

Backgrounder: Supporting Equitable Access to Medicines in the WHO Pandemic Accord March 12, 2024

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, often referred to as the "pandemic accord", 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 accord text with a planned conclusion in May 2024.

There are concurrent efforts to undermine a strong accord: 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 accord, 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 <u>subsequently announced</u> 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 <u>draft pandemic accord</u> 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 and price gouging, but rather put to broad use to help end 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 <u>draft accord</u> 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 accord should explicitly mention health-focused pooling mechanisms (such as the Medicines Patent Pool (MPP) and the new WHO Health Technology Access Pool), as well as obligate governments to license to these pools in order to promote 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 resulting products needed for a future pandemic response.

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 <u>draft accord</u> (Article 11) includes provisions on the use of IP flexibilities, such as compulsory licensing, to ensure adequate access to pandemic-related products. The accord 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.