

## PERSPECTIVE

# We Cannot Win the Access to Medicines Struggle Using the Same Thinking That Causes the Chronic Access Crisis

GAËLLE KRIKORIAN AND ELS TORREELE

### Abstract

The inequity in access to COVID-19 vaccines that we are witnessing today is yet another symptom of a pharmaceutical economy that is not fit for purpose. That it was possible to develop multiple COVID-19 vaccines in less than a year, while at the same time fostering extreme inequities, calls for transformative change in the health innovation and access ecosystem. Brought into the spotlight through the AIDS drugs access crisis, challenges in accessing lifesaving medicines and vaccines—because they are either not available or inaccessible due to excessive pricing—are being faced by people all over the world. To appreciate the underlying framing of current access discussions, it is important to understand past trends in global health policies and the thinking behind the institutions and mechanisms that were designed to solve access problems. Contrary to what might be expected, certain types of solutions intrinsically carry the conditions that enable scarcity, rationing, and inequity, and lead us away from ensuring the right to health. Analyzing the root causes of access problems and the political economy that allows them to persist and even become exacerbated is necessary to fix access inequities today and to design better solutions to ensure equitable access to health technologies in the future.

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## Introduction

The access to medicines (A2M) movement as we know it today materialized in the late 1990s, in the context of an out-of-control epidemic, rooted in the injustice of having a breakthrough medical innovation—antiretroviral combination therapy against HIV—that could turn AIDS from a fatal disease into a chronically manageable one, available in wealthy countries and largely inaccessible in countries hardest hit by the epidemic.<sup>1</sup>

Although times and circumstances are different, we can see similarities with the current inequities in access to COVID-19 vaccines across the world. Understanding how the debates on access to medical innovation and related policy changes developed over the past two decades is useful to appreciate the nature and arguments of current access discussions. It should inspire reflection on strategies for improving access to the various health technologies we need to curb the COVID-19 pandemic, without repeating mistakes from the past or engaging in strategies that further anchor an untenable status quo.

## Evolution of A2M activism and mainstreaming of access solutions

### *A growing reliance on market-based ideology underlying access solutions*

Early HIV/AIDS treatment activism in the late 1990s and early 2000s was deeply rooted in health and human rights claims that access to lifesaving medicines was a right for everybody, challenging the premise that medicines could be regarded, and traded, as luxury commodities.<sup>2</sup> Patients, health and rights activists, and health professionals in countries like South Africa, Thailand, and Brazil mobilized allies globally to challenge pharmaceutical companies and governments to put lives before profits and use accessible generic medicines instead of expensive brand name products.<sup>3</sup> In a few years, they successfully shifted the narrative and power dynamics around access to AIDS medicines.<sup>4</sup> Access to HIV diagnosis and treatment, thanks

to the availability of generic antiretroviral drugs (ARVs), became a core element of the response to the epidemic.<sup>5</sup>

If rights-based treatment activism contributed to profoundly changing the political economy and reality of access to medicines in particular for HIV, tuberculosis, malaria, and a few neglected tropical diseases, there were also other forces at work that affected global health structurally. Initial solutions spearheaded by activists and policy makers in developing countries provided a constitutional right to health and challenged the monopoly powers of pharmaceutical corporations over a country's sovereign right and ability to provide lifesaving generics for its population. While successful at the domestic level, such approaches were often seen to threaten the global world order, in particular global trade, and were gradually overtaken by a more technocratic, less contentious, and more business-friendly approach that relied on voluntarism by donors and the pharmaceutical industry and focused mainly on low-income countries (LICs, a World Bank-invented grouping of countries based on macroeconomic indicators, not people's health needs).

Designed to work in the margins of the prevailing global pharmaceutical economy, this approach aimed to create donor-supported markets to supply selected pharmaceuticals to the poorest.<sup>6</sup> Donor funds were channeled toward newly created institutions that promoted one-size-fits-all policy solutions, mainly market push and pull mechanisms to ensure large-scale supply at reduced prices. These include demand creation and supply diversification through geographically limited voluntary licensing, scaling up and concentrating production capacity to benefit from economies of scale, generic competition, and demand pooling, among others.<sup>7</sup>

For instance, the Global Fund to Fight HIV/AIDS, Tuberculosis and Malaria was created in 2002 to allow scale-up of the early rights-based HIV treatment programs by paying for health technologies at agreed-on lower prices and for their rollout in countries. It was followed by other international initiatives with variable status (including govern-

ment initiatives, United Nations institutions, and public-private partnerships) focused on either the demand or supply side of the medical commodities market. These include the US PEPFAR initiative for HIV/AIDS, the Clinton Health Access Initiative, Unitaid, and Gavi, the Vaccine Alliance, all dedicated to financing, negotiating, and facilitating the procurement and deployment of treatments, diagnostics, and vaccines for neglected populations. In parallel, multiple not-for-profit product development partnerships were created to address the lack of research and development (R&D) for diseases that did not constitute an attractive market for pharmaceutical companies. These included the TB Alliance, Medicines for Malaria Venture, International AIDS Vaccine Initiative, Foundation for Innovative New Diagnostics, and the Drugs for Neglected Diseases Initiative, among others.

This approach allowed the “global health community”—comprising donors and the assembled actors mentioned above—to respond to some of the most urgent access challenges in an ad hoc way, without confronting the overall pharmaceutical business model. Designed as exceptions within a globalized trade and market environment, the solutions were focused on specific gaps and did little in other disease areas that remained neglected, or for populations who remained excluded from access to key medical tools. In particular, people living in middle-income countries—home to 75% of the world’s population, including many of the most vulnerable—were typically excluded from the pricing and supply exceptions created for LIC markets.

The same approaches, and the same global health actors, have so far dominated the COVID-19 discussions and approach to equitable access, with the Access to COVID-19 Tools Accelerator (ACT-A) and COVAX as central mechanisms to accelerate access to COVID-19 health technologies for developing countries.<sup>8</sup> A dose of charity associated with the traditional market approach risks once again diverting us from the profound moral, political, and economic questioning of the way we finance, govern, and ensure the development and use of essential health tools.

### *Intellectual property as the cornerstone of market-based solutions*

Health policies during the 2000s were designed under a double premise: on the one hand, the positivist belief that technological innovations, particularly biomedical ones, are key to solving all health problems (as we also see today for the COVID-19 response) and, on the other, the prevailing ideology that framed access problems as punctual “market failures” within a globalizing trade environment in which the supply of technologies, including medical ones, was best left to the private sector. At the intersection of both, stringent intellectual property (IP) protection rules were established as an unsailable principle.

The gradual rollout of the 1995 World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights had globalized new IP protections as minimal norms, undermining the ability of countries such as India to produce generics unless explicitly authorized.<sup>9</sup> While the 2001 Doha Declaration had confirmed countries’ rights to prioritize protecting public health over IP in what was seen as a major victory by civil society and developing countries, enforcing this right remained mostly elusive under the tremendous pressures exercised by countries hosting the major pharmaceutical corporations.<sup>10</sup>

With the globalization of the IP regimen, the pharmaceutical industry gained unprecedented control over medical R&D priorities and over the resulting health products, for which they could charge monopoly prices. Since this economic model was considered to work well in delivering medical innovation for populations in wealthy countries (even if at high prices) and in building a prosperous pharmaceutical industry, it was largely left unchallenged. The access inequities it created for people living in less well-off countries were considered as collaterals that could be addressed through ad hoc solutions based on donor goodwill and market shaping. In line with these geopolitical power dynamics, the voluntary Medicines Patent Pool was created as part of global health institutions to broker licenses between corporations and generic companies that would be allowed to supply LICs

and a number of middle-income countries.<sup>11</sup> Meanwhile, some developing countries not benefitting from these mechanisms would discreetly make use of their right to use compulsory licenses, avoiding publicity to minimize retaliation and addressing health issues mostly in areas where civil society had exposed access problems.<sup>12</sup> As we see in the ongoing debates around COVID-19 vaccines, especially around the World Trade Organization IP-waiver, most policy makers in wealthy countries still believe or defend the idea that benevolent solutions such as voluntary licenses and the COVID-19 Technology Access Pool can be solutions for fundamental inequities and structural monopoly power (ab)use.<sup>13</sup>

*A new global health order whose solutions are reflecting its governance*

By the end of the 2000s, a new donor-shaped “global health architecture” or “global health order” was established. While multilateralism was still prominent in the 1990s and the 2000s, with world leaders ready to put health on the international political agenda (for example, the 2001 United Nations General Assembly Special Session on HIV/AIDS and the 2006 G8 Summit on emerging infectious diseases), newly created international organizations that work alongside but separately from the United Nations system—such as the Global Fund, Gavi, Unitaid, and the likes—multiplied. This new global health architecture relied on a central role given to the private sector, primarily the multinational pharmaceutical industry and a handful of large generic producers, as the supplier of health technologies. The primary role of the public sector became to fix the market failure through financing and shaping the market to incentivize this private sector, often according to its conditions. The new preferred modus operandi became public-private partnerships. Their governance typically takes the form of a multistakeholder board that validates large orientations (with a marked presence of philanthropic donors such as the Gates Foundation and Wellcome and of pharmaceutical industry representation, despite potential conflicts of interests) and a secretariat that designs and implements

policies on a day-to-day basis.<sup>14</sup>

The public-private partnership model assumes that the commercial sector is not only adequate but also more effective than the public sector in serving the public interest. Based on an assumed “win-win” scenario, often developed by management consulting firms funded by the Gates Foundation, public resources are deployed to subsidize pharmaceutical market segments to make them profitable for the private sector.<sup>15</sup> Importantly, the companies remain largely in control over the availability and pricing of health technologies through intellectual property rights and regulatory monopolies. This new preferred modus operandi is both popular and largely unquestioned, despite significant gaps in democratic oversight and a general deficit in transparency around the deals, the modes of collaboration between private and public entities, and the use of financial resources.<sup>16</sup>

Not surprisingly, there has been a large influx of private sector professionals, from management consulting firms to former bankers and pharma executives, to staff the new initiatives and institutions created under the global health architecture, which has infused even more market thinking into global health. This has culminated into the now-dominant assumption that the market-based mechanisms developed to ensure access to selected health technologies for LICs are adequate solutions, financially sustainable, and scalable to all developing countries, provided that “innovative financing” can be found to keep money flowing to support these “markets.”

Although the pharmaceutical industry was directly challenged in the early days of the A2M movement for pursuing profit at the expense of people’s health and lives, it seems to have successfully repositioned itself from being (part of) the problem to being an integral part of the solution, including influencing public health policies. In the context of COVID-19, pharmaceutical companies have been heralded by many for the rapid development of effective vaccines, while their CEOs are directly discussing with head of states about funding, production, and purchase in private bilateral meetings. At the same time, availability and access

to these vaccines has remained highly inequitable, in part because companies insist on retaining their monopolies and refuse to share technologies, despite many contributions of public research and massive public investments and de-risking, including through advance purchase commitments.<sup>17</sup>

Meanwhile, solutions divide countries into two categories—donors and recipients of aid—with consequent power dynamics. The donors determine which countries are “eligible” to benefit from the solutions they created, and under which conditionalities. The voices of “recipient” countries and the concerned populations are largely absent in the design and governance of the new global health order. The continued demands by developing countries for systemic solutions to address structural inequities and the dominance of the market over health rights and socioeconomic justice remain largely ignored. A brief look at the design and governance of ACT-A and COVAX reveals the same fundamental flaws, as countries’ calls for more autonomy and technological resilience to develop and manufacture their own solutions are growing louder, especially from African leaders.<sup>18</sup>

## Exploring new avenues to secure access to health products

### *Going beyond market-based solutions*

Increasing financial incentives and monopoly rights for the private sector to make the market work better for global health has not prevented the multiplication of “market failures” and therefore public health failures. Over the past ten years, it has become apparent that access to medicines is no longer just a problem of “poor people in poor countries.” Most high-income countries are facing access challenges, in particular for new lifesaving treatments sold at such high prices that even the richest social security systems cannot provide them to all their citizens in need. Claims for affordable treatment access are now being raised by patients and medical practitioners globally and for multiple diseases (hepatitis C, diabetes, cancers, etc.), while policy makers are struggling to stand up against the global pharmaceutical industry.<sup>19</sup> There are also

demands for truly needs-driven R&D that delivers adequate health technologies for unmet or new medical needs, such as antimicrobial resistance and emerging infectious diseases (including Ebola, Zika, and COVID-19).<sup>20</sup>

In recent years, we have also begun seeing instances of pharmaceutical companies choosing to not register or sell their product in some countries because doing so is not financially attractive enough, despite clear medical needs and demand for the product.<sup>21</sup> This supply control by companies over where to make products available has become a daily reality with COVID-19 vaccines and other medical technologies needed for pandemic control. Through monopolies on products, technology platforms, and manufacturing capacity, companies are deciding to whom to sell their technologies. Taken together with wealthy countries competing to hoard most of the world’s vaccine supply to vaccinate their own populations first, many of the poorest countries—and even the international mechanism COVAX—are unable to purchase vaccines in a timely way, even if they have the money.<sup>22</sup>

Supply gaps and market failures are also increasing for health products considered not profitable enough to continue production. The availability of medicines and diagnostics required in small volumes is being increasingly threatened, as is the case for many neglected diseases such as tuberculosis, sleeping sickness, leishmaniasis, and diphtheria. We are also seeing shortages of old and inexpensive yet essential medicines, such as penicillin and cotrimoxazole.<sup>23</sup> In the context of the COVID-19 pandemic, we have witnessed global shortages of key antibiotics (such as amoxicillin and doxycycline), morphine, and basic reagents for diagnostics.<sup>24</sup> At various points since the start of the pandemic, even if one wanted to buy these, they are simply not available or have already been sold to the highest bidder. This has led to calls for considering essential medicines strategic products that every country or region should be self-sufficient in and for creating nonprofit- and government-controlled production to ensure this.<sup>25</sup>

These emerging tensions are questioning the efficiency, cost-effectiveness, and fairness of the

dominant system. Another extraordinary example of unjustified control by pharmaceutical companies that affects patients worldwide is the rising prices of previously cheap—yet lifesaving—medicines, such as insulin, where a few corporations control the market for their mutual benefit and are able to increase prices year after year to the detriment of many people with diabetes who can no longer afford the treatment.<sup>26</sup> Seeking to challenge this status quo, a group of scientists is exploring small-scale community-based open source production of insulin.<sup>27</sup> In a similar move to increase access to overly expensive medicines and circumvent monopolies, doctors and pharmacists are looking into bedside magistral production as a way to provide personalized medicine.<sup>28</sup>

The COVID-19 crisis has added to the growing understanding that the scarcity of many essential medicines, vaccines, and raw materials is not inevitable but rather the consequence of policies and decisions from the industry and governments. On the one hand, pharmaceutical companies have wielded unrivaled power to determine the scope and direction of medical innovation and to decide who gets access and under which conditions. On the other hand, states, relinquishing their power to exert their health sovereignty, agree to rely on the private sector for the provision of these essential health tools. They thus became dependent on a handful of producers and a globalized supply that cannot fulfill all existing needs, chose to adopt economic and industrial policies that prioritized business interests over the needs of their populations and health systems.<sup>29</sup>

*Business-as-usual is not an option; we must break the deadlock*

Wishing to replicate past successes, health advocates have pushed for broadening the scope of existing solutions to encompass additional diseases and health technologies and to expand the set of “eligible” countries for the exceptions created in earlier years. This has been welcomed by some of the organizations embodying those solutions, as they see it as an opportunity to expand their mandate and scope of activities across disease areas or

to new territories and be able to tap into additional funding sources for sustainability. This applies for instance to Gavi, the Coalition for Epidemic Preparedness Innovations, the Global Fund, the Foundation for Innovative Diagnostics, and Unitaid, which positioned themselves as key players in the design, setup, and functioning of ACT-A together with the Gates Foundation and Wellcome. The same players are now advocating for ACT-A’s evolution into a permanent epidemic response infrastructure.<sup>30</sup>

But the replication and routinization of ad hoc and donor-driven solutions, bringing more and more public health areas under the control of self-declared global health institutions that focus on narrowly defined biomedical solutions, does not necessarily suit all current and future health challenges or take into account existing shortfalls or pitfalls of these mechanisms. It also does not address the governance gaps that exist in many international organizations that function more like untransparent public-private partnerships than institutions whose policies are dictated by public interest. Because countries’ ability to set priorities and develop an integrated health policy are often hampered and skewed by donor subsidies and their priorities, there are growing voices from “beneficiary” countries calling for increased agency and participation, if not leadership and autonomy, in designing the solutions they deem most fit to promote the health and well-being of their populations—a movement that also includes #DecolonizeGlobalHealth.<sup>31</sup>

For the ongoing COVID-19 pandemic, it is clear that the established global health architecture is unable—and ill suited—to work out relevant and equitable solutions for the developing world, as exemplified by ACT-A and its well-intended but so far ineffective COVAX facility, held hostage to supply restrictions by companies and the vaccine nationalism from those who created it in the first place.<sup>32</sup> Voluntary proposals that keep developing nations captive to the willingness of corporations and wealthy countries to access lifesaving public health tools are being increasingly criticized.<sup>33</sup> The political tensions on an IP waiver on COVID-19-re-

lated technologies at the World Trade Organization are reopening an old battle that raged during the HIV epidemic 20 years ago between developing countries challenging monopolies on medical technologies and the wealthy countries defending the pharmaceutical corporations located in their countries.<sup>34</sup> However, the COVID-19 vaccine scarcity affects people everywhere, rendering the flaws of the monopoly-based yet highly subsidized pharmaceutical economy visible to more people, and making it obvious that limited exceptions to the IP regimes (for a few patents, for one virus, for a few months, and so forth) will not fix the problems.

The COVID-19 crisis illustrates the critical role of public contributions in the research, development, production, and deployment of medical innovations for global public health.<sup>35</sup> The inequities in vaccine access that we are seeing due to the fact that control over such innovations was left in the hands of a few private companies highlights the colossal unbalance that exists between the public health interest and private profits. They illustrate how public resources are used without adequate checks and balances to ensure public value, and fail to prevent growing inequalities in access, even in the wealthiest countries.

Tinkering in the margins of the status quo is unlikely to be successful. The market-based health, pharmaceutical, and medical innovation policies that our governments designed are unable to generate the relevant health technologies and make them available—at an affordable price—to all who need them. Therefore, we need transparent R&D and access policies and governance that are no longer captive to the current, Western-driven global health order. The design of needs-driven research and production of pharmaceuticals could be organized to deliver health commons, not market commodities, making the best of public capacities and setting up transparent and fair collaboration with the private sector for the public interest.<sup>36</sup>

## Conclusion

The inability of the current health innovation and access ecosystem to provide equitable access to

lifesaving technologies has never been so clear. The conditions that made it possible to develop multiple COVID-19 vaccines in less than a year, while at the same time fostering extreme inequities in access and disregarding human dignity and the right to health, call for transformative change in the pharmaceutical economy.

Reforming R&D, production, and availability of pharmaceuticals in the public interest must rely on the following key elements:

- Rebalance the power dynamics between public and private actors in the medical innovation ecosystem and redesign the governance of knowledge and financial resources to prioritize the public interest over private and financial interests. This will require an end-to-end approach to medical innovation and access, as well as full transparency over economic and scientific inputs and outputs throughout the innovation-to-access chain, for which the World Health Assembly's 2019 transparency resolution is a pivotal starting point.<sup>37</sup>
- Establish adequate governance mechanisms for issues ranging from R&D to access that reflect the reality of medical innovation as a collective effort and of public health as a fundamental democratic and human rights matter. Such governance must be participative and inclusive of all concerned actors, including health professionals, users of health systems, civil society groups, governments, other payers and funders, researchers, and industry. For global governance mechanisms, there should be a particular emphasis on Global South representation.
- Shape economic, industrial, and financing policies in line with health policies, and design them with the explicit purpose of delivering solutions to address people's health needs in equitable ways.
- Embrace the idea that one size does not fit all. Instead, the diversification, deconcentration, and devolution of health innovation and manufacturing must be catalyzed, allowing for locally and regionally driven solutions adapted to specific health needs and contexts, and fostering

countries' agency, resilience and autonomy in improving the health of their own communities.

These elements form a solid basis for a new health innovation ecosystem charged with providing access to health products to the populations who need them, in fulfilment of the rights to health and to the benefits from scientific advancement, which are rooted in the principles of equity, nondiscrimination, and transparency. They can also help shape governance and financing models that are fit for purpose to reach this objective, as well as an economic model that is sustainable for health systems.

Importantly, they would change the political economy against which the right to medicines is currently articulated, removing the risk of undermining health equity. Courts in a number of countries have explicitly recognized that human rights impose obligations on states to find solutions to the provision of even high-cost medicines. For example, a high court in India has stated that "no government can wriggle out of its core obligation of ensuring the right of access to health facilities for vulnerable and marginalized section[s] of society ... by saying that it cannot afford to provide treatment for rare and chronic diseases."<sup>38</sup>

In conclusion, we need to reassert the purpose of medical innovation so that it aims to improve people's health outcomes everywhere, including through equitable access to adapted health technologies, and actively shape the innovation ecosystem toward achieving that goal. This will allow us to develop out-of-the-box solutions that revisit the articulation between industrial and health policies, including financing. Such solutions must also reimagine the governance of medical R&D and access between different public and private actors, and include individual citizens as co-creators of solutions to improve their health.

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