The WHO Council on the Economics of Health for All

Governing health innovation for the common good

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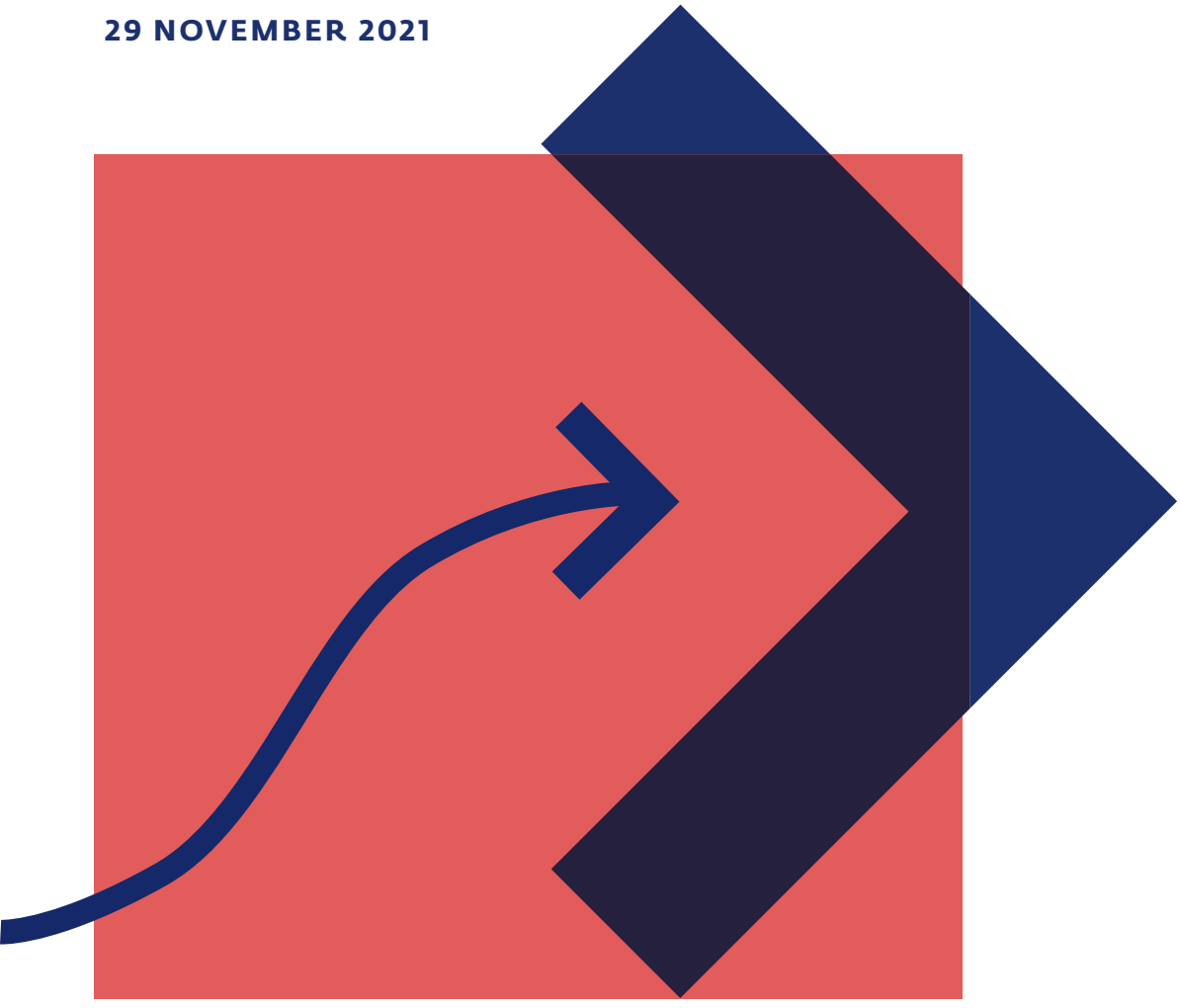

World Health Organization

The development of multiple coronavirus disease 2019 (COVID-19) vaccines inless than a year shows how much can be accomplished when human ingenuity and solid medical research and development capabilities are given extensive public support. However, this experience also demonstrates that unless innovation is governed for the common good, many people remain excluded from its benefits, limiting the positive impact of health interventions, and creating unacceptable inequities that potentially exacerbate the health needs that it is supposed to address.

Governing health innovation for the common good is a key element towards creating a new political economy for Health for All, one that has the ambition of shaping the economy with the objective of building healthy societies that are just, inclusive, equitable and sustainable.

This is the vision behind the recently created World Health Organization (WHO) Council on the Economics of Health for All comprised of economists and experts in health and development that seek to develop a new understanding and a new narrative about the deep interconnectedness between health and the economy with a focus on the intertwined core themes which follow.

- **MEASUREMENT:**
  Valuing and measuring Health for All.
- **CAPACITY:**
  Strengthening public sector leadership in building resilient capacity and creating partnerships to deliver Health for All.
- **FINANCE:**
  Providing strategic, long-term, and transformative finance for Health for All.
- **INNOVATION:**
  Governing innovation towards Health for All.

The Council has written this brief to focus on the governance of innovation, a critical building block of healthy economies, and lays out the key problems with the health innovation ecosystem and why radical changes are needed to ensure it delivers Health for All. In future briefs, the Council will look at how to measure and value Health for All in ways that are informed by common good principles, how to finance Health for All with new purpose-driven public and private partnerships, and how to build strong collective capacities able to deliver Health for All. These different dimensions are interrelated and connected. For instance, the way the financing of health innovation is structured must reflect its purpose (common good), value and governance, and be connected to building capacities to deliver it in equitable ways.

At multiple high-level policy forums such as the G7, G20, United Nations General Assembly, World Trade Organization and World Health Assembly, political leaders and financial institutions are discussing solutions to address the COVID-19 vaccine inequity and the need for "building forward better" including financing pandemic preparedness and response as a matter of health and economic security and resilience. But mobilizing money to throw at solutions that fail to address the underlying causes of longstanding structural problems will not be sufficient. We all must look forward towards re-imagining health innovation as part of a new economic ecosystem that can deliver Health for All. The Council believes that the way to do so is to focus on the underlying business models and governance of both public and private actors.

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SUMMARY OF KEY PRINCIPLES

The Council's proposals address deep structural flaws in the current health innovation ecosystem, which require both immediate and long-term changes.

LONG-TERM VISION

The long-term vision must be one that guides the establishment of a new, end-to-end health innovation ecosystem that shapes the way in which public and private sectors work together throughout the innovation chain to deliver equitable access toneeded vaccines, therapeutics, diagnostics and other essential health supplies. The system should be underlined by the building blocks of a health innovation ecosystem governed towards the common good, including:

- creating purpose-driven innovation through a mission-oriented approach;
- reshaping knowledge governance for the **common good;**
- reforming **corporate governance** to better reflect stakeholder value in the long term;
- building **resilient and diverse manufacturing** capacity and infrastructure;
- introducing **conditionalities** for public investments to build **symbiotic public-private partnerships;**
- strengthening the **capacity of the public sector** in health innovation.

SHORT-TERM ACTIONS

In the short term, urgent action must be taken to remedy the extreme inequities in access to vaccines and other critical health technologies. Rather than reinforcing approaches aimed merely at fixing market failures in the health innovation ecosystem, actions must be adopted as a starting point to change and reform the ecosystem oriented towards the common good.

- Available vaccine doses should be redistributed immediately, not as acts of charity, but as a shared imperative for pandemic control and inclusive, equitable and sustainable access.
- Technology transfer and building manufacturing capacity must be supported and financed, not as the responsibility or property of any single actor, but as a collective responsibility towards building greater health security, and resilience in all regions, governed as common goods.
- Knowledge should not be kept as privatized intellectual property (IP) under monopoly control, but considered as collective rewards from a collective value creation process, to be openly shared and exchanged.
- Existing mechanisms set up to address the above aspects, including the Access to COVID-19 Tools Accelerator (ACT-A) and its vaccine pillar the COVID-19 Vaccine Global Access Facility (COVAX), and the COVID-19 Technology Access Pool (C-TAP), should be utilized and strengthened, not as an approach to fix market failures, but as turning points for creating market-shaping approaches designed for the common good.

1. Rethinking health innovation in light of COVID-19

The rapid development of COVID-19 vaccines is a triumph for science, but their availability and deployment have so far been highly uneven and suboptimal. While nearly 2.06 billion vaccine doses have been administered in the world just 18 months into the pandemic,[1] 75% have gone to just 10 countries.[2,3] As of 4 June 2021, fewer than 32 million vaccine doses have been administered in the whole African continent, for a total population of 1.36 billion[4] — creating what some have called a "necropolitics" of COVID-19.[5,6]

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Vaccine inequity and injustice is not just a moral failure. It is also a health and economic catastrophe. Indeed existing inequities before COVID-19 only became worse during the pandemic: precarious contracts with no income security during bad times, the digital divide allowing only some to prosper in the digital age and underfunded stretched health systems.[7] The key failures in the health innovation ecosystem in effectively addressing people's health globally and making products available and accessible equitably were widely described and analysed before the COVID-19 pandemic, including by the 2016 UN High-Level Panel on Access to Medicines and Innovation.[8] Specifically for medical innovation to respond to epidemics, the Global Preparedness Monitoring Board and the Independent Panel for Pandemic Preparedness and Response (IPPPR) highlight the additional challenges for ensuring medical innovation to protect against unpredictable health threats.[9–11]

Commercial imperatives and charitable efforts are clearly insufficient to deliver vaccine equity. In providing solutions merely to fix market failures, they also reinforce the problems of the existing ecosystem. Despite calls for considering COVID-19 vaccines as People's Vaccines or global health commons,[12,13] these vaccines have largely remained under the exclusive control of private companies through intellectual property and manufacturing capacity monopolies, resulting in deadly vaccine inequity.[14] The fierce competition by wealthy countries to buy up the vaccines even before they were produced through advance purchasing agreements has exacerbated the access crisis.

By now, the economic case for COVID-19 health equity is well recognized. For example, the International Monetary Fund estimates that US$ 50 billion from donors and national governments to strengthen existing mechanisms, in particular, the ACT-A and including the vaccine purchase and distribution facility COVAX, could generate US$ 9 trillion of additional global output by 2025, of which 60% of gains would benefit developing countries.[15]

But investing in health for the long-term resilience of economies is not the main reason for action. The objective of Health for All is an end in itself, an intrinsic element of human welfare. Given this aim for public policy, the instruments to achieve it can then be developed by reviewing the design of economic policies and approaches, including financial institutions, innovation incentives, budgets, tax regimes, procurement contracts and public-private partnerships such as ACT-A.

The need for a new narrative for health innovation

Health and the economy are deeply intertwined. Yet, for too long, the world has accepted economic and industrial policies that are blind, if not detrimental, to the collective health needs of society. This is why people-centred and sustainable economic policies are needed that can deliver Health for All. It means changing the rules by which the industry is playing, and shaping health and industrial policies with a clear purpose and mission to deliver needed health innovation in a timely and equitable way to people everywhere.[16,17]

Strong public health infrastructure, adequate testing capacity and safe and effective treatment options and vaccines are key to protecting societies from COVID-19. The ambition of Health for All requires unprecedented collective investment and adequate financing, and a globally coordinated innovation ecosystem that can deliver the needed technologies and ensure their wider availability and equitable access.[11,18]

However, it is clear that when it comes to addressing societal challenges such as those posed by the COVID-19 pandemic, governments have ceded much of their leverage as active market and health innovation ecosystem shapers. This is especially problematic given the very large sums of public money that are spent every year on health-related research and development (R&D), and yet the prices of the drugs do not reflect that, and neither does the governance of intellectual property rights.[19] The initial price setting does not take into account the substantial public investment. For example, sofosbuvir was the product of over 10 years of research funded by the United States Department of Veterans Affairs and National Institutes of Health (NIH)-funded research at Emory University as well as NIH small business innovation grants.[20] Gilead Sciences acquired the company that developed the product, Pharmasset, and proceeded to market the drug at the monopoly price of US$ 84 000 in the USA at launch for a 12-week course at 1 pill a day.[20] Even though subsequent price reduction was achieved (under US$ 100 per course in eligible countries), the key question remains: How was an innovative treatment that has benefited from significant public investment, priced out of reach at the beginning?

COVID-19 vaccine development has benefited from unprecedented public support, from massive investments in infectious disease research and vaccine platforms prior to the pandemic, to direct subsidies to accelerate vaccine development during 2020 and advance purchase commitments to further de-risk the industry.[14] Still, as the ongoing discussions around a possible IP waiver and the C-TAP show, this contribution is yet to result in knowledge or ownership sharing.

Public investment should not come with zero strings attached. In both of the cases above, it seems clear that while risks are socialized, profits are privatized. A purpose-oriented system, driven by true stakeholder value must begin by debunking the old narrative that value is created only in business and redistributed by the state.[21] Indeed, health innovation is a key area where both the state and business, and other entities — for example, philanthropies, the global research community including the health facilities that host the clinical trials, and the many clinical trial participants that share risks — co-create value. How to govern that collective value creation for the common good is the focus of our brief.

2. Problems in the pharmaceutical innovation ecosystem

Innovation in the health sector is a result of the collective efforts of many actors, from basic research to product development and manufacturing to deployment. However, it is not enough to "partner" in innovation: it is crucial to build the right partnership. The prevailing narrative is one that sees the role of the state as solely "fixing market failures", bandaging up missing investments and de-risking private investments by market "push and pull" approaches. In this approach, the "public good" is seen as something that fills the gap for what is not being done by the private sector. While this approach is important for justifying public sector investment in R&D, it is not enough to address key structural problems and societal challenges. For this reason, the Council makes use of the broader, more ambitious notion of the "common good", driven by envisioning what type of system we want to build. That is, the common good is an objective, while the public good tends to be framed as a correction.

Redesigning the health innovation ecosystem for the common good thus requires a major shift from a model where innovation is seen as being driven by market forces, to a model that is collectively governed in the public interest.[22] This fundamentally requires changing the narrative about value creation in the health-economic ecosystem and how medical technologies are discovered, made, sold and deployed.

The current pandemic exposes how governance affects the direction and pace of innovation. The Council summarizes five major problems in the pharmaceutical innovation ecosystem below.[16]

Misaligned directionality and priority-setting

Many public health needs are unmet and remain under-researched. While public and academic research typically focus on high-risk areas of research, industry will only invest in the commercialization of the most financially interesting projects. Diseases relevant to high-income countries are seven to eight times more likely to be investigated than those that mainly affect low- and middle-income countries.[23]

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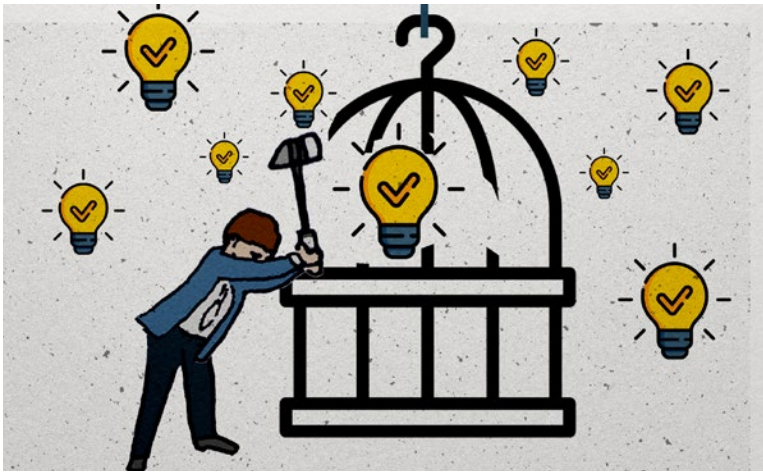
For example, due to the success of prevention of mother-to-child transmission of HIV in high-income countries, the paediatric formulations of antiretrovirals have limited commercial market and appeal for R&D investment, despite their significant potential for many other countries, including low-income settings.[24] This reality reflects the interests and priorities of the pharmaceutical industry, responding to shareholder expectations rather than health needs. This imbalance even applies to major health and security threats, such as the rise of antimicrobial resistance (AMR) for which the development of novel antibiotics has remained largely neglected.[25] The lack of innovation into vaccines to prevent infectious disease epidemics – exemplified by coronaviruses or Ebola – follows this trend. Poverty-related diseases, such as tuberculosis, are also largely overlooked. Instead, companies target lucrative pockets where they can sell "niche busters" – treatments for rare diseases for which they can charge extortionately high prices – or pursue low-risk strategies that can more easily yield commercial success, yet with little added therapeutic value.[26] This dynamic of eschewing early-stage and riskier research results in major unmet needs unless the public sector steps in.

Knowledge and access barriers

Knowledge generation and sharing are critical for medical research and public health. But stringent IP protections and corporate secrecy restrict the availability and use of vital health technologies and data, hamper follow-on innovation, and preclude the widest possible use to improve health outcomes. The current system incentivizes innovation through monopolies, in which governments allow the privatization of biomedical knowledge through granting patent protections.



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While patents — and the promise of future profits derived from simply owning patents — serve as a lure for capital, growing evidence indicates that such a system impairs crucial steps along the innovation process.[27,28]

It is often argued that patents are essential for medical innovation, yet some of the most impactful products, such as polio and smallpox vaccines, penicillin and insulin, had been developed without patents. The human genome project is an example of a highly successful international collaboration driven by the need to produce collective intelligence for the common good.[29,30]

Patents in the pharmaceutical industry have become increasingly upstream, too wide, and too strong, presenting a barrier to productive innovation and technology diffusion,[31] and leading to what Baumol called "unproductive entrepreneurship".[32] Instead of creating

new drugs, the pharmaceutical industry extends existing patents beyond the initial 20-year protection and creates patent "thickets" around biopharmaceutical products, which have resulted in increasingly strong and lengthy monopolies – 53 patents have been granted to the cancer drug pembrolizumab alone.[33] An effective patent system would eliminate such rent-seeking and foster productive follow-on innovation and the collective intelligence effort needed to allow scientists all over the world to create a diverse and innovative portfolio of medical innovation – including for COVID-19.[34,35]

A further barrier to knowledge and access is the preference for secrecy over transparency around critical aspects of the R&D value chain, including clinical trial and other research data, patent information and R&D expenditures and pricing.[36] Their importance for health innovation was recognized by the World Health Assembly when it passed a potentially game-changing resolution to improve transparency in 2019.[37]

As it stands, current policy fails to adequately promote knowledge sharing or foster the technology transfer needed to effectively diffuse know-how among research scientists and, for instance, rapidly expand manufacturing capacity in public health emergencies like the COVID-19 pandemic. Vaccine producers can stand behind trade secrets to slow down and prevent manufacturing scale-up by other willing and capable producers.

Extensive financialization and de-industrialization

Pharmaceutical companies have become highly financialized, limiting reinvestment into production and innovation, and focusing instead on short-term profit. From 2009 to 2018, the top 18 biopharmaceutical firms spent US$ 335 billion repurchasing their own shares, which is 114% of their R&D expenditures during that period.[38,39] Large biopharmaceutical firms increasingly disinvest from riskier early-stage research, and instead focus on acquiring products from biotech companies that are already in later clinical trial stages.[40] As biotech start-up companies seek to boost market valuation, the possibility of charging increasingly high prices (including in third-party-payer markets with little or no price regulation) becomes an essential strategy for seeking higher profitability. Current government policies fail to regulate biopharmaceutical companies profiting from R&D heavily funded by the public purse. During the COVID-19 pandemic, a number of biopharmaceutical firms have profited richly, thanks to weak regulatory regimes, with some seeing their share prices more than quadruple on COVID-19 expectations and executives cashing in stock awards in 2020 and 2021.[41,42]

Lack of resilience and limited geographic spread of manufacturing infrastructure

Before the pandemic, 90% of all vaccine production by value was concentrated with four companies: GSK, Pfizer, Merck and Sanofi.[43] By volume, the Serum Institute of India (SII) alone was the largest producer, with 28% of the estimated 5.5 billion vaccines produced in 2020.[43] The enormous surge needed in vaccine manufacturing capacity for COVID-19 vaccines has shown the limitations of the highly concentrated global manufacturing infrastructure, with relatively little vaccine capacity able to produce at a large scale outside of the major vaccine corporations and SII, and a high dependency on a very limited number of producers. Africa, for instance, imports 99% of the vaccine it uses for routine immunizations from abroad, making it highly vulnerable to supply shortages or global scarcity as in the case of COVID-19.[14] At the same time, new global players are emerging in the vaccine innovation landscape, such as Chinese and Russian producers, which can be expected to help diversify the global manufacturing supply.

To respond to the unprecedented need for COVID-19 vaccines, major efforts are under way to build new and expand existing vaccine manufacturing capacity, balancing speed with the aspiration to build greater resilience by ensuring all regions develop their own capacity for greater self-sufficiency (particularly in the face of COVID-19 vaccine nationalism). Establishing vaccine manufacturing capacity is complex, and requires technology transfer and knowledge sharing. This is especially important for mRNA vaccines, which represent a novel technology with great promise that can be rapidly adapted to new COVID-19 variants, or possibly other diseases, and are relatively easy to produce in large quantities as the rapid scale-up by Pfizer/BioNTech and Moderna shows. However, these companies have been reluctant to share technology outside the networks under their control.

So far, investments into scaling up manufacturing capacity for the COVID-19 vaccine candidates have primarily benefited private firms under licence from the "originator" companies. This is a missed opportunity for the global health community and its aspirations to build greater pandemic preparedness: this crisis should instead be used to expand technological capacity to produce vaccines as common goods, and challenge the oligopoly of major vaccine producers.

Lack of public stewardship for access

Health innovation is a highly complex process that requires a long-term financial commitment and efficient collaboration between public and private sectors along the R&D value chain. Although the public sector makes huge investments in health innovation,[39,44] it fails to ensure that the resulting medical technologies will be available and accessible to those in need. Examples of high pricing of medicines that have received public investment are myriad, as noted hepatitis treatment sofosbuvir and others, such as CAR T-cell cancer therapy, key HIV/AIDS drug emtricitabine and rheumatoid arthritis medicine infliximab.[20]

The development of COVID-19 vaccines puts the criticality of public investment in sharp relief. Governments are major investors in vaccines, from early-stage science through to manufacturing. The underlying technology of Moderna's and Pfizer/BioNTech's mRNA vaccines has benefited from more than 20 years of publicly funded scientific research,[45] and the development of both COVID-19 vaccine candidates has been further supported by governments. The United States' Operation Warp Speed alone has invested over US$ 10 billion in the R&D of six promising vaccines, including US$ 2.5 billion for Moderna and US$ 1.5 billion for Johnson & Johnson.[46] The German government provided nearly US$ 450 million to BioNTech.[47] It is estimated that 97% of the financing to develop the AstraZeneca/Oxford vaccine came from public funds, including from the European Union and the government of the United Kingdom of Great Britain and Northern Ireland.[48]

Additionally, the development of COVID-19 vaccines was further de-risked by large advance market commitments, which was the main strategy used by certain governments to secure priority access to the new vaccines (often in combination with significant investments in R&D and even manufacturing) at the expense of global equitable distribution.

Meanwhile, current practices in pharmaceutical price regulation, financing and public procurement all fail to account for the contribution of these public investments to value creation. Pricing and sales practices exerted by companies, and their reluctance to share knowledge and transfer technology, continue to ignore the collective nature of value creation.[48–50] The lack of transparency about R&D contributions (directly and indirectly by different actors) and pricing information also preclude constructive discussions about fair pricing.[51,52] As the imbalance in monopoly control over the technology including its price-setting and bargaining power remains unchanged, the public continues to either pay multiple times for health innovation or is restricted in accessing it or being able to produce it themselves. In a scenario where the public often makes significant investments in the most uncertain stages of research, it means the risks of innovation are largely socialized – taken on by the public – but the rewards (ownership and profits) are privatized.[53,54]

TABLE 1. Rethinking the health innovation ecosystem for the common good – from market fixing to co-shaping and co-creating

	STATUS QUO: Public sector as a repairer of	NEW ECOSYSTEM: Public sector as a co-shaper