

## Supporting Equitable Access to Medicines in the WHO Pandemic Agreement

In 2021, in response to the ongoing COVID-19 pandemic, the United States and Member States of the World Health Organization (WHO) agreed to negotiate a [new international instrument](#) on pandemic preparedness, prevention, and response. The instrument aims to ensure the world is better prepared for future pandemics. A core goal is to prevent the extreme inequity in access to pandemic-related medical tools (including vaccines, diagnostics, treatments, oxygen, and protective equipment) that contributed to [15 million estimated deaths](#) and [\\$13.8 trillion](#) in global economic loss as a result of the COVID-19 pandemic. Over the last two years, Member States have been drafting and negotiating the agreement text with a planned conclusion in May 2024.

There are concurrent efforts to undermine a strong agreement: disinformation and misinformation regarding the role of WHO and of vaccines and, separately, big pharma opposition to the sharing of medical tools and technology. Both efforts contributed to the fractured and unequal COVID-19 pandemic response. Both risk weakening the world's future pandemic readiness and response.

**The Biden administration should support stronger measures for equity and access in the agreement, including to:**

- **Support global access to medical tools developed with public funds;**
- **Share public technology and information needed to make pandemic health tools; and**
- **Support countries that use flexibilities in intellectual property rules to increase access to pandemic-related products.**

### 1) Support global access to medical tools developed with public funds.

Public funding and federal science support the development of many new medicines and vaccines, including those needed to fight pandemics, such as the NIH-Moderna vaccine against COVID-19. Including conditions in the licensing and funding agreements for these technologies can help ensure affordable pricing of end products, adequate and timely supply, and transparency.

For example, the U.S. recently included a “reasonable pricing” provision in a contract with Regeneron Pharmaceuticals to develop a COVID-19 therapy. In exchange for U.S. funding support, Regeneron agreed to limit its U.S. prices. The White House [subsequently announced](#) that fair pricing would become a standard part of contract negotiations under the Administration for Strategic Preparedness and Response (ASPR). These provisions, however, do not protect people outside the U.S.

The [draft pandemic agreement](#) includes a provision (Article 9) to include equitable access conditions in government research and development (R&D) funding agreements. But it excludes agreements to license government-owned technology, and its vague terms may apply weakly and to few circumstances. The U.S. should support strong and specific access terms that apply not only to emergency response, but to pandemic prevention and preparedness, and ensure that in the future, a publicly supported invention like the NIH-Moderna vaccine will not be subject to corporate secrecy, monopoly control, and price gouging. Instead funding conditionalities should help speed the end to pandemics.

## 2) Share public technology and information needed to make pandemic health tools.

Many funders and inventors, both public and private, contributed to the technology used in COVID-19 vaccines. However, during the pandemic, most manufacturers, driven by commercial priorities, kept technology secret or limited transfer to a handful of producers. Facilitating non-exclusive intellectual property (IP) licensing and know-how sharing will help expand global R&D collaboration and the ability to scale up production in an emergency. The U.S. has contributed in this respect more than once by licensing government-owned COVID-19 and HIV technologies to WHO-affiliated technology and patent pools. When the federal government licenses its patents to these multilateral mechanisms, it sets an example for drugmakers to do the same.

The [draft agreement](#) includes provisions on facilitating the sharing of technology, know-how and licenses with pooling mechanisms, but does not specify how (Articles 10 and 11). The agreement should explicitly mention health-focused pooling mechanisms (such as the Medicines Patent Pool and the new WHO Health Technology Access Pool), as well as obligate governments to license to these pools in order to promote open, collaborative research and the expanded, timely, and more affordable production of pandemic-related products. By supporting non-exclusive licensing of government technologies, including to health-focused pools, the U.S. will protect against monopolization of knowledge and of resulting products needed for a future pandemic response.

Additionally, while voluntary sharing via health-focused entities is important, there are also limits to these mechanisms. During the COVID-19 pandemic, pharmaceutical companies showed extreme reluctance to make needed medical tools available to alternative producers, refusing to license to WHO's COVID-19 technology pool and waiting years to negotiate licenses that would facilitate affordable access in too few developing countries. The agreement should acknowledge that when voluntary mechanisms fail, government power can facilitate production and sharing of pandemic-related products, IP, and knowledge. For example, the U.S. routinely allowed the use of third party patents without the authorization of the patent holder to support development and supply of COVID-19 countermeasures. President Biden also recently announced a policy of supporting affordable access to publicly-funded medicines through compulsory licensing of patents (march-in rights).

## 3) Support countries that use flexibilities in intellectual property rules to increase access to pandemic-related products.

The World Trade Organization's (WTO's) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) sets out minimum standards for pharmaceutical patent protection and includes flexibilities that countries can use to safeguard public health and access to medicines. These flexibilities are needed where IP protections create barriers to timely access to medical tools, and drugmakers decline to solve the problem voluntarily. Many countries experience political pressure from drugmakers and wealthy countries inhibiting use of flexibilities. Additionally, many countries may need to adjust domestic laws to provide for the use of flexibilities to increase access to medicines.

The [draft agreement](#) (Article 11) includes provisions on the use of IP flexibilities, such as compulsory licensing, to ensure adequate access to pandemic-related products, and goes further to require that WTO Members should fully respect the use ... [of IP flexibilities] by others." Thus the U.S. should ensure that countries will not be criticized or pressured for updating laws or subsequently using flexibilities to facilitate access to pandemic-related products. Additionally, parties should commit to not seek or enforce more stringent IP protections in bilateral and regional trade agreements that would harm public health and emergency response. Finally, in cases where these safeguards are not sufficient, such as during a global pandemic, temporary waivers to certain intellectual property protections may be needed.

## 4) Reach consensus on pathogen access and benefit sharing.

Sharing of pathogen data, such as genetic sequences and virus samples, is critical to coordinating timely global research efforts and facilitating the expeditious production of effective diagnostics, vaccines and treatments. During the COVID-19 pandemic, despite the sharing of genetic information that enabled production of effective vaccines, these products were not accessible to many.

The proposed pathogen access and benefit sharing (PABS) mechanism in the agreement aims to remedy this by ensuring that sharing of pathogen data also enables equitable access to resulting medical tools. It is therefore key that negotiators agree that the “benefits” in the mechanism refer to more than simply access to pathogen data. Benefits should include the sharing of IP, knowledge, and technology developed on the basis of pathogen access with geographically distributed producers via IP licensing and technology transfer and, separately, allocation of health products pursuant to criteria developed by WHO in a way that encourages earliest access to highest risk populations and ultimately equitable access to all in need. Medical products developed based on pathogen access provisions should be made available on a timely, affordable, and equitable basis to all persons in all countries. Additionally, the draft text concentrates obligations on pathogen sharing while the benefit sharing language is noticeably weaker. The U.S. should support a balance of obligations between pathogen and benefit sharing. Doing so would show that the U.S. values equity commitments alongside pathogen access commitments.

It is necessary to reach meaningful consensus on this point. However, as discussed above, equity provisions across the agreement will be important to adequately ensure global preparation for future pandemic response, including equitable access to pandemic-related health tools. “Trading off” one equitable access provision for another in negotiations will not deliver adequate pandemic preparedness and response. Doing so harms all parties and undermines the aim of the agreement as well as the U.S.’ stated goals for the negotiations. The U.S. has considerable influence and should show leadership in this respect by supporting equity provisions in the proposed PABS mechanism as well as in the other articles discussed above.

## Text suggestions

Select textual suggestions are based on the March 7th draft [text](#).

Suggested changes appear in [blue](#). Suggested additions appear in brackets and deletions appear stricken.

### Article 9. Research and development

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. Each Party shall develop national policies to:

(a) include provisions in government-funded research and development agreements [[and in licensing of government-owned technologies](#)] for the development of pandemic-related products that promote [[affordable,](#)] timely and equitable global access to such products during public health emergencies of international concern and pandemics. Such provisions ~~may~~ [should](#) include: (i) licensing and/or sublicensing, preferably on a non-exclusive basis; (ii) [[affordable pricing of end-products or](#)] affordable pricing policies; (iii) technology [[and know-how](#)] transfer ~~on voluntary terms~~; (iv) publication of relevant information on research inputs and outputs; ~~and/or~~ (v) adherence to product allocation frameworks adopted by WHO; [[\(vi\) retention of rights by the public funder, through ownership or licensing; and/or \(vii\) transparency on pricing, licensing and technology transfer agreements to others, procurement and advance purchasing agreements, and patent and regulatory landscapes](#)] and

(b) publish relevant terms of government-funded research and development [[and licensing](#)] agreements promoting [[affordable,](#)] equitable and timely access to such products during a pandemic emergency.

**Comment: Article 9.6 should support conditions in both government R&D funding agreements and licensing of government-owned technologies, and should specify additional terms useful for access. These terms should cover retention of rights by the public funder, affordability, transfer of technology and know-how during pandemics, and transparency. Additionally, instead of recommending certain conditions, the Agreement should provide for them.**

### Article 10. Sustainable and geographically diversified production

1. The Parties commit to achieving a more equitable geographical distribution and scaling up of the global production of pandemic-related products, and increasing sustainable, timely, fair and equitable access to such products, as well as reducing the potential gap between supply and demand during pandemics.

2. The Parties, in collaboration with WHO and other relevant organizations, shall:

(a) take measures, in cooperation with regional organizations, to provide support, maintain and strengthen production facilities at national and/or regional levels, particularly in developing countries, and to facilitate scaling up of production of pandemic-related products during emergencies, including through promoting and/or incentivizing [[licensing, transfer of technology and know-how and](#)] public and private investment aimed at creating or expanding economically viable manufacturing facilities of relevant health products;

(b) facilitate the continuous and sustainable operations of the facilities referred to in subparagraph 2(a), including through promoting transparency of relevant **unprotected** information on pandemic-related products and raw materials across the value chain;

**Comment: The qualifier “unprotected” unnecessarily narrows the scope of Article 10.2(b). Removing the term more appropriately captures cases where data exclusivity is a barrier to knowledge sharing, including where such knowledge is produced from publicly funded clinical trials. Additionally, as the term is undefined, providing an opportunity for companies to self-define the term or unilaterally impose non-disclosure terms.**

## **Article 11. Transfer of technology and know-how**

1. In order to enable sufficient, sustainable and geographically-diversified production of pandemic-related products each Party, taking into account its national circumstances, shall:

(a) [~~take measures to facilitate, incentivize or require, as necessary,~~ ~~promote and otherwise facilitate or incentivize~~ the transfer of technology and know-how for both pandemic-related and routine health products, including through the use of licensing and collaboration with regional or global technology transfer partnerships and initiatives, and in particular for the benefit of developing countries and for technologies that have received public funding for their development;

(b) [~~require~~ ~~promote~~ the timely publication by private rights holders of the terms of licensing agreements and/or technology transfer agreements for pandemic-related products, in accordance with national laws;

(c) make available licenses, on a non-exclusive, worldwide and transparent basis and for the benefit of developing countries, for government-owned pandemic-related products, and shall publish the terms of these licenses at the earliest reasonable opportunity and in accordance with national laws; and

(d) provide, within its capabilities, support for capacity-building for the transfer of technology and know-how for pandemic-related products.

**Comment: The removal of the previously strong emphasis on “voluntary and mutually agreed terms” in Article 11 is welcome. For example, Article 11.1(a) can now be read to imply both voluntary measures and mandatory measures imposed by governments. However, including mandatory language would clarify that parties may employ compulsory measures to facilitate licensing and compel technology and know-how sharing important for access to pandemic-related products.**

2. The Parties shall develop and strengthen, as appropriate, mechanisms coordinated by WHO with the participation of other relevant technology transfer mechanisms as well as other relevant organizations, to promote and facilitate the transfer of technology and know-how for pandemic-related products to geographically diverse research and development institutes and manufacturers, particularly in developing countries, through the pooling of knowledge, intellectual property, know-how and data to all developing countries. [~~, such as through WHO-affiliated pooling entities, including the WHO Health Technology Access Pool, Medicines Patent Pool, or other pooling mechanism of the pandemic agreement.~~]

**Comment: Specifically mentioning WHO-affiliated pooling entities will clarify that pooling is most supportive of equity when conducted via health-oriented mechanisms with established access and transparency experience.**

3. During pandemics, in addition to the undertakings in paragraph 1 of this Article, each Party shall:

(a) encourage holders of relevant patents [~~and confidential information~~] regarding pandemic-related products, in particular those who received public funding, to forgo or otherwise charge reasonable royalties to developing country manufacturers for the use, during the pandemic, of their technology and know-how for the production of pandemic-related products; and

(b) ~~consider supporting~~ [commit to], within the framework of relevant institutions, time-bound waivers of intellectual property rights to accelerate or scale up the manufacturing of pandemic-related products to the extent necessary to increase the availability and adequacy of affordable pandemic-related products.

**Comment: The U.S. should support a stronger commitment to the timely introduction of waivers when IP poses additional barriers to an expedient pandemic response.**

4. The Parties that are WTO Members recognize that they have the right to use to the full, the flexibilities inherent in the TRIPS Agreement as reiterated in the Doha Declaration on the TRIPS Agreement and Public Health of 2001, which provide flexibility to protect public health including in future pandemics, and shall fully respect the use thereof by others.

5. Each Party shall, ~~as necessary and appropriate~~, review and update its national legislation in order to ensure the implementation of such flexibilities referred to in paragraph 5 in a timely and effective manner.

[6. The Parties shall endeavour to make use of the flexibilities provided in the TRIPS Agreement, and the Doha Declaration on the TRIPS Agreement and Public Health and including but not limited to, Articles 27, 30, 39, 44 and 73 of the TRIPS Agreement, to promote public health and access to medicines, including in future pandemics to ensure access to pandemic-related products.]

[7. The Parties shall, with a view to effective pandemic response, not seek or enforce provisions in bilateral or regional trade or investment negotiations, that interfere with the full use of the flexibilities provided in the TRIPS Agreement.]

**Comment: Listing TRIPS articles clarifies which flexibilities may be useful for pandemic response, and shows that respect for use of flexibilities extends beyond compulsory licensing. The U.S. and other high income countries have a long history of pressuring countries against the use of flexibilities and seeking measures in trade agreements that impede their use. The U.S. can show a commitment to remedy this history by supporting measures in the agreement that will empower national governments to take the steps needed to protect health.**

6 [8]. The WHO Secretariat shall work towards the improvement of access to pandemic-related products, especially during pandemic emergencies, through transfer of technology and know-how, including through cooperation with relevant international organizations.

#### **Article 13bis: National procurement- and distribution-related provisions**

1. Each Party shall publish the terms of its government-funded purchase agreements for pandemic-related products at the earliest reasonable opportunity ~~and in accordance with applicable laws~~, and shall exclude confidentiality provisions that serve to limit such disclosure. Each Party shall also encourage regional and global purchasing mechanisms to do the same.

2. Each Party, ~~in accordance with national laws~~, shall include provisions in government-funded purchase agreements for pandemic-related products that promote timely and equitable global access to such products, such as provisions that:

- (a) permit the donation of such products outside of its territories;
- (b) facilitate potential modifications in order to address supply gaps around the world;
- (c) incentivize or otherwise encourage [or require, as necessary] licensing and other transfer of technology, in particular for the benefit of developing countries; and
- (d) incentivize or otherwise encourage [or require, as necessary] the formulation and sharing of global access plans for the products.

**Comment:** Provisions in procurement agreements, as in R&D funding and government licensing agreements, are key points of government leverage in a pandemic response. This leverage can include reserving the right to require action if necessary. Additionally, the reference here and throughout the text to obligations “in accordance with national laws” limits the potential impact of the provision.