Policy Brief

EMPOWERING INNOVATION, ENABLING COLLABORATION: A BLUEPRINT FOR PANDEMIC PREPAREDNESS

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INTRODUCTION

This Policy Brief highlights key lessons from the COVID-19 pandemic response and explains how to incorporate them into the new pandemic preparedness treaty being negotiated by the World Health Organization (WHO) and its member states.

It is crucial to learn the right lessons from the COVID-19 pandemic response.

What worked? Collaboration and innovation by the private sector. The private sector developed and deployed innovative vaccines, treatments, and diagnostics with unprecedented speed, partnering with businesses worldwide to manufacture vast amounts of vaccines and therapeutics quickly.

Effective IP protection gave companies the confidence to engage in widespread voluntary cooperation and technology sharing, take substantial risks, and invest massive resources.

What didn't work as well as it should have? Government coordination and collaboration fell short. Vaccine nationalism, trade barriers, red tape, and other governance failures impeded the timely and equitable distribution of vaccines and treatment. Governments and public institutions played essential roles but have much to learn from where they faltered.

Unfortunately, many treaty proposals focus on fixing what isn't broken. Some aim to weaken IP protections and force technology transfer. Instead, the treaty should focus on bolstering voluntary cooperation and remedying shortcomings in the government-led aspects of the pandemic response.

THE WAY FORWARD

- Improve intergovernmental coordination and capabilities in procurement, distribution, and health infrastructure.
- Remove vaccine supply chain trade barriers and harmonize regulations.
- Bolster voluntary cooperation for innovation and manufacturing through incentives and supportive policies.
- Maintain effective IP protections to enable future collaboration and knowledge-sharing.

POLICY LESSONS FROM THE COVID-19 RESPONSE

1. IP Rights Enabled a Successful Innovation Response to COVID-19

The astonishingly swift development of COVID-19 vaccines and treatments was built on a foundation of earlier research and technologies, much of it funded and conducted by the private sector. Vaccine platform technologies like mRNA and viral vectors, which allowed the rapid design of COVID-19 vaccines, were the product of billions of dollars in private investment and decades of IP-enabled research and development. Existing drugs and therapies provided a starting point for repurposing efforts, while proprietary diagnostic tools and techniques enabled the creation of new COVID-19 tests.

A. IP Rights Were Essential to Supporting COVID-19 R&D

COVID-19 vaccines and treatments resulted from years of investments in research and development. In many cases, that research started as publicly funded basic research that occurred long ago. The private sector took the next step, working to translate that basic research into treatments for patients, using private funding over the course of many more years. When the pandemic emerged in early 2020, hundreds of actors worked together to partner to apply that knowledge to fight COVID-19.

A common complaint about COVID-19 treatments is that governments "paid" for the research, so the public should not have to "pay again" for the treatments. This lament is based on a fundamental misunderstanding about the role of public funding in drug development.

Unfortunately, many treaty negotiators seem to share this misunderstanding about the role that governments play in drug R&D.

While government funding is crucial for basic research, the private sector takes on the substantial additional investment and risk to turn early academic insights into treatments for patients. Several proposals fail to recognize this reality and would impose stringent IP and pricing restrictions on any entity receiving public funds and encourage disclosure of technology.

Technology transferred by research institutions to start-ups and biopharma companies typically needs substantial additional private sector investment to yield treatments for patients. One study explained this division of labor by examining contributions from public versus private sectors in developing pivotal drugs.[1] This study identified four stages of drug development, and the results shown in Figure 1 illustrate the divided responsibilities and the growing responsibility of the private sector as drugs progress through development:

The results show that the private sector takes on an increasingly dominant role after initial basic research, with industry contributing the majority of effort in later stages like clinical trials, regulatory approval, and manufacturing process development.

The development of COVID-19 treatments exemplifies the need for private sector involvement. For instance, while mRNA vaccines seemed like an overnight success, they actually required decades of work and billions in private investment to go from the lab to widespread patient use. The building blocks of mRNA vaccines emerged in publicly funded labs, but they likely would have stayed there without further development if the private sector had not taken the risk to invest resources and years to develop applications.

The involvement of the private sector reflects a natural division of labor. Shortly before the pandemic, we interviewed Dr. Derrick Rossi, the academic founder of Moderna. We discussed his experience seeing his discoveries in the lab translated into cures for patients.

We asked Dr. Rossi whether the public sector could handle this expensive development process itself. He was more than skeptical: "Not a chance. Academics are good at academia and fundamental science. They are not good at developing drugs for patients." In his view, it takes an "industry of professionals" to successfully bring treatments to market.[2]

Similarly, while Oxford University developed an adenovirus vector vaccine for COVID-19, it needed AstraZeneca as a partner for its global manufacturing, regulatory, and distribution capabilities. By the time the vaccine's successful Phase III results were announced, AstraZeneca had manufactured hundreds of millions of doses and established over 30 supply agreements and partner networks.[3]

The intensive, often unsuccessful, grind of drug development, manufacturing, and distribution takes tremendous investment and a team with a wide variety of skills. From further research and pre-clinical trials, through clinical trials, to regulatory filings, and then the development and refinement of new manufacturing processes, vast investments are required. Failure stalks every

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stage of development, as almost all potential new drugs fail to make it to market.

IP rights are the foundation for all this investment and risk-taking. As Dr. Rossi observed: "you can be working on the coolest thing, but investors need to know that there is some protection for their investment, plain and simple." IP is "the future prospect that reassures investors."[4]

The private sector's willingness to take on the financial risks of drug development is what ultimately gets safe and effective treatments to patients. It's what enables partnerships between the public and private sector to work. Governments contribute important funding, resources, and supportive policies, but overriding IP protections could significantly chill the private investments and industry involvement needed to bridge the gap from basic research to finished products.

B. IP Facilitated Unprecedented Cooperation and Voluntary Technology Transfer

When COVID-19 emerged, IP rights gave companies the security to collaborate on solutions. For example, the key relationship between BioNTech and Pfizer that led to an mRNA vaccine was founded on IP protections that gave BioNTech the security it needed to collaborate.

At the start of the pandemic, BioNTech wanted to use its proprietary mRNA technology to develop a COVID-19 vaccine, but it needed a larger partner with manufacturing and regulatory expertise and capacity. It turned to Pfizer, and the parties immediately started work in early March 2020. The parties had not yet reached a final agreement, but they shared confidential information for over two weeks during this crucial time in the crisis.[5]

Trust, secured by IP protection, was essential to quickly launching the BioNTech – Pfizer partnership.[6] As Pfizer's Matthew Pugmire, Assistant General Counsel, told us:

IP protection was critical. We had an ongoing collaboration with BioNTech before the pandemic. . . . I can't speak for them, but I cannot imagine they would be comfortable coming and sharing their mRNA construct with a company like Pfizer without IP protection. This is their core technology and the result of all the investments they have made over the years. IP protection gave them [the] assurance [that] they could share it without losing all their investments from over the years."[7]

Such voluntary collaboration and knowledge sharing occurred at every stage – from R&D to manufacturing to fill and finish – parties willingly and voluntarily worked together on vaccines and therapeutics *because of*, not in spite of, IP protection.

Vaccine innovators willingly licensed their technology to numerous contract manufacturers and even competitors to scale up production. Pfizer, for instance, repeatedly engaged new partners, sending employees to work side-by-side with them for months to transfer the necessary knowledge. This level of collaboration is only feasible through voluntary arrangements, not forced ones.[8]

Data collected on these partnerships shows their impressive scale.[9] As of August 2021, among the five leading vaccine makers, there were over 40 manufacturing partnerships, 27 "fill and finish" partnerships, and six distribution partnerships covering over 25 countries. These voluntary licensing agreements grew significantly over time, reaching 372 by May 2022, with the majority involving technology transfer.[10]

COVID-19 therapeutic manufacturers also embraced voluntary licensing of the IP and tech transfer. Gilead provided nine royalty-free licenses for Remdesivir (Veklury) to generic producers in developing countries, and those contracts and relationships involved extensive technology transfer.[11] Pfizer and Merck later struck similar deals through the Medicines Patent Pool (MPP) for their antiviral pills, enabling manufacturing for low- and middle-income nations. Pfizer made a royalty-free licensing agreement with the MPP to produce Paxlovid in November 2021, and by March 2022 35 manufacturers had signed on.[12] MSD (Merck Sharpe & Dohme) entered into a similar agreement with the MPP for distribution of Molnupiravir in almost 100 low- and middle-income countries.[13]

The rapid innovation response was only possible because IP rights secured the extensive collaboration and encouraged the massive investments needed to address a crisis at warp speed. Attacking foundational IP protections could have significantly slowed progress.

2. Governments and International Organizations Struggled in their Response

While the private sector's innovation response was a remarkable success, governments and international organizations often fell short in their efforts to ensure equitable access to COVID-19 vaccines and treatments. This is not to say that governments and public entities did not contribute positively – quite the contrary. Nevertheless, the long wait many endured for vaccines and treatments largely falls on the public sector.

A. "Vaccine Nationalism" Impeded Equitable Vaccine Distribution

Vaccine procurement and distribution during the pandemic was hampered by collective action problems. Countries prioritized their own citizens' access to vaccines, sometimes even after their populations had the opportunity to be fully vaccinated. In several instances, political leaders spoke the language of equity and fairness while ruthlessly prioritizing their own citizenry.

Things started well enough. In the early stages of the pandemic, advance purchase commitments from wealthy countries played a crucial role in incentivizing private sector investment in vaccine development and manufacturing. These commitments provided assurance that there would be a market for successful vaccines, giving companies the confidence to take on the substantial risks and costs involved.

The advance purchase commitments were a successful response to lessons from past pandemics – initially, at least. In recent years, the pharmaceutical industry had grown skeptical of developing vaccines for pandemics after governments reneged on commitments to purchase them. A 2018 article in STAT News related that vaccine developers felt "burned," especially after losing significant sums on effective, but disregarded, vaccines for the H1N1 virus.[14]

Unfortunately, countries with pre-existing agreements insisted on maintaining their place at the front of the line, even after their most vulnerable populations had received initial doses. For example, both the U.S. and U.K. initially required that doses manufactured in their country stay in their country. Such restrictions left limited supplies for nations without such commitments, many of them low- and middle-income countries.

By the fall of 2021, the US, EU, and Canada had managed to offer vaccines to all or most willing adults, yet only 8.4% of people in lower-middle-income countries had been vaccinated. In fact, wealthy countries began to offer booster doses to previously vaccinated citizens while fewer than 1% of citizens in low-income countries were fully vaccinated.[15] Estimates suggest that those early boosters could have supplied between 850 million and 2 billion doses to completely unvaccinated populations over the course of the next year – almost a fifth of the necessary 11 billion doses.[16]

Some governments also imposed export restrictions on vaccines and raw materials, further hampering efforts to distribute doses equitably around the world. For example, India banned export of vaccines from April to October 2021 while it prioritized vaccinating its own population.[17]

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COVAX, an international organization co-led by CEPI, Gavi, and the WHO, was set up early in the pandemic to facilitate collective action in vaccine procurement and equitable distribution. However, COVAX struggled to procure and deliver vaccines as quickly as promised due to vaccine nationalism, India's six-month ban on vaccine exports, and wealthy countries' reluctance to participate in the purchasing pool.[18] Advanced purchase contracts between wealthier governments and vaccine manufacturers put COVAX at a disadvantage, leading many nations to turn to bilateral agreements or endure long waits.[19]

B. Trade Barriers and Other Impediments to Vaccine Production and Distribution

High tariffs, export restrictions, and red tape impeded vaccine production and distribution. WTO analyses found that tariffs on critical vaccine inputs remained high in many countries, with 23 out of 27 top vaccine manufacturing countries having at least five "choke points" (tariff rates of 5% or more).[20] Export restrictions on key inputs, supplies for clinical trials, and raw vaccine ingredients further delayed manufacturing scale-up.[21] Complex supply chains involving numerous participants made these barriers particularly disruptive.

Lack of regulatory coordination also slowed vaccine distribution. The OECD reported that vaccines and their components face some of the highest numbers of non-tariff measures, such as labeling and packaging requirements.[22] Among other problems, such barriers sometimes made it impossible or difficult to move doses from countries with surpluses to those in need.

These restrictions delayed the scale-up of vaccine manufacturing in some regions. Supply chains for vaccines and biologics can be highly complex and include many different participants – raw materials suppliers, equipment suppliers, contract manufacturers, and logistics companies. All these moving parts must work together smoothly to keep doses rolling off the production line. For example, production of the Pfizer/BioNTech COVID-19 vaccine relies on over 280 physical inputs, some of them unique and novel materials.[23]

The WTO urged that member cooperation could eliminate or reduce such tariffs and vaccine barriers to increase vaccine output.[24] Although governments were uniquely well-positioned to mitigate these supply chain issues, many failed to do so.

C. Many Health Systems Were Unprepared for Mass Vaccination Campaigns

Many countries' health systems lacked the infrastructure, cold chain logistics, and trained personnel needed to carry out mass vaccination campaigns. Inadequate funding for distribution, particularly in low- and middle-income countries, slowed the rollout of vaccines. These challenges persist in many parts of the world, leaving large populations still vulnerable to COVID-19.

The Pfizer/BioNTech and Moderna vaccines, for example, require the use of "ultra-cold" freezers to preserve viability. However, many countries lack the necessary facilities. As vaccine distribution started, Peru had only 30 of these ultra-cold freezers, falling far short of even a single Pfizer facility in the US.[25]

As John Nkengasong, head of the Africa Centres for Disease Control and Prevention (Africa CDC) observed in 2021, even as vaccine supply shortages eased: "What we are seeing now is a lot more vaccines coming in and the uptake is challenged because of the logistics and delivery… . It's not necessarily about hesitancy, it's about moving vaccines from the airport to the arms (of people), it's about logistics."[26]

3. Treaty Negotiators Should Learn from Failures and Build on Successes

The negotiating parties should focus reforms on the less successful aspects of the pandemic response - namely, government failures to cooperate on equitable vaccine distribution, supply chain barriers, and delivery of vaccines and treatments to patients. An advantage of this approach is that the actions it requires are within the power of governments to affect most directly.

Meanwhile, governments should support voluntary cooperation and technology transfer while avoiding harm to the IP-based innovation ecosystem that enabled the rapid development and deployment of vaccines and treatments.

A. Remedy Past Failings by Improving Government Coordination and Capabilities

One priority of treaty negotiators and policymakers generally should be to remedy the governance issues we identified earlier. The advantage of such measures is that they are most and best within the capacity of governments to address.

Greater collective action in vaccine procurement. A future effort at pooled procurement should draw the right lessons from the disappointments of COVAX. Two things that would help are a greater, broader commitment to pooled procurement. It would also be useful to accept some limitation on the extent that nations can make first claim to vaccine supplies, at least after their most vulnerable populations are treated. These suggestions may take the most political will but would provide a great boost to equity.

Remove trade related barriers and impediments to vaccine production and distribution. High tariffs on vaccines, medicines, and their inputs are simply counterproductive and irrational, even in normal times. Governments should remove them, and, at the very least, set up laws that allow for their swift suspension.

Countries should firmly commit to foregoing export bans on ingredients, vaccines, and treatments. The political temptation to protect one's own citizens will always be present, but countries must recognize that complex supply chains make collaboration in everyone's interest.

Some proposals regarding the treaty call for greater regulatory harmonization, and negotiators should embrace and expand these. There were good examples of removing delays for approvals, well-executed emergency approvals, and intensified cooperation among regulators in different countries, and countries should adopt such measures widely. Just as important, harmonizing regulations regarding things like labeling can be challenging but well worth the work.

Build capacity for national vaccine distribution. The treaty should prioritize measures to enhance governments' ability to procure and distribute vaccine and treatments equitably and efficiently. This includes investing in health infrastructure, cold chain logistics, and funding mechanisms to support timely and widespread vaccine and treatment access. Improving trade facilitation and reducing barriers to the movement of essential goods can help strengthen supply chain resilience for all.

B. Bolster Voluntary Cooperation in Innovation and Manufacturing

For many, one of the most important lessons of the COVID-19 response was a need for more localized production of vaccines and treatments. More global manufacturing capacity is certainly better than less in the event of a pandemic. During the pandemic, vaccine manufacturers worked hard to

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find partners with the capability to manufacture vaccines and treatments within regulatory standards.[27]

A further motivation driving the push for localized production – even more than the need to expand global capacity – is a desire for self-reliance. Many nations feel burned after experiencing COVAX's failure to deliver, suffering from India's six-month export ban, and waiting while wealthy nations loitered at the front of the line for vaccines as less wealthy nations suffered.

This understandable desire for self-reliance has led to proposals and demands that seem pragmatic on their face but actually are counter-productive. Countries cannot produce their own vaccines and treatments without the technology and know-how to do so, thus many policymakers and advocates have sought waivers of treaty obligations to protect IP as well as forced or strongly "encouraged" technology transfer. While such proposals have the seductive logic of all straightforward solutions, they are unsuited to the complexities of the real world.

Reluctant technology transfer will be ineffective for today's complex biopharma technologies. New workers need to develop know-how, which is mostly transmitted through collaborative learning-by-doing at the side of experts. As one biopharma executive related, "people don't usually set out to develop know-how. Rather, it is often the natural product of doing scientific and technical work. It's hard to distill and put in a manual. Real know-how cannot just be written on a paper. You have to share know-how through doing and through collaboration."[28]

> There were three common threads that ran through all of these successes: partnership with global technology experts, an enabling policy environment that supported collaborative tech transfer, and a functioning regulatory system.

Voluntary technology transfer, on the other hand, can be achieved through various pathways that attract global technology partners willing to engage in extensive knowledge sharing with local partners. The right policies can attract eager partners to voluntarily work side-by-side with locals and teach what they know. A 2022 report identified four successful approaches used by emerging economies to expand their vaccine and biologics production capabilities.[29]

State sponsored strategic investment. Governments can improve local capabilities to attract foreign investment. For example, Brazil established Public-Private Partnerships (PPPs) between Brazilian manufacturers and foreign biologics producers as an alternative to expensive importation of medicine. South Korea provided substantial tax incentives to local manufacturers to enable them to meet the highest global regulatory standards and form partnerships with global firms.

Backwards integration. Local firms can establish relationships with foreign partners to handle lower-value steps in the biomanufacturing process, such as the fill-and-finish stage. The local firms develop expertise and partnerships, while government policies further encourage investment and partnerships to enable "backwards integration" moving up the value chain to higher-end manufacturing and R&D. South Africa offered incentives to foreign firms to develop partnerships with local firms and invested in training for those local firms. Turkey invested in human capital with R&D training programs, cut tariffs, and provided purchase guarantees.

Leverage related expertise. Established industries with expertise in related business can leverage those skills toward developing a bio-manufacturing industry. Argentina leveraged genetic engineering expertise from its agricultural industries to life sciences. Singapore incentivized migration of pharmaceutical experts small-molecule production to bio-manufacturing.

Expand existing capabilities. For countries with an established but not fully developed bio-manufacturing industry, systematic augmentation of existing R&D in biologics provides for growth over time. In Indonesia, a government-run institute for research and development grew progressively into Bio Farma, a state-owned bio-manufacturer with multiple international partnerships. The Indonesian government made regular investments in education and funded knowledge transfer partnerships with other nations.

Security of rights. In all of these cases, technology transfer resulted from fostering a secure environment for voluntary collaborations. Governments can make productive interventions by focusing on "pulling" technology by ensuring demand and supportive commercial and regulatory conditions. By contrast, "pushing" the transfer of technology through compulsory licensing of IP is likely to yield poor results.

A logical business case. Sustainable local production requires a market for the products made. A recent report on African vaccine manufacturing capacity by Africa CDC observed that "Uncertain demand commitments from governments . . . further complicate manufacturers' abilities to secure technology transfer agreements. The build-up of vaccine manufacturing capacity in other regions (e.g., India or China) has historically been supported through government- backed demand commitments." [30] Individual vaccine manufacturers have repeatedly emphasized the need for demand certainty, as have organizations like AVMI (African Vaccine Manufacturing Initiative) and DCVMN (Developing Countries Vaccine Manufacturing Network).

Regulatory effectiveness. The biopharma industry uniquely thrives on the trust created by a sound regulatory environment. Effective regulation provides assurance of compliance with global standards for the WHO and regulators in potential export markets. It also fosters confidence among donor organizations, procurement agencies, health care systems, doctors, and patients. Regulators need to act expeditiously, consistently, and transparently.

By encouraging voluntary technology transfer rather than mandating disclosure, these countries have sustainably grown biomanufacturing and R&D capacity suited to regional needs and resources. Compulsory disclosure approaches risk disrupting the very ecosystems of expertise and openness underpinning readiness. Conversely, collaborative frameworks that facilitate trust-building and reward innovation appear most constructive for improving pandemic preparedness globally.

CONCLUSION

The success of the global response to future pandemics depends on building on the lessons learned from the COVID-19 experience. Cooperation and innovation by the private sector, enabled by robust IP rights, will remain essential to the rapid development and deployment of vaccines, treatments, and diagnostics. Governments must also focus on improving their own coordination, capabilities, and policy frameworks to ensure equitable access and efficient delivery of medical countermeasures.

As negotiations for the WHO treaty continue, policymakers and stakeholders must prioritize measures that address the real challenges faced during the COVID-19 pandemic while preserving the incentives and legal certainty that underpin the innovation ecosystem, an essential enabler of any future pandemic response. By focusing on improving government coordination, bolstering voluntary cooperation, and maintaining strong IP protections, negotiators can build a more resilient and equitable global health security framework.

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