit governments and international agencies to procure from regional hubs in the South, 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

We welcome the draft acknowledgement of the need for developing multilateral mechanisms for technology and know-how transfer. However, provisions in the current draft need to secure strong government commitments to enforce sharing of technology, data and know-how with potential developers and manufacturers in the South.

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

COVID-19 clearly illustrates that technology transfer and IP sharing left to pharmaceutical companies will have a limited impact on equitable access. COVID-19 products will still be sold by profit-driven companies to the highest bidders. Clearly, this is not the way for the world to control a pandemic.

To make a meaningful difference, the Pandemic Accord should lead to governments in developing countries being in control of the technology, being able to adapt it to local needs and being in charge of distributing the end products.

ARTICLE 7.3

MECHANISMS FOR INTER-PANDEMIC TIMES

Article 7.3, and 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 South Africa mRNA hub 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 request multilateral initiatives that fund health technology development, such as CEPI, to prioritize financing these hubs.

ARTICLE 7.4(A)

WAIVER OF INTELLECTUAL PROPERTY RIGHTS

The current wording on 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.

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

Lastly, the Accord should require that WHO Parties not enforce provisions in other agreements that conflict with a Pandemic Accord's obligation. For example, sharing technology and know-how must take precedents over any obligations to the opposite in other agreements.

ARTICLE 7.4(B)

TRIPS FLEXIBILITIES

The Pandemic Accord should also commit WHO Parties to prepare their national laws to be able to use non-voluntary sharing of the rights to patents, data, know-how and biological resources needed for pandemic response.

ARTICLE 8

REGULATORY STRENGTHENING

The current draft focuses on harmonization and coordination but pays little attention to increasing regulatory capacity. The Pandemic Accord should require:

- governments to reinforce the role of the WHO pre-qualification scheme, including through fully financing its operations
- governments to invest in the capacity of regional and national regulatory authorities
- regulatory authorities to share dossiers in a transparent manner
- manufacturers to register products in all countries
- governments to invest in national post-regulatory processes, such as pharmacovigilance

ARTICLE 10

WHO PATHOGEN ACCESS AND BENEFIT-SHARING SYSTEM

The proposed framework of allocating a percentage of production to WHO is inadequate. The Pandemic Accord should require governments /parties to:

- share technology, knowledge and intellectual property to ensure equitable access to all medical countermeasures during a pandemic as part of legal agreements on sharing pathogens
- All parties to commit to sharing the profit made from the technology developed based on sharing pathogens with the countries providing the pathogens
- Parties to use open science to develop products based on the shared pathogen and its data, and digital information
- Parties to base product allocation on therapeutic basis defined by WHO not by countries' ability to pay the highest price allocation of products. The 20% allocation to WHO is not sufficient to provide products for 80% of the world population