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Transforming the medical innovation and access ecosystem in pandemic preparedness and response: reform proposals to break the status quo and improve global public health outcomes

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Table of Contents

Glossary of abbreviations

ACDC – African Centres for Disease Control and Prevention

ACT-A – Access to COVID-19 Tools Accelerator

AIDS – acquired immunodeficiency syndrome

AMA – African Medicines Agency

AMC – Advance market commitment

AMR – Antimicrobial Resistance

APA – Advance Purchase Agreement

ARPA-E – Advanced Research Projects Agency-Energy

AZT – Azidothymidine

BARDA – Biomedical Advanced Research and Development Authority

BRIDGS – Bridging Interventional Development Gaps Programme

CARB-X – Combating Antibiotic-Resistant Bacteria Biopharmaceutical Accelerator

CECMED – Center for State Control of Medicines and Medical Devices

CEME – Centre for Medicines

CEO – Chief Executive Officer

CEPI – Coalition for Epidemic Preparedness Innovations

CERD – Committee on the Elimination of Racial Discrimination

CERN – European Organization for Nuclear Research

CESCR – Committee on Economic, Social and Cultural Rights

CFO – Chief Financial Officer

COVAX – COVID-19 Vaccines Global Access

COVID-19 – Coronavirus disease 2019

C-TAP – WHO COVID-19 Technology Access Pool

DARPA – U.S. Defense Advanced Research Projects Agency

DNDi – Drugs for Neglected Diseases initiative

DRIVe – BARDA's Research, Innovation and Venture Division

EDCTP – European Developing Countries Clinical Trials Partnerships

EMA – European Medicines Agency

EMBL – European Molecular Biology Laboratory

ESA – European Space Agency

ESI – Emergency Support Instrument

EU – European Union

EVI – European Vaccine Initiative

FDA – Food and Drug Administration

FIND – Foundation For Innovative New Diagnostics

G77 – Group of 77

GDP – Gross domestic product

GHIC – Global Health Investment Corporation

GHIT – Global Health Innovative Technology Fund

GPI – Global Public Investment

HERA – European Health Emergency Response Authority

HIV – human immunodeficiency virus

HTA – Health Technology Assessment

IAVG – WHO's Independent Initiative on Vaccine Allocation Group

ICESCR – International Covenant on Economic, Social and Cultural Rights

IDRI – Infectious Disease Research Institute

IHSI – International Horizon Scanning Initiative

IMI – Innovative Medicine Initiative

IP – Intellectual Property

LAC – Latin America and the Caribbean Region

MAV+ – Team Europe Initiative on Manufacturing and Access to Vaccines, Medicines and Health Technologies

MDGH – MEDICINES Development For Global Health

MEDICC – High-Level Fact-Finding Delegation to Cuba

MERS – Middle East Respiratory Syndrome

MMV – Medicines for Malaria Venture

MPP – Medicines Patent Pool

mRNA – Messenger RNA

MSF – Médecins Sans Frontiers

NGO – Non-governmental Organisation

NIAID – U.S. National Institute of Allergy and Infectious Diseases

NIH – National Institute of Health

OSRD – Office of Scientific Research and Development

PATH – Program For Appropriate Technology in Health

PAVM – Partnerships for African Vaccine Manufacturing

PDP – Product Development Partnership

PPP – Public-private Partnership

PR – Public Relations

PRV – priority review voucher

R&D – Research and Development

RIVM – Dutch National Institute for Public Health and the Environment

SARS – Severe Acute Respiratory Syndrome

SARS-CoV-2 – Severe acute respiratory syndrome coronavirus 2

SDG – Sustainable Development Goals

SME – Small and Medium-sized Enterprise

SOMO – Centre for Research on Multinational Corporations

TBVI – Tuberculosis Vaccine Initiative

TRIPS Agreement – Trade-Related Aspects of Intellectual Property Rights Agreement

UDHR – Universal Declaration of Human Rights

U.K. – United Kingdom

UNAIDS – Joint United Nations Programme on HIV/AIDS

U.S. – United States

WHO – World Health Organisation

WIPO - World Intellectual Property Organization

WTO – World Trade Organisation

Introduction

Right to health

Health is a human right.[1] Access to healthcare, including access to essential medicines, is a prerequisite for its realisation.

Under international human rights law, states have a *core obligation* to ensure their domestic law, policy, and practice protect and promote this right.[2] Governments are required to develop national health regulations and strategies to provide essential medicines to their populations on a non-discriminatory basis and without delay.[3]

Universal access to essential medicines is also a key component of universal health coverage (UHC), affirmed in the Sustainable Development Goal (SDG) 3 for Health.[4]

International declarations further affirm the right to equal access to medical innovation. Article 27 of the Universal Declaration of Human Rights (UDHR) says that everyone has the right to freely participate in the cultural life of the community, to share scientific advances and its benefits.[5]

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[1] See e.g.,: Preamble of the Constitution of the World Health Organisation, adopted by the International Health Conference held in New York from 19 June to 22 July 1946, Official Record, World Health Organisation 2, 100, https://apps.who.int/gb/bd/PDF/bd47/EN/constitution-en.pdf (23 May 2023).; See also: *Human rights*, Fact sheet, 10 December 2022.; https://www.who.int/news-room/fact-sheets/detail/human-rights-and-health#:~:text=%E2%80%9CThe%20right%20to%20the%20highest,for%20all%20people%20without%20discrimination (23 May 2023). Health is recognised as a fundamental human right in at least 135 national constitutions of sovereign states. See: United Nations, *MDG GAP Task Force Report 2008: Delivering on the Global Partnership for Achieving the Millennium Development Goals*, New York, June 2008; https://desapublications.un.org/publications/mdg-gap-task-force-report-2008-delivering-global-partnership-achieving-millennium (27 May 2023).

[2] It is reflected in, among others, four international human rights treaties and declarations collectively known as "International Bills of Human Rights", including the International Covenant on Economic, Social and Cultural Rights (ICESCRs) ratified by a total of 165 States. Core obligations under the ICESCRs are further specified in Comment no 14 and include e.g., the provision of essential drugs as defined under the WHO Action Programme on Essential Drugs. See: UN Committee on Economic, Social and Cultural Rights (CESCR), *General comment no. 14 on the Right to the highest attainable standard of health*, Document No.: E/C.12/(2000)/4, 2020.; https://www.refworld.org/pdfid/4538838d0.pdf (27 May 2023).

[3] See: Special Rapporteur on the right to health, *Access to medicines and the right to health*, OHCR; https://www.ohchr.org/en/special-procedures/sr-health/access-medicines-and-right-health%20 (27 May 2023).

[4] SDG Target 3.8 on UHC aims to ensure that all have access to health services, including essential medicines without risking financial hardship. See: UN General Assembly, *Resolution on transforming our world: the 2030 agenda for sustainable development*, Document No.: A/RES/70/1, 2015. See also: H. V. Hogerzeil, *Essential medicines and human rights: what can they learn from each other?*, Bulletin of the World Health Organisation, 84(5), May 2006, p. 371–375; https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2627335/ (27 May 2023).

[5] Office of the High Commissioner for Human Rights, *Universal Declaration of Human Rights at 70: 30 Articles on 30 Articles - Article 27*, Press release, 6 December 2018;

Similarly, Article 15 of the International Covenant on Economic, Social and Cultural Rights (ICESCR) establishes the right *to participate in and enjoy the benefits of scientific progress and its applications*.[6] These benefits *refer first to the material results of the applications of scientific research, such as vaccinations (…). Secondly, benefits refer to the scientific knowledge and information directly deriving from scientific activity, as science provides benefits through the development and dissemination of the knowledge itself.*[7]

According to the UN Committee on Economic, Social and Cultural Rights (CESCR), *accessibility means that scientific progress and its applications should be accessible for all persons, without discrimination*.[8] States should ensure that everyone has equal access to the applications of science, particularly when it is instrumental for the enjoyment of other economic, social and cultural rights.

In the context of health emergencies, under ICESCR, states are obliged to prevent, treat and control epidemics and other diseases by, inter alia, making available relevant technologies and implementing or enhancing immunisation programmes.[9]

International law also places obligations on states to each other in this regard. In line with the International Health Regulations (2005), they should provide financial and technical support to each other in realising their populations' right to health.[10] According to CESCR, *such international assistance and cooperation include the sharing of research, medical equipment and supplies, (…) coordinated action to reduce the economic and social impacts of the crisis*.[11]

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https://www.ohchr.org/en/press-releases/2018/12/universal-declaration-human-rights-70-30-articles-30-articles-article-27#:~:text=Article%2027%20says%20everyone%20has,as%20human%20rights%20for%20all (27 May 2023).

[6] UN Committee on Economic, Social and Cultural Rights (CESCR), *General comment No. 25 (2020) on article 15: science and economic, social and cultural rights, General Comments and Recommendations*, E/C.12/GC/25, 30 April 2020; https://www.ohchr.org/en/documents/general-comments-and-recommendations/general-comment-no-25-2020-article-15-science-and%20 (27 May 2023).

[7] *Ibidem, para.* 8.

[8] *Ibidem, para.* 17.

[9] UN Committee on Economic, Social and Cultural Rights (CESCR), *General Comment 14: The Right to the Highest Attainable Standard of Health (Art. 12)*, 11 August 2000, UN Doc. E/C.12/2000/4, *para.* 16 and 43; https://www.refworld.org/pdfid/4538838d0.pdf%20 (27 May 2023).

[10] World Health Organisation, *International Health Regulations (2005)*, Third Edition, 1 January 2016, Art. 43.; who.int/publications/i/item/9789241580496 (27 May 2023).

[11] UN Committee on Economic, Social and Cultural Rights (CESCR), *Statement on the Coronavirus Disease (COVID-19) Pandemic and Economic, Social and Cultural Rights*, UN, Doc. E/C.12/2020/1, 17 April 2020, *para.*19; https://digitallibrary.un.org/record/3856957?ln=en (27 May 2023).

At the beginning of the COVID-19 pandemic, CESCR reiterated these commitments, stating that *pandemics are a crucial example of the need for scientific international cooperation to face transnational threats*.[12]

However, finding a reflection of these obligations in countries' existing public policies and laws shaping the pharmaceutical system remains a daunting challenge.

At least half of the world's population cannot obtain essential health services.[13] This inequity is rooted in structural political and economic imbalances, resulting in an uneven allocation of power and resources.

An estimated two billion people today cannot access the medicines they need.[14] The reason for this is rarely scientific or technical limitations, but rather political choices that make the availability of medical innovations dependent on business models and their pricing determined by profit maximisation strategies.[15]

Biomedical innovation model unfit for purpose

Over time, trust in the pharmaceutical sector and its ability to promote the development of appropriate medical innovations while ensuring sustainable, affordable, and equitable access to them has been eroded.

The failure of the current system to achieve these goals stems from its design, which shifts important responsibility for meeting public health needs to corporations whose statutory objectives make them particularly unable to fulfil this mission.

The pharmaceutical research and development (R&D) process is often based on publicly funded highest-risk early-stage research. It is further spurred through numerous direct and indirect public financial supports and incentives. However, the resulting innovations are most often privatised and monopolised at later stages, limiting their availability and affordability.

This is not to say that private companies do not invest in medical innovation. They certainly do. However, when the private industry invests in R&D, they more often pursue

[12] *Ibidem*, *para*. 23.
[13] World Bank, *Lack of Health Care is a Waste of Human Capital*, news article, 2018; https://www.worldbank.org/en/news/immersive-story/2018/12/07/lack-of-health-care-is-a-waste-of-human-capital-5-ways-to-achieve-universal-health-coverage-by-2030 (23 May 2023).
[14] See: Access to Medicine Foundation. https://accesstomedicinefoundation.org/ (27 May 2023).
[15] E. Torreele, *20 Years On, the Access-to-Medicines Battle Is Going Global*, Letter from the director, 20th Anniversary Magazine, MSF, 2015. https://20years.msfaccess.org/ (27 May 2023).

low-risk strategies that can more easily bring commercial success. Big pharma companies are also more likely to pay billions to acquire smaller firms with promising drug candidates in the pipeline, rather than conduct in-house research and early-stage preclinical and clinical trials. Pharmaceutical companies are also increasingly financialised, which results in their reduced reinvestment in R&D and focus on the short-term return for their shareholders.

The current medical innovation system is therefore biased toward high revenue-generating diseases, leading to an increasing gap between unmet medical needs and investment.

This is due to the fact that the incentives that drive private companies' investments in the pharmaceutical sector are disconnected from public health needs. For-profit companies operating in the sector are driven by the sole goal of maximising profit and increasing shareholder value, often regardless of competing considerations.

Overreliance on the private sector

Nevertheless, despite these evident conflicts, the current biomedical R&D and access model is built on the prevalent ideology that a globalised market driven by private actors works best for the development and supply of health technologies. From this perspective, any problems that arise are framed as *market failures* needed to be fixed by the public sector, whose overall role should be limited to just that.[16]

The private industry is able to steer the biomedical R&D agenda, control the availability and pricing of pharmaceutical products and reap outsized benefits from them thanks to an extensive web of incentives and data and market exclusivities, which are stacked atop a stringent intellectual property rights framework.

It maintains this profitable status quo by extensive regulatory capture, in which companies influence policymakers and regulators in effect designing their own markets in pursuit of commercial gain.

In consequence, from the public interest perspective, the pharmaceutical system is riddled with inherent problems.

[16] E. Torreele, *Business-as-Usual will not Deliver the COVID-19 Vaccines We Need*, Development, Springer, Volume 63, 2020, p. 191–199; https://link.springer.com/article/10.1057/s41301-020-00261-1 (27 May 2023).

Widening divergence of interests in health emergency context

It can be argued that this system is particularly inadequate to ensure adequate preparedness and response to health emergencies such as pandemics. The divergence between public health needs and pharmaceutical companies' business strategies even widens in that context.[17]

Over the past decades, several outbreaks, epidemics and pandemics have raised alarms about the incapability of the current R&D system to respond to them. These shortcomings are also evident in the failure to prioritise infectious disease research prior to a crisis.

The blame for this lies primarily with the lack of adequate public policies and funding, but also, as Peter Hotez, a vaccine specialist from the National School of Tropical Medicine in Houston, points out, this is due to the fact that medical countermeasures such as *vaccines for neglected and emerging infections fall through the cracks because they are not a priority for pharma and biotechs*.[18]

Perhaps the most glaring failure of this system is global inequalities in access to these lifesaving products. Time and again, during health emergencies, citizens of rich countries have much quicker access to them than those in the Global South. The remnants of the colonisation era are all too evident in these cases. Just a glimpse at the response to the previous and current pandemics provides clear evidence in this regard.

Neglected medical innovation in Ebola virus and Mpox epidemics

The vast majority of the disease outbreaks take place in remote areas or in poor countries where the opportunities for profits from pharmaceutical products are slim.

[17] M. Mazzucato, H. L. Li, *A market-shaping approach for the biopharmaceutical industry*, UCL Institute for Innovation and Public Purpose, Working Paper Series (IIPP WP 2020-21), 2021, p. 2-4.; https://link.springer.com/article/10.1057/s41301-020-00261-1 (27 May 2023).; G. Krikorian, E. Torreele, *We Cannot Win the Access to Medicines Struggle Using the Same Thinking That Causes the Chronic Access Crisis*, Health Hum Rights, 23(1), June 2021, p. 119–127, 2021; https://pubmed.ncbi.nlm.nih.gov/34194206/ (27 May 2023); Y. Heled, A. S. Rutschman, L. Vertinsky, *The problem with relying on profit-driven models to produce pandemic drugs*, Journal of Law and the Biosciences, Volume 7, Issue 1, January-June 2020; https://academic.oup.com/jlb/article/7/1/lsaa060/5882039?login=false (27 May 2023).

[18] Peter Hotez, a vaccine specialist and dean of the National School of Tropical Medicine in Houston, made the same crucial point in testimony before the U.S. Congress, see: https://www.c-span.org/video/?c4873495/user-clip-hotez-coronavirus-vaccine-testimony (27 May 2023).

The lack of investment in diseases endemic in the Global South has been clear for the Ebola outbreak. [19] When Ebola emerged in 1976, the system did not incentivise research into vaccines or treatments against the virus as the market for these products has not been sufficiently lucrative. It was not until Ebola became a major international health crisis that there was any real interest in bringing medical countermeasures to market.

The development of a vaccine against Ebola virus, from its initial discovery to its approval for widespread use took over 20 years.[20] The lack of the vaccine and effective treatments for so long has exacerbated the crisis.

The Ebola outbreaks are a continuous risk in Africa, but little interest is paid to ensure sufficient preparedness for them. During the outbreak in Uganda in late 2022, it took months before candidate vaccines were made available for testing.[21]

The latest example of the lack of medical innovation in the Global South's health emergencies is Mpox.[22] Mpox has been endemic for the last 50 years in Nigeria, the Democratic Republic of the Congo, and the Central African Republic but research programs into vaccines or treatment to tackle it have been prioritised by neither the public nor private sector.[23]

Only once the disease spread to rich countries it sparked more R&D interest and has become the focus of international agencies and global public health strategies.

Inequitable access in HIV/AIDS and COVID-19 pandemics

The HIV/AIDS crisis, particularly in Africa at the turn of the 20th century, is one of the best-known examples of inequitable access to lifesaving products and the negative

[19] M. Kamal-Yanni, *Never Again*, 203 Oxfam Briefing Paper, April 2015; https://oxfamilibrary.openrepository.com/bitstream/handle/10546/550092/bp-never-again-resilient-health-systems-ebola-160415-en.pdf;jsessionid=FD6899F5BA90DC0594B69A5297324A0E?sequence=7 (27 April 2023).

[20] Medecins Sans Frontiers, *Public funds, private failure: Canada's Ebola vaccine could have saved more lives*, 26 May 2020; https://www.doctorswithoutborders.ca/public-funds-private-failure-canada%E2%80%99s-ebola-vaccine-could-have-saved-more-lives (27 May 2023)

[21] J. Nickerson, A. Houston, *A viable vaccine for Ebola's latest strain is shamefully collecting a decade of dust in Canada*, The Globe and Mail, 15 November 2022; https://www.theglobeandmail.com/opinion/article-aviable-vaccine-for-ebolas-latest-strain-is-shamefully-collecting-a/ (27 may 2022).

[22] A preferred term, replacing "monkeypox". See: https://www.who.int/news/item/28-11-2022-who-recommends-new-name-for-monkeypox-disease#:~:text=Mpox%20will%20become%20a%20preferred,and%20to%20update%20WHO%20publications (27 May 2023).

[23] D. Gleeson, *Monkeypox—the next global vaccine equity failure?*, The Conversation, 30 August 2022; https://theconversation.com/monkeypox-the-next-global-vaccine-equity-failure-189045 (27 May 2023).

impact of the international legal and policy framework established to protect the Global North's economic interests.[24]

The first effective treatment against the virus, azidothymidine (known as AZT) has been approved in the U.S. in 1987 and marketed at about $8,000 (more than $17,000 in today's U.S. dollars) for a year's course.[25] Such a price made it out of reach for almost all of the world's 25 million AIDS patients but a few in wealthy countries (home to only around 10 per cent of global cases).

Zaitchik, an American journalist writing about the pharmaceutical sector, reported that *for many developing countries, the cost of providing the pills for every infected citizen would have exceeded the national GDP*.[26]

These glaring inequalities in access to lifesaving products were repeated to an even greater extent during the COVID-19 pandemic in terms of the allocation of medical countermeasures against SARS-CoV-2. While the recent pandemic provides multiple examples of the current system's failures, this one stands out.[27] Six months after the first COVID-19 vaccines were approved and marketed, 85 per cent of them were administered in high- and upper-middle-income countries and less than 1 per cent in low-income countries.[28]

Despite the fact that, after more than two years of a global immunisation campaign, vaccination rates were much higher in rich countries (accounting for just 16 per cent of the world's population) than in low- and middle-income countries, the former also hoarded the vast majority (74 per cent of all courses ordered by late 2022) of Ritonavir-Boosted Nirmatrelvir (Paxlovid), the most effective treatment for COVID-19.[29]

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[24] The fact that these inequalities affected some populations more than others also drew attention to socio-economic and gender issues related to access to medicines. See: M. Kamal-Yanni, *Key Issues and Recommendations for the International Treaty on Pandemic Prevention, Preparedness, Response and Recovery*, People's Vaccine Alliance, 2022. p.3; https://peoplesvaccine.org/wp-content/uploads/2022/10/PVA-PPPRR-report.pdf (27 May 2023).

[25] A. Park, *The Story Behind the First AIDS Drug*, Time, 19 March 2017; https://time.com/4705809/first-aids-drug-azt/ (27 May 2023).

[26] A. Zaitchik, *Owning the Sun: A People's History of Monopoly Medicine from Aspirin to COVID-19 Vaccines*, Counterpoint Press, 2022, p. 218.

[27] Oxfam International, *Pandemic of Greed*, Oxfam Media Briefing, March 2022; https://oi-files-d8-prod.s3.eu-west-2.amazonaws.com/s3fs-public/2022-03/Pandemic_of_greed-Oxfam_media_briefing-March2022.pdf (27 May 2023).

[28] C. M. Correa, *Vaccination inequalities and the role of the multilateral system*, South Centre, July 2021, p.1.; https://www.southcentre.int/wp-content/uploads/2021/07/SouthViews-Correa.pdf (27 May 2023).

[29] Data by November 2022. See: People's Vaccine Alliance, *Just a quarter of Pfizer's COVID-19 treatment orders will go to developing countries*, Press release, November 2022. https://peoplesvaccine.org/resources/media-releases/just-a-quarter-of-pfizers-covid-19-treatment-orders-will-go-to-developing-countries/ (27 May 2023).

Need for transforming the pharmaceutical system

Response to health emergencies over the past decades provides a wealth of evidence and fundamental lessons – many of which will be examined in more detail in this dissertation – on the importance of appropriate public health and health security strategies and the roles the public and private actors have to play in them, calling for structural interventions.

The international framework and domestic policies have proved to be grossly inadequate. Responsibility for undertaking critically important biomedical R&D, advancing manufacturing capacities and controlling access to medical countermeasures, left to the private sector, has been neglected, despite urgent and repeated concerns raised by the scientific community.

Transformative reforms are therefore of critical importance and must address the imbalance of power between the public and private sectors. This will require challenging the status quo by assuming greater public responsibility for medical innovation.

Instead of de-risking the medical innovation process, the public sector should take leadership in shaping (and funding, including at late stage) medical countermeasure R&D and ensuring access and equitable distribution of end products. In times of health crises, governments should be able to decide how and when tests, vaccines and treatments are developed, manufactured, and distributed, instead of leaving it to the discretion of the private sector. How this can be achieved is the subject of this dissertation.

What this dissertation discusses

Future health emergencies may look different from the COVID-19 pandemic. However, it is highly likely that climate change, environmental degradation and loss of biodiversity will make them more frequent.[30]

[30] ProPublica examined deadly disease outbreaks in Guinea — where the first Ebola case was reported — and found a clear link between outbreaks and deforestation. See: C. Chen et al., *On the Edge*, ProPublica, 27 February 2021; https://www.propublica.org/article/pandemic-spillover-outbreak-guinea-forest-clearing (27 May 2023).

This dissertation provides evidence on why the existing medical innovation and access ecosystem is not suitable – not by accident, but by design – to prepare and respond to them effectively.

It examines how the current legal and political framework governing health emergency preparedness and response and market forces driving R&D and access to medical countermeasures are not able to deliver the most relevant health interventions to as many people as possible.

Evidence is also provided on how the existing system perpetuates or even expands the imbalance of power between countries and how limitations of charity and donor-recipient aid models foster global inequalities.

While pharmaceutical companies are often criticised for prioritising profit over public health outcomes and ineffectively responding to health crises, the underlying system that enables that is less often scrutinised. This dissertation, therefore, discusses how public policies and the existing legal frameworks fall far short of realising the public interest in ensuring the most appropriate medical technologies are developed and made equitably available worldwide.

It is argued that to prevent gaming the pharmaceutical system and make it more responsive to public health needs, attention should be paid to rethinking not only the medical innovation and access ecosystem but also broader economic and industrial policies.

The dissertation explores how to transform the way public and private entities are governed, including their approaches, goals, and business models, to achieve this goal.

From ensuring a fair return on public investments and changing incentives for medical R&D to adapting the statutory forms of companies operating on the pharmaceutical market and having the public actors directly involved in the pharmaceutical value chain, this dissertation aims to expand the prospects of what is possible with alternative approaches.

Political momentum

The international rules established at the World Health Organisation (WHO) and the World Trade Organisation (WTO) to protect public health have significantly failed, either due to poor compliance and the lack of enforcement measures or their overcomplexity and political pressure.

As the COVID-19 pandemic recedes, political leaders are discussing ways to *build forward better*.[31] Political and legal processes have been launched to revise the international framework,[32] adapt the global health architecture, and improve the system of health products development, production, and access.[33]

New governance structures, political and legal agreements, financial instruments, and technical mechanisms are being proposed and implemented. These negotiations at the national, regional and international levels will define how prepared the world is for future emergencies and determine countries' ability to effectively respond to them. This is arguably the best chance the world has to challenge the status quo.

This momentum provides an opportunity to reimagine the global health architecture to make the system work for those most in need, those who experience the greatest burden of historical inequalities and society at large.

However, without an in-depth understanding of the system's structural problems and the root causes of its failure, these discussions may only result in superficial improvements, but will not lead to substantial change.

Continuing with the business-as-usual means worsening health outcomes, prolonging global inequalities, draining public resources, hindering the dissemination of knowledge and innovation, and wasting time.

The purpose of this dissertation is to inform the ongoing processes with the understanding that some of the proposed reforms may go beyond current political agendas.

This dissertation is focused on systemic changes in the medical innovation and access ecosystem, as well as in political thinking about the role the public sector should play in it.

The emphasis is placed on policy reforms in recognition that it is politics and states' ideological and cultural heritage that shape the law. This is also true at the international level, where most regulations and guidelines are *soft law* rather than legally binding instruments. Changing states' approaches to pharmaceutical R&D and access will have

[31]The WHO Council on the Economics of Health for All, *Governing health innovation for the common good*, Council Brief No. 1, 9 June 2021, p. 1; https://cdn.who.int/media/docs/default-source/council-on-the-economics-of-health-for-all/councilbrief-no1_20210609_corr.pdf (27 May 2023).

[32] For example, the revision of the International Health Regulations from 2005 and the negotiations of the new Pandemic Accord at the World Health Organisation.

[33] Including international initiatives such as the WHO mRNA Technology Transfer Programme or regional ones, such as the Partnerships for African Vaccine Manufacturing (PAVM).

a direct impact on the formation of law and practices at national, regional and international levels.

The fundamental reforms discussed here would form the basis for specific regulations which should be then introduced to achieve the desired objectives. This thesis, however, does not aim to provide an in-depth analysis of the current legal framework or to present comprehensive legal proposals. It does, however, touches upon some legal problems, for example in the context of human rights, including the right to health and the responsibility of private companies in this regard, and makes general *de lege ferenda* proposals. These observations refer, among other things, to establishing an appropriate policy and legal environment for companies pursuing public interest so that they can be sustainable and competitive in the pharmaceutical market (while at the same time not being able to game the system), or to revising the international legal framework to improve global pandemic preparedness and response through greater cooperation between countries on R&D of medical countermeasures and ensuring equal access to them worldwide.

While the dissertation makes these selected observations on existing regulations and points to the need for new ones, its objective is to identify flaws in the design of the current medical innovation and access ecosystem and show how its underlying principles and ways of working can be transformed to better serve the public interest. This policy and conceptual shift should be supported by appropriate legal changes in order for the pharmaceutical sector to operate effectively under the new conditions. However, as noted, proposing these detailed legal options is beyond the scope of this dissertation.

Structure of the dissertation

The dissertation is divided into two parts. The first analyses the status quo and the second suggests how to break it. The aim of the proposed changes is to increase the efficiency of the pharmaceutical R&D and access ecosystem and to make it an effective tool in fulfilling the state’s obligation to ensure people's right to health.

The analysis begins with a look back at the origins of the pharmaceutical industry and the role the public and private sectors have played in it. Examining early successes and failures in developing relevant pharmaceuticals, including medical countermeasures, help to outline the early patterns of dynamics between public and private actors that can be traced to the COVID-19 pandemic and many other health emergencies before it.

The recent pandemic serves as an example of the many failures and inefficiencies of the prevailing pharmaceutical innovation and access model, in which public responsibilities have been largely ceded to profit-driven private companies with fundamentally different interests than meeting the health needs of as many people as possible. It is argued how the divergence between public interest and private considerations in medical innovation is evident in all pharmaceutical R&D efforts and how it even worsens in the context of pandemic preparedness and response with dire consequences. From the failures of relying on private sector engagement and the imbalance of power between public and private actors, to the privatisation of public research and the hindering of knowledge dissemination and limiting access to health products, the dissertation analyses how the existing model is not fit for purpose. The analysis concludes by discussing one of the main consequences of this failure – global inequalities in access to health technologies.

Whereas the first part of the dissertation argues that the current system of incentivising medical innovation through monopolies is grossly inefficient, the second part presents alternative options. These are based on the premise that the public sector should take greater responsibility for determining the direction of health innovation, ensuring access to it based on equity and human rights principles, and shaping the R&D ecosystem accordingly. As such, the discussion includes how this change can be achieved even through small but consequential measures (for example, by attaching stringent conditions to public funding) and how the ultimate transformation needs to be brought about through setting up an end-to-end system that, from basic research to clinical trials, manufacturing and procurement to end-product delivery, is guided by public interest principles. Various alternative approaches are presented and analysed with examples of their application in specific disease areas. Conclusions are then drawn on how these models can be used to develop medical countermeasures and ensure wide access to them.

Beyond the proposals to transform public sector governance and leadership, increase multilateral cooperation, shape the market, and influence the decision-making of private companies, other even more far-reaching options are also considered. These include changing the ways in which private actors operate in the market – or even changing the actors themselves – to promote corporate governance which considers aspects beyond profit and leads to better value creation. The discussion also touches on why and how public policy should encourage the involvement of corporations with other legal forms, such as non-profit or limited-profit companies and benefit or social purpose corporations in the sector.

Finally, besides changing the ways for-profit companies operate in the pharmaceutical sector and introducing corporations that have other statutory forms and hence could more efficiently serve the public interest on the market, direct public sector involvement in pharmaceutical research and development, the so-called *public option*, is also discussed, with an emphasis on how public pharmaceutical research and development, production and supply may be of particular relevance in the context of health emergencies.

PART I – Status quo

Chapter 1. Rise and fall of public capacity

1.1. Origins of the pharmaceutical sector

The world came a long way in learning how to treat infectious diseases.

First apothecaries and pharmacies offering traditional remedies can be traced back to the Middle Ages, providing a hit-or-miss assortment of treatments based on folk wisdom.[34] When the Black Death rattled the world in the 14th century, however, causing the deaths of 75–200 million people, no effective cure was available, and people could only minimise the risk of infection through preventive measures.[35]

The following centuries brought little improvement. While the Scientific Revolution fuelled rationalism and experimentation during the 16th and 17th centuries, and the Industrial Revolution transformed the production of goods in the late 18th century, they failed to bring about a breakthrough in medical R&D and manufacturing processes. This started to change significantly only in the mid-19th century when the pharmaceutical industry as it is known today really has its origins.

1.2. Early days of the pharmaceutical industry

The modern pharmaceutical industry has evolved primarily from European pharmacies. Retail pharmacies laid the foundation for pharmaceutical corporations, which multiplied steadily in the second half of the 19th century.[36]

Merck, in Germany, was probably the earliest pharmaceutical company to, around 1827, take advantage of the advances of the Industrial Revolution and combined them with the idea of experimentation.[37]

Switzerland also saw the rapid development of a homegrown pharmaceutical industry in the second half of the 19th century, which, however, did not evolve out of

[34] Pharmaphorum, *A history of the pharmaceutical industry*, 1 September 2021; https://pharmaphorum.com/r-d/a_history_of_the_pharmaceutical_industry/ (23 May 2023).
[35] G. Lawton, *Plague: Black death bacteria persists and could cause a pandemic*, New Scientist, ISSN 0262-4079 London, 30 May 2022; https://www.newscientist.com/article/mg25433880-400-plague-never-went-away-now-it-could-re-emerge-in-drug-resistant-form/ (27 May 2023).
[36] J. Swann, *8 - The Pharmaceutical Industries*, in: P. J. Bowler, J. V. Pickstone, *The Cambridge History of Science, Volume 6: The Modern Biological and Earth Sciences*, Cambridge University Press, November 2009, p. 126-140.
[37] Pharmaphorum, *op. cit.*

pharmacies, but was based on the textile and dyeing industries. Sandoz, CIBA-Geigy, Roche and the pharma industry centre in Basel have their roots in these times.

Beecham's Pills, an English company that later merged into what is now known today as GlaxoSmithKline, opened the world's first drug-only manufacturing plant in 1859.

Similarly, in the US, the first pharmaceutical companies began to emerge around the same time. Their rise is linked to the surge in demand for antiseptics and painkillers for combat troops fighting in the Mexican-American War in the mid-19th century.[38] For example, Pfizer was founded in 1849, and Eli Lilly in 1876. The latter is considered a pioneer of a new business model, being one of the first companies to focus not only on manufacturing but also on R&D.

The further development of the pharmaceutical sector was greatly impacted by rivalries between countries and political blocs, conflicts and wars that characterised this period. [39]

The German pharmaceutical industry dominated the world medicine market from the late 19th century until World War I, during which its position weakened.[40] For example, the U.S. seized Bayer's assets, including its aspirin trademark while Merck's subsidiary was forced to separate from its German parent company.[41] Also during the Russian Revolution, Bayer's subsidiary was seized by state authorities.

As Germany's leadership in pharmaceuticals waned, companies from other countries, especially the US, began to take over the market. During World War II, the balance of power in the industry was further shifting away from Germany and toward the United States. The negative impact of the war on German industry certainly contributed to this, but an even greater factor was the rapid ability of American industry to cultivate research and bold public policies. The origin of the U.S. Big Pharma as it is known today can be traced back to the U.S. government's decision to incentive and subsidise mass production of penicillin during the war.[42]

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[38] E.g., those fighting in the Mexican-American War in the mid-19th century.

[39] T. Cramer, *Building the "World's Pharmacy": The Rise of the German Pharmaceutical Industry, 1871–1914*, in: W. A. Friedman, G. Jones, *Bulletin of the Business Historical Society (1926 - 1953)*, Business History Review, Volume 89, Issue 1, April 2015, p. 43-73.

[40] *Ibidem*, p. 126-140.

[41] The division still exists today. Now, there is Merck & Co. in the U.S. or Merck Sharp & Dohme (MSD) elsewhere.

[42] U.S. War Production Board in 1943 determined mass production of penicillin as the top priority next to the development of an atomic bomb. See: E. Lax, *The Mold in Dr. Florey's Coat: The Story of the Penicillin Miracle*, New York: Henry Holt, 2005, p. 206–7.; See also: C. Garrison, *Ensuring that intellectual property rights aren't a barrier to scaling-up*, April 2021; https://medicineslawandpolicy.org/wp-

1.3. Lack of medical innovation prior to World War II

Before World War II, pharmaceutical companies were focused on opiates such as morphine or heroin, sales of which were at a record high during World War I. The next best-selling products were narcotics with the peak of cocaine production after the war. Due to huge overproduction and drug trafficking, narcotics provided upward of half of pharmaceutical profits in the US. Over time, with stricter regulations, narcotics were replaced as the most income-generating products by hypnotics, such as barbiturates and amphetamines.

The fact that these types of medicines brought most in companies' revenues results from the fact that hardly any others were on the market at the time and those that were had very little potential to cure diseases and at most could reduce their symptoms and relieve pain.

There was only one notable exception to the general lack of innovation, the diabetes drug insulin developed by public researchers.[43]

In 1922, two years after the Spanish flu was eradicated, scientists at the University of Toronto made one of the most significant medical breakthroughs to date, developing insulin. They decided to not patent the treatment, recognising that it should not become anyone's property, but be a common good. Insulin was, however, exclusively licensed to the U.S. private pharmaceutical company Eli Lilly for further development and marketing in North and South America. Over the following decades, the insulin market grew exponentially, as did the "patent thickets" around the product erected by the company to fend off competition and keep prices high, especially in the US. The fact that insulin was developed by scientists from a public university who believed it should be cheaply available to everyone but for decades many patients could not afford it (1 in 10 Americans admit they ration their insulin because they cannot pay for a full treatment) is one of the flagship examples of the problems facing the pharmaceutical system today.[44]

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content/uploads/2021/04/Ensuring-IP-rights-arent-a-barrier-to-scaling-up-the-example-of-penicillin.pdf (27 May 2023).

[43] A later president of Merck noted: *You could count the basic medications on the fingers of your two hands*. The drugs mentioned were *morphine, quinine, digitalis, insulin, codeine, aspirin, arsenicals, nitroglycerin, mercurial, and a few biologicals.* See: M. L. Podolsky, *Cures out of Chaos: How Unexpected Discoveries Led to Breakthroughs in Medicine and Health*, Amsterdam: Harwood Academic Publishers, 1997, p. 59.

[44] The insulin market has grown exponentially over several decades and the company controls access with exorbitant prices.

It was no coincidence that insulin was developed at a public university. In the first half of the 20th century, most of pharmaceutical companies depended on academic R&D and focused only on manufacturing.[45]

An adequate illustration of the industry's lack of innovation in the early 20th century is the companies' inability to tackle the deadly influenza epidemic of 1918. Called the Spanish Flu, it infected half a billion people, about a third of the world's population. By some estimates, it killed 100 million just over several weeks. Pharmaceutical companies had nothing to slow down the pandemic or treat the disease.

This tragedy, and the helplessness that accompanied it, were enough of a wake-up call for the public sector to assume greater responsibility for research and development and the production of pharmaceutical products for health emergencies. As a result, following the aftermath of the Spanish flu, many developed countries established innovative, full-cycle public pharmaceutical industries. This was most pronounced in the US, where the decades following the influenza saw significant successes in vaccine innovation.

1.4. The U.S. public vaccine production in the late 20th century

The U.S. biomedical research and development during this period was based on a culture of strong public leadership, investment and cooperation.

The medical innovation system in country from World War II to the 1980s is an excellent example of the possibilities of a publicly driven medical innovation model, unfettered by market forces and intellectual property monopolies, but managed by strong institutions and based on the public interest.[46]

During that period, the federal program brought together R&D efforts across disciplines, ensuring rapid information exchange and technology transfer between them. It encouraged collegiality, collaboration, and trust.[47]

[45] They did not advertise to doctors because until 1938 any nonnarcotic medication could be bought without a prescription. As for narcotic-based drugs that required a prescription, about half were made in compounding pharmacies, cutting into pharma profits.

[46] Medical countermeasures have certainly not been the only medical area in which the public sector financed and steered innovation. For example, many of the tools used today to prevent or treat malaria emerged from the efforts of (and significant funding from) national military research institutions.

[47] A stark contrast to today's model in which, although the knowledge pool is much larger, the strong intellectual property rights system encourages actors to work in secrecy and isolation, leading to knowledge fragmentation and limiting the ability of science to be disseminated and translated into future innovation.

Success resulting from the U.S. government being in charge of critical innovation and manufacturing did not come from major, overnight scientific breakthroughs. Often, the scientific bases for successful vaccines were laid for years, if not decades, before being turned into final products. However, it was the wartime public program that was the main driver of the translation of medical technologies from laboratories to effective vaccines. It shows the power of public policy dedicated to achieving a specific and ambitious mission driven by strong public leadership and companies pursuing an integrated approach to R&D.[48]

Wartime R&D programs excelled in purposefulness and organisational efficiency. This approach continued even after the end of World War II, with tangible results. Of 28 vaccines against infectious diseases invented in the 20th century, as many as 18, including the most famous against flu, measles, and rubella, were developed with significant government involvement.[49]

1.5. Birth of public medical innovation and manufacturing around the world

Strong public sector capacities in vaccine R&D and production were not exclusive to the US.

In Europe, for example, the Dutch government has historically played a significant role in the establishment of vaccine development in the country, setting up a publicly owned national vaccine institute and production facilities. Vaccine R&D and manufacturing started at the Dutch National Institute for Public Health and the Environment (RIVM), after World War I.[50]

[48] K. Hoyt, *Long Shot: Vaccines for National Defense*, Cambridge: Harvard University Press, 2012, p.5.

[49] A. Zaitchik, *No Vaccine in Sight*, New Republic, May 2020; https://newrepublic.com/article/157594/no-coronavirus-vaccine-big-pharma-drug-patent-system (27 May 2023).

[50] According to the official information, *in the 1970s, the Dutch government took part in an exchange program initiated by the World Health Organization, which taught students from developing countries about vaccine development. One participant was Dr. Cyrus Poonawalla, who trained in Bilthoven at the Netherlands Vaccine Institute (NVI). Upon completion of the program, Dr. Poonawalla went on to further build the Serum Institute of India (SII) — now the world's largest vaccine manufacturer*. See: https://investinholland.com/news/how-the-netherlands-became-a-key-player-for-vaccine-development/ (27 May 2023).

In the U.K., the British military has been involved in infectious and tropical disease research since the 16th century.[51]

Public pharmaceutical R&D and manufacturing activities were (and in many cases still are) also carried out in South America. In the 1970s, Brazil began developing its pharmaceutical self-sufficiency by designating various medicinal products as *priority drugs* and setting up a public infrastructure for their production. The public production and distribution of medicines in *official laboratories* was considered an essential project for national sovereignty. It linked public and private capacities and was led by the Centre for Medicines (CEME) established in 1971. The institute has also set up central procurement of medicines and invested in national R&D programmes.[52]

Also in the 1970s, Cuba's public R&D and manufacturing capacity has been set up and grew rapidly, influenced by the political situation and the 1962 U.S. embargo, which limited the country's ability to import medicines from abroad. As a result of strong government support, in just the first 20 years after the establishment of Medicuba, public pharmaceutical R&D and manufacturing industry in 1972, it is estimated that Cuba managed to produce 1150 biological and diagnostic products.[53] To this day, the country has one of the strongest public pharmaceutical industry in the world (see also Chapter 9.2.1.).

1.6. Ideological and policy shift – privatisation

In the late 1970s, however, in many countries, the ideological approach and consequently the policies that assumed public leadership in the sector have been gradually changing, beginning the process of government withdrawal from pharmaceutical R&D.

In the US, with the election of President Nixon, came a systemic shift. It centred around the transfer of government science into private hands and resulted in a transformation of the landscape of vaccine development. The 1970s marked the beginning

[51] M. S. Bailey, *A brief history of British military experiences with infectious and tropical diseases*, British Medical Journal, Volume 159, Issue 3, 2013; https://militaryhealth.bmj.com/content/159/3/150.long (27 May 2023).

[52] While successful in the first decades after its establishment, the CEME was dissolved in 1997 due to deviations from its main mission and allegations of corruption. See: OTMeds, *Relocation of the Pharmaceutical Industry in Europe and in the Member States*, March 2022, p. 38; https://otmeds.org/wp-content/uploads/2022/02/otmeds_rapport_2022_EN.pdf%20 (27 May 2023).

[53] R. S. Tancer, *The pharmaceutical industry in Cuba*, Clinical Therapeutics, Volume 17, Issue 4, July 1995, p. 791-798; https://www.clinicaltherapeutics.com/article/0149-2918(95)80056-5/pdf (27 May 2023).

of the business model that dominates the sector today, with companies focusing on researching the most profitable drugs, leaving out the likes of vaccines and antibiotics.

The neoliberal policy of outsourcing key aspects of R&D and pharmaceutical production to private companies has not contributed to the increase in innovation envisioned by the government and industry. On the contrary, studies of the private industry's involvement in the vaccine market after the 1970s along with the development of scientific monopolies and the financialisation of the pharmaceutical business, show that innovation in this field has been declining steadily. Despite reports demonstrating that prevailing theories about innovation excellence in private industry in this field are unsubstantiated, the process of privatisation and weakening of public ownership and leadership has continued.

In 1967, dozens of U.S. companies had vaccine research divisions and production capacity, primarily because of their involvement in wartime partnerships, but also, it can be argued, because of a sense of public duty that only began to fade around that time. In the years that followed, many manufacturers pulled out of the vaccine business or considered doing so.

Several factors discouraged the private sector from investing in vaccines at the time, yet analysts often attribute the greatest significance to the swine flu vaccine campaign fiasco, seeing it as the beginning of a wave of companies leaving the sector and market consolidation.[54]

Until the onset of swine flu, the U.S. produced about 80 per cent of the world's annual vaccine supply.[55] The swine flu vaccination campaign was full of failures related to adverse reactions to the vaccines, lawsuits and damages (paid by the U.S. government, which took full responsibility) and public relations losses for pharmaceutical companies, which altogether horrified the industry and its insurers.

The events surrounding the swine flu response have changed not only the economic case for investing in vaccines but as argued by Hoyt, an expert on the U.S. biodefense policy, perhaps more importantly, the political and PR arguments for doing so: *the swine*

[54] Office of Technology Assessment, *Review of Selected Federal Vaccine and Immunization Policies*, Institute of Medicine, Vaccine Supply and Innovation, Washington, DC, National Academies Press, 1985.; See also: K. Hoyt, *op. cit*., p. 110.

[55] J. C. Gaydos et al., *Swine Influenza A at Fort Dix, New Jersey (January–February 1976). II. Transmission and Morbidity in Units with Cases*, The Journal of Infectious Diseases, December 1977, p. 363-368.

flu experience damaged the reputation of immunization campaigns and overturned a belief that the social obligation to respond to government vaccine requests (and the associated public relations benefits) outweighed the financial costs. This belief (…) was forged during World War II and homed in the post-war years, but it did not survive the swine flu affair.[56]

Once industry executives began assessing vaccine development projects solely on their commercial value, industry scientists had less freedom to pursue projects selected based on scientific and public health criteria. Opportunities for cooperation between the military and public industry also diminished.[57]

In 1979, as the number of U.S. vaccine manufacturers fell to a single figure, the Office of Technology Assessment alarmed that *the apparently diminishing commitment—and possibly capacity—of the American pharmaceutical industry to research, develop, and produce vaccines may (…) be reaching levels of real concern*.[58]

The new privatisation policy launched by U.S. President Reagan, however, ignored these reports. In 1980, the U.S. Congress passed the Bayh-Dole Act, permitting private actors' ownership of inventions arising from federal government-funded research (see also Chapter 2.4.1.), accelerating the shift toward extended patent protections over medical innovation and away from public control over government-funded research.[59]

By the late 1980s, only a few U.S. pharmaceutical companies remained active in the field. In an effort to keep them in the business (as well as to stem the trend toward higher vaccine prices), the U.S. passed the Vaccine Compensation Act in 1986, which exempted manufacturers from liability for non-fault vaccine-related injuries suffered under mandatory vaccination programs.[60]

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[56] K. Hoyt, *op. cit.*, p. 113.

[57] A. Zaitchik, *No Vaccine in Sight, op. cit.*

[58] Congress of the United States, Office of technology Assessment, *A Review of Selected Federal Vaccine and Immunization Policies, Based on Case Studies of Pneumococcal Vaccine*, United States. Congress. Office of Technology Assessment. September 1979. The report warned that *since 1968, the number of licensed manufacturing establishments that produce vaccines has dropped about 50 percent—from about 37 to 18. The number of licensed vaccine products has dropped about 60 percent—from 385 to around 150. The impact of this recent decline on the U.S. pharmaceutical industry's ability to develop and produce supplies of vaccines commensurate with public need is unknown*.; https://repository.library.georgetown.edu/bitstream/handle/10822/708638/7915.PDF?sequence=1&isAllowed=y (27 May 2023).

[59] See: *Patent and Trademark Law Amendments* Act, Pub. L. 96-517, December, 1980; https://www.govinfo.gov/content/pkg/STATUTE-94/pdf/STATUTE-94-Pg3015.pdf (27 May 2023).

[60] The Act is still in force during the COVID-19 pandemic and will play a significant role in the power dynamic between the pharmaceutical companies, the U.S. government and third countries. The protection offered by the U.S. law was the most favourable and pharmaceutical companies have demanded similar level of protection in other countries as a condition to supply the vaccines.

The disappearing U.S. vaccine research and development base was brought to light during the HIV/AIDS pandemic. In 1985, the non-profit Institute of Medicine warned that America's *reliance on market incentives to ensure vaccine availability may lead to a failure to meet public health needs [and] may not result in optimal levels of vaccine innovation*.[61]

Warning signals about the dismal state of the vaccine R&D system were even delivered by the industry itself. In 1986, Douglas MacMaster, the president of Merck, similarly warned that due to the lack of *profitability of such products*, his company, might no longer be able to fund vaccine R&D.[62] Three years into the HIV/AIDS pandemic, no pharmaceutical company has announced a research project to better understand the disease and develop a vaccine or treatment.[63]

Over the discussed period, this trend was characteristic of many countries where pro-business decisions led to gaps in capacities to tackle epidemics and pandemics.[64]

The shutdown of vaccine divisions by one company after another has led to the vaccine market becoming an oligopoly. Prior to the outbreak of the COVID-19 pandemic, the industry had consolidated to four large players who hold about 85 per cent of the market - British GlaxoSmithKline, French Sanofi and U.S. Merck and Pfizer.[65]

Studying the transformation of the U.S. model of vaccine R&D is important for understanding changes that followed in the broader medical innovation field around the world. By embracing the trend of privatisation, the US, through its international clout, prompted other countries to follow suit.

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[61] National Research Council (US) Division of Health Promotion and Disease Prevention, *Vaccine Supply and Innovation*, Washington (DC): National Academies Press (US), 1985; https://www.ncbi.nlm.nih.gov/books/NBK216819/ (27 May 2023).

[62] In the end, Merck kept its vaccine department and before the COVID-19 pandemic was one of the major vaccine producers along with GSK, Pfizer and Sanofi.

[63] In the case of the HIV/AIDS pandemic, it is argued that the stigma surrounding the disease reinforced the industry's reluctance to develop countermeasures against it. See: Zaitchik, *Owning...*, *op.cit.*, p. 187.

[64] J. D. Pluss, *With no prospects for profits, big pharma neglects new infectious diseases*, Swissinfo, 6 March 2020; https://www.swissinfo.ch/eng/covid-19_with-no-prospects-for-profits--big-pharma-turns-back-on-new-infectious-diseases/45598436?fbclid=IwAR1NybAmszN1D6G9xBCe19Jg_Pv5wBoSHKgDmduWOinnXj_5uMo-tYoNndw (27 May 2023).

[65] At that time, the index of Access to Medicines, the non-profit organization, reveals that almost half of the R&D projects of the 20 largest pharmaceutical companies are related to cancer, while there were no projects related to coronaviruses (neither MERS nor SARS). See: Access to Medicines Foundation, 2018 Access to Medicine Index, November 2018; https://accesstomedicinefoundation.org/resource/2018-access-to-medicine-index (27 May 2023). See aslo: L. Yun, *Coronavirus highlights the $35 billion vaccine market. Here are the key players*, CNBC, February 2021; https://www.cnbc.com/2020/02/21/coronavirus-brings-light-to-the-35-billion-vaccine-market.html (27 May 2023).

In the 1970s and 1980s, the U.S. not only began privatising the state-owned medical industry and extensively protecting private rights to health technologies domestically but also (under pressure from Big Pharma companies) used its geopolitical and economic power to make other countries do the same. For example, the U.S. Trade Act adopted in 1984 threatened sanctions against countries that failed to provide equally rigorous protection for U.S. intellectual property (IP), including 20-year patents on medical inventions.

Currently, the public sector invests in basic research used by these companies and encourages them to develop crisis-related medical countermeasures, which it can then buy back at a premium while leaving them in charge of pricing and distribution. The process of legal, economic, and political transition that disrupted military-industrial cooperation in the 1970s and 1980s, built on the premise of serving both sides (public and private) equally, offers important lessons on how to rebuild lost capacity.[66]

1.6.1. Results of privatisation in the vaccine sector

The four decades that followed the 1980s provided ample evidence that the existing research and development model for medical countermeasures is unable to deliver the expected results.

Disease outbreaks, including Severe Acute Respiratory Syndrome (SARS) and Middle East Respiratory Syndrome (MERS), ended naturally before the vaccine was ready or pharmaceutical firms even had a chance to complete clinical trials.[67] This is also true of the vaccine against the bird flu (H5N1) that spread in the late 1990s and had a 60 per cent mortality rate.[68]

A few companies still active in the field attempted to tackle various outbreaks of infectious diseases over the past decades but with no significant successes. Sanofi has been developing its dengue fever vaccine for over a decade only to stop the program after finding out that it increases the risk of the disease in some children. GSK was even able to bring a malaria vaccine to the market, but it took 30 years. There were very few examples of

[66] K. Hoyt, *op. cit.*, p.9.
[67] H. Kuchler, L. Abboud, *Why the three biggest vaccine makers failed on Covid-19*, Financial Times, 16 February 2021; https://www.ft.com/content/657b123a-78ba-4fba-b18e-23c07e313331 (27 May 2023).
[68] P. K. S. Chan, *Outbreak of Avian Influenza A(H5N1) Virus Infection in Hong Kong in 1997*, Clinical Infectious Diseases, Volume 34, Issue Supplement 2, May 2002, p. 58-64; https://pubmed.ncbi.nlm.nih.gov/11938498/ (27 May 2023).

profitable vaccine endeavours, such as Merck's Gardasil for HPV, and GSK's Shingrix for shingles.

1.6.2. Example of Ebola virus vaccine

A more recent example of the current system's ineffectiveness in responding to the outbreaks of infectious diseases is the development of a vaccine against Ebola virus. This case also presents the failure of the belief that the state can conduct basic research, but it is only the private sector that is capable of transforming innovation from labs to concrete products.

The most widespread outbreak of the Ebola virus occurred in West Africa between 2013 and 2016, causing major loss of life and socio-economic disruption in the region, mainly in Guinea, Liberia and Sierra Leone. Given that Ebola virus is highly contagious, developing an effective vaccine was crucial to help stop transmission.[69]

In fact, government-funded Canadian researchers discovered such a vaccine already in 2001 and even conducted early tests on it, making it ready for clinical trials. However, following the prevailing pharmaceutical R&D model, instead of retaining the technology, conducting clinical trials (requiring significant public investment) and seeking regulatory approval within the public sector's institutions, the government licensed the vaccine to a small U.S. biotech firm in 2010 to bring it to market.

However, the company's business priorities eventually deviated from plans to achieve this goal. Instead, a few years later, after making almost no progress in developing the vaccine that existed only because of public investment and research, it profited from it by selling its rights for $50 million to Merck, which saw a business opportunity when the impact of the outbreak in West Africa was becoming clear.[70] Subsequently, Merck, holding all commercial rights to the vaccine, conducted clinical trials, which again were largely

[69] Medecins Sans Frontiers, *Public funds…, op.cit.*

[70] See: M. Herder et al., *From discovery to delivery: public sector development of the rVSV-ZEBOV Ebola vaccine*, Journal of Law and the Biosciences, Volume 7, Issue 1, January-June 2020; https://academic.oup.com/jlb/advance-article/doi/10.1093/jlb/lsz019/5706941 (23 May 2023).; T. Walkom, *The strange tale of Canada's ebola vaccine: Walkom*, Toronto Star, 25 November 2014; https://www.thestar.com/news/canada/2014/11/25/the_strange_tale_of_canadas_ebola_vaccine_walkom.html (27 May 2023);

funded by the public sector.[71] The vaccine did not receive regulatory approval until late 2019.

1.6.3. Public policy failure

As pointed out by the South Centre, an intergovernmental policy research think-tank, the vaccine industry is – and has been for a long time – notoriously prone to market failures. As a result, it is underperforming.[72]

The overall inability of the existing business model to respond to unfolding health emergencies has however brought about little change in public policy and the industry's commercial strategies focused on the development of blockbuster drugs.[73]

Today, most public institutions lack the capacity to either continue the late-stage R&D processes or to lead a mutually beneficial cooperation with private actors to a degree similar to the vaccine initiatives of the first half of the 20th century. Continued belief in the private sector's ingenuity and engagement results in the incessant transfer of resources to private companies in hopes of better outcomes. Since the SARS outbreak, the U.S. National Institutes of Health alone has spent nearly $700 million on coronavirus R&D.[74]

The public policies on the development of COVID-19 vaccines, such as the U.S. *Operation Warp Speed* or the EU *Vaccines Strategy* follows the exact same pattern that has failed again and again in the past.

1.7. Larger trend of privatising public services

The ideological shift in the 1980s toward reliance on the private sector, the outsourcing of public initiatives to for-profit companies, and the belief that the government's role should be limited to incentivising them and fixing problems as they arise have not been exclusive to the pharmaceutical market.

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[71] M. Herder et al., *The public science behind the 'Merck' Ebola vaccine*, STATNews, January 2020; https://www.statnews.com/2020/01/16/public-science-behind-merck-ebola-vaccine/ (23 May 2023).

[72] F. Lobo, *Restructuring the Global Vaccine Industry*, *South Centre*, Research paper 134, September 2021, p. 1.; https://www.southcentre.int/wp-content/uploads/2021/09/RP134_Restructuring-the-Global-Vaccine-Industry_EN-1.pdf%20 (27 May 2023).

[73] A. Zaitchik, *No Vaccine…, op. cit.*

[74] Zain Rizvi, *Blind Spot: How the COVID-19 Outbreak Shows the Limits of Pharma's Monopoly Model*, Public Citizen, 19 February 2020; https://www.citizen.org/article/blind-spot/?eType=EmailBlastContent&eId=0a4b146b-3346-496c-8ff3-f294d3028bc9#_ftn2 (27 May 2023).

The past four decades have seen less investment in public infrastructure across all sectors, significantly weakening its capacity. As a result, reliance on private entities, including consulting firms and philanthropic organisations benefiting from billions of dollars in government contracts, has become almost indispensable to fulfilling public responsibilities.[75]

A clear trail of declining public sector capacities can be traced all the way up to early 2020 when governments were caught unprepared and unable to respond effectively to the SARS-CoV-2 outbreak.[76]

1.7.1. Use of consulting companies

Consequently, countries were reliant on the overuse of consulting firms for tasks ranging from COVID-19 vaccination campaigns to logistics or general pandemic management, without strong public entities in place to guide, coordinate and control their efforts.

For example, in the US, McKinsey has been awarded work for state, city and federal agencies worth well over $100 million.[77] In the U.K., for example, 40 consultants working on the virus test-and-trace program over the course of four months cost the government £10 million.[78] In France, which has traditionally prided itself in the quality of its public sector and was careful about external influence over policymaking, since March 2020, the French health ministry has signed 28 coronavirus-related contracts collectively worth over €11 million with consultancies.[79]

In the process of outsourcing public responsibilities, the belief that the private sector can perform them more efficiently has started becoming a self-fulfilling prophecy.

[75] In 2018 alone, the U.K. government outsourced £9.2bn worth of health contracts. Outsourcing has been coupled with cuts in public investment. See: M. Mazzucato, *Mission Economy: A Moonshot Guide to Changing Capitalism*, Allen Lane, 2021, p. 15.

[76] K. Cooper, *A public health resurgence*, *British Medical Association*, 1 May 2020; https://www.bma.org.uk/news-and-opinion/a-public-health-resurgence (27 May 2023).

[77] I. MacDougall, *How McKinsey Is Making $100 Million (and Counting) Advising on the Government's Bumbling Coronavirus Response*, ProPublica, 15 July 2020; https://www.propublica.org/article/how-mckinsey-is-making-100-million-and-counting-advising-on-the-governments-bumbling-coronavirus-response (27 May 2023).

[78] J. Jolly, R. Syal, *Consultants' fees 'up to £6,250 a day' for work on Covid test system*, Guardian, 14 October 2020; https://www.theguardian.com/world/2020/oct/14/consultants-fees-up-to-6250-a-day-for-work-on-covid-test-system (27 May 2023).

[79] E. Braun, P. de Villepin, *How consultants like McKinsey took over France*, Politico, 8 February 2021; https://www.politico.eu/article/how-consultants-like-mckinsey-accenture-deloitte-took-over-france-bureaucracy-emmanuel-macron-coronavirus-vaccines/ (27 May 2023).

Continued reliance on private companies has led to the state's inability to shape cooperation between the sectors in the public interest and the creation of a *parasitic* relationship in which private actors extract public resources and privatise public value.

Shrinking public budgets by paying for external services has reduced investment in in-house expertise to the point that governments' ability to structure contracts with private entities that adequately represent the public interest has eroded. As a result, private companies benefit from unbalanced public-private partnerships designed with few conditions on public investment, allowing the latter to capture the public agenda and control operations in accordance with their business strategies.[80]

1.7.2. Example of the Innovative Medicines Initiative

This trend is well reflected in the EU-funded but Big Pharma-controlled pharmaceutical R&D program Innovative Medicine Initiative (IMI).

While EU countries have invested billions of euros, the initiative's research agenda has been set by major pharmaceutical companies. A report of Global Health Advocates and Corporate Europe Observatory, French and Belgian non-profit organisations, revealed how IMI failed to address areas where public funding is urgently needed, prioritising instead high profit generating diseases where the industry has already been putting considerable resources on its own.[81]

When the European Commission proposed in 2018 to make *biopreparedness* one of the initiative's priorities, the industry rejected the idea. [82] Given the Commission's *hands-off approach to agenda-setting*, the decision was made – as noted in the minutes from the IMI Governing Board meeting – that *no immediate co-investment is expected* for R&D of medical countermeasures.[83]

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[80] Imbalanced public-private partnerships in health sector are certainly not limited to pharmaceutical R&D system. There are multiple examples of private companies over-benefiting from them e.g., in the development and aid sector. See: B. Faith, *The Danger of Digitalizing Aid*, Project Syndicate, 20 December 2021; https://www.project-syndicate.org/commentary/digitizing-aid-systems-puts-vulnerable-populations-at-risk-by-becky-faith-2021-12?utm_source=twitter&utm_medium=organic-social&utm_campaign=page-posts-december21&utm_post-type=link&utm_format=16:9&utm_creative=link-image&utm_post-date=2021-12-22 (27 May 2023).

[81] The first partnership, IMI, ran from 2008-2013, and was renewed as IMI2 to run from 2014-2020, followed by the Innovative Health Initiative (IHI) launched for the period 2021-2027.

[82] J. McArdle, R. Tansey, *In the Name of Innovation*, Global Health Advocates, Corporate Europe Observatory, Brussels, April 2020, p. 15; https://corporateeurope.org/sites/default/files/2020-05/IMI-report-final_0.pdf (27 May 2023).

[83] *Ibidem*, p. 59.

It was not until March 2020, months since the new coronavirus spread to Europe and the public sector began subsidising the industry and de-risking its operations to push companies to become more involved in innovation and production of products for COVID-19, that IMI issued a €45 million call for proposals for the development of therapeutics and diagnostics to tackle the coronavirus infections.[84]

1.8. Need for reform

To reverse this course, it is necessary to consider alternative ideas about the role government should play in the economy and what instruments, structures, policies and capabilities it requires to fulfil its mission.

The way the system should be changed depends on *what sort of capitalism we want to build, how to govern the relationships between the public and private sectors and how to structure rules, relationships and investments so that all people can flourish and planetary boundaries are respected,* as argued by Mazzucato, an economics professor and founding director of the University College London Institute for Innovation and Public Purpose.[85]

One of the lessons from the history of the public and private sector's involvement in pharmaceutical R&D and production is that in emergency situations, the government's ability to intervene quickly and adequately is critical to an effective response. However, in order to do so, it must have adequate capacity to act. [86] Instead of limiting their role to fixing market failures and outsourcing its responsibilities to private companies, states should increase their leadership and capacities in critical areas.

[84] Innovative Medicines Initiative, *Zoonotic anticipation and preparedness initiative*, see: https://www.imi.europa.eu/projects-results/project-factsheets/zapi (27 May 2023).
[85] M. Mazzucato, *Mission Economy*…, *op.cit.*, p. 16.
[86] *Ibidem*, p. 16.

Chapter 2. Publicly driven medical innovation

2.1. Unprepared

Every region of the world has a wealth of experience with health crises and lessons from which to learn how to properly prepare for them. But for most countries, decades of reducing public capacity, including disinvestment in health care and outsourcing responsibilities related to medical innovation and access to private entities, uninterested in investing in areas that do not yield high enough returns, have left them unprepared for the COVID-19 pandemic.

As argued by 't Hoen, an expert in medicines policy and intellectual property law, *the Covid-19 crisis lays bare the faults in the drug system in the most painful manner possible. It's not news for the global south, but now rich countries are waking up very harshly to the consequences of the belief that market forces will deliver the needed biomedical solutions*.[87]

The size and toll of the pandemic were the consequence of policy choices and negligence, which are becoming more and more apparent in increasingly global health security during the emergence or re-emergence of infectious diseases in different parts of the world.[88]

The outbreak of a new coronavirus with pandemic potential was not only predictable but actually predicted by scientists and researchers. Over the last decades, there have already been two outbreaks of a zoonotic coronavirus that transmitted from animals to humans – SARS in 2002 and MERS in 2012.[89] Beyond coronaviruses, there have also been multiple Ebola and Zika outbreaks or the avian flu pandemic, among many others.

These crises brought numerous warnings about the need for a better policy framework for responding to infectious diseases and evidence that the current pharmaceutical innovation and access system is not fit for the purpose. However, they went unanswered by either governments or the industry. Before the COVID-19 outbreak, in

[87] A. Zaitchik, *No Vaccine in Sight, op. cit.*
[88] P. Hotez, *Covid-19: a disaster five years in the making*, British Medical Journal, 2021; https://doi.org/10.1136/bmj.n657 (27 May 2023).
[89] S. Perlman, *Another Decade, Another Coronavirus*, Editorial, The New England Journal of Medicine, 2020, p. 760-762; https://www.nejm.org/doi/full/10.1056/NEJMe2001126 (27 May 2023).

2019, there were only six clinical trials recorded by the WHO and no medicine registered by the industry for any type of coronavirus.[90]

When the pandemic started, the world's three biggest vaccine producers had not much to offer. While before the SARS-CoV-2 outbreak, GSK, Sanofi, Merck and Pfizer held oligopoly on the vaccine market with products for flu, pneumonia, HPV and shingles, in 2021, only one of them, Pfizer, has a successful Covid-19 vaccine thanks to its partnership with German start-up BioNTech.

2.2. Unreliable

Following the COVID-19 outbreak in early 2020, no major pharmaceutical company was interested in developing and producing a vaccine for the novel coronavirus. Big Pharma companies did not even want to step in to manufacture the vaccine developed by the U.S. government's National Institute of Health, which was met with frustration by Dr Fauci, director of the National Institute of Allergy and Infectious Diseases (NIAID), stressing that *companies that have the skill to be able to do it are not going to just sit around and have a warm facility, ready to go for when you need it*.[91] His impatience was shared by many political leaders and public health officials.

What is more, the Coalition for Epidemic Preparedness Innovations (CEPI) was leading three different projects to develop a vaccine at the time but was also unable to find a commercial partner with the facilities to mass produce it. The long-standing problem of relying on pharmaceutical markets to respond to a health emergency became evident again during the pandemic.

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[90] Pharmaceutical companies are not necessarily eager to reverse their approach and focus more on R&D on infectious diseases. As reported by a not-for-profit organisation Access to Medicine Foundation, out of the 16 pathogens identified by the WHO as the greatest risk to public health, only six were under development in 2022 See: Company report cards & comparison, Access to medicine Foundation, 2022; https://accesstomedicinefoundation.org/sectors-and-research/index-ranking (27 May 2023); See also: Z. Rizvi, *op. cit.;* It has also been admitted by the OECD General Secretary, Angel Gurrìa, in a letter to the G20: *Had a vaccine for the SARS-CoV-1 been developed at the time, it would have accelerated the development of one for the current outbreak given that the two viruses are 80% similar* See: OECD, Coronavirus (COVID-19): Joint actions to win the war, Coronavirus (covid19): joint actions to win the war, 2020; https://www.oecd.org/about/secretary-general/Coronavirus-COVID-19-Joint-actions-to-win-the-war.pdf (27 May 2023); S. Buranyi, *How profit makes the fight for a coronavirus vaccine harder*, Guardian, 4 March 2020; https://www.theguardian.com/commentisfree/2020/mar/04/market-coronavirus-vaccine-us-health-virus-pharmaceutical-business (27 May 2023).

[91] N. Florko, *Major drug makers haven't stepped up to manufacture NIH coronavirus vaccine, top U.S. health official says*, STATNews, 11 February 2020; https://www.statnews.com/2020/02/11/major-drug-makers-havent-stepped-up-to-manufacture-coronavirus-vaccine-top-u-s-health-official-says/ (27 May 2023).

Dozens of small biotechnological firms, major pharmaceutical companies and universities entered into vaccine development, adapting and reorienting their technology platforms only after obtaining unprecedented public funding.[92] This reflects the misplaced belief in the private sector to save the day.

2.3. Debunking the belief in the private sector's exclusive ingenuity

2.3.1. Ideology-driven health emergency preparedness and response

Public strategies are guided by policies grounded in certain views, ideologies and beliefs. In the case of health emergencies, market-driven ideology and the positivist belief that technological innovation is the key to solving all health problems have underpinned public interventions in global health over the past decades, including during the COVID-19 pandemic.

The prevailing view that the private sector is best suited to deliver medical technologies reflects a seemingly unshakeable faith in the efficacy of markets in the health sector. It is therefore important to put things into perspective, to see how public institutions have driven medical innovation over the last century and how major pharmaceutical companies grew and were sustained by public money.

2.3.2. The health emergency that revolutionised the industry

The grandeur of today's pharmaceutical industry has not been built solely on the ingenuity and investment of the private sector, far from it. In particular, Big Pharma, as we know it today, owes its origins (as well as its current prosperity) to public policies and funding.

The U.S. biomedical R&D boomed when it became an official part of the country's national defence strategy during World War II. In June 1941, with the development of the public military biomedical sector, U.S. President Franklin D. Roosevelt established an

[92] L. Spinney, *When will a coronavirus vaccine be ready?*, Guardian, 6 April 2020; https://www.theguardian.com/world/2020/mar/18/when-will-a-coronavirus-vaccine-be-ready (27 May 2023).

Office of Scientific Research and Development (OSRD) responsible for scientific and medical innovations serving national security. The government's strategy for selecting scientists (civilian scientists served as key OSRD directors) and investing in research was bold and ambitious. Any project deemed by the bureau as likely to help the state and the Allies win the war could benefit from massive R&D funding.

While perhaps the best-known example of it is the atomic bomb, it was one of the OSRD's other huge developments that turned the pharmaceutical business upside down – scaling up the production of penicillin.

2.3.3. U.S. wartime penicillin project

Although penicillin was discovered and its medical use established in the first half of the 20th century at Oxford University in the U.K., the scientists from the Oxford team were neither able to produce usable amounts of it in their laboratory, nor to gather the political support to fund its further development and production in England engaged in war with Germany.[93] For this reason, they sought money abroad and approached U.S. companies and policymakers to support advancing the development of the product.

While their requests were initially unsuccessful, the unfolding events of World War II, particularly the Japanese attack on Pearl Harbour, convinced the U.S. officials of penicillin's potential value for soldiers fighting on the front lines. The industry has been more reluctant to join such a risky initiative. In the end, Merck was the first company to agree and as one government official put it, Merck's reversal marked the moment *a new pharmaceutical industry was born*.[94] The role of the public sector in this process cannot be overstated.

To encourage company involvement in scaling up the development of penicillin, the U.S. exempted those participating in the project from newly revised regulations on medicine quality control and antitrust law.[95]

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[93] Thomson Scientific, *Making Penicillin Possible: Norman Heatley Remembers*, ScienceWatch, 21 February, 2007; https://web.archive.org/web/20070221041204/http:/www.sciencewatch.com/interviews/norman_heatly.htm (27 May 2023).

[94] P. Neushul, *Science, Government and the Mass Production of Penicillin*, Journal of the History of Medicine and Allied Sciences, Volume 48, Issue 4, October 1993, p. 371-395; https://academic.oup.com/jhmas/article-abstract/48/4/371/777929?redirectedFrom=fulltext&login=false (27 May 2023).

[95] S. Aldridge et al., *The Discovery and Development of Penicillin, 1928–1945*, The Alexander Fleming Museum, November 19, 1999, p. 5. See also: E. Lax, *op. cit.*, p. 185–86.

The government recruited researchers to develop more efficient technological processes to scale up penicillin production.[96] Public resources were also directed toward constructing six massive new penicillin manufacturing plants and pharmaceutical companies selected to take part in the program[97] received tax breaks on all investments to retrofit their own factories.[98]

The original government contractors benefited not only from the steady profits made by fulfilling *cost-plus* contracts in a guaranteed wartime market but were also recipients of a state-facilitated transformative technology transfer operation. According to medical historian Roswell Quinn, it *propelled the U.S. pharmaceutical industry into one of the country's most successful sectors*.[99]

In the end, the public goal was achieved. Penicillin production capacity grew steadily, and two years after the project was launched, American companies were producing a skyrocketing 650 billion units of penicillin (enough to treat more than 250,000 soldiers a month).

Bringing huge benefits to the public cause, the companies were earning millions of dollars from the product. Although many from the Oxford team hoped that at least some of the revenue from publicly funded medicine could help finance further research, the companies had no intention of sharing it.[100] Most importantly, they were under no obligation to do so, as the government did not include any such conditions in its million-dollar contracts with them. All of the production capacity and profits gained through public investment stayed with the industry.

There were also concerns about the behaviour of some of the companies involved in the project. For example, there were doubts on whether the largest contractors such as Pfizer, Squibb and Merck were sticking to their contractual obligations to place all of their research and know-how in a common technology and knowledge pool that had been

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[96] R. Bud, *Upheaval in the moral economy of science? Patenting, teamwork and the World War II experience of penicillin*, History and Technology no. 2, March 2008, p. 173-190; https://www.tandfonline.com/doi/abs/10.1080/07341510701810955 (27 May 2023).

[97] The total of 17 companies have been qualified to participate in the project, including Merck, Squibb, Pfizer, Abbott or Eli Lilly.

[98] For example, Pfizer turned a former ice factory into a fermentation plant.; See: E. Lax, *op. cit., p. 206-7.*

[99] R. Quinn, *Rethinking Antibiotic Research and Development: World War II and the Penicillin Collaborative*, American Journal of Public Health, March 2013, p. 426-434.; https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3673487/ (27 May 2023).

[100] Ernst Chain told The New York Times in late 1945: *No one in our group has received a penny out of this but arms are making millions of dollars.… I don't see why a commercial development should get so much money. I thought the governments would take over the production of penicillin and there would be no great profits*. E. Lax, *op. cit., p.* 46–47, after: A. Zaitchik, *Owning…, op. cit.*

established to ensure collaboration and transparency. Zaitchik quotes a scientific director of one of the departments as saying in a 1942 letter to the OSRD that *as far as we are concerned here at Peoria, it has been largely a case of giving all our information and receiving very little*.[101]

The industry back then – as it did after the COVID-19 pandemic – did not hesitate to claim that it was entitled to all the current and future profits stemming from the use of the publicly-developed technology and production capacity set up through public funds, pointing out that even though it had not discovered the product, without its role in boosting productivity the R&D and production initiatives would have failed.

2.3.4. Repercussions of the penicillin project

The pharmaceutical industry successfully exploited the economic potential of penicillin after World War II.[102]

The influx of millions in direct federal subsidies to private pharmaceutical companies was the cornerstone of their remarkable expansions in the following years. U.S. companies were able to buy new production plants built with public funds at less than half the cost and keep – without any conditionalities – their own facilities retrofitted through lucrative tax breaks with the large, costly equipment required for commercial-scale production.[103]

While in 1939 German pharmaceutical firms accounted for 43 per cent of all drug sales, six years later U.S. companies took over the sector, accounting for half the world market.[104]

The impact of public investment on corporate performance is perhaps best demonstrated by the fact that in the US, the 15 companies selected by the War Production Board for the penicillin project had 80 per cent of all medicine sales and a staggering 90

[101] A. Zaitchik, *Owning, op. cit*., p. 121.

[102] 11 U.S. companies that manufactured penicillin after the war owned 250 patents related to it. Pfizer has captured nearly half of the global penicillin market.

[103] *In total, the companies spent $23 million to build sixteen state-of-the-art antibiotics plants and recovered half their investments with savings on federal income tax. The government also sold to the companies—at less than half their investments—the six state-of-the art penicillin production plants (…) The government spent $7.6 million on the plants and sold them for $3.4 million*. See: G. Posner, *Pharma*, Avid Reader Press, 2020, p. 55.

[104] G. Dutfield, *Intellectual Property Rights and the Life Sciences Industry*, Routledge, 2003, p. 75–76.

per cent of profits after the war.[105] Even more than seventy years later, the top ten U.S. pharmaceutical companies owe their growth to being selected for this program.

Publicly funded wartime research enabled the so-called *therapeutic revolution*, which resulted in the steady marketing of new breakthrough drugs with broad applications, including antibiotics, steroids and diabetes drugs.

The U.S. penicillin programme gave companies a huge confidence boost and greatly accelerated the development of the pharmaceutical industry. In the mid-20th century, it also capitalised on the widespread belief that technology and science were at the dawn of a historic golden age and mankind was entering the era of *Big Science*.[106] As Zaitchik reports, U.S. pharmaceutical companies introduced an average of fifty new products a year in the 1950s—twice the rate of the previous decade.[107]

The industry's rapid growth in the 1950s was not based solely on innovation, but largely on profits from monopolisation (thanks to expanding intellectual property rules) of publicly funded technologies acquired through lucrative public contracts and technology transfers.

In addition, the growth of medical advertising aimed not only at doctors but also directly at patients, has expanded the market for medicines with often inflated prices.

2.3.5. Changing pharmaceutical industry's perception on its own role

This period marks a recognisable shift in the pharmaceutical industry's perspective on its role. While *ethical* business had been their mission since the mid-19th century, it changed beyond recognition into a profit-driven and monopolistic one a century later.

An industry that once saw its remits in providing people with the medicines they need has begun spending more on advertising and shareholder dividends than on research. Its salespeople, known as detail men, working on the edge (and sometimes crossing the line) of not only ethics but also law, have boosted pharmaceutical sales.

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[105] The top four companies controlled 28 percent of all sales. See: Federal Trade Commission, *Economic Report on Antibiotics Manufacture*, Washington, D.C.: Government Printing Office, 1958, p. 47–49, p. 92–95.

[106] The term coined by Alvin M. Weinberg to describe the belief that everything from routine space travel to eradicating all disease was possible. Inventions and new products would come in a steady stream after the war.

[107] A. Zaitchik, *Owning, op. cit.*, p. 110.

The post-war pharmaceutical industry, grounding its business model on stringent intellectual property law and steadily expanding its political capture enabling huge markups, began to deliver profit margins unmatched in other sectors. The time also represents the eventual transformation of the pharmaceutical system, both in the U.S. and Europe, in which the balance between public and private interests tilted in favour of the latter.

2.4. Role of the public sector in medical breakthroughs

The role of the public sector in advancing medical innovation and contributing to the success of the pharmaceutical industry is not limited to wartime projects. A number of technological breakthroughs were (and still are) funded by government programs and institutes, such as the U.S. National Institutes of Health (NIH).

Data compiled by Lazonick and Tulum and cited by Mazzucato, show that between 1936 and 2011, the NIH spent $792 billion on health technologies R&D.[108] While venture capital and stock market investment rose and fell in this period, NIH funding increased in nominal terms, every year from 1970 to 2009, except for a slight decline in 2006.

This proves how the state has *long been the nation's (and the world's) most important investor in knowledge creation in the medical fields*.[109] As argued by Mazzucato, the knowledge base built from public funding has been essential to creating medical breakthroughs and making the pharmaceutical sector attractive to private investors, who otherwise would likely not have gotten involved in the industry. In Mazzucato's words, the investors *have 'surfed the wave' rather than created it*.

2.4.1. How the U.S. government brought the biopharmaceutical industry to life

Just as the birth and continued growth of the pharmaceutical industry was sparked and sustained by public programs, the emergence of the biotechnological industry and its further expansion can also be traced to government funding, rather than venture capital as is often claimed.

[108] In 2011 dollars. See: M. Mazzucato, *The Entrepreneurial State: Debunking Public vs. Private Sector Myths*, Anthem Press, London 2013, p.87.
[109] W. Lazonick, O. Tulum, *U.S. Biopharmaceutical Finance and the Sustainability of the Biotech Business Model*, Research Policy 40, no. 9, November 2011, p. 1170–87.

As Lazonick and Tulum demonstrate, the specific government policies directing the development of the knowledge base in this area have ensured the overall rise of biotech companies. [110] This was driven by policy changes in the 1970s discussed in Chapter 1.6.[111] For example, while previously only non-profit organisations were eligible for NIH research grants (which were subject to strict conditionalities and government oversight), by 1975 the U.S. government allowed private, for-profit companies to apply for research subsidies and decided that strict scrutiny over their use is *detrimental to creative scientists*, opting for a *light touch* approach to research oversight.[112]

With a massively increased budget (from $1 billion in the mid-1970s to $37 billion in 2019), the NIH has become the world's largest biomedical funder and, as such, has played a significant role in the burgeoning new biopharmaceutical industry.[113]

Vallas et al. outline the dynamics in the early years of biotech emphasising that *the knowledge economy did not spontaneously emerge from the bottom up, but was prompted by a top-down stealth industrial policy; government and industry leaders simultaneously advocated government intervention to foster the development of the biotechnology industry and argued hypocritically that government should 'let the free market work.*[114]

While companies call for more subsidies, incentives, tax breaks and deregulations, their business strategies are often *greatly dependent on the finance of the tax receipts which they fight against.*[115]

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[110] *Ibidem*, p. 1170–87.
[111] G. Posner, *op. cit.*, p. 364.
[112] N. Henderson, M. Schrage, *The Roots of Biotechnology: Government R&D Spawns a New Industry*, Washington Post, December 16, 1984; https://www.washingtonpost.com/archive/politics/1984/12/16/government-r38/cb580e3d-4ce2-4950-bf12-a717b4d3ca36/ (27 May 2023).
[113] National Institutes of Health, *History of Congressional Appropriations,1960–1969*. See: https://officeofbudget.od.nih.gov/pdfs/FY08/FY08%20COMPLETED/appic3806%20-%20transposed%20%2060%20-%2069.pdf (27 May 2023).
[114] S. P. Vallas, D. L. Kleinman and D. Biscotti, *Political Structures and the Making of US Biotechnology'. In State of Innovation: The U.S. Government's Role in Technology Development*, Paradigm Publishers, 2009, p. 66., after: M. Mazzucato, *op. cit.*
[115] M. Mazzucato, *op. cit.*, p. 87.

Chapter 3. Response to COVID-19 pandemic based on public innovation

3.1. Public sector innovation and investment in COVID-19 medical innovation

The public sector continues to fund the highest-risk research and is most likely to discover medicines that offer significant therapeutic benefits over the existing ones.[116] The U.S. government alone invests over $40 billion a year on health-related innovation.[117]

States also provide private companies with numerous direct and indirect financial supports and incentives for pharmaceutical R&D. This is done in the form of tax credits that enable companies to reduce the salary costs for staff engaged in R&D efforts, a reduced tax rate on profits generated through innovative activities, capital to support the creation of biotechnology companies and help with funding clinical trials.[118] What is more, private companies are increasingly developing medicines in partnership with public universities.

In the context of the COVID-19 pandemic, the public sector has made significant investments in the basic science behind the technologies used in the most effective vaccines, including their preclinical development, and clinical trials. It also significantly mitigated traditional industry risks (such as scientific failures, failure to demonstrate safety and efficacy, manufacturing risks, and market uncertainties associated with low demand), provided funding for scaling up production, and agreed on procurement contracts that were critical to creating successful vaccines.

[116] For example, the method for generating monoclonal antibodies (MABs) was developed at the publicly funded U.K. Medical Research Council Laboratory of Molecular Biology in Cambridge. However, the technique has not been patented as its inventor did not patent the technique because he disapproved of the principle. Six of the ten drugs with the highest global sales of all time are MABs., See: Global Justice Now, *How drug companies make a killing out of public research*, October 2017.; Prescrire, *Drug research: public funding, private profits*, Prescrire International, Volume 29 N° 221, December 2020, p.30.

[117] M. Mazzucato, *Mission Economy: A Moonshot Guide to Changing Capitalism*, Penguin Books Ltd, 2021.

[118] See: Global Justice Now, *Pills and profits...*, October 2017.

3.1.1. Example of mRNA technology

The most effective COVID-19 vaccines developed by Pfizer/BioNTech and NIH/Moderna are based on mRNA technology that has been developed over 30 years through public and private research.

A recent study of Lalani et al. identified 34 NIH-funded research grants that were directly related to COVID-19 mRNA vaccines. These grants, combined with other identified U.S. government investments and contracts in this field, totalled $31.9 billion, of which $337 million was invested before the pandemic.[119]

Research and funding in this area can be traced back to the 1960s. Over those decades, national scientists worked on mRNA vaccines before further development of the technology was picked up by private industry.[120] Big Pharma companies and smaller start-ups only entered the field after the U.S. government introduced incentive mechanisms in the late 2000s. BioNTech itself was one of such companies founded in 2008, soon after the U.S. Defense Advanced Research Projects Agency (DARPA) began funding industry researchers to study RNA medicines and vaccines.

The vaccine co-developed by Moderna, is based on a longstanding research program of the U.S. National Institute of Allergy and Infectious Diseases (NIAID) Vaccine Research Center.[121] Typical of the current R&D model, this publicly co-developed and co-funded research has been privatised by licensing the technology to private companies for further development and production of the end products. The licensing lacked sufficient public interest conditions. The NIH has not even had the option to make the successful vaccine available for clinical trials to scientists who wanted to improve it.

Following the success of mRNA technology during the pandemic, private companies have started suing each other over its use. In its lawsuit against Pfizer and BioNTech, for example, Moderna cites its ethos of innovation and decades of research into

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[119] S. L. Hussain, *U.S. public investment in development of mRNA covid-19 vaccines: retrospective cohort study*, British Medical Journal, 380, March 2023; https://www.bmj.com/content/380/bmj-2022-073747 (27 May 2023).

[120] E. Dolgin, *The tangled history of mRNA vaccines*, Nature 597, September 2021, p. 318-324; https://www.nature.com/articles/d41586-021-02483-w (27 May 2023); S. C. Kizzmekia et al., *SARS-CoV-2 mRNA vaccine design enabled by prototype pathogen preparedness*, Nature volume 586 2020, p. 567–571.; https://www.nature.com/articles/s41586-020-2622-0 (27 May 2023).

[121] National Institute of Allergy and Infectious Diseases, *Coronavirus Vaccines and Prevention*, see: https://www.niaid.nih.gov/diseases-conditions/coronavirus-vaccines-prevention (27 May 2023).

mRNA vaccine technology, claiming it is entitled to even greater monopoly protection. The company does not even mention public contributions.[122]

Perhaps the most evident and striking example of a denial of the public sector's role in medical innovation is Moderna's refusal to admit NIAD scientists' co-development and co-ownership of the specific technology related to the mRNA sequence that was central to the creation of the COVID-19 vaccine. After years of dispute between the government and the company, Moderna decided to withdraw its patent application on the technology to avoid naming the NIAD scientists as its co-inventors.[123] To end another dispute, in February 2023, Moderna agreed to pay NIH and two U.S. universities $400 million (a little more than 1% of its 35-billion-dollar vaccine revenue) for the use of one of the other publicly developed technology in the vaccine.[124]

As they did after World War II and the penicillin project, pharmaceutical companies using public resources and technologies tried to hide the state's role in the development of COVID-19 medical countermeasures. Besides Moderna's case, Pfizer, for example, which states that it took no government money, does not acknowledge the public R&D efforts behind the technology or the fact that its work on the vaccine was de-risked by government advance payments of nearly $2 billion in the U.S. alone.[125]

This is a stark example of how the current pharmaceutical R&D system serves the private business model. It also shows how inefficient it is, from a public interest perspective.

[122] Moderna, *Moderna Sues Pfizer and Biontech for Infringing Patents Central to Moderna's Innovative mrna Technology Platform*, see: https://investors.modernatx.com/news/news-details/2022/Moderna-Sues-Pfizer-and-BioNTech-for-Infringing-Patents-Central-to-Modernas-Innovative-mRNA-Technology-Platform/default.aspx (27 May 2023).

[123] K. E. Foley, D. Lim, *Lilly's perfect timing for insulin cost cuts*, Politico, July 2023; https://www.politico.com/newsletters/prescription-pulse/2023/03/07/eli-lilly-insulin-cost-cuts-00085724 (27 May 2023).

[124] I.e., a solution to freeze spike proteins to keep their shape, a crucial step in producing stronger immune response.

[125] N. Dearden, *Big Pharma's Pandemic Profiteering Isn't Over*, Tribune, May 2022; https://tribunemag.co.uk/2022/05/pfizer-covid-vaccine-pandemic-big-pharma-monopoly-profiteering (27 May 2023).

3.1.2. Public investment in COVID-19 vaccines

There are varying estimates of total public spending on COVID-19 vaccine R&D and manufacturing.[126] In the US, some analyses put total government funding at between $18 billion and $23 billion while others put it around $39.5 billion.[127] The Congressional Budget Office estimated that the Biomedical Research and Development Authority (BARDA) alone spent $19.3 billion on this effort.[128]

Under *Operation Warp Speed*, a public–private partnership initiated by the U.S. federal government to facilitate and accelerate the development, manufacturing, and distribution of COVID-19 medical countermeasures, the U.S. public invested $5 billion.[129] The U.S. government made large advance purchases of potential vaccines and supported U.S. companies conducting clinical trials while working with numerous distant and lesser-known contract manufacturers and suppliers of equipment and ingredients (from cellular material to glass tubing for syringes) to make producing the vaccines and related materials possible.[130] The U.S. spent a total of more than $30 billion on vaccines during the pandemic, (including full payment for them) under the advance purchase agreements (APAs).[131]

In Europe, between 2014 and 2020, the EU spent more than €1 billion on vaccine research. During the pandemic, the European Commission invested €2.9 billion in scaling

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[126] R. G. Frank, L. Dach, N. Lurie, *It Was The Government That Produced COVID-19 Vaccine Success*, Health Affairs, 14 May 2021; https://www.healthaffairs.org/do/10.1377/forefront.20210512.191448/full/ (27 May 2023).

[127] See e.g.: Confessional Research Service, *Domestic Funding for COVID-19 Vaccines: An Overview*, 29 March 2021; https://crsreports.congress.gov/product/pdf/IN/IN11556 (27 May 2023).; *COVID-19: Urgent Actions Needed to Better Ensure an Effective Federal Response*, GAO, November 2020.; https://www.gao.gov/products/gao-21-191 (27 May 2023).; Ch. P. Bown, T. J. Bollyky, *Here's how to get billions of COVID-19 vaccine doses to the world*, PIIE, 18 March 2021.; https://www.piie.com/blogs/trade-and-investment-policy-watch/heres-how-get-billions-covid-19-vaccine-doses-world (27 May 2023).

[128] Congressional Budget Office, *Research and Development in the Pharmaceutical Industry*, April 2021.; https://www.cbo.gov/system/files/2021-04/57025-Rx-RnD.pdf (27 May 2023).

[129] More about Operation Warp Speed read e.g., in *Operation Warp Speed: Accelerated COVID-19 Vaccine Development Status and Efforts to Address Manufacturing Challenges*, GAO, 11 February 2021.; https://www.gao.gov/products/gao-21-319 (27 May 2023).; C. T. Lopez, *Operation Warp Speed accelerates COVID-19 vaccines development*, US Department of Defense, DOD News, 16 June 2020.; https://www.defense.gov/News/News-Stories/Article/Article/2222284/operation-warp-speedaccelerates-COVID-19-vaccine-development/ (27 May 2023); E. de Haan, *Pharma's pandemic profits*, SOMO, February 2023, p. 17.; https://www.somo.nl/pharmas-pandemic-profits/ (27 May 2023).

[130] Ch. P. Bown, T. J. Bollyky, *op. cit.*

[131] J. Kates, C. Cox, J. Michaud, *How Much Could COVID-19 Vaccines Cost the U.S. After Commercialization?*, KFF, 10 March 2023.; https://www.kff.org/coronavirus-covid-19/issue-brief/how-much-could-covid-19-vaccines-cost-the-u-s-after-commercialization/#endnote_link_573802-1 (27 May 2023).

up R&D and manufacturing capacity under APAs.[132] Taking into account the prices paid by EU countries, the total amount of public investment in COVID-19 vaccines reached more than €30 billion.[133]

Public funding for R&D of medical countermeasures was directed towards numerous companies and projects. In total, around 51 vaccines from 35 vaccine developers had been approved for use.[134] Total global spending on COVID-19 vaccines is expected to reach $157 billion by 2025.[135]

Determining the level of private sector investment in vaccine development and production is problematic due to the industry's refusal to disclose its R&D investments.[136]

While private companies have long been benefiting from public investments, the scale this has reached during the pandemic for some of them has exceeded any previous cases. For example, Moderna received $10 billion from the U.S. government to develop the vaccine co-created by the NIH, conduct clinical trials, scale up manufacturing capacity, and supply it.[137]

3.1.3. Private profits

Moderna sold the vaccine doses to governments at a 66 per cent net profit margin. An analysis by Public Citizen and Imperial College suggests that vaccinating the entire world population (8 billion doses) with the NIH/Moderna vaccine would cost $22.83

[132] European Commission, *EU support for vaccines*, see: https://research-and-innovation.ec.europa.eu/research-area/health/coronavirus/vaccines_en (27 May 2023).

[133] *Ibidem.*

[134] UNICEF, *COVID-19 market dashboard*, see: https://www.unicef.org/supply/COVID-19-market-dashboard (27 May 2023).

[135] M. Mishra, *World to spend $157 billion on COVID-19 vaccines through 2025 - report*, Reuters, 29 April 2021.; https://www.reuters.com/business/healthcare-pharmaceuticals/world-spend-157-billion-covid-19-vaccines-through-2025-report-2021-04-29/ (27 May 2023).

[136] For example, Pfizer decided to invest significant resources in its in-house capacity. Along with BioNTech, they had nine of their own facilities, with the largest in Kalamazoo, Michigan and Puurs, Belgium, as well as 20 contract manufacturers. The Company has not shied away from massive investment. When Pfizer was unable to find appropriate ultra cold storage for its vaccines while in transit, it designed a thermal container itself. In order to secure dry ice to cool them, it built its own dry ice factory. See: H. Kuchler, D. P. Mancini, D. Pilling, *The inside story of the Pfizer vaccine: 'a once-in-an-epoch windfall'*, Financial Times, 30 November 2021.; https://www.ft.com/content/0cea5e3f-d4c4-4ee2-961a-3aa150f388ec (27 May 2023).

[137] U.S. Department of Health & Human Services, *COVID-19 Portfolio*, See: https://www.medicalcountermeasures.gov/app/barda/coronavirus/COVID19.aspx?filter=vaccine (27 May 2023).

billion,[138] estimating that generic production of the vaccine would cost $2.85 per dose.[139] However, its average price tag during the pandemic was $21, and some countries, like the U.K. have been paying as much as $37 a dose.[140]

The vaccine has earned the company more than $35 billion in revenue (as of early 2023).[141]

In January 2023, entering a new phase of the pandemic and thus facing the pressure from shareholders to adjust its pricing strategy to offset waning market demand, Moderna announced that it would increase the price of its vaccine roughly fourfold, to $110-130 per dose, once its original contract with the U.S. government expires.[142] After criticism from U.S. officials, the company promised to offer a scheme whereby U.S. citizens would not have to pay for it out-of-pocket (with the costs being covered by either the U.S. public program or private insurers, who are likely to pass the costs indirectly on to their customers, for example by raising premiums).[143]

Moderna's pricing strategy may fit in with the trend seen with other vaccines. Researchers have analysed the implications of routine SARS-Cov-2 vaccination for healthcare budgets based on pricing patterns observed during influenza pandemics. Over the past two decades, average flu vaccine prices have increased by about 150% in the US, despite a steady increase in the number of available products and manufacturers. [144]

Moderna is not the only company to have benefited greatly from COVID-19 medical countermeasures.

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[138] Z. Kis, Z. Rizvi, *How to Make Enough Vaccine for the World in One Year*, Public Citizen, 26 May 2021.; https://www.citizen.org/article/how-to-make-enough-vaccine-for-the-world-in-one-year/ (27 May 2023).

[139] People's Vaccine Alliance, *Moderna vaccine price hike…*, Press Release, 10 January 2023.; https://peoplesvaccine.org/resources/media-releases/moderna-vaccine-price-hike-would-be-4000-mark-up-above-cost/ (27 May 2023).

[140] Oxfam International, *Pandemic of Greed*, *op. cit.*

[141] K. Dunleavy, *JPM23: Moderna reaped $18.4B in COVID vaccine sales last year, projects at least $5B in 2023*, FiercePharma, 9 January 2023.; https://www.fiercepharma.com/pharma/moderna-covid-vax-scarfed-sales-184b-2022-company-says (27 May 2023).

[142] Reuters, *Moderna considers pricing COVID vaccine at $110-$130 – WSJ*, 9 January 2023.; https://www.reuters.com/business/healthcare-pharmaceuticals/moderna-considers-pricing-covid-vaccine-110-130-wsj-2023-01-09/ (27 May 2023).; Similar announcement has been made by Pfizer to respond to shareholders expectations to meet revenue forecasts for 2023 and beyond, see: M. Erman, *Pfizer expects to hike U.S. COVID vaccine price to $110-$130 per dose*, Reuters, 21 October 2022.; https://www.reuters.com/business/healthcare-pharmaceuticals/pfizer-expects-price-covid-vaccine-110-130-per-dose-2022-10-20/ (27 May 2023).

[143] N. DeFeudis, *Moderna promises to provide vaccines at no out-of-pocket cost*, EndpointsNews, 15 February 2023.; https://endpts.com/moderna-promises-to-provide-vaccines-at-no-out-of-pocket-cost/ (27 May 2023).

[144] R. Ramachandran et al., *Future of covid-19 vaccine pricing: lessons from influenza*, British Medical Journal, 373, June 2021.; https://www.bmj.com/content/373/bmj.n1467.full (27 May 2023).

Companies responsible for the development and production of COVID-19 vaccines have received a total of at least $86.5 billion in advance purchase agreements (the exact number is difficult to estimate due to a lack of transparency in the agreements).[145]

In the first months of the pandemic, vast public funding drove up pharmaceutical companies' stock prices. The value of those firms that succeeded in launching COVID-19 vaccines rose significantly. For example, by 2021, Pfizer's value had risen by 6 per cent and Sinopharm's by 58 per cent.[146]

Even more startling may be the fact that the stock market value of Novavax, a biotech that has never turned a profit in more than two decades, rose tenfold to $10 billion after it received $1.6 billion to make a vaccine. Novavax has never brought its vaccine to the market.[147]

Profits from the public investment, however, have not altered companies' aggressive pricing strategies. Besides Moderna, Pfizer/BioNTech also chose to increase the price of their vaccines by 56% between 2020 and 2022.

Companies were also innovative in the ways they generated additional profits from medical countermeasures. Pfizer and BioNTech did so when it turned out that six doses could be made from each vial of their vaccine, rather than five doses as previously thought. After this discovery, the companies decided not to keep the same price per vial, but per dose, meaning that without additional production costs, they began charging more per vial. It is estimated that this change also benefited companies over €3 million a year during the pandemic.[148]

Thanks to COVID-19 products, Pfizer's revenues almost doubled from $41.9 billion in 2020 to $81.3 billion in 2021, with profits soaring from $9.6 billion to $22.0 billion. As calculated by Oxfam, an international charitable organisation, in 2021, Pfizer, BioNTech

[145] E. de Haan, *Big Pharma raked in USD 90 billion in profits with COVID-19 vaccines*, SOMO, 27 February 2023.; https://www.somo.nl/big-pharma-raked-in-usd-90-billion-in-profits-with-covid-19-vaccines/ (27 May 2023).

[146] BrandFinance, *Healthcare 2021*, Report, June 2021.; https://brandirectory.com/download-report/brand-finance-healthcare-2021-preview.pdf (27 May 2023).

[147] *Ibidem.*

[148] F. Lamata, *Pfizer / BioNTech vaccine: With a simple change in the product information sheet, € 3,120 million more per year in profit?*, 23 January 2021.; http://fernandolamata.blogspot.com/2021/01/pfizer-biontech-vaccine-with-simple.html (27 May 2023).

and Moderna have been making combined profits of $1,000 every second or $65,000 every minute.[149]

Pfizer, BioNTech, Moderna, and Sinovac made an estimated $90 billion in profits on their COVID-19 vaccines and medicines in 2021 and 2022.[150] In 2022, Pfizer reported a total of $100.3bn in revenue,[151] an amount that exceeds the health expenditure of more than 100 countries combined.[152]

3.1.4. Long-standing approach

While the amount of public funding was unprecedented during the COVID-19 pandemic, the patterns outlined above are characteristic of the current model of health emergency-related R&D process: the public sector provides significant funding for it, transfers the technology to private that develop it further and manufacture the end products, which are eventually bought by governments at a premium.

Despite the pharmaceutical industry's claims that any loss of their profits from medical countermeasures would discourage investment in the field, given the numbers above, there is arguably much room to make private companies' work in this area profitable enough while ensuring lower prices in the Global North and equitable access in the Global South.

[149] Oxfam International, *Pfizer, BioNTech and Moderna making $1,000 profit every second while world's poorest countries remain largely unvaccinated*, Press Release, 16 November 2021.; https://www.oxfam.org/en/press-releases/pfizer-biontech-and-moderna-making-1000-profit-every-second-while-worlds-poorest (27 May 2023).

[150] E. de Haan, *Pharma's pandemic profits*, *op. cit.*

[151] Pfizer, *Pfizer Reports Record Full-Year 2022 Results and Provides Full-Year 2023 Financial Guidance*, 31 January 2023.; https://investors.pfizer.com/Investors/News/news-details/2023/PFIZER-REPORTS-RECORD-FULL-YEAR-2022-RESULTS-AND-PROVIDES-FULL-YEAR-2023-FINANCIAL-GUIDANCE/default.aspx (27 May 2023).

[152] People's Vaccine Alliance, *Pfizer Q4 Earnings*…, Press Release, 31 January 2023.; https://peoplesvaccine.org/resources/media-releases/pfizer-q4-earnings-pfizer-has-plundered-health-systems-for-profit-campaigners-say/ (27 May 2023).

3.1.5. Privatisation of public research – example of Oxford/AstraZeneca vaccine

As discussed in previous chapters, publicly funded institutes are most often responsible for developing relevant early-stage medical innovations, which are then acquired by pharmaceutical companies.

In the context of the COVID-19 pandemic, this model was applied not only to the mRNA technology and vaccine developed for example by the U.S. NIH and Moderna but also to the viral vector technology used by the University of Oxford in the U.K. to develop a vaccine later produced by a British-Swedish pharmaceutical company AstraZeneca.

A study by the non-profit organisation Medicines Law & Policy analyses the intellectual property pathway of the technologies used in the vaccine from invention to production and distribution.[153]

Oxford-AstraZeneca's COVID-19 vaccine based on the ChAdOx platform builds on nearly two decades of research and development of the Chimpanzee adenovirus-vectored vaccine, which, among other things, was intended for use against MERS disease.[154] R&D of the platform was 97.1-99.0% publicly funded, according to a study by Cross et al.[155]

The Jenner Institute (a research institute at Oxford University) and Vaccitech (a spin-out company founded by Jenner's top researchers in 2016 to further develop the ChAdOx platform through a commercial model)[156] have advanced the work on the technology to adapt it for SARS-CoV-2 and scale-up production. To this end, they have teamed up with various partners such as U.K. government bodies, CEPI and the Serum Institute of India.

In April 2020, Oxford University promised to transfer the rights to its ChAdOx1 COVID-19 vaccine candidate to any manufacturer capable of producing it *…to ensure that no one hoards or unduly prices these products…*[157] The Jenner Institute has reportedly

[153] C. Garrison, *How the 'Oxford' Covid-19 vaccine became the 'AstraZeneca' Covid-19 vaccine, Medicines Law & Policy*, October 2020.; https://medicineslawandpolicy.org/wp-content/uploads/2020/10/How-the-Oxford-Covid-19-Vaccine-became-the-AstraZeneca-Covid-19-Vaccine-Final.pdf (27 May 2023).

[154] *Ibidem*, p. 5-6.

[155] S. Cross et al., *Who funded the research behind the Oxford-AstraZeneca COVID-19 vaccine? Approximating the funding to the University of Oxford for the research and development of the ChAdOx vaccine technology*, medRxiv, 10 April 2021.; https://www.medrxiv.org/content/10.1101/2021.04.08.21255103v1 (27 May 2023).

[156] See: Vaccitech, *Our Mission*: https://www.vaccitech.co.uk/ (27 May 2023).

[157] A. Kalis, *Vaccitech Shares its Progress on a Covid-19 Vaccine*, MillTrust International, 20 April 2020.; https://www.milltrust.com/vaccitechs-progress-on-a-covid-19-vaccine/ (27 May 2023).

stated that no manufacturing partner will be granted exclusive marketing rights to the vaccine. Jenner's director stressed: *I personally don't believe that in a time of pandemic, there should be exclusive licenses…So we are asking a lot of them. Nobody is going to make a lot of money off this.*[158]

This heralded a potential upheaval in the pharmaceutical market.

The proposed approach provided an opportunity to break out of the commercial business model. At the time, ChAdOx1 was a leading vaccine candidate and the whole world was focused on its development and production. The choice of Oxford University to allow any capable company to produce it, had the potential to greatly accelerate vaccination around the world and to show the possibilities in expanding the availability and affordability of medical technologies when the commercial system is sidestepped, and decisions are driven by the public health considerations.

This, however, has not happened.

Only a few weeks later, the university's stance on non-exclusive licensing to various companies changed fundamentally, after the Jenner Institute and Vaccitech were urged to partner with a Big Pharma company. Reportedly, Bill Gates, billionaire and founder of the Bill and Melinda Gates Foundation, which has a significant influence on the global health agenda and other funders such as Gavi and CEPI (both founded themselves by the Gates Foundation) played a key role in changing the university's decision.[159] Shortly thereafter, the university signed an agreement with AstraZeneca that gave the company exclusive rights to the vaccine.

AstraZeneca agreed to sell it at a not-for-profit rate, explaining that …*for the duration of the coronavirus pandemic, with only the costs of production and distribution being covered* and signed several licensing agreements with generic manufacturers around the world.[160] The company assured its investors that selling the vaccine without profit

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[158] D. D. Kirkpatrick, *In Race for a Coronavirus Vaccine, an Oxford Group Leaps Ahead, New York Times*, 27 April 2020.; https://www.nytimes.com/2020/04/27/world/europe/coronavirus-vaccine-update-oxford.html (27 May 2023).

[159] S. Baker, *Covid Vaccine Front-Runner Is Months Ahead of Her Competition*, Bloomberg, 15 July 2020.; https://www.bloomberg.com/news/features/2020-07-15/oxford-s-covid-19-vaccine-is-the-coronavirus-front-runner (27 May 2023).; C. Garrison, *op. cit*., p.7.; J. Cohen, *Doses of reality*, Science, 14 May 2021.; https://www.science.org/content/article/pandemic-surge-home-threatening-indian-vaccinemaker-s-bid-protect-world (27 May 2023).

[160] Vaccitech, *Vaccitech and Oxford University announce landmark partnership with AstraZeneca for the development and large-scale distribution of the COVID-19 vaccine candidate*, 30 April 2020.; https://www.vaccitech.co.uk/vaccitech-and-oxford-university-announce-landmark-partnership-with-astrazeneca-for-the-development-and-large-scale-distribution-of-the-covid-19-vaccine-candidate/ (23 May 2023).

during the pandemic would not hurt the company financially, as it would be offset by government funding.[161]

Ultimately, for a variety of reasons (from the vaccine's lower efficacy than its competitors based on the mRNA technology developed by NIH/Modern and Pfizer/BioNTech to safety concerns - later dismissed by regulatory agencies - and supply issues), the deal did not prove very lucrative for AstraZeneca. However, the company and its executives have still been able to benefit from it.

AstraZeneca's stock and options owned by its CEO Pascal Soriot have increased by nearly $15 million in value between April and August 2020.[162] In 2021, the company's value increased by 18 per cent.

Only in 2021, about 2.5 billion of the COVID-19 Vaxzevria vaccine doses were supplied to more than 180 countries generating a revenue of $37.4 billion for AstraZeneca.[163] In 2021, the company reported that it is *expecting to progressively transition the vaccine to modest profitability as new orders are received*.[164] Between 2021-2022, the company has profited about $1.5 billion from the vaccine.[165]

The fact that both NIH-Modern and Oxford-AstraZeneca vaccines have been almost entirely publicly funded exemplifies the distribution of public and private sector investment in key technologies on the one hand and profit rewards on the other.

In the case of Oxford-AstraZeneca, private profiteering from publicly funded technology while limiting access to it is just one of the regrets. The other, however, is the missed opportunity to demonstrate the possibility of sharing the most needed public medical technology with the world on a non-exclusive basis and the ability to prove the effectiveness of public health interventions, which could be brought by transforming the current pharmaceutical business model.

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[161] See: https://www.youtube.com/watch?v=VLl8d5TEsKk&ab_channel=KEIWashDC

[162] J. Hancock, *They Pledged to Donate Rights to Their COVID Vaccine, Then Sold Them to Pharma*, KFF, 25 August 2020.; https://khn.org/news/rather-than-give-away-its-covid-vaccine-oxford-makes-a-deal-with-drugmaker/ (27 May 2023).

[163] According to the company, the majority of these doses were subject to not-for-profit contracts. Only during the last quarter of 2021, it supplied the vaccine on commercial terms with moderate profitability. See E. de Haan, *Pharma's pandemic profits*, *op. cit.*, p. 54.

[164] AstraZeneca, *Year-to-date and Q3 2021 results*, 12 November 2021.; https://www.astrazeneca.com/media-centre/press-releases/2021/year-to-date-and-q3-2021-results.html (27 May 2023).

[165] E. de Haan, *Pharma's pandemic profits*, *op. cit., p. 55.*

3.2. Philantrocapitalism in the pharmaceutical sector

The alleged influence of the Gates Foundation in reversing Oxford University's decision to exclusively license the rights to its technology (and other examples of the Foundation's ability to sway certain decisions during the pandemic, see, for example, Chapter 6.7.), raises questions of the broader influence of philanthropic organisations on public health policies in the current system.

There are various reports of the growing role of *philantrocapitalism* in global health architecture.[166]

Private foundations and the companies behind them, funding and influencing the public health agenda, not only integrate capitalist thinking into the sector but also contribute to shaping the system so that it works in accordance with their values and interests. In the pandemic context, for example, they often support the prevailing market mechanisms in the pharmaceutical innovation and access ecosystem by being staunch defenders of patent monopolies.[167]

Their beliefs in the excellence of the private sector and the application of corporate solutions to public health problems are reflected in their positions on tackling global health challenges, which ensure the status quo remains intact.[168]

The influx of business thinking brought by philanthropic organisations to the public health sector is reinforced by the fact that they often fund services of consulting firms to advise governments and multilateral organisations on public policy issues.[169]

In many cases of philanthropists' involvement, as Tim Swab, an American investigative journalist put it, *what the right hand gives in charity the left-hand takes away structurally*. As further argued by Schwab, *these foundations perpetuate the false ideological impression that they are… solving the problem even when they're not. And they*

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[166] J. Wilson, *Philanthrocapitalism and Global Health*, in: G. Brock, S. Benatar (ed.), *Global Health and Global Health Ethics*, Cambridge University Press, March 2011.; https://discovery.ucl.ac.uk/id/eprint/10079534/3/Wilson%20Philanthrocapitalism%20and%20global%20health%20clean%20final%20version.pdf (27 May 2023).

[167] A. Zaitchik, *How Bill Gates Impeded Global Access to Covid Vaccines*, The New Republic, 12 April 2021.; https://newrepublic.com/article/162000/bill-gates-impeded-global-access-covid-vaccines (27 May 2023).

[168] See: *Philanthropy and the State: who is funding what and why?*, UCL Institute for Innovation and Public Purpose.; https://www.ucl.ac.uk/bartlett/public-purpose/events/2021/may/philanthropy-and-state-who-funding-what-and-why (27 May 2023).

[169] For example, it has been the consulting firm McKinsey that reportedly recommended that the US government halt public production of vaccines.

might be compounding it by perpetuating this ideological impression of private sector saviourism.[170]

While philanthropic organisations such as Wellcome Trust, a charitable foundation focused on health research, and Gates Foundation have played a significant role in the response to the pandemic, their actions should not be seen in isolation from their business interests. Indeed, in addition to the ideological influence on how the public health sector operates, the broad role given to charitable organizations in public initiatives (despite potential conflicts of interest) puts them in a position to benefit financially from their involvement. It is, however, subject to little scrutiny.

For example, while during the pandemic Wellcome Trust has co-led the WHO mechanism, which aimed to raise funds for the development of COVID-19 treatments, the foundation itself had investments in companies producing potential product candidates.[171] Similarly, the Gates Foundation has positioned itself to potentially benefit financially from its role in the mechanism.[172]

The lack of transparency and accountability associated with the involvement of philanthropists (who are not subject to the same oversight mechanisms as public institutions) in public policies results in little attention paid to their financial interests and with few checks and balances put on their work.

Although they can play an important role in tackling global health challenges, including pandemic responses, they should not be able to influence the public decision-making process. This is why, the public sector, while working with philanthropic organisations, should always involve them in strictly prescribed roles, not outsource initiatives to them.

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[170] T, Schwab, *Covid-19, trust, and Wellcome: how charity's pharma investments overlap with its research efforts*, British Medical Journal, 372, March 2021.; http://dx.doi.org/10.1136/bmj.n556 (27 May 2023).

[171] As reported by the British Medical Journal, *financial disclosures from late 2020 show that Wellcome has a £275m (€318m; $389m) stake in Novartis, which manufactures dexamethasone and is investigating additional therapeutics. And Roche, in which Wellcome holds a £252m stake, is helping to manufacture monoclonal antibodies with Regeneron. Wellcome reports gains of £3.3bn from all investments in 2020, three times more money than the trust gave away in charity*. See: T. Schwab, *Covid-19, trust, and Wellcome…*, *op. cit.*

[172] Gates had more than €206m invested in companies working on COVID-19 technologies.

Chapter 4. Imbalance of power in the pharmaceutical ecosystem

4.1. Unfavourable dynamics

The preceding analysis seeks to demonstrate the scale of public investment in R&D and the production of medical countermeasures for COVID-19 and the ineffectiveness of the current model. However, it would be difficult to conclude that countries such as the US, U.K. or EU member states have had many better choices than to inject billions of dollars into private companies on the brink of the pandemic.

The lack of adequate public policies on health emergency preparedness and response, and the longstanding overreliance on pharmaceutical companies for vaccine R&D have left governments dependent on their willingness to engage.

This dynamic benefited private actors (who eventually gained, as it were, from their own neglect of research on the infectious disease), whose capabilities proved crucial to tackling the pandemic.

The oligopoly prevailing in the vaccine market, the limited raw materials and other ingredients needed for vaccine production, as well as the scarce manufacturing capacity, meant that despite the initial assurances of cooperation and solidarity (not only among Global North countries but also Global North - Global South), countries began to compete and outbid each other for supplies.

In the process, compared to other high-income regions, the EU was at a disadvantage since it has not had the institutions or infrastructure to conduct medical R&D on the same scale as the U.S. and has not been involved in vaccine development and production to the same extent as for, example, the U.K.

Guido Rasi, former executive director of the European Medicines Agency, made it clear why the U.S. and U.K. could have made better deals with COVID-19 vaccine producers by stressing: *They were partners with industry and Europe behaved as a client. EU's investment was 'peanuts' compared to the US*.

Concluding favourable contracts for COVID-19 vaccines with pharmaceutical companies has indeed proved a challenging task for the EU. Looking through the provisions of these contracts gives a useful insight into the imbalance of bargaining positions between the public and private actors under the current system.

4.1.1. Example of EU Advance Purchase Agreements for COVID-19 vaccines

In order to secure the supply of vaccines early on, EU countries decided to sidestep the international mechanism established for joint procurement and negotiate as a bloc advance purchase agreements directly with companies.

This decision was deemed necessary to reduce the risk that the EU would fall behind the U.S. or U.K. on the waiting list given that these countries had already begun to enter into similar agreements in the first months of the pandemic.

Under APAs, the EU de-risked vaccine manufacturers' investment in the development and production of COVID-19 vaccines and ensured a market for them in return for a specific number of vaccine doses delivered within a given timeframe and at a fixed price.[173]

From August 2020 to November 2021, the European Commission and Member States signed eight APAs with companies. The upfront payments were funded through the Emergency Support Instrument (ESI), a €2.7 billion EU financing scheme made available to tackle the COVID-19 pandemic.[174] The fund has also covered part of the price of future vaccine doses, while the rest was to be paid directly by member states upon delivery.

Negotiated under pressure and with limited experience on the EU side, these agreements were – from a public interest perspective – far from perfect.[175]

First of all, the negotiations were opaque. The public learned more often about the provisions in the agreements from companies' shareholder meeting updates or media leaks than from public communications. Although the Commission published the contracts after being pressured by civil society and members of the European Parliament, they were

[173] European Commission, *Annex to the Commission decision on approving the agreement with Member States on procuring COVID-19 vaccines on behalf of the Member States and related procedures*, 18 June 2020. https://ec.europa.eu/info/sites/default/files/annex_to_the_commission_decision_on_approving_the_agreement_with_member_states_on_procuring_covid-19_vaccines_on_behalf_of_the_member_states_and_related_procedures_.pdf (27 May 2023).

[174] The redactions in the APA contracts published by the Commission do not allow to calculate how much has been disbursed in advance payments. However, the leaked (unredacted) contracts show that Pfizer got €700 million, AstraZeneca €336 million and Moderna €318 million. ESI's budget allocation for vaccines was topped up with at least €750 million from Member States' contributions to be able to make all the advance payments. See also: European Commission, *Questions & Answers on vaccine negotiations** 8 January 2021.; https://ec.europa.eu/commission/presscorner/detail/en/QANDA_21_48 (27 May 2023).

[175] See also an analysis of the contracts signed by the Canadian government here: https://www.ijhpm.com/jufile?ar_sfile=65911 (27 May 2023).

heavily redacted. None of them revealed, for example, the price the EU paid for different vaccines.[176]

A particular criticism of the secrecy around EU deals with companies concerned European Commission President Ursula von der Leyen's personal involvement in agreeing on the initial terms of the EU's largest vaccine contract, involving up to 1.8 billion doses of BioNTech/Pfizer vaccine, through text messages with Pfizer CEO Albert Bourla. Von der Leyen has refused to disclose the messages despite accusations of misconduct by the European Court of Auditors[177] and the European Ombudsman.[178] As of early 2023, the investigation by the European Public Prosecutor's Office on the matter is ongoing.[179] Commenting on the contract, Poland's health minister Adam Niedzielski said the deal favoured the pharmaceutical company rather than EU citizens.[180]

In the disclosed APAs, the Commission also redacted information on the intellectual property more often than other countries signing similar deals with the industry.[181] This secrecy prevented independent scrutiny and gave the industry an advantage in further negotiations.

What is more, in June 2020, in an agreement with Member States on joint vaccine procurement, the Commission committed to addressing intellectual property sharing in negotiations with the pharmaceutical industry to ensure access for developing countries in sufficient quantity and at low prices.[182] The disclosed documents indicate that in subsequent

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[176] Interestingly, while the Commission argued that it could not reveal prices since these are confidential clauses, the US disclosed them its contracts. See: U.S. Department of Health & Human Services, FOIA Library / Electronic Reading Room: https://www.hhs.gov/foia/electronic-reading-room/index.html (27 May 2023).

[177] European Court of Auditors, *EU COVID-19 vaccine procurement*, Special report, 2022.; https://www.eca.europa.eu/Lists/ECADocuments/SR22_19/SR_EU_COVID_vaccine_procurement_EN.pdf (27 May 2023).

[178] See European Ombudsman investigation: How EU institutions, bodies, offices and agencies record text and instant messages sent/received by staff members in their professional capacity, 30 June 2021.; https://www.ombudsman.europa.eu/en/case/en/59322 (27 May 2023).

[179] European Public Prosecutor's Office, *Ongoing EPPO investigation into the acquisition of COVID-19 vaccines in the EU*, 14 October 2020.; https://www.eppo.europa.eu/en/news/ongoing-eppo-investigation-acquisition-covid-19-vaccines-eu (27 May 2023).

[180] A. Bounds, D. P. Mancini, *Pfizer's revised EU Covid vaccine contract meets resistance*, Financial Times, 14 March 2023.; https://www.ft.com/content/62c225f5-0652-4acd-977b-99fb357dbd3f (27 May 2023).

[181] Stopaids & Global Health Advocates, *Access Denied: What Happens When Big Pharma is in the Driver's Seat*, January 2023, p. 13.; https://stopaids.org.uk/wp-content/uploads/2023/01/Report-2.pdf (27 May 2023).

[182] See: *Study supporting the preparation of the impact assessment: Civil aspects of the cross-border protection of vulnerable adults*.; https://ec.europa.eu/info/sites/default/files/annex_to_the_commission_decision_on_approving_the_agreement_with_member_states_on_procuring_covid-19_vaccines_on_behalf_of_the_member_states_and_related_procedures_.pdf (27 May 2023).

contracts signed between August 2020 and November 2021, the EU refrained from including any IP-related commitments from the industry. Richard Bergström, a Swedish representative in the Steering Board negotiating APAs admitted in a report published by civil society organisations that *in the steering board we never talked about intellectual property. It was never discussed*.[183] This is especially surprising given that the Commission had a clear mandate from member states to work towards ensuring COVID-19 vaccines as a global public good.

Pharmaceutical companies have also succeeded in getting the EU to agree to liability exemptions in case of safety incidents. All APAs contain indemnification clauses, protecting manufacturers from the financial risks of liability claims.[184] What is more, the contracts also lack the requirements to share the generated data and knowledge either back to the EU or through open source. Companies kept these benefits gained with public investment solely for their own profit.[185] Some APAs have also limited the EU's ability to decide on the use of purchased vaccines, for example, making member states ask for permission to transfer them to third countries.[186]

As in the case of the U.S. wartime penicillin project (see Chapter 2.3.3.), the contracts have not included the requirement to depreciate the production capacity that had been created thanks to the APAs, after their expiration. The production infrastructure thus established or scaled up became the property of the companies.

Problems arising from the asymmetry of power between the Commission and the companies have also resulted in significant shortcomings related to delivery schedules, pricing, or reimbursement of down payments if vaccines do not reach the market.[187] Perhaps the best example of the contracts' flaws in this context is the debacle regarding the supply of vaccine doses by the British-Swedish company AstraZeneca.

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[183] Stopaids & Global Health Advocates, *op. cit*., p. 8.

[184] Indemnification refers to absolving manufacturers of liability for claims resulting from unforeseen harms caused by their product. See: P. Boulet et al., *Advanced Purchase Agreements for Covid-19 Vaccines Analysis and Comments*, July 2021, p. 24.; https://left.eu/content/uploads/2021/07/Advanced-purchase-agreements-1.pdf (27 May 2023).

[185] Boulet et al., *op. cit.*

[186] Due to the manufacturers concerns related to the liability issues.

[187] BEUC, *Making the most of EU advance purchases of medicines*, December 2021.; https://www.beuc.eu/sites/default/files/publications/beuc-x-2021-110_making_the_most_of_eu_advance_purchases_of_medicines.pdf (27 May 2023).

4.1.2. EU-AstraZeneca contract debacle

The EU's vaccination campaign against COVID-19 has been hampered by a significant undersupply of the vaccine developed by the Oxford Institute and produced by AstraZeneca, which was due to be the main one in the EU's rollout in the first months of 2021.

However, the EU did not include sufficiently stringent provisions in the contract with the company and the latter overstated the supply based on overly optimistic schedules. Under the contract, the company committed to undertake *Best Reasonable Efforts* to deliver its vaccine according to agreed estimated timeframes.[188]

AstraZeneca's failure to meet the agreed timelines, which was allegedly due to the company's prioritisation of U.K. deliveries,[189] was met with harsh criticism from the EU Health Commissioner, Stella Kyriakides, who stressed that *no company should be under any illusion that we don't have the means to understand what is happening*. Expressing her frustration, Kyriakides also said that *we do have a knowledge of the production of the doses, where they have been produced and — if they have been sent anywhere — where this is*, adding that first come first served approach *may work at neighbourhood butcher but not in contracts*.[190]

The Commission even initiated legal proceedings against the company in April 2021 for non-compliance with the contract and the lack of a *reliable* plan to ensure timely deliveries. The court case was settled a few months later with an agreement on the new delivery schedules and rebates.[191]

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[188] The company had committed to making its "best reasonable efforts" to deliver 180 million vaccine doses to the EU in the second quarter of this year, for a total of 300 million in the period from December to June but in March 2021 said it would aim to deliver only one-third of that by the end of June, of which about 70 million would be in the second quarter. Best Reasonable Efforts in the AstraZeneca contracts is defined as *the activities and degree of effort that a company of similar size with a similarly-sized infrastructure and similar resources as AstraZeneca would undertake or use at the relevant stage of development or commercialisation, having regard to the urgent need for a vaccine to end a global pandemic which is resulting in serious public health issues, restrictions on personal freedoms and economic impact, across the world but taking into account efficacy and safety*.

[189] The supply of vaccines in the first months of the COVID-19 pandemic also exposes an unseen level of politicisation of global health, health security and medical countermeasures. Countries have become entangled in political ties between pharmaceutical companies and their host governments.

[190] J. Deutsch, D. M. Herszenhorn, *EU commissioner: AstraZeneca logic might work at the butcher's, but not in vaccine contracts*, Politico, 27 January 2021.; https://www.politico.eu/article/health-commissioner-astrazeneca-logic-might-work-at-butcher-but-not-in-contracts/ (27 May 2023).

[191] J. Deutsch, *EU and AstraZeneca settle court case over vaccine supply*, Politico, 3 September 2021.; https://www.politico.eu/article/eu-and-astrazeneca-settle-court-case-over-vaccine-supply/ (27 May 2023).

In a CSO report on the EU's APAs, Richard Bergström states, *we should have been much more suspicious about manufacturing capabilities, which unlike for clinical trials is much more secretive. Manufacturing was internal. We did not know anything. We were caught by surprise by this AstraZeneca debacle.*[192]

In response to this crisis and in an effort to enforce companies' responsibility for delivering vaccine doses to the EU, the Commission has also introduced export restrictions to shed light on when and where manufacturers ship the vaccines.[193] This method of backtracking on bad agreements has brought the EU to the brink of a trade war over vaccine supplies. The fact that even supposedly open EU markets decided to introduce such restrictions threatened a global domino effect. Given that vaccine supply chains are often intertwined among several countries, the effect of mutually escalating restrictions on the flow of vaccines or their components risked spilling over into other regions.[194]

The close public and media attention to the pharmaceutical industry's detrimental strategies and clear examples of risk of the over-reliance on for-profit companies may have been seen as a watershed moment in relations between the governments and the industry – a breakthrough similar to a turning point in campaigning for access to medicines during the HIV/AIDS crisis in the 1990s.

Things, however, have not taken the turn they did 30 years ago. The result of this failure was a political blame game between the Commission and EU governments, which many used to whitewash the industry and place all the blame on public officials. Instead of attaching greater conditions to public investment and holding companies accountable, some even saw the problem in not giving the industry everything it wanted in exchange for vaccine doses, criticising the Commission for even negotiating prices.[195]

4.1.3. EU's *self-inflicted* crisis

While all EU countries speaking with one voice during the COVID-19 vaccine procurement was an unprecedented success for the bloc, the overreliance on pharmaceutical

[192] Stopaids & Global Health Advocates, *op. cit*., p. 7.
[193] European Commission, *Commission strengthens transparency and authorisation mechanism for exports of COVID-19 vaccines*, 24 March 2021.; https://ec.europa.eu/commission/presscorner/detail/en/ip_21_1352 (27 May 2023).
[194] J. Hanke Vela, R Heath, *Brussels blocks vaccine exports in all but name*, Politico, 7 April 2021.; https://www.politico.eu/article/vaccine-export-block-europe-coronavirus-astrazeneca/ (27 May 2023).
[195] See: https://twitter.com/GuntramWolff/status/1352899970517626880

companies and unjustifiable secrecy around the negotiations resulted in a *self-inflicted* crisis.

Genuine transparency on the vaccine purchase agreements would be a powerful tool for the EU enabling public debate and parliamentary scrutiny, potentially exposing weaknesses in the Commission's approach before it was too late to correct them, and strengthening the position of EU negotiators with Big Pharma companies.[196]

4.2. Distribution of power between governments and the pharmaceutical industry

The pharmaceutical industry has been able to take full advantage of the position it has found itself in during the COVID-19 pandemic.

While the growing power of states during the pandemic through measures such as lockdowns or vaccination requirements has been broadly debated, the power of certain pharmaceutical companies, which has increased significantly over that time due to states' dependence on their services, is less often analysed.

In fact, the pandemic and unprecedented global vaccination campaigns have made Big Pharma companies not only much more profitable but also highly influential.[197] Control over access to COVID-19 vaccines has given companies direct leverage over public policies. Companies such as Pfizer had an impact on the course of the pandemic and the economic and health welfare across countries by controlling the allocation and price of key medical countermeasures. In this sense, the private sector has been effectively driving the pandemic response.

At the same time, the industry sought to take advantage of the pandemic to change its public perception from price-gougers to world-savers. While before the COVID-19 outbreak, pharmaceutical companies were among the least trusted businesses in the US[198] there were points in the first months of the pandemic when it was portrayed as a public

[196] O. Hoedeman, H. van Scharen, *Abuse of power by Big Pharma drives the EU 'Jab Race'*, Domani, 8 April 2021.; https://www.editorialedomani.it/idee/commenti/abuse-of-power-by-big-pharma-drives-the-eu-jab-race-i7cj59av (27 May 2023).

[197] A. Allen, *How Pfizer Won the Pandemic, Reaping Outsize Profit and Influence*, KFF, July 2022.; https://khn.org/news/article/pfizer-pandemic-vaccine-market-paxlovid-outsize-profit-influence/ (27 May 2023).

[198] Ch. Hu, *These are the most — and least — reputable drug companies in the US*, Insider, 19 June 2018.; https://www.businessinsider.com/pharmaceutical-company-reputation-rankings-2018-6?r=US&IR=T (27 May 2023).

champion.[199] The industry's strategy for vaccine distribution has been indeed carefully crafted. By fear-mongering about scarcity, companies have fuelled the hoarding of vaccines by rich countries and pressured them to agree on controversial provisions.

In addition, the public sector was at a disadvantage from the outset, as national governments lacked the expertise and government officials were not prepared to negotiate with a *lawyered-up* pharmaceutical companies such as Pfizer.[200]

Pfizer's ability to exercise its power to extract significant concessions from governments can also be illustrated by the fact that the company's contract with the EU was the most significantly redacted of any concluded by the bloc.[201] As Moncef Slaoui, the head of the U.S. *Operation Warp Speed*, put it, *the company that has contributed so much to saving the world from Covid has also ensured it is such a lucrative business*.[202], adding that Pfizer tried to *play hardball during a time of national emergency*.[203]

4.2.1. Disadvantaged position of the Global South countries

The power imbalance between governments and companies during the pandemic was particularly striking for countries in the Global South (see Chapter 6). Many less powerful states were effectively pinned down by the industry.

While the media reported about the line between Pfizer's CEO Bourla and the Global North leaders being always open, African countries stressed that no one at the company has returned their calls. Even when contact was made, developing countries' leaders shared the view that Pfizer was imposing additional burdens on them, demanding changes in national laws to protect the company from lawsuits.[204] From South America[205] to Asia[206], governments have been hiring specialised lawyers and sometimes enacting complex new legislation so that manufacturers' liability could be waived, and the vaccine supply secured.

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[199] R. Tansey, *Power and profit during a pandemic*, Corporate European Observatory, 21 September 2020.; https://corporateeurope.org/en/2020/09/power-and-profit-during-pandemic (27 May 2023).
[200] See: https://www.youtube.com/watch?v=Kja3g_zamdU&t=262s&ab_channel=EuropeanPublicHealthAlliance-EPHA
[201] Stopaids & Global Health Advocates, *op. cit*., p. 12.
[202] H. Kuchler, D. P. Mancini, D. Pilling, *The inside story of the Pfizer vaccine…, op. cit.*
[203] *Ibidem*
[204] E.g., Lebanon or Philippines.
[205] E.g., Brazil or Argentina.
[206] E.g., Lebanon or Philippines.

Pfizer was accused of *bullying* Latin American governments in vaccine negotiations, asking them to put up sovereign assets as a guarantee for the cost of any future litigation, as reported by the Bureau of Investigative Journalism in February 2021.[207]

Similarly, Zweli Mkhize, South African Health Minister, argued that the delivery of Pfizer's vaccine to the country has been delayed due to *unreasonable demands* that his government set aside sovereign assets for that purpose.[208] According to the Financial Times, South Africa's Treasury Ministry perceived the company's conditions as a demand for *surrender[ing] national sovereignty*.[209]

According to the media report, one official present at the negotiations with Pfizer described how the government felt like it was being *held to ransom* in order to access the vaccine doses.[210] Some low- and middle-income countries' governments also suspect that the overly strict conditions imposed by the company have served to delay the distribution of vaccines to poorer countries in order to supply the rich ones first.

The analysis by Public Citizen shows how Pfizer pressured governments to agree to, among other things, not impose penalties on the company for late deliveries, settle disputes in secret private arbitration, or broadly exempt the company from liability for civil claims.[211]

Pfizer is also reported to tell the Indian government that it can produce its coronavirus vaccine locally in exchange of receiving faster regulatory approval and freedom over pricing and exports.[212]

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[207] M. Davies, R. Furneaux , I. Ruiz, J. Langlois, *'Held to Ransom': Pfizer Demands Governments Gamble with State Assets to Secure Vaccine Deal*, Bureau of Investigative Journalism, 23 February 2021.; https://www.thebureauinvestigates.com/stories/2021-02-23/held-to-ransom-pfizer-demands-governments-gamble-with-state-assets-to-secure-vaccine-deal (27 May 2023).

[208] M. Davies, R. Furneaux, *Pfizer backs down over "unreasonable" terms in South Africa vaccine deal*, Bureau of Investigative Journalism, 19 April 2021.; https://www.thebureauinvestigates.com/stories/2021-04-19/pfizer-backs-down-over-asset-seizing-clause-in-south-africa-vaccine-deal (27 May 2023). According to the Bureau of Investigative Journalism, Pfizer also demanded putting up sovereign assets as a guarantee against the cost of any future legal case from some Latin American governments. In these cases, they included embassy buildings and military bases.

[209] *But Pfizer did insist on indemnity against civil claims and required the government to provide finance for an indemnity fund*. See: H. Kuchler, D. P. Mancini, D. Pilling, *The inside story of the Pfizer vaccine…, op. cit.*

[210] M. Davies, R. Furneaux , I. Ruiz, J. Langlois, *op. cit.*

[211] Z. Rizvi, *Pfizer's Power*, Public Citizen, 19 October 2021.; https://www.yls.es/docs/sanidad/contrato_pfizer.pdf (27 May 2023). Exactly what powers and profits companies have managed to secure by providing access to medical countermeasures is hidden behind redactions in procurement contracts and non-disclosure agreements.

[212] N. Arora, K. N. Das, *Exclusive: Pfizer wants to make vaccine in India if faster clearance, export freedom assured – sources, Reuters*, 10 March 2021.; https://www.reuters.com/article/us-health-coronavirus-india-pfizer-

The Financial Times quotes Jillian Kohler, the director of the WHO's collaborating centre for governance, transparency and accountability in the pharmaceutical sector, saying that Pfizer has historically had a reputation for being *quite aggressive* and *interested in profit maximisation at the expense of everything else*, adding that the pandemic amplified its power, *exacerbating Pfizer's ability to ask extraordinary demands from governments*.[213]

While Albert Bourla, the company's CEO has been speaking highly of his central role in helping the Global South countries recover from the pandemic, Winnie Byanyima, director of UNAIDS, the Joint United Nations Programme on HIV and AIDS, questioned this claim, stressing that Bourla *hasn't saved the world. He could have done it but he hasn't*, pointing to Pfizer's very low supply of vaccines in Africa (read more about it in Chapter 6.).[214]

Companies took advantage of their strong position during the crisis and how little room governments had in negotiations. With limited supply, a firm disagreement on contractual terms put forward by the industry could have meant a delay in delivery. The sooner a contract was signed, the sooner the vaccines were delivered, the economy could have been restored and lives saved.

4.2.2. Conflicting interests weakening the Global South countries

One of the reasons why the Global South countries have not been able to protect their interests to a greater extent in the international arena (for example, in procuring more vaccine doses early in the pandemic or easing intellectual property rights on COVID-19 products), as they did for example in the 1970s or even in the late 1990s during the Doha Declaration negotiations, is that nowadays, they are economically much more divided and tied to high-income countries and their industries.

Developing countries are more conflicted when it comes to their international agenda to counter the economic policies of rich countries. For example, those that work with pharmaceutical companies to develop their own domestic industries or have signed free trade agreements with the Global North countries can be much less willing to openly criticise them. One such example can be Jordan, which has a free trade agreement with the

idUSKBN2B21AY?taid=6048c664eaf59800011cd761&utm_campaign=trueanthem&utm_medium=trueanthem&utm_source=twitter (27 May 2023).

[213] H. Kuchler, D. P. Mancini, D. Pilling, *The inside story of the Pfizer vaccine…, op. cit.*

[214] *Ibidem*

US, under which American pharmaceutical companies invest in the country and become an important part of its economy, which may influence the country's political stance on issues affecting the industry's business case.

As Susan K Sell, a Professor of Political Science and International Affairs at George Washington University in the U.S. argues, *It is a much more variegated landscape than it was back in the day*.[215]

4.3. Geopolitical games with vaccine donations

The COVID-19 pandemic elevated global health to a geopolitically critical sector and medical countermeasures to important assets in advancing countries' political goals.

This became particularly evident in the case of vaccine donations when governments' decisions regarding recipient countries have been made in alignment with their national strategic interests.

Rich countries, bypassing international mechanisms designed to ensure equal access to medical supplies, hoarded vaccines at the start of the pandemic. Once they met their needs, they began to donate excess doses bilaterally to selected countries as part of a broader strategy to increase their influence in developing countries.[216]

For example, the EU side-lined COVAX, the mechanism for equitable vaccine delivery set up by the WHO (see Chapter 6.7.) in its vaccine donations by establishing a parallel donation mechanism in January 2021 to allow for targeted vaccine sharing, providing member states with greater political visibility and allowing them to get the most political leverage out of it.[217]

Sharing vaccine doses with the rest of the world has become part of the widening geopolitical clout of wealthy countries. When some European countries halted the use of the Oxford-AstraZeneca vaccine due to safety concerns (later dismissed by regulatory

[215] P. Patnaik, *Deconstructing the TRIPS Waiver Discussions: The Susan Sell Interview*, Geneva Health Files, 5 August, 2022.; https://genevahealthfiles.substack.com/p/deconstructing-the-trips-waiver-discussions (27 May 2023).

[216] S. Wheaton, J. Deutsch, *Europe prepares late entry in vaccine diplomacy race*, Politico, 6 May 2021.; https://www.politico.eu/article/eu-europe-excess-coronavirus-vaccine-doses/ (27 May 2023).

[217] F. Guarascio, J. Chalmers, *How a WHO push for global vaccines needled Europe*, Reuters, 21 April 2021.; https://www.reuters.com/world/china/how-who-push-global-vaccines-needled-europe-2021-04-21/ (27 May 2023).

agencies), there were concerns that bad press for the British-Swedish vaccine could bolster Russia's Sputnik vaccine.

These fears were not unfounded. The use of medical countermeasures as a political tool was also recognised by Russia and China, which were trying to establish close relations with developing countries and increase their economic and political leverage over them through donations.[218] For example, of the 72 countries to which China has pledged doses' delivery, all but two are participants in its Belt and Road Initiative.[219]

This political leverage was exercised by the Global North despite calls by WHO Director-General Tedros that *to end this pandemic the only choice we have is cooperation. Vaccine diplomacy is not cooperation, it is actually geopolitical manoeuvring*.[220]

Rather than realising the principle of solidarity and providing equal aid to those most in need, rich countries have chosen to use donations to entrench their traditional spheres of influence.

4.4. Failure by design

From the massive public investment and direct involvement in medical innovation that does not provide an adequate return to the public in terms of equitable and affordable access to end products, to the dependence of public health interventions on the willingness of private companies to engage in them, the above discussion provides ample examples of how the current pharmaceutical R&D and access ecosystem is unable to effectively respond to public health needs.

This failure is neither accidental nor exclusive to health emergencies. It stems from inherent problems in the design of a pharmaceutical system that is not fit for purpose. The next chapter will examine the root causes of this failure and how it affects key aspects of pharmaceutical research and development under *normal conditions* as well as in the context of pandemics.

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[218] B. Westcott, *China and Russia want to vaccinate the developing world before the West. It's brought them closer than ever*, CNN, 11 May 2021.; https://edition.cnn.com/2021/05/11/china/china-russia-covid-vaccine-dst-intl-hnk/ (27 May 2023).

[219] S. Kiernan et al., *The Politics of Vaccine Donation and Diplomacy*, Think Global, 4 June 2021.; https://www.thinkglobalhealth.org/article/politics-vaccine-donation-and-diplomacy (27 May 2023).

[220] M. Taddele Maru, *Solidarity, Not Competition, Is Key to Overcoming Inequity*, Henley & Partners, 2021.; https://www.henleyglobal.com/publications/global-mobility-report/2021-q3/global-mobility-trends/solidarity-not-competition-key-overcoming-inequity (27 May 2023).

Chapter 5. Problems with profit-driven medical innovation ecosystem

5.1. Inherent flaws of the mainstream medical R&D model

The pharmaceutical sector proved to be unable to promote the development of appropriate medical innovations while ensuring sustainable, affordable, and equitable access to them.

The inability of the current system to achieve these goals stems from its design based on for-profit companies that are driven by the sole purpose of maximising profit.

These companies beholden to corporate interests simply by doing what they were created to do contribute to the problems besetting the pharmaceutical market. However divergent from the public health interests their approach is, it can be argued that it is the only way for profit- and shareholder-value-driven corporations to operate.[221] Their executives answer to the companies' shareholders (and their profit expectations) before anybody else. They are not only rewarded for reaching profit thresholds but also legally bound to act in accordance with the companies' best financial interests, even at the expense of public health objectives.[222]

This is the case despite their duty to respect all human rights, which is a widely recognised standard of corporate responsibility set out in the UN Guiding Principles on Business and Human Rights.[223] They state that companies should *avoid causing or contributing to adverse human rights impacts through their own activities and address such impacts when they occur*.[224]

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[221] *Our duty is to our shareholders and to maximize the value [of our products]… Sometimes pricing comes into it, sometimes volume comes into it*. See: J. Rockoff, E. Silverman, *Pharmaceutical Companies Buy Rivals' Drugs, Then Jack up the Prices*, Wall Street Journal, 26 April 2015.; https://www.wsj.com/articles/pharmaceutical-companies-buy-rivals-drugs-then-jack-up-the-prices-1430096431 (27 May 2023).

[222] Y. Heled, L. Vertinsky, C. Brewer, *Why Healthcare Companies Should Be(come) Benefit Corporations*, 60 B.C.L. Rev. 73 (2019), 2019, p.104.; https://lawdigitalcommons.bc.edu/bclr/vol60/iss1/3/ (27 May 2023).

[223] Principle 11: Business enterprises should respect human rights. This means that they should avoid infringing on the human rights of others and should address adverse human rights impacts with which they are involved.

[224] OHCHR, *Guiding Principles on Business and Human Rights*, New Yor and Geneva 2011, point 13.; https://www.ohchr.org/sites/default/files/documents/publications/guidingprinciplesbusinesshr_en.pdf (27 May 2023).

Similarly, the 2008 UN Human Rights Guidelines for Pharmaceutical Companies in relation to Access to Medicines reaffirms that corporations have a *human rights responsibility to extend access to medicines for all including disadvantaged individuals, communities and populations*.[225]

However, these guidelines are non-binding and in practice have little power to influence companies' profit-maximising policies.

In consequence, entrusting these corporations with responding to public health needs and expecting them to prioritise the public interests over their own financial gains is, in fact, expecting them to act in ways that are both contrary to their very *raison d'être* and may even result in violations of their legal obligations.[226] It is clear, then, that the incentives that drive private companies' investments in the pharmaceutical sector are disconnected from public health needs.

5.1.1. Unmet medical needs

As a result, the current R&D system is biased towards high revenue-generating diseases, leading to an increasing gap between real unmet medical needs and investments. Profit-driven decisions on innovation and supply of pharmaceuticals are ineffective or even in *direct conflict with public health outcomes*.[227]

While R&D strategies and priorities often depend on scientific opportunities, economic considerations such as potential profitability and level of risk may play an even greater role in the decision-making process.

Pharmaceutical companies often pursue low-risk strategies that can more easily bring commercial success, rather than developing innovations to address neglected areas. This has led to the proliferation of *me-too* medicines – those that offer little or no therapeutic advances on existing ones but are sufficiently different to obtain patent protection.[228] Consequently, the majority of medicines approved by the European Medicines Agency between 2000 and 2014 were modified versions of existing ones with

[225] OHCHR, *Human Rights Guidelines for Pharmaceutical Companies*, *Guideline 38 commentary*. See also: Amnesty International, *A Double Dose of Inequality: Pharma Companies and the Covid-19 Vaccines Crisis*, p. 17-18.
[226] *Ibidem*, p.105.
[227] See: Y. Heled, L. Vertinsky, C. Brewer, *Why Healthcare Companies Should Be(come) Benefit Corporations*, 60 B.C.L. Rev. 73 (2019), 2019.
[228] R. Feldman, *May your drug price be evergreen*, *Journal of Law and the Biosciences*, Volume 5, Issue 3, December 2018, p. 590–647.; https://academic.oup.com/jlb/article/5/3/590/5232981 (27 May 2023).

no evidence of additional therapeutic benefits, while 95% of rare diseases remain without treatments.[229]

To better understand the decision-making process in pharmaceutical innovation and the distribution of risks and rewards among the actors involved, it is useful to analyse current mainstream R&D models, identifying their critical points and the roles of public and private entities in them.

5.2. Medical innovation and access cycle

The medical innovation process consists of a system of processes, operations and organisations governed by a strict set of rules, involved in the discovery, development, manufacturing and supply of medical products.[230]

The full innovation and access cycle comprises (1) discovery and development, (2) preclinical research, (3) clinical trials, (4) regulatory approval, (5) manufacturing, including sourcing of raw materials, the production of intermediates and active pharmaceutical ingredients (APIs), and the fill and finish phase, (6) marketing and distribution, and (7) post-marketing safety monitoring.[231]

The process of discovering a new drug begins with an understanding of the functioning of the human body and disease activity to determine its causes, progression and consequences. It can take from several years to many decades to select a target that the medicine's molecules can potentially affect.

During the *discovery phase*, often a large number of compounds are tested in the lab to see if they can effectively hit the target while not being overly toxic. They can be

[229] Prescrire International, *New drugs and indications in 2014…*, Volume 24 N° 159, April 2015, p. 107–110.; https://english.prescrire.org/en/109B561E03CAD2313B7046521B310752/Download.aspx (27 May 2023).;
D. Marselis, L. Hordijk, *From blockbuster to "nichebuster": how a flawed legislation helped create a new profit model for the drug industry*, British Medical Journal, 370, July 2020, p. 2.; https://www.bmj.com/content/370/bmj.m2983 (27 May 2023).

[230] S. Moniz et al., *On the complexity of production planning and scheduling in the pharmaceutical industry: the Delivery Trade-offs Matrix*, Computer Aided Chemical Engineering, Elsevier, Volume 37, 2015, p. 1865-
1870.

[231] See e.g., FDA, The Drug Development Process: https://www.fda.gov/patients/learn-about-drug-and-device-approvals/drug-development-process (23 May 2023).; M. Florio, et al., *European pharmaceutical research and development*, Study Panel for the Future of Science and Technology, European Parliamentary Research Service, December 2021, p. 4.; https://www.europarl.europa.eu/RegData/etudes/STUD/2021/697197/EPRS_STU(2021)697197_EN.pdf (27 May 2023).

tweaked and optimised to improve their performance. Then, in the so-called *translation phase*, the leading candidate is tested both in the lab and on animals before human clinical trials begin.

Traditionally, such early scientific research is conducted by public institutes and academic laboratories. Pharmaceutical companies most often enter the R&D process after these initial stages (when an innovation offers the hope of being turned into a patentable product) in order to carry out further steps in the process and bring the product to market.

This includes conducting clinical trials in a series of phases.[232] In *phase I trials*, researchers test a drug on a small group of patients (20–80) to learn about its safety and identify potential side effects. In *phase II trials*, a new drug is given to a larger group of people (100–300) to determine its effectiveness and further study its safety.

Phase III trials are conducted on a large group of people (1,000-3,000) to confirm the drug's effectiveness, monitor side effects, compare it to standard or similar products, and gather information that will allow it to be used safely.

If the drug succeeds in the third phase, an application for regulatory approval can be submitted based on the data generated. Once approved, manufacturing can begin, which includes the sourcing of raw materials, production of intermediates and APIs, and the fill and finish phase, followed by marketing and distribution.

After making a drug available to the public, *phase IV clinical trials* track its safety in the general population, including risk management and pharmacovigilance, seeking more information on its benefits and optimal use.

The above process refers to drugs based on new compounds and will differ for those that (a) build on existing drug concepts (precedented), (b) is a copy of or biologically highly similar to existing product (generic and biosimilar medicines).[233]

5.2.1. *Relay race* model

When it comes to the roles played by different actors in medical innovation, according to Moon et al. over the past decades, the traditional process in which the public

[232] National Institute of Health, NIH Clinical Research Trials and you: https://www.nih.gov/health-information/nih-clinical-research-trials-you/basics (27 May 2023).

[233] See e.g.: R. Werner er al., *Post Covid-19 value chains: options for reshoring production back to Europe in a globalised economy*, STOA, 19 February 2021.; https://www.europarl.europa.eu/RegData/etudes/STUD/2021/653626/EXPO_STU(2021)653626_EN.pdf (27 May 2023).

sector is responsible for the early-stage R&D, which is then taken over by private companies, has been evolving into a one that resembles a *relay race*, with various public, non-profit, and private entities participating at different stages.[234]

For example, scientists working in a publicly funded academic laboratory who discover a promising drug may try to take it further through development and testing in preclinical studies by setting up a commercial start-up company and obtaining funding from investors such as venture capital funds (this approach is even encouraged by public policies, such as the Bayh-Dole Act in the US).[235] Such a company can later out-license the technology to a larger company or even be entirely acquired by it.

From the public interest perspective, the ability of academic institutes to negotiate agreements for the licensing or sale of health technologies is crucial to securing a return on public investment and protecting the public interest further down the road. Often, however, these entities significantly lack the capacity to do this adequately.[236]

The product can be further developed by small and medium-sized enterprises (SMEs), for example through the first two stages of clinical trials. The role of SMEs in early- and later-stage R&D is increasingly important as evidenced by research showing that most new drugs obtaining regulatory approval in the U.S. originated from SMEs.[237]

As the probability of the product's value rises and the risk falls, the SME can sell or license the technology to (or be acquired by) a large pharmaceutical company that has the financial resources to complete the costliest parts of the trials, register the product and bring it to market.

In fact, large pharmaceutical companies are currently far more likely to acquire products during clinical trials than to develop them from scratch.[238] The 2019 data show

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[234] S. Moon et al., *New Business Models for Pharmaceutical Research and Development as a Global Public Good: Considerations for the WHO European Region*, Oslo Medicines Initiative technical Report, WHO Europe, 2022.; F. Capo et al., *Innovative business models in the pharmaceutical industry: a case on exploiting value networks to stay competitive*, International Journal of Engineering Business Management 6(1), November 2014, p. 1-11.

[235] S. Moon et al., *New Business Models, op. cit..;* D. J. Hemel, L. L. Ouellette, *Bayh-Dole Beyond Borders*, Journal of Law and the Biosciences, Vol. 4, No. 2, October 2017, p. 282-310.; https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2919093 (27 May 2023). For example, the Janner institute responsible for the development of Oxford-AstraZeneca vaccine

[236] I. Bernal Carcelen, J. M. Lorenzo, *Licensing and Access to health Technologies*, Health Action International and Salud por Derecho, November 2022.; https://haiweb.org/wp-content/uploads/2022/11/Licensing_Access-to-Health-Technologies.pdf (27 May 2023).

[237] U. Geilinger, C. Leo, *HBM new drug approval report: analysis of FDA new drug approvals in 2018 (and multi-year trends)*, HBM Partners, 2019.; www.hbmpartners.com/media/docs/industry-reports/Analysis-of-FDA-Approvals-2018-and-Previous-Years.pdf (27 May 2023).

[238] R. Bhambra, *Biopharma deals of 2020 break through*, Nature, 30 November 2020.; https://www.nature.com/articles/d43747-020-01176-z (27 May 2023).

that 33 per cent of the forecast sales of the 12 largest pharmaceutical companies are derived from acquiring products from small biotechs, university spin-offs and other research institutions rather than in-house innovation.[239]

In fact, pharmaceutical R&D has long ceased to be a top Big Pharma companies' expense. According to a study by Angelis et al., from 1999 to 2018, the world's 15 largest biopharmaceutical companies with revenues of $7.7 trillion spent more on marketing and administration ($2.2 trillion) than on R&D ($1.4 trillion). [240]

Mergers and acquisitions have led to the situation in which today a relatively small number of companies control the majority of medicine sales worldwide.[241]

For example, Pfizer, fuelled by profits from the record sales during the COVID-19 pandemic, acquired two companies focused on cancer-related R&D, Arena Pharmaceutical for $6.7 billion and Trillium Therapeutics for $2.3 billion in 2021.[242] A year later it made two of the three largest acquisitions in the pharmaceutical sector buying Biohaven (developing migraine-related health technologies) for $11.6 billion and Global Blood Therapeutics (focused on sickle cell) for $5.4 billion.[243] Already in the first quarter of 2023, it bought Seagen (developing cancer medicines) for $43 billion.[244]

From the access perspective, the costs of such substantial acquisitions are included in the prices of the final products. With the technology being sold or licensed several times

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[239] Deloitte, *Measuring the return from pharmaceutical innovation*, 2019.; https://www2.deloitte.com/uk/en/pages/life-sciences-and-healthcare/articles/ten-years-on-measuring-return.html (27 May 2023).

[240] A. Angelis, *High drug prices are not justified by industry's spending on research and development,* British Medical Journal, 380, February 2023.; https://www.bmj.com/content/380/bmj-2022-071710 (27 May 2023).; See also: W. Lazonick, O. Tulum, *Sick with "Shareholder Value": US Pharma's Financialized Business Model During the Pandemic*, Institute for New Economic Thinking, December 2022.; https://www.ineteconomics.org/perspectives/blog/sick-with-shareholder-value-us-pharmas-financialized-business-model-during-the-pandemic (27 May 2023).; AHIP, *New Study: In the Midst of COVID-19 Crisis, 7 out of 10 Big Pharma Companies Spent More on Sales and Marketing than R&D*, AHIP, 27 October 2021.; https://www.ahip.org/news/articles/new-study-in-the-midst-of-covid-19-crisis-7-out-of-10-big-pharma-companies-spent-more-on-sales-and-marketing-than-r-d (27 May 2023).

[241] J. P. Swann, A*cademic scientists and the pharmaceutical industry: cooperative research in twentieth-century America*, Baltimore and London, Johns Hopkins University Press, 1988, p. xi, 249.

[242] Pfizer, *Pfizer Completes Acquisition of Arena Pharmaceuticals*, 11 March 2022.; https://www.pfizer.com/news/press-release/press-release-detail/pfizer-completes-acquisition-arena-pharmaceuticals (27 May 2023); Pfizer, *Pfizer Completes Acquisition of Trillium Therapeutics* , 17 November 2021.; https://www.pfizer.com/news/press-release/press-release-detail/pfizer-completes-acquisition-trillium-therapeutics (27 May 2023).

[243] Pfizer, *Pfizer Completes Acquisition of Biohaven Pharmaceuticals*, 3 October 2022.; https://www.pfizer.com/news/press-release/press-release-detail/pfizer-completes-acquisition-biohaven-pharmaceuticals (27 May 2023); Pfizer, *Pfizer Completes Acquisition of Global Blood Therapeutics*, 5 October 2022.; https://www.pfizer.com/news/press-release/press-release-detail/pfizer-completes-acquisition-global-blood-therapeutics (27 May 2023).

[244] https://www.businesswire.com/news/home/20230313005335/en/Pfizer-Invests-43-Billion-to-Battle-Cancer

during the R&D process, each such transaction is based on a contract the terms and provisions of which can affect the price, availability and characteristics of the final product.

Large companies, after acquiring a product and conducting successful clinical trials, may produce it themselves and/or further license it to other companies for this purpose. They can also license or sell marketing and/or distribution rights to different companies in different countries.[245]

This *relay race* model has many advantages for the entities involved and outside investors compared to the traditional process. The return on investment in this case can be realised at various stages of the R&D process, not just at the end of it through the successful sale of the final product. In this way, risks can be broken down into smaller pieces and the time to wait for a return on investment shortened.[246]

5.2.2. Costs, time and risk of medical innovation

Medical innovation is neither easy nor cheap.

In general, for a new drug bringing a therapeutic advantage over existing ones, pharmaceutical R&D is risky, costly and time-consuming.[247] Its cost is estimated at between $60 million to $2.6 billion. Given the refusal of pharmaceutical companies to disclose R&D costs, it is not possible to give a precise figure.[248]

The probability of obtaining marketing approval for a drug entering *phase I clinical trials* ranges from 7% to 45%, depending on the type of medicine and the approval process.[249] Brand-name pharmaceutical companies claim that it takes an average of 10–15 years to develop a medicine or vaccine.

[245] S. Moon et al., *New Business Models, op. cit.*
[246] *Ibidem*, p. 13.
[247] United Nations Conference on Trade and Development, *The role of competition in the pharmaceutical sector and its benefits for consumers*, Note by the UNCTAD secretariat, 27 April 2015.; https://unctad.org/system/files/official-document/tdrbpconf8d3_en.pdf (27 May 2023).
[248] T. van der Gronde, *Addressing the challenge of high-priced prescription drugs in the era of precision medicine: A systematic review of drug life cycles, therapeutic drug markets and regulatory frameworks*, Plos One, 16 August 2017.; https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0182613 (27 May 2023).
[249] OECD, *Pharmaceutical Innovation and Access to Medicines*, OECD Health Policy Studies, OECD Publishing, Paris, 2018.

5.2.3. Incentives and rewards

Given the above, the model dependent on the private sector's engagement needs not only to ensure an attractive environment for R&D but also encourage it by guaranteeing stringent protection of the ownership of developed technologies afterwards. As such, the cornerstone of this model is a strong system of intellectual property rights (such as patents or trade secrets) and other forms of protection from competition (such as data and market exclusivity).

Creating, acquiring, protecting and managing intellectual property and exclusivities has become one of the most important activities of pharmaceutical companies. Restricting competition through these protections allows them to charge high prices for a drug and make a profit. Once these protections expire, generic/biosimilar version of the drug can enter the market, often leading to a significant price drop, reducing revenue for the originator company.[250]

5.3. Flawed design of the pharmaceutical market

5.3.1. Not fitting the neo-capitalist model

Under the current system, R&D of and access to pharmaceuticals are driven by the neo-capitalist markets. The decision of what innovation to advance, where to make it available and at what price is left to their forces. Public policies can only encourage, for example, through the regulatory system or subsidies, the development of certain kinds of products for specific patient groups (see, for example, Chapter 7.5.2.), thereby influencing market decisions.[251]

However, the pharmaceutical market differs significantly from the neo-capitalist model which results in delivering sub-optimal outcomes for a very high price.

As Heled et al. argue, the market-based approach works in a variety of sectors where decisions on production and pricing are made in response to *(1) consumer demand and*

[250] H. G. Grabowski, *The Roles Of Patents And Research And Development Incentives In Biopharmaceutical Innovation*, Health Affairs, February 2015.; https://www.healthaffairs.org/doi/10.1377/hlthaff.2014.1047 (27 May 2023).
[251] E.g., Orphan and Paediatric Regulations in the EU and US.

willingness to pay; (2) their own costs of production; and (3) competition from other producers. None of this, however, is true for the pharmaceutical market.

The pharmaceutical sector differs mainly in three ways: *(1) the failure of price to serve as a good indicator of public health value; (2) the public sharing of costs but not benefits; and (3) regulation and market structure that limit competition*.[252]

It also lacks other conditions to ensure the effectiveness of the market-based model, such as consumers having sufficient information about products and their benefits, and the ability to assess their value, compare them with each other and choose among competing alternatives.

The following sections look into these characteristics in greater detail.

5.3.2. Pharmaceutical pricing

First of all, pharmaceutical pricing is neither driven by R&D costs nor by product value.

As evidenced by multiple studies and even acknowledged by the industry, medicine prices are driven by market considerations. Companies set the price as high as they can while they are protected from competition.[253]

As observed by Heled et al., *where a product has a substantial impact on health and there are no alternatives and no competition, demand is inelastic, and companies have the ability to raise their prices to what the market will bear, raising prices is exactly what profit-maximizing companies do*.[254]

While the standard explanation given by pharmaceutical companies for high medicine prices is that they are necessary to cover research and development costs and to

[252] Y. Heled, *Why Healthcare Companies Should…, op. cit.,* p. 80.

[253] B. Mixter, *Greater Transparency on Drug Prices Needed, Lawmakers Told*, BNA NEWS, 16 March 2016.; https://perma.cc/TN57-7TW8 (27 May 2023). In addition, it is worth noting how the industry takes advantage of secrecy around national pricing negotiations. Pharmaceutical companies disclose the official prices set in different countries. However, these prices may differ significantly from the actual ones paid by national health systems, as pricing authorities often receive discounts or rebates based on a medicine's sales volume or performance. Importantly, these reductions in official unit prices are subject to confidentiality clauses and are not publicly disclosed. Consequently, national governments cannot know the real net prices paid by other countries. This can result in some states paying more for the same medicines than others for no particular reason, resulting in inequalities in access.

[254] Y. Heled et al., *Why Healthcare Companies Should…, op. cit.,* p. 113.

compensate for the associated risks is increasingly questioned, the industry seems to be changing its rationale, arguing that drug prices actually correspond to their *value*.[255]

However, various studies provide evidence of the lack of correlation between drug prices and the medical benefits they provide (such as research showing no correlation between the price of cancer drugs and their benefits[256] or a study indicating that the value-based price of most drugs is lower than their market price might indicate[257]).

5.3.3. Pharmaceutical value assessment

Under the current system, it is difficult to accurately assess the value of drugs, including their comparative therapeutic benefits and cost effectiveness.[258]

In response to significant increases in the costs of new drugs, various value-based pricing models have been developed to provide a standardised approach to prioritising *high-value* ones.[259] The implicit purpose of these models is to empower healthcare payers in pricing negotiations.

Most often, the value assessment of new medicine is composed of various factors such as its efficacy (often assessed through the added therapeutic benefit of the new medicine over existing therapeutic alternatives) and safety outcomes, as well as the improvement in patient quality of life.[260]

Although healthcare payers and patients may be willing to pay more for medicines that have greater value for the wider public and economy, establishing a clear link between a medicine and the societal and economic savings it brings, and calculating them precisely,

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[255] See more: P. Kolczyński, *How the pharmaceutical industry misuses concept of value to justify high medicine prices*, June 2022., p. 16; https://www.cpme.eu/api/documents/adopted/2022/10/cpme_magazine_Summer_2022_Print_Edition.pdf (27 May 2023).

[256] B. E. Hillner, T. J. Smith, *Efficacy does not necessarily translate to cost effectiveness: a case study in the challenges associated with 21st-century cancer drug pricing*, Journal of Clinical Oncology, May 2009.; https://pubmed.ncbi.nlm.nih.gov/19332715/ (27 May 2023).

[257] Drug Pricing Lab, *Drug Abacus*: https://www.drugpricinglab.org/tools/drug-abacus/ (27 May 2023).

[258] While the public can attempt to assess the value of medicines it decides to reimburse (through a health technology assessment (HTA) process), the lack of comparable data from clinical and post-marketing studies and the obscurity of price negotiations make this difficult.

[259] E. Basch, *Toward a Patient-Centered Value Framework in Oncology*, JAMA, 17 May 2016.; https://jamanetwork.com/journals/jama/article-abstract/2521946 (27 May 2023).

[260] The quality of evidence i.e., its sources or scenarios evaluated in clinical trials, is also often considered. In addition, models using economic evaluation also look into cost-effectiveness, cost-utility or cost-benefit analysis. In several countries, a wider societal perspective is also included in the evaluation process to assess the medicine's costs and benefits. OECD, *Value in Pharmaceutical Pricing*, OECD, 2013 p.34.; https://www.oecd-ilibrary.org/social-issues-migration-health/value-in-pharmaceutical-pricing_5k43jc9v6knx-en (27 May 2023).

constitutes a great challenge (even more so for comparative assessments, given little consistency of evidence across products).

In consequence, in the pharmaceutical market, unlike in well-functioning neo-capitalist markets, patients with non-expert knowledge are left with limited information about the value of their therapies and with limited input into their choice. They make their decisions based on advice or prescriptions from doctors who neither use the product nor pay for it and are often not even encouraged or rewarded for selecting the *cheapest way of achieving the anticipated health benefit*.[261]

To this point, it is important to note another important distinction of the pharmaceutical market, reflected in the purchasing model, in which there is a disconnect between *(1) the person or entity making many of the healthcare purchasing decisions; (2) the person or entity paying for those decisions; and (3) the end user*.[262]

Consequently, *the forces of competition do not work well in [pharmaceutical markets] where the consumer who pays does not choose [the treatment] and the physician who chooses [it] does not pay [for it]*.[263] Given the existence of health insurance systems (both public and private), it is often not the consumer who pays directly for prescribed medicines, which further *distances consumer value and purchasing power*.[264]

The bottom line is that limited information on medicines' added therapeutic benefits, fragmentation of pharmaceutical purchasing, and multiple intermediaries lead to medicine *pricing that is not commensurate with or responsive to the patient or public health value*.[265]

5.3.4. Inelastic demand

As also argued by Heled et al., the demand for medicines is inelastic and sometimes even irrational. The purchase of medicines is seen by patients as a matter of life or death or a choice between good quality of life and suffering.[266]

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[261] Y. Heled, *Why Healthcare Companies Should…, op. cit.,* p. 110.
[262] *Ibidem*, p. 110.
[263] A. B. Engelberg, *How Government Policy Promotes High Drug Prices*, health Affairs, 2October 2015.; https://perma.cc/MCR3-8TS7 (27 May 2023).
[264] M. A. Hall, C. E. Schneider, *Patients as Consumers: Courts, Contracts, and the New Medical Marketplace*, 106 Michigan Law Review, 64, 2008.
[265] Y. Heled, *Why Healthcare Companies Should…, op. cit.,* p. 112.
[266] *Ibidem*, p. 112.

The value of almost all pharmaceuticals may be argued as immense, especially given the way people value life, health and comfort is subjective and can be irrational. The life and health of any person may be of incalculable value as from an individual perspective, buying decisions for health care do not follow ordinary economic logic.[267] Even in non-life-threatening cases, making rational decisions about healthcare choices is difficult.[268]

That way *companies (...) can get away with raising prices without losing customers because the demand for certain medications is insensitive to their cost. If a drug will save your life, you'll probably pay whatever the cost, if you can*.[269]

The fact that the prices of pharmaceuticals do not reflect their value can also lead to their undervaluation. This is true, for example, for antibiotics and vaccines. In these cases, prices reflect neither the negative externalities (for example, the consequences of antibiotic overuse for increasing antimicrobial resistance) nor the positive ones (for example, the added value of vaccination for public health) associated with these products.

5.3.5. Socialisation of costs but privatisation of benefits

Another inefficiency, from the public interest perspective, of the mainstream medical innovation model, is that the public co-finances and co-develops early-stage medical innovations, which are then privatised by private companies. It also provides the companies with various financial incentives to engage in the R&D process. Recognition of these contributions has critical implications for the distribution of risks and rewards in the pharmaceutical R&D system.

However, while the benefits for the private sector are tangible, it is questionable whether the system yields a fair return on investment for the public, as the most pressing

[267] For example, the value to an individual of giving their child a polio vaccine may be $1 million per dose, because it would be worth that to avoid their child succumbing to polio. But such pricing is both utterly impractical — any health care system would collapse if each vaccine cost $1 million per dose — and would defeat the purpose of eradicating the disease. Polio plagued millions before 1955, but today the basic vaccine is routinely given to European children at an affordable cost.

[268] This irrationality is further exacerbated by direct-to-consumer advertising of pharmaceuticals.

[269] I. Islam, *Rising Cost of Drugs: Where Do We Go from Here?*, Health Affairs, 31 August 2015.; https://perma.cc/M974-ZQDS (27 May 2023).; See also : M. Arak,S. Tschinkel, *Why the 'Free Market' for Drugs Doesn't Work and What We Can Do About It*, the Conversation, 18 January 2017.; https://perma.cc/H426-3DD7 (27 May 2023).

unmet needs remain unaddressed and high prices of patented innovative medicines are unsustainable for health systems and unaffordable for patients.[270]

5.3.6. Regulatory barriers to competition

The final feature that differentiates the pharmaceutical markets discussed here is the level of regulation. The existing system provides various ways to protect originator companies against competition, for example, through an intellectual property rights framework and specialised medicine regulations. While by themselves they provide strong protection against competition, companies tend to additionally game or abuse them to further extend their monopolies.[271]

As the use of generic and biosimilar versions of medicines leads to lowering costs and increasing access to drugs, their immediate market entry after the expiry of patents on brand-name products is of crucial interest to the public. However, the current intellectual property framework is often abused as patents of questionable quality are repeatedly granted for irrelevant *innovations* and unjustly extended.[272] While patents are intended to incentivise relevant health innovation, they are often strategically misused to present a barrier to generic and biosimilar entry. There is a clear need to address and remedy deficiencies in the quality of the patent granting system, the creation of patent thickets and filing of numerous follow-on patents or the abuse of patent litigation procedures.[273]

The immediate market entry of generics and biosimilars can also be blocked by anti-competitive practices and illegal agreements between originator companies and generic

[270] M. Mazzucato, H. L. Li., *op. cit.* Moreover, public gains through the taxation system due to new jobs being generated, as well as taxes being paid by companies benefiting from the investments are offset in several ways (like tax avoidance, evasion and cuts, the knowledge spill overs hindered by fragmented patent rights and the intended impact of increased domestic investment in R&D have hardly materialised, while stock buyback and dividends have increased.

[271] American Economic Liberties Project and Initiative for Medicines, Access, & Knowledge (I-MAK), *The Costs of Pharma Cheating*, Report, May 2023.; http://www.economicliberties.us/wp-content/uploads/2023/05/AELP_052023_PharmaCheats_Report_FINAL.pdf (27 May 2023).

[272] Patents should be granted only for genuine innovation and not for simple changes, for example, in chemistry or formulation that offer little or no therapeutic advance on existing medicines. Moreover, patents should be narrow to protect only the area that is fundamentally new, and focused downstream to avoid tools and processes being privatised, while at the same time enabling licensing and diffusion.

[273] European Generic Medicines Association, *Patent-related Barriers to Market Entry for Generic Medicines in the European Union*, May 2008.; https://www.medicinesforeurope.com/wp-content/uploads/2009/06/EGA-IP_Barriers_web.pdf (27 May 2023).

manufacturers. For example, the European Commission has recently decided to fine the pharmaceutical companies Teva and Cephalon for agreeing to delay for six years the market entry of a cheaper generic version of Cephalon's drug after its main patents had expired.[274]

This and three other previously concluded investigations in the EU provide positive examples of the use of antitrust law as a tool to expose and penalise illegal practices that prevent patients and health systems from benefitting from lower drug prices as soon as possible.[275] Antitrust enforcement can complement other efforts to increase the accessibility and affordability of drugs.

5.3.7. The system riddled with inefficiencies

The above discussion aims to make the case that the neo-capitalist market is inadequate to drive medical R&D and ensure access. Pharmaceutical policies allowing public research and knowledge to be privatised and the resulting products to be supplied and priced based on market forces to maximise profits instead of becoming the most effective public health tools results in gross inefficiencies.

Due to limited information about drugs' value, the inelasticity of demand, and particularly limited competition in the sector, pharmaceutical companies have considerable power to determine the availability and affordability of medicines.

This model is particularly lucrative for the private sector but has dire consequences for the public.

5.4. Financialisation of pharmaceutical companies

Another reason for the inefficiency of relying on for-profit pharmaceutical companies to deliver relevant medical innovations is their increasing financialisation, which results in reduced reinvestment in R&D efforts and a preoccupation with short-term profits.[276]

[274] European Commission, *Antitrust: Commission fines Teva and Cephalon €60.5 million...*, Press release, November 2020.; https://ec.europa.eu/commission/presscorner/detail/en/ip_20_2220 (27 May 2023).
[275] One concerning perindopril, a cardiovascular medicine, one concerning citalopram, an anti-depressant, and one concerning fentanyl, a painkiller.
[276] Financialisation can be measured on the basis of three indicators: (1) the size of the balance sheet, (2) the size of shareholder compensation and (3) the size of intangible assets.

Publicly traded companies focus not on delivering the most appropriate products, but on increasing their stock prices. As Heled et al. point out, for such companies, it is not a product price or profit itself that drives corporate decisions but capital gains as well as stock price and linked with it executive compensation.[277]

The financialised business model is not an aberration in the pharmaceutical market, but the logical choice of companies unrestricted by regulations to maximise profits to the detriment of other objectives. This phenomenon is clearly intensifying in the pharmaceutical sector.

Research on this problem conducted by the Centre for Research on Multinational Corporations (SOMO), a Dutch not-for-profit organisation, finds a shift in pharmaceutical companies' business model towards financialisation over the past 18 years in order to increase their own profit margins.[278]

For example, total payouts to shareholders have increased by almost 400 per cent – from $30 billion in 2000 to $146 billion in 2018. The 27 of the world's largest pharmaceutical companies' payouts amount to a total of $1,540 billion during the period analysed by SOMO.[279]

This has been achieved at the cost of R&D spending and soaring drug prices.

From 2009 to 2018, the top 18 biopharmaceutical firms spent $335 billion repurchasing their own shares – more than they invested in R&D.[280] The number is much higher if complemented by the amounts spent on dividend payments. According to the investigation of the U.S. House Committee on Oversight and Reform, only between 2016 to 2020, the 14 largest pharmaceutical companies spent on share buybacks and dividends combined a total of $577 billion – $56bn more than on R&D. Over that time, annual executive compensation in the pharmaceutical sector also increased by 14 per cent.[281]

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[277] Executive compensation includes the use of stock options and bonuses tied to corporate performance indicators such as stock price.

[278] R. Fernandez, T. J. Klinge, *The financialisation of Big Pharma*, Report, April 2020.; https://www.somo.nl/private-gains-we-can-ill-afford/ (27 May 2023).

[279] *Ibidem*, p. 5.

[280] W. Lazonick et al., *Financialization of the U.S. Pharmaceutical Industry*, Institute of New Economic Thinking, 2 December, 2019.; https://www.ineteconomics.org/perspectives/blog/financialization-us-pharma-industry (27 May 2023).

[281] A. Angelis, *op. cit*.; Committee on Oversight and Reform, *Industry spending on buybacks, dividends, and executive compensation*, Drug pricing investigation, Staff Report, July 2021.; https://oversightdemocrats.house.gov/sites/democrats.oversight.house.gov/files/COR%20Staff%20Report%20-%20Pharmaceutical%20Industry%20Buybacks%20Dividends%20Compared%20to%20Research.pdf (27 May 2023).

The 18 U.S. pharmaceutical companies in the S&P 500 Index, distributed 99 per cent of their profits to shareholders over the decade between 2006-2015.[282] According to Lazonick et al., the total of $261 billion spent on buybacks alone in that period was equivalent to 56 per cent of their combined R&D expenditures.

For example, in 2019 alone, Pfizer spent more than $6 billion on share buybacks to boost its share price and more than $7 billion in stock dividends. During the COVID-19 pandemic, between January and November 2022, the company paid nearly $9 billion to shareholders.[283]

The pandemic period also provides a good illustration of the role played by companies' stock prices in executive compensations. In 2021, as companies' stocks were rising, the average total direct compensation of 27 pharmaceutical company executives (among the 500 largest corporations) increased to an all-time high of $61.6 million, 93 per cent of which came from realised gains on stock-based compensation.[284]

Meanwhile, the median starting price for a newly approved medicine nearly tripled to $7,034 per patient monthly in 2022, from $2,624 in 2011.[285]

5.5. Consequences of market forces driving health emergency-related medical innovation

5.5.1. Widening gap

The various aspects of the inefficiencies of the current model based on an under-regulated private pharmaceutical industry are true throughout the pharmaceutical R&D sector. While the divergence between public interest and private considerations driving medical innovation decisions is evident in all types of products and circumstances, it is further worsened in the context of health emergency preparedness and response.[286]

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[282] W. Lazonick, *U.S. Pharma's Financialized Business Model*, Institute for New Economic Thinking, Working Paper No. 60, July 2017, p. 3-4.; https://www.ineteconomics.org/uploads/papers/WP_60-Lazonick-et-al-US-Pharma-Business-Model.pdf (27 May 2023).

[283] E.Torreele, *Global health should not be determined by pharma investors and shareholders*, First Opinion, STAT news, 3 May 2022.; https://www.statnews.com/2022/05/03/pharma-investors-shareholders-should-not-determine-global-health/ (27 May 2023).

[284] W. Lazonick, O. Tulum, *Sick with "Shareholder Value", op. cit.,* p. 7.

[285] See: Welcome to the 46brooklyn Drug Price Launchpad: https://www.46brooklyn.com/launch-price-viz (27 May 2023).

[286] Y. Heled, A. S. Rutschman, L. Vertinsky, *The problem with relying…, op. cit.*

Heled et al. argue that the market forces that drive pharmaceutical R&D in the mainstream model (i.e., supply, demand and price) particularly fail to effectively steer the R&D agenda in inter-emergency periods and to develop the most suitable medical countermeasures and allocate them efficiently (from the public health perspective) during health crises.

5.5.2. Pricing and value assessment of medical countermeasures

As discussed in Chapter 5.3.2., pricing in pharmaceutical markets does not reflect the value of health products. This is even more true in the case of health crisis preparedness, which requires *inefficiencies* (from an economic standpoint), such as investing in research and development of medical countermeasures against viruses that may affect only a small group of people.[287]

What has become clear during the COVID-19 pandemic is that the *just in time* rationale used in the pharmaceutical sector cannot be applied in public health without severe risks and it is necessary to adopt a *just in case* model. This includes creating structures and providing permanent and guaranteed funding for, for example, surge capacity and stockpiles in acceptance of obsolescence and opportunity costs.[288]

Preventative and therapeutic efforts based on the use of medical countermeasures are undervalued before an outbreak occurs and the disease spreads further. What is more, pandemics usually start in some localities and are initially limited to regions that are often poor and neglected. Therefore, there is no business case for corporations to invest in tackling them.

Subsequently, once an infectious disease spreads *it is sure to result in inelastic, and sometimes irrational – driven by panic – maximal market demand* for medical countermeasures.[289] As proven repeatedly, including during the COVID-19 pandemic, when a pandemic starts, the allocation of available or anticipated countermeasures is based on the ability to pay rather than health needs or health benefits. While this is highly

[287] Y. Heled, L. Vertinsky, C. Brewer, *Why Healthcare Companies Should…, op. cit.,* p. 5.
[288] CPME, *Pandemic Preparedness - European Doctors' Recommendations to the EU*, Position Paper, 21 November 2020.; https://www.cpme.eu/api/documents/adopted/2020/11/CPME_AD_Brd_21112020_111.FINAL_.CPME_.COVID19.pandemic.preparedness.lessons.learned.pdf (27 May 2023).
[289] Y. Heled, L. Vertinsky, C. Brewer, *Why Healthcare Companies Should…, op. cit.,* p. 21.

inefficient (and unethical) from a public health perspective, it is perfectly logical from a commercial market standpoint.

5.5.3. Making lack of preparedness lucrative

The favouring of short-term profits, resulting from the financialisation of the pharmaceutical industry is at odds with public policies aimed to ensure emergency preparedness.[290]

As Heled et al. noted, this system of unpreparedness is greatly lucrative for the private sector. Not only do pharmaceutical companies not lose money on R&D on viruses with pandemic potential, but they are able to secure record profits during crises precisely because of inadequate availability of medical countermeasures when the pandemic occurs. Panic and irrationality resulting in inelastic demand allow corporations to raise prices while trying to fend off any potential competition and perpetuate a *fake scarcity* in order to maximise profits.

Therefore, as such, *market incentives might even encourage non-preparedness, untimely response, and profiteering*.[291]

5.5.4. Allocation based on ability to pay

The market rules that drive the pharmaceutical companies' decision-making do not change during the spread of an infectious disease. Products are therefore allocated based on who can pay the most.

Given the central role of medical countermeasures to the health, companies holding these products have much more bargaining power when negotiating where to supply them than governments or international organisations seeking to procure them.

While the mere influence of private companies on states' policies serves no one but the companies themselves, the system is sustained in part by the fact that it meets the needs of the richest and most powerful countries first. Taking advantage of it, wealthy countries guarantee themselves a priority in access to the most critical products.

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[290] J. Ponciano, M*oderna Crash Wipes Out $22 Billion In Value After Merck's Covid Pill Triggers Vaccine Stock Plunge*, Forbes, 1 October 2021.; https://www.forbes.com/sites/jonathanponciano/2021/10/01/moderna-crash-wipes-out-22-billion-in-value-after-mercks-covid-pill-triggers-vaccine-stock-plunge/?sh=45fd74545f67 (27 May 2023).

[291] Y. Heled, L. Vertinsky, C. Brewer, *Why Healthcare Companies Should…, op. cit.,* p. 7.

For example, during the COVID-19 pandemic, once the first vaccine candidates emerged, the EU ordered 1.6 billion doses through bilateral contracts for its adult population of approximately 375 million people.[292] Six months after the first COVID-19 vaccines were approved, 85 per cent of them were administered in high- and upper-middle-income countries and less than 1 per cent in low-income countries.[293]

5.5.5. Failure to prioritise the most appropriate tools

The current system is not shaped to lead to the development of the most effective medical countermeasures. States' reliance on the private sector during an emergency to access vaccines and treatments leads them to hand out money to any actors that can even remotely claim to have such products in hand.

Currently, the system promotes the development of medical countermeasures in a way that is ineffective in ensuring that the best ones reach the market. During emergencies, countries bet on selected medical countermeasure candidates by supporting their development in advance through mechanisms such as APAs. As a result, significant public investment in the candidates is in practice a much more important factor for their ultimate success over competitors than suitability, efficacy and safety.[294]

At present, regulatory authorities are not empowered to require developers to comply with specific criteria of medical countermeasures to become effective public health interventions. The WHO published the Target Product Profile[295] for that purpose in April 2020, which, however, remained aspirational.

Under the existing framework, regulators cannot impose public health imperatives on pharmaceutical companies. It is, therefore, left at the discretion of developers to define vaccine and treatment efficacy targets they will measure in clinical trials. As the clinical trials' objective is to provide sufficient data to obtain market authorisation as quickly as

[292] R. Cohen, *COVID vaccines: rich countries have bought more than they need – here's how they could be redistributed*, The Conversation, 9 February 2021.; https://theconversation.com/covid-vaccines-rich-countries-have-bought-more-than-they-need-heres-how-they-could-be-redistributed-153732 (27 May 2023).

[293] C. M. Correa, *Vaccination inequalities and the role of the multilateral system*, South Centre, 19 July 2021.; https://www.southcentre.int/wp-content/uploads/2021/07/SouthViews-Correa.pdf (27 May 2023).

[294] E. Torreele, *Business-as-Usual will not Deliver the COVID-19 Vaccines We Need*, Development, 2020, p. 4.; https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7649577/pdf/41301_2020_Article_261.pdf (27 May 2023).

[295] See: WHO Target Product Profiles for COVID-19 Vaccines, April 2022: https://www.who.int/publications/m/item/who-target-product-profiles-for-covid-19-vaccines (27 May 2023).

possible, their endpoints do not necessarily coincide with the most important aspects from the public health perspective.[296] Getting quick, and not necessarily the most relevant answers, is currently the priority.[297]

In the context of the COVID-19 pandemic, the WHO proposed a collaborative efficacy *Solidarity trial* to directly compare the performance of different vaccines. However, the companies developing COVID-19 vaccine candidates preferred to compare their candidates to placebos and measure efficacy in different ways, making the results impossible to compare.

Importantly, regulatory authorities when approving medical countermeasures do not assess their adequacy to tackle pandemics. They also do not take into consideration their future availability and affordability.

5.5.6. Evidence-free public policies

The fact that countries finding themselves on the back foot during an emergency, rush to buy anything remotely helpful make them prone to overbuying. Companies are therefore eager to overstate the effectiveness of their products as even the unsubstantiated promise of a useful tool to tackle a pandemic drives a company's stock price up in view of potential profits.[298]

Perhaps the best examples of this are the debacles involving ineffective medicines like oseltamivir during the 2009 swine flu pandemic[299] or remdesivir during the COVID-19 pandemic[300] purchased by states on a large scale.

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[296] E. Torreele, *The rush to create a covid-19 vaccine may do more harm than good*, British Medical Journal, 370, August 2020.; https://www.bmj.com/content/370/bmj.m3209 (27 May 2023).

[297] C. Zimmer, *2 Companies Say Their Vaccines Are 95% Effective. What Does That Mean?*, New York Times, 20 November 2020.; https://www.nytimes.com/2020/11/20/health/covid-vaccine-95-effective.html (27 May 2023).

[298] Thanks to obscurity in the current systems, companies can take additional advantage by strategic release – or hiding – clinical trials' results to increase their stock price.

[299] F. Godlee, *Covid-19: The lost lessons of Tamiflu*, British Medical Journal, 371, December 2020.; https://www.bmj.com/content/371/bmj.m4701 (27 May 2023).

[300] During the COVID-19 pandemic, companies with vaccine candidates have been publishing press releases informing about successes in trials without releasing the data. Such communication about product's effectiveness and safety proved to be very lucrative strategy.

5.5.6.1. Examples of Remdesivir and Tamiflu

In March 2020, Gilead Sciences announced that one of its investigational drugs, remdesivir – an antiviral treatment largely invented and studied by a consortium of NIH-funded academic laboratories – has potential as a treatment for COVID-19.[301] This news alone caused the company's shares to rise by 8 per cent.

In order to extend the medicine's monopoly protection and benefit from additional market and data exclusivities, Gilead applied for orphan designation for the treatment (arguing that COVID-19 is a rare disease).[302] Given that there were no more than 200,000 patients infected with SARS-CoV-2 in the U.S. at the time of the application, the Food and Drug Administration granted remdesivir the status (two days later, after a public outcry, the company submitted a request to rescind it).[303]

Following the company's press release about remdesivir's efficiency, the available supply has been hoarded by rich countries even before this information was confirmed by any clinical trial data. For example, in October 2020, the European Commission signed a contract with Gilead for 500,000 doses of the treatment for a total cost of €1.035 billion.[304]

The contract was signed a week before the publication of a study carried out by WHO in 405 hospitals in 30 countries covering more than 11 000 COVID-19 patients, which ruled out *the suggestion that remdesivir can prevent a substantial fraction of all deaths*.[305] While the EU was unaware of those results when signing the contract, Gilead, on the other hand, having donated remdesivir to the trial, was most likely informed of the results ahead of the official data publication, before concluding the deal.[306]

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[301] A. Zaitchik, *No Vaccine in Sight…, op. cit.*

[302] L. Fang, S. Lerner, *Coronavirus Treatment Developed by Gilead Sciences Granted "Rare Disease" Status, Potentially Limiting Affordability,* The Intercept, 23 March 2020.; https://theintercept.com/2020/03/23/gilead-sciences-coronavirus-treatment-orphan-drug-status/ (27 May 2023).

[303] S. Lerner, *Gilead Sciences Backs Off Monopoly Claim for Promising Coronavirus Drug*, The Intercept, 25 March 2020.; https://theintercept.com/2020/03/25/gilead-sciences-coronavirus-drug/ (27 May 2023).

[304] See the Parliamentary questions on Remdesivir: the EUR 1 billion scandal of the fake treatment for COVID-19 purchased by the Commission: https://www.europarl.europa.eu/doceo/document/E-9-2020-006511_EN.html#def1; https://www.europarl.europa.eu/doceo/document/E-9-2020-006511_EN.html#def2; https://www.europarl.europa.eu/doceo/document/E-9-2020-006511_EN.html#def3 (27 May 2023).

[305] WHO Solidarity trial consortium, *Repurposed antiviral drugs for COVID-19 –interim WHO SOLIDARITY trial results*, medRxiv, 15 October 2020.; https://www.medrxiv.org/content/10.1101/2020.10.15.20209817v1.full#disqus_thread (27 May 2023).

[306] F. Guarascio, *CORRECTED-EU urged to review remdesivir supply deal after COVID trial results*, Reuters, 16 October 2020.; https://www.reuters.com/article/health-coronavirus-remdesivir-eu-idINL8N2H74Q8 ; *Gilead confirmed to Science that WHO in "late September" provided the company with a manuscript about the study results, but a spokesperson for the European Commission (…) said*

In November 2020, WHO officially advised *against the use of remdesivir in hospitalized patients, regardless of disease severity, as there is currently no evidence that remdesivir improves survival and other outcomes in these patients*.[307]

The remdesivir debacle could have been avoided if lessons had been learnt from previous crises. Its fiasco is similar in many ways to the story of oseltamivir (Tamiflu), a medicine on which governments spent billions of dollars during the 2009 swine flu pandemic based on false claims by its manufacturer.

Countries affected by the swine flu outbreak have been trying to secure any medical countermeasures that could help stop the spread of the disease and treat those infected. Roche, a Swiss pharmaceutical company, claimed that based on the results of its clinical trials, oseltamivir was effective in containing a potential pandemic.

As the subsequent whistleblower lawsuits showed, the trial data was misrepresented, and the claims were false.[308] Roche has sold $18 billion worth of oseltamivir since the drug's 1999 introduction.[309]

As presented in the British Medical Journal, remdesivir and oseltamivir have a lot in common: *At the start of the pandemics, both were hyped on limited, poor-quality research, mainly funded by drug companies. Both were bought in large amounts by governments without data to back up their purchase. Both have harms that have been inadequately researched and reported*.[310]

The widespread use of medical countermeasures without full data transparency raises concerns over the rational use of such interventions and the public resources spent on them.[311] Data transparency has become a well-established norm in biomedical research and is especially important for broadly used public health interventions.

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these weren't revealed during its negotiations. See: J. Cohen, K. Kupferschmidt, *The 'very, very bad look' of remdesivir, the first FDA-approved COVID-19 drug*, Science, 28 October 2020.; https://www.science.org/content/article/very-very-bad-look-remdesivir-first-fda-approved-covid-19-drug (27 May 2023).

[307] WHO, *WHO recommends against the use of remdesivir in COVID-19 patients*, 20 November 2020.; https://www.who.int/news-room/feature-stories/detail/who-recommends-against-the-use-of-remdesivir-in-covid-19-patients (27 May 2023).

[308] The Pharma Letter, *Roche misrepresented flu drug's ability to contain influenza pandemic, claims whistleblower lawsuit*, 14 January 2020.; https://www.thepharmaletter.com/article/roche-misrepresented-flu-drug-s-ability-to-contain-influenza-pandemic-claims-whistleblower-lawsuit (27 May 2023).

[309] Y. K. Gupta et al., *The Tamiflu fiasco and lessons learnt*, Indian Journal of Pharmacology, 2015.; https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4375804/ (27 May 2023).

[310] F. Godlee, *op. cit.*

[311] S. Tanveer, *Transparency of COVID-19 vaccine trials: decisions without data*, British Medical Journal, Volume 27, Issue 4, 2022.; https://ebm.bmj.com/content/27/4/199 (27 May 2023).

5.5.7. Race to market and fend off the competition

The current model is based on a *race* to get a product to market as quickly as possible, rather than ensuring that it has the features that make it the most appropriate public health intervention.

For one, this is due to the protection of medical innovation by intellectual property rights, which, while not suitable for stimulating pharmaceutical research and development in *normal times*, can be particularly detrimental to developing health emergency-related technologies.

While the role of a strong intellectual property framework to incentivise investments is often emphasised, its negative impact on knowledge sharing and scientific progress is overlooked. A stringent intellectual property system encourages actors to work in secrecy and isolation, leading to knowledge fragmentation and limiting the ability of science to be disseminated and translated into future innovation. It also results in wasted financial resources and duplication.

Companies hide their knowledge behind intellectual property protections hindering collaboration between laboratories and slowing the flow of scientific discovery. As a result, researchers, for example, must navigate multiple patents to accumulate the knowledge needed to develop a medical product.

The development of COVID-19-related technologies can serve as an example of the system's inadequacy. While companies have been conducting research on vaccines only within the boundaries of their own proprietary technologies covered by patents, combining the best elements of different platforms could have resulted in a much more suitable portfolio of adequate public health interventions.[312]

As soon as the companies launched their vaccines and treatments, they sought to thwart any competition. They refused to share their technologies even when they faced bottlenecks in their supply chain, leading to a *fake scarcity* – more vaccine doses could have been effectively produced if only the rights holders had agreed (or been forced by governments) to share the needed technologies and know-how.

[312] Intellectual property rights for some of the high-tech ingredients indispensable for mRNA vaccines, for example, lipid nanoparticles or a special nucleotide (called a five-prime-cap), being a part of the mRNA instructions, were held by only a few companies.

What is more, Moderna, for example, refused to make its vaccine available for animal studies on a new generation of vaccines conducted by WHO, even as millions of doses expired and were destroyed. The U.S. National Institutes of Health, which co-developed and co-funded the vaccine, did not reserve the right to make such a decision without the company's consent.[313] Similarly, Pfizer refused to share its vaccine with researchers for next-generation vaccine clinical trials.[314]

Another argument used by the industry not to share intellectual property and technology that could allow increased production of medical countermeasures is that the lack of technical sophistication of manufacturers in developing countries makes them unable to copy vaccines and drugs developed in rich countries.

This is exemplified by Gilead, a U.S. company which holds patents on remdesivir, a treatment believed in the early months of the pandemic to be effective against COVID-19 and so, in high demand.

While even rich countries were not able to secure a sufficient supply of the drug, the calls were growing for the company to license its patents to generic manufacturers. Gilead, however, insisted that setting up the production of the treatment takes too long to make any such project effective.[315]

This claim has been proved wrong when a Bangladeshi generic manufacturer – not limited by the company's intellectual property rights since Bangladesh is classified in a group of least developed countries and so it is not bound by the international IP law – produced remdesivir on a commercial scale and started exporting it in less than six months even without any know-how transfer from the company.[316]

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[313] B. Muller, *The End of Vaccines at 'Warp Speed'*, The New York Times, 18 November 2022.; https://www.nytimes.com/2022/11/18/health/covid-nasal-vaccines-warp-speed.html (27 May 2023). It also shows a failure to protect public investment. In fact, one of the biggest mistake of government policy regarding the COVID vaccine development is the failure to force the sharing of know-how and other rights to increase production capacity, and the secrecy of contracts when billions of public funds and huge public interest have been at stake.

[314] R. Cohrs, *Pfizer isn't sharing Covid vaccines with researchers for next-gen studies*, STATNews, 6 September 2022.; https://www.statnews.com/2022/09/06/pfizer-covid-vaccines-researchers-next-gen-studies/ (27 May 2023).

[315] Gilead, *Gilead Sciences Statement on State Attorneys General Letter on Remdesivir*, Company Statements, 5 August 2020.; https://www.gilead.com/news-and-press/company-statements/gilead-sciences-statement-on-state-attorneys-general-letter-on-remdesivir (27 May 2023).

[316] A. Z. M. Anas, *Bangladesh's Beximco thrives on coronavirus challenges*, Nikkei Asia, 26 July 2020.; https://asia.nikkei.com/Business/Pharmaceuticals/Bangladesh-s-Beximco-thrives-on-coronavirus-challenges (27 May 2023).

Similar arguments were raised by vaccine manufacturers who were setting up new production facilities in the Global North but claimed that there was not enough technological capacity and infrastructure to do the same in the Global South.

In response to such claims, Médecins Sans Frontiers (MSF), a non-governmental organisation providing humanitarian medical care, prepared an overview of more than 100 companies in the Global South with capabilities similar to those of manufacturing facilities in wealthy countries that could potentially produce COVID-19 vaccines.[317] Manufacturers around the world were confirming they *could start producing hundreds of millions of COVID-19 vaccines on short notice if only they had the blueprints and technical know-how*.[318] The media reported, for example, a factory with *gleaming new equipment imported from Germany, [their] immaculate hallways lined with hermetically sealed rooms (…) operating at just a quarter of its capacity*.

The claims of the COVID-19 vaccine manufacturers were finding support in certain influential crowds. For example, Bill Gates, founder of the Bill & Melinda Gates Foundation, has argued that sharing technology and intellectual property would not be helpful in scaling up supply, adding that *there is only so many vaccine factories in the world and people are very serious about the safety of vaccines*.[319]

The same tactic taken by COVID-19 vaccines manufacturers, which argued that a vaccine scarcity was inevitable and the public sector's interventions (for example, forcing them to share technologies broadly) can only harm the ongoing efforts,[320] was also used during the HIV/AIDS pandemic in 1990s and 2000s.[321]

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[317] A. Prabhala, A. Alsalhani, *Pharmaceutical manufacturers across Asia, Africa and Latin America with the technical requirements and quality standards to manufacture mRNA vaccines*, MSF, 10 Decmber 2021.; https://msfaccess.org/sites/default/files/2021-12/COVID19_TechBrief_Manufacturing-mRNA-Report-10DEC2021_ENG_0.pdf (27 May 2023).

[318] M. Cheng, L. Hinnant, *Countries urge drug companies to share vaccine know-how*, AP News, 1 March 2021.; https://apnews.com/article/technology-europe-global-trade-coronavirus-vaccine-coronavirus-pandemic-22d92afbc3ea9ed519be007f8887bcf6 (27 May 2023).

[319] See: C. Byrne, *Bill Gates says vaccine formulas shouldn't be shared with developing world,* The Independent.*;* https://www.independent.co.uk/tv/news/bill-gates-says-vaccine-formulas-shouldn-t-be-shared-with-developing-world-va9b224c4 (27 May 2023).

[320] According to the scarcity principle, the price of a good, which has low supply and high demand, rises to meet the expected demand. Marketers often use the principle to create artificial scarcity for a given product or good—and make it exclusive—in order to generate demand for it.

[321] M. Petersen, *Lifting the Curtain on the Real Costs of Making AIDS Drugs*, The New York Times, 24 April 2001.; https://www.nytimes.com/2001/04/24/business/lifting-the-curtain-on-the-real-costs-of-making-aids-drugs.html (27 May 2023).

A system that, during a pandemic, is based on competition among companies maximising their profits and fighting potential rivals out of the market is unable to maximise the potential for the development and delivery of medical countermeasures with the most effective outcomes for public health.[322]

5.5.7.1. Voluntary approaches to overcoming access barriers

The international framework provides options to ease these intellectual property barriers to R&D cooperation and access. One of them is voluntary licensing. Through this mechanism, an intellectual property rights holder can allow others to make use of its technology. The license can include additional clauses such as a waiver allowing others to use test data even if there are market exclusivities in place or an agreement to engage in technology transfer. Licences can be made directly between the rights holder and a licensee, or through licensing bodies or pools.[323]

Voluntary licensing has been used many times in the past, including during the COVID-19 pandemic. Companies like Moderna and Pfizer/BioNTech have been agreeing bilaterally with generic companies from around the world to license certain parts of R&D and production processes.

However, it has been often limited, ad hoc and late. Bilateral voluntary licenses are not transparency and include territorial restrictions and conditionalities that limit the value of the license for developing countries.

For example, the pharmaceutical industry has refused to participate in the WHO COVID-19 Technology Access Pool (C-TAP) established for a broad sharing of intellectual property rights, technologies and data to scale up the development and production of medical countermeasures, which Pfizer's CEO described as *nonsense, and also dangerous* in May 2020.[324]

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[322] N. C. Smith, M. Scholz, *In the Face of a Pandemic, Can Pharma Shift Gears?*, MIT Sloan Management Review, 16 April 2020.; https://research.birmingham.ac.uk/en/publications/in-the-face-of-a-pandemic-can-pharma-shift-gears (27 May 2023).

[323] E. 't Hoen et al., *Scaling-up Vaccine Production Capacity: Legal Challenges and Recommendations*, The Independent Panel for Pandemic Preparedness and Response, Background paper 6, May 2021, p. 3.; https://theindependentpanel.org/wp-content/uploads/2021/05/Background-paper-6-Scaling-up-vaccinationlegal-aspects.pdf (27 May 2023).

[324] E. Silverman, *Pharma leaders shoot down WHO voluntary pool for patent rights on Covid-19 products*, STATNews, 28 May , 2020.; https://www.statnews.com/pharmalot/2020/05/28/who-voluntary-pool-patents-pfizer/ (27 May 2023).

Companies are usually slow to engage in voluntary deals.[325] Time and again, they use this option only under the government's threats to use compulsory measures or under public pressure. What is more, voluntary cooperation is often limited to strategic licensing. This mechanism along with tiered pricing or donations are tools to protect companies against losing control over their technologies and distort markets for generic competition. Importantly, in most cases, the originator companies remain in full control over the allocation and pricing of the products based on the licensed technologies.

One example of the potentially strategic voluntary licensing during the COVID-19 pandemic is agreements on therapeutics, which both Pfizer with its nirmatrelvir/ritonavir and Merck with its molnupiravir made through the Medicines Patent Pool (MPP). [326] The mission of MPP is to broker licenses of individual products between brand name companies and generic firms in order to improve access in low-income countries and a number of middle-income countries. The MPP deals with Pfizer and Merck, however, excluded nearly half the world's population, including many developing countries.

While MPP agreements undeniably help expand access to licensed products in the poorer countries to which they apply, the approach is not without negative consequences. For example, MSF criticised the deal with Pfizer for excluding from the license many upper-middle-income countries, such as Argentina, Brazil, China, Malaysia and Thailand, where there is established generic production capacity. The NGO stressed that such voluntary licensing by pharmaceutical corporations that create uncertainties and results in segmentation for generic production and supply continues to be *part of the problem rather than part of a real solution*.[327]

In this case, it can also be argued that after reaping record profits from the vaccine it developed with BioNTech, Pfizer was practically forced into the licensing deal, particularly given that Merck has done so earlier for molnupiravir. Public outrage, the risk

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[325] L. Paremoer, *Berlin Declaration: Key Claims and Critiques*, People's Vaccine Alliance, October 2022, p. 9.; https://peoplesvaccine.org/wp-content/uploads/2022/11/Berlin-Declaration_2022.pdf (27 May 2023).

[326] Medicines Patent Pool, *Pfizer and The Medicines Patent Pool (MPP) Sign Licensing Agreement for COVID-19 Oral Antiviral Treatment Candidate to Expand Access in Low- and Middle-Income Countries*, 16 November 2021.; https://medicinespatentpool.org/news-publications-post/pfizer-and-the-medicines-patent-pool-mpp-sign-licensing-agreement-for-covid-19-oral-antiviral-treatment-candidate-to-expand-access-in-low-and-middle-income-countries (27 May 2023).

[327] MSF Access Campaign, *MSF response to license between Pfizer and Medicines Patent Pool for new COVID-19 treatment Paxlovid*, MSF, Press Release, 16 November 2021.; https://msfaccess.org/msf-response-license-between-pfizer-and-medicines-patent-pool-new-covid-19-treatment-paxlovid (27 May 2023).

of compulsory licensing and potential reputational damage might have been too much of a risk for the company.[328]

While voluntary measures can be helpful in increasing access to certain medicines in certain countries, relying on them to achieve the necessary large-scale and rapid access to medical countermeasures in health emergencies is inadequate.[329] Instead, states should base their strategies on other ways to overcome intellectual property barriers such as compulsory licensing or waivers (see Chapter 6.8.4.).

5.5.8. Ending pandemics when profits are put over public health outcomes

Analysing the current R&D model and the economic incentives driving pharmaceutical companies' investments, one can argue that not only fending off competition but also prolonging health emergencies may be in the companies' economic interest. An example of this could be found in the development and supply of COVID-19 booster vaccines.

COVID-19 vaccines have brought pharmaceutical companies unprecedented profits. However, after the first rounds of vaccinations have been completed in high-income countries, the manufacturers' revenues depended on demand for their next-generation vaccines and boosters.[330] Logically, the companies' attention quickly turned to them.

[328] This also has likely been a reason why Pfizer stepped back from demanding $200 for a course of its initial vaccine in summer 2020. According to Financial Times, Moncef Slaoui who had been appointed by the administration to secure vaccines warned Pfizer CEO Bourla that if he stuck to the price the company would look like it was trying to benefit from a *once-in-a-century pandemic*. Eventually Pfizer settled on $19.50 a dose in the initial contract with the US. See: H. Kuchler, D. P. Mancini, D. Pilling, *op. cit.*

[329] Ineffectiveness of companies' voluntary measures is evident also in other aspects of pharmaceutical policies, such as sustainability policies, which are now often seen as a side project or a PR strategy. But for environmental commitments to be truly effective, they should be integrated into an organisation's fabric and business model. This problem is also visible in other sectors e.g., in climate change where Over the last 20 years, a diverse array of climate initiatives has sought to persuade businesses and investors to accept the idea of setting climate-related targets, cutting emissions, and then setting even more ambitious targets. However, given that all there measures were voluntary, their effect is futile. See: C. McKenna, *Making Net-Zero Pledges Count*, Project Syndicate, 22 September 2022.; https://www.project-syndicate.org/commentary/corporations-net-zero-commitments-risk-greenwashing-by-catherine-mckenna-2022-09 (27 May 2023).

[330] K. Speights, *Investing in Coronavirus Vaccine Stocks*, The Motley Fool, 11 July 2022.; https://www.fool.com/investing/stock-market/market-sectors/healthcare/pharmaceutical-stocks/vaccine-stocks/ (27 May 2023).

Dr Tedros Adhanom Ghebreyesus, the WHO Director-General bluntly commented that *devoting resources and production to a potential third shot, while most of the world hasn't even received a first shot, is the most recent instance of Pfizer's drive for profit*.[331]

Mike Ryan, executive director of the WHO's Health Emergencies Programme, described the situation with booster vaccinations in wealthy countries as follows: *Right now we're planning to hand out extra life jackets to people who already have life jackets while we're leaving other people to drown without a single life jacket, that is the reality*.[332] Ryan argued that fair access goes beyond politics and diplomacy since it is fundamentally an ethical issue.

However, the decision-making process in profit-driven corporations is not guided by ethics and from the economic perspective, focusing on the development of booster vaccines for high-income countries instead of providing primary vaccination for all people around the world was a rational decision dictated by a profit maximising strategy.

Demand for vaccine boosters depends on how long initial shots remain effective and, more importantly, whether new variants emerge. These arise when the virus spreads and multiplies – a process that occurs primarily in unvaccinated populations. Indeed, the most concerning variants of SARS-CoV-2 occurred in countries with low vaccination rates. Three of COVID-19's four *variants of concern*, as classified by the WHO, came from Brazil, India and South Africa, where less than 15 per cent of the population was fully vaccinated at the time of their occurrence.

Eight major shareholders of Pfizer and Moderna earned more than $10 billion in a week in which the new Omicron variant was discovered as the companies' stock prices skyrocketed after the news broke.[333]

This means that from these corporations' strictly economic point of view, it makes more sense to leave people in some parts of the world not fully vaccinated with insufficiently strong immunity, allowing the virus to continue to spread and mutate (and thus evade the immunity gained by those vaccinated with previous vaccines), hence generating the need for new booster shots.

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[331] A. Pallard, *Pfizer's Bottom Line*, The American Prospect, 19 July 2021.; https://prospect.org/coronavirus/pfizers-bottom-line-covid-vaccines/ (27 May 2023).

[332] Agence France-Presse in Geneva, *WHO condemns rush by wealthy nations to give Covid vaccine booster*, Guardian, 18 August, 2021.; https://www.theguardian.com/world/2021/aug/18/who-condemns-rush-by-wealth-nations-to-give-covid-vaccine-booster (27 May 2023).

[333] N. Dearden, *As World Confronts Omicron Variant, Top 8 Pfizer & Moderna Investors Make $10 Billion in a Week*, Democracy Now, December 2021.; https://www.democracynow.org/2021/12/7/pfizer_and_moderna_shareholders_profit (27 May 2023).

Therefore, for economic reasons, they may decide not to make all the efforts to vaccinate the world, for example, by producing enough vaccines. Perpetuating a pandemic pays off from a business perspective. The companies themselves spoke bluntly about the profit opportunities presented by the prolonged prevalence of the disease. Pfizer's CFO called COVID-19 as a durable *franchise* for the company finding the disease a *significant opportunity* if it becomes endemic.[334] Similarly, Moderna's CEO portrayed in bright colours the future of COVID-19 vaccine boosters sold annually as similar to seasonal flu vaccines.[335]

What is a lucrative model for profit-driven companies is a policy failure for – in particular – the Global North countries and multilateral organisations investing in R&D activities.

Trust in private companies to put forth their best efforts to meet public health challenges is, as argued above, an expectation that they will act contrary to their statutory objectives. Such confidence is also unwarranted given their past behaviour. One such example is pricing of the Gilead's treatment during the hepatitis C epidemic. At the time, Gilead had the best-selling, effective treatment against the disease and *asserted that its primary concern in developing and marketing [it] was to treat the largest number of HCV patients possible*.[336] However, a U.S. Senate investigation concluded that i*n reality, Gilead's marketing, pricing, and contracting strategies were focused on maximizing revenue—even as the company's analysis showed a lower price would allow more people to be treated*.[337]

5.5.9. The model sustained by the lack of political leadership

The *socialisation* of costs and privatisation of benefits discussed in the previous chapter, leading to great inefficiencies for the public, clearly worsens in the context of

[334] Refinitiv Statements, *Edited Transcript*, PFE.N…, 11 March 2021.; https://www.documentcloud.org/documents/20514141-pfe-usq_transcript_2021-03-11 (27 May 2023).

[335] K. Stankiewicz, *Moderna hopes to have Covid booster shot for its vaccine ready by the fall, CEO says*, CNBC, 14 April 2021.; https://www.cnbc.com/2021/04/14/covid-vaccine-moderna-hopes-to-have-booster-shot-ready-by-the-fall-says-ceo.html (27 May 2023).

[336] Committee on Finance United States Senate, *The Price of Sovaldi and Its Impact on the U.S. Health Care System*, December 2015.; https://www.finance.senate.gov/imo/media/doc/1%20The%20Price%20of%20Sovaldi%20and%20Its%20Impact%20on%20the%20U.S.%20Health%20Care%20System%20(Full%20Report).pdf 27 May 2023).

[337] Ch. Morten, M. Herder, *We Can't Trust Big Pharma to Make Enough Vaccines*, The Nation, 31 May 2021.; https://www.thenation.com/article/world/covid-vaccines-pharma/ (27 May 2023).

health emergencies. By choosing to rely on this system, however, risk-averse governments avoid the large upfront investment in pharmaceutical R&D that would be needed in other more effective models, such as those based on the delinked model (see Chapter 7.4.2.). As a result, the public sector ends up paying much more for much less, without full control over end products.

Supporting existing market forces and incentivising the private sector prove much less cumbersome because the costs to states are spread out (between initial research investments and paying high prices over a long period of time). Large expenditures during crises are also easier to justify than significant R&D investments during the *preparedness phase*. This lack of leadership reinforces reliance on private companies, ultimately driving the narrative of the need for unfettered private sector innovation.

It is also argued that ideological reliance on the ingenuity and superiority of the private sector to provide medical countermeasures allows governments to *evade accountability for ensuring pandemic preparedness by shifting responsibility to the private sector*.

5.5.10. Lessons not learnt – example of Mpox outbreak

Rebuilding the existing pharmaceutical R&D and access model was probably never more likely than at the time when the lessons of the pandemic were still vivid.[338]

Significant changes, if any were to come, are certainly not immediate. Existing mechanisms, and perhaps more importantly, the thinking and approach of policymakers, do not appear to have changed much under the recent experience. For example, when Mpox spread to the Global North in the second half of 2022, the world had a vaccine, Imvanex, available, but its supply was limited by the fact that it was produced by only one small Danish company, Bavarian Nordic, and the company has closed its production facility from August 2021 to the end of 2022 to upgrade for Respiratory Syncytial Virus (RSV) and rabies vaccine production.

Although the company has licensed the commercialisation of other vaccines in the past (RSV vaccine to the Chinese company, Nuance Pharma), it has decided not to do the

[338] N. Lurie et al., *Urgent lessons from COVID 19: why the world needs a standing, coordinated system and sustainable financing for global research and development*, The Lancet, Health Policy Volume 397, Issue 10280, 9 March 2021.; https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(21)00503-1/fulltext (27 May 2023).

same for the Mpox vaccine even though several companies, including Aspen in South Africa, offered to help with the fill and finish phase to enhance global supply.[339]

Even though the vaccine was based on public funding and public science from Germany and the US, its availability was dependent on the company's decisions.[340] The limited available vaccine doses were again hoarded by rich countries while WHO were again asking them to donate the spare ones to the Global South.[341]

The above discussion points out that it is unlikely that public policies on health emergency-related R&D and access, which rely primarily on increasing market incentives for for-profit companies, will be effective and efficient.[342]

However, the flaws in the current system go way beyond that resulting in stark global inequalities in access to lifesaving products. This has particularly profound consequences for people in the Global South. The existing global inequity and injustice are not only a moral failure. It is also a health and economic catastrophe.

[339] Bavarian Nordic, *Bavarian Nordic Announces Interim Results for the First Three Months of 2022*, Company Announcement, 9 May 2022.; https://www.bavarian-nordic.com/media/317964/2022-q1-en.pdf (27 May 2023).

[340] Z. Rizvi, *How a Danish Company Grabbed Control of the Monkeypox Vaccine*, The American Prospect, 22 September 2022.; https://prospect.org/health/how-danish-company-grabbed-control-of-monkeypox-vaccine/ (27 May 2023).

[341] E. R. Fletcher, *World Needs 180,000 – 360,000 Monkeypox Vaccine Doses For People Exposed – Up to 10 million for High Risk Groups*, Health Policy Watch, 27 July 2022.; https://healthpolicy-watch.news/monkeypox-vaccine-doses-high-risk-groups/ (27 May 2023).

[342] *See e.g.:* Editorial Board, *Drug Innovation to the Rescue*, Wall Street Journal, 1 May 2020.; https://www.wsj.com/articles/drug-innovation-to-the-rescue-11588373344 (27 May 2023).

Chapter 6. *A deliberate global architecture of unfairness*

6.1. Global inequalities

The COVID-19 pandemic has reversed gains made in global poverty reduction over the past generation. For example, a UN-backed report indicates that extreme poverty in West Africa increased by nearly 3 per cent in 2020 due to the pandemic. Data from the first half of 2022 show that 160 million people were pushed into poverty over the past three years.

Economic inequalities translate into inequalities in living conditions, which directly correlate with those in people's access to health care.[343]

In places with stronger economies and where incomes are higher, people are healthier and live longer. People living there have better access to health care and education. Hospitals are able to admit and treat more patients, and doctors can devote more time to them. Overall, people are more satisfied with their lives.

As observed by Max Roser, the founder and director of Our World in Data, for a variety of reasons, very few people live outside the country in which they were born: *The vast majority of the world population [97 per cent] live in the country they were born in. And so for most people in the world, it is not only the country they live in that determines their income, but it is the country they were born in*.[344]

In other words, *where a person finds themselves in the unequal global income distribution is largely outside of their control*.[345]

6.2. Countries equal only on paper

In recent decades, the dominant approach to solving global health problems has been based on biomedical innovation, often neglecting the importance of addressing the root causes of health inequities. As a result, insufficient attention has been paid to understanding how the global political economy affects health.

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[343] M. Roser, *Global economic inequality: what matters most for your living conditions is not who you are, but where you are*, Our World in Data, 9 December 2021.; https://ourworldindata.org/global-economic-inequality-introduction (27 May 2023).
[344] *Ibidem.*
[345] *Ibidem.*

As Ottersen et al. argue, *the deep causes of health inequity cannot be diagnosed and remedied with technical solutions, or by the health sector alone, because the causes of health inequity are tied to fairness in the distribution of power and resources…*[346]

In principle, countries are politically on par in the global system. In reality, there are significant power disparities between those with high and low incomes.[347] Although on paper the international rules may appear to be the same for all countries, the imbalance of power, for example in global trade and ownership of intellectual property rights makes their practical application incomparable.[348]

Claiming that the international legal norms provide all states with equal tools (for example, freedom to adapt their national laws so that intellectual property rights do not have a detrimental effect on public health) ignores these circumstances.

Public health is determined by the distribution of economic, intellectual, normative, and political resources that are rooted in power structures.[349] Although the level of global public health has increased significantly in recent decades, this growth is extremely uneven geographically.

According to the *Global Burden of Disease* study, access to and quality of health care worldwide has improved since 1990, but inequalities between the best and worst performing countries have increased.[350]

One of the factors perpetuating these inequalities is that attempts to improve the situation are often at odds with the economic interests of wealthy countries in the Global North and the private industries they host. The status quo is in fact largely maintained by these actors.

This is well illustrated by the globalisation of the U.S. intellectual property rules through the international multilateral framework to protect the economic interests of its

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[346] O. P. Ottersen et al., *The political origins of health inequity: prospects for change*, The Lance Commissions, 11 February 2014.; https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(13)62407-1/fulltext (27 May 2023).

[347] *Ibidem*.

[348] P. Patnaik, *Understanding Germany's Trenchant Opposition To the TRIPS Waiver*, Geneva Health Files, 13 August 2021.; https://genevahealthfiles.substack.com/p/understanding-germanys-trenchant?s=r (27 May 2023).

[349] O. P. Ottersen et al., *Closing the gap in a generation: health equity through action on the social determinants of health - Final report of the commission on social determinants of health*, World Health Organization, Geneva, 2008.; https://www.who.int/publications/i/item/WHO-IER-CSDH-08.1 (27 May 2023).

[350] GBD 2015 Healthcare Access and Quality Collaborators, *Healthcare Access and Quality Index based on mortality from causes amenable to personal health care in 195 countries and territories, 1990–2015: a novel analysis from the Global Burden of Disease Study 2015*, The Lancet, 18 May 2017.; https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(17)30818-8/fulltext (27 May 2023).

industries, with the collateral effect of negatively impacting the provision of affordable medicines in poorer countries.

When in the 1990s, high-income countries, led by the U.S. working in tandem with the pharmaceutical industry, concluded that their power advantage was not sufficiently reflected in the World Health Organisation and that another international forum was needed to broker agreements more favourable to their interests, they led the creation of the World Trade Organisation (WTO) and put pressure on developing countries to sign the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).[351]

The gradual implementation of the new international intellectual property law by pressuring developing countries to abide by its rules has undermined the ability of the likes of India and Brazil to produce low-cost, generic copies of patented drugs for their populations.[352]

Wealthy countries have been using WTO to enforce a quasi-colonial economic order that puts the Global South at a disadvantage in accessing lifesaving medicines, including COVID-19 vaccines and treatments during the pandemic.[353]

Another example of wealthy countries protecting their own interests at the expense of access to medicines in poorer countries is the stance of the former toward initiatives that could scale up the production of COVID-19 medical countermeasures around the world. For example, the EU emphasised in its new Pharmaceutical Strategy the importance of developing a strong pharmaceutical industry on the European continent and boasted that it was the *largest exporter of [COVID-19] vaccines*. During the pandemic, EU countries, through their stance in international fora, have effectively prevented African countries from building their own independent medical countermeasure manufacturing capacity by not expressing their support to the WHO COVID-19 Technology Access Pool (C-TAP) and blocking the TRIPS waiver proposal.

Such global rules and politics reinforce power inequalities by widening the gap in access to expertise and products between high-income countries and the brand-name companies they host and low-income countries with their generic medicine manufacturers.

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[351] A. Zaitchik, *Owning the sun…, op. cit.* p. 209.
[352] C. Correa, *Intellectual property rights, the WTO and developing countries: The TRIPS Agreement and policy options*, London: Zed Books, 2000.
[353] See: https://twitter.com/realtahiramin/status/1370521123465625602?s=21 (27 May 2023).

6.2.1. Corporate power

The problem of power imbalance is not restricted to international relations between states but is also prominent between public and private actors.

The power of private companies in the health sector has historically grown. While for most of the 20th century, governments steered pandemic-related pharmaceutical R&D and production through state-owned facilities, the ideological shift toward privatisation of public operations has led to a situation in which the commercial strategies play an important role in shaping the course of pandemics.

Changes in the ways public health emergency preparedness and response approaches are designed have increased the political influence of pharmaceutical companies. As a result of economic, industrial and health policies discussed in the previous chapters, the public became dependent on a handful of producers and globalised supply chains. Ultimately, governments have become dependent on private companies to provide essential health tools, de facto relinquishing much of their power to drive effective healthcare interventions.

Similarly, global governance is also heavily influenced by private corporations, which use the economic power they wield to advance their interests in global markets. This is also true for philanthropic organisations, which can exert influence on the functioning of the pharmaceutical sector. For example, the Bill and Melinda Gates Foundation, through its funding and political clout, has the ability to impact the shaping of the global health agenda and direct certain types of efforts and activities to specific health areas.[354]

As proved during the COVID-19 pandemic, the leaders of wealthy countries believe in and defend the current globalised pharmaceutical R&D and access model. The prevailing assumption is still that solving problems with access to medical technology with existing tools is possible. As a result, fundamental inequalities and structural abuses of power remain unaddressed. This pharmaceutical system was never going to provide developing countries with anything close to equitable access to COVID-19 vaccines. Strive Masiyiwa, head of the African Vaccine Acquisition Task Force, called it *a deliberate global architecture of unfairness*.[355]

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[354] D. McCoy et al., *The Bill & Melinda Gates Foundation's grant-making programme for global health*, The Lancet, May 2009.; https://pubmed.ncbi.nlm.nih.gov/19427959/ (27 May 2023).

[355] See: https://milkeninstitute.org/video/covid-vaccines-global-coordination (27 May 2023). On June 23 at a summit on vaccine equity, Masiyiwa continued: *Imagine we live in a village, and there is a drought.*

6.3. Legacy of colonialism

Inequality in access to medicines is rooted in colonialism.[356] Some authors argue that the legacy of the current global health system, including the pharmaceutical R&D model, can be traced back to the colonial enterprise of *tropical health*.[357]

According to E. Tendayi Achiume, Special Rapporteur on contemporary forms of racism, racial discrimination, xenophobia and related intolerance,[358] the current system of *international trade law, including international intellectual property law, perpetuates racial discrimination in access to lifesaving COVID-19 vaccines and medicines*.[359]

Achiume points out, following the findings of the Committee on the Elimination of Racial Discrimination (CERD), how the disproportionate impact of COVID-19 around the world reproduces colonial hierarchies and represents the failure of the international community to *redress the effects of racism rooted in slavery, colonialism and apartheid*.[360]

The power of some wealthy countries and private corporations based within their jurisdictions puts them de facto in the position of determining who can have access to lifesaving products and when. As Achiume further argues, this power *cannot be unlined from its colonial origins*. The policies and approaches that made such inequalities in access to COVID-19 vaccines possible are often referred to as *vaccine apartheid*. A study by Aloudat et al. observes that [*t]he map of winners and losers in the COVID-19 vaccination race appears almost indistinguishable from the map of European colonialism*.[361]

There is not going to be enough bread, and the richest guys grab the baker and they take control of the production of bread and we all have to go to those guys and have to ask them for a loaf of bread: That is the architecture that is in place.

[356] S. Geiger, C. Conlan, *Global Access to Medicines and the Legacies of Coloniality in COVID-19 Vaccine Inequity*, Development Education and Health, issue 34, Spring 2022.; https://www.developmenteducationreview.com/issue/issue-34/global-access-medicines-and-legacies-coloniality-covid-19-vaccine-inequity (27 May 2023).

[357] M. O. Fofana, *Decolonising global health in the time of COVID-19*, Global Public Health, Vol. 16, No. 8-9, August-September 2021, p. 1155-1166.; https://pubmed.ncbi.nlm.nih.gov/33370211/ (27 May 2023).

[358] From September 2017 to November 2022.

[359] OHCHR, *Open Letter from the Special Rapporteur on contemporary forms of racism, racial discrimination, xenophobia and related intolerance to the World Trade Organization's Twelfth Ministerial Conference*, 13 June 2022.; https://www.ohchr.org/sites/default/files/2022-06/2022-06-13-WTO-Open-Letter.pdf (27 May 2023).

[360] Committee on the Elimination of Racial Discrimination, *Statement on the lack of equitable and non-discriminatory access to COVID-19 vaccine*, statement at the 106th session of CERD, April 2022.

[361] T. Aloudat, D. A. Kirpalani, M. Davis, *Decolonisation and Global Health*, Geneva Graduate Institute, October 2021.

Achiume, in her letter to the Twelve WTO Ministerial Conference, concludes that the uneven multilateral playing field has thus generated a *two-track pandemic*, in which some countries are *plunged into multiple interlinked emergencies – a debt crisis, a development crisis and a human rights crisis.*[362]

The donor-recipient aid model, travel bans, and vaccine diplomacy can also be seen as practices derived from dynamics characteristic of colonialism.[363]

Some authors also argue that colonial legacies in the current system are reflected in the underfunding of specific disease areas prevalent in the Global South because they do not constitute a sufficiently *viable market*.[364]

Lastly, this legacy is also evident in the locations, where global health actors are headquartered. Of the 203 global health actors surveyed by the U.K.-based policy institute Chatham House, the vast majority were based in the U.S. and Europe. It can be argued that locating global health activities in Euro-American countries perpetuates colonial hierarchies and supports an ideological orientation to health based on capitalist logic.

6.4. Unprecedented inequalities during COVID-19 pandemic

COVID-19 has affected virtually the entire world, with no respect for borders and no distinction between people's wealth, race or gender. However, it has not affected everyone to the same extent. The pandemic has revealed and deepened inequalities between countries, as well as within them. People sick or elderly, those whose jobs required more frequent contact with others or those living in situations that made them more susceptible to infection were most at risk of contracting the disease. As a result, it has disproportionately affected the poor, especially in developing countries and places with worse access to health care.

There are significant differences in how the pandemic has been managed around the world. These are due to a number of factors, including countries' ability to provide health services, such as primary care consultations and hospitalisation, or their access to medical countermeasures. In addition, the quality of the states' response, economic preparedness

[362] M. Bachelet, *United Nations High Commissioner for Human Rights, statement to the 49th session of the Human Rights Council*, Geneva, 11 March 2022.
[363] D. Fidler, *Vaccine nationalism's politics*, Science, Vol. 369 (6505), 14 August 2020, p. 749.
[364] E. 't Hoen, J. Berger, A. Calmy, S. Moon, *Driving a decade of change: HIV/AIDS, patents and access to medicines for all*, Journal of the International AIDS Society, Vol. 14, No. 1, 2021, p. 1-12.

and resilience, or citizens' trust in government guidance, have also had an influence on the extent to which countries have been able to tackle the pandemic.

The consequences of this are unequivocally tragic. For every life lost due to a pandemic in a rich country, four were lost in a poor one. The poorest and people from minority ethnic groups were more likely to die from COVID-19. These inequalities have also been observed within countries. In Brazil, black people were 1.5 times more likely to die from COVID-19 than white people. In the US, Native Americans, Hispanics and black people were two to three times more likely to die from COVID-19 than white people.

Global inequality during the pandemic was probably in no aspect more striking than in the context of access to medical countermeasures. While the pharmaceutical system was able to develop multiple vaccines in less than a year, it also fostered extreme inequalities.[365]

COVID-19 vaccinations significantly altered the course of the pandemic, saving tens of millions of lives around the world. However, limited access to vaccines in the Global South countries limited their impact and prolonged the crisis with immense preventable suffering and death.[366]

To understand the internal conflicts in the global pharmaceutical system, rendering it unable to achieve what it is intended to do, it is worth tracing the significant changes in global health architecture over the past decades and identifying their consequences on access to vaccines and treatments during the COVID-19 pandemic.

6.5. Evolution of the global health architecture

High-income country markets are the target of the pharmaceutical industry. All Big Pharma companies were founded in the Global North. They are focused on providing products according to the needs of the populations of these countries and benefit from their governments' political and financial support and protection.

This results not only in prioritising the development of treatments for diseases affecting wealthy countries but also in the unequal availability of breakthrough medical

[365] T. A. Ghebreyesus, WHO's Director-General concluded that, '*the rapid development of Covid-19 vaccines is a triumph of science, but their inequitable distribution is a failure of humanity'*. See: COVID-19: UN chief calls for G20 vaccine task force, in 'war' against the virus, UN News, 21 May 2021.; https://news.un.org/en/story/2021/05/1092442 (27 May 2023).

[366] O. J. Watson, *Global impact of the first year of COVID-19 vaccination: a mathematical modelling study*, Lancet Infectious Diseases, 23 June, 2022.; https://www.thelancet.com/action/showPdf?pii=S1473-3099%2822%2900320-6 (27 May 2023).

innovations around the world, regardless of actual needs. Indeed, it may be more profitable for companies to sell their high-priced products in a few rich countries than to make them available in larger markets at a lower price.

Therefore, the new therapies are often a luxury commodity, beyond the reach of many leaving in the Global South.

One of the most striking examples of this was in the 1990s, when antiretroviral combination therapy against HIV was developed and marketed in the US, but unavailable in African countries hardest hit by the AIDS epidemic. That sparked a public outcry demanding that companies and governments allow cheaper and more accessible generic versions of the therapies to be produced around the world. Protesters appealed to health and human rights claims that access to lifesaving medicines should be a right for everyone and accused companies of seeking profit at the expense of people's health. In the early 2000s, the movement succeeded in increasing access to affordable HIV/AIDS therapies and changing the narrative and power dynamics around access to medicines.

Emerging from this campaign, rights-based treatment activism, which materialised as the Access to Medicines (A2M) movement, was a significant force in shifting the political and economic status quo on the right to health and equitable access. Developing countries began to introduce constitutional rights to health and increase their capacity to provide lifesaving generic medicines to their citizens.[367]

This approach could undermine the Global North companies' monopoly powers over their products and threaten to change the dynamics and power of global trade in pharmaceuticals. As a result, not only were companies' profits at risk but also the basis of their business model including full control over medicine prices and availability.

Inexpensive markets around the world could no longer be ignored by the pharmaceutical industry and wealthy countries without risking a growing shift toward treating pharmaceuticals as common goods rather than exclusive, highly profitable products. As argued by Torreele and Krikorian, in the face of this risk, the industry tried to find a way to reposition itself from being (part of) the problem to being an integral part of the solution.[368] The best option for the Big Pharma companies – supported by wealthy

[367] G. Krikorian, E. Torreele, *We Cannot Win the Access to Medicines Struggle Using the Same Thinking That Causes the Chronic Access Crisis*, Health and Human Rights, June 2021, p. 119-127.; https://pubmed.ncbi.nlm.nih.gov/34194206/ (27 May 2023).
[368] *Ibidem*.

countries benefiting from the status quo – was to create a new structure governing poor countries' access to medicines developed by these companies, thus deepening their dependence on the external supply and leaving private industry in the driving seat when it comes to pricing and availability of their products. This way, the right-based approach was gradually overtaken by a *business-friendly* one. Its objective was to create donor-dependent markets to provide controlled access to medicines for those who cannot afford the high price tags.[369]

Leaving more space in public health to private companies was also a result of systemic underfunding of public health institutions. This new trend has created a global health architecture that depends on donor and pharmaceutical industry voluntarism, which has ultimately failed poor countries in having equal access to innovative therapies over the past two decades.[370]

6.5.1. Capture of global health by the private sector

New institutions were created for this model, tasked with developing policies to channel donor and corporate funds and products to the Global South.

In this structure, public-private partnerships (PPPs) have become the new favoured *modus operandi*.[371] They are modelled on the private sector's virtues and based on the premise that private companies are best suited to serve the public interest.[372] Under this approach, governments play a facilitating role, deploying public resources in the form of financial incentives and subsidies for companies and implementing favourable political instruments.

The system has been supported by secretariats set up within multilateral organisations, consulting companies that are often responsible for developing partnerships,

[369] *Ibidem*, p. 127.

[370] Donor- and industry-dependence is not unique for the pharmaceutical sector and its consequences are far more reaching. Decades of dependency on foreign aid (often from former colonial master countries) results in weak national governance and institutions in recipient countries. This is sustained by both reach and poor countries. See e.g.: O. Adeyi, *Global health, narcissistic charity, and neo-dependency*, Development Today, 31 December 2021.; https://www.development-today.com/archive/dt-2021/dt-9--2021/global-health-narcissistic-charity-and-neo-dependency (27 May 2023).

[371] G. Krikorian, E. Torreele, *op. cit.*, p. 122.

[372] K. T. Storeng, *COVAX and the rise of the 'super public private partnership' for global health*, An International Journal for Research, Policy and Practice, Taylor & Francis, 28 June 2021.; https://www.tandfonline.com/doi/full/10.1080/17441692.2021.1987502 (27 May 2023).

and philanthropists that provide additional funding and influence decision-making. The system has formalised the influence and gave significant power to non-state actors.

The public-private partnerships that emerged during this time brought a business ethos to public health. They introduced models that prioritised measurable results based on technological solutions.[373] Torreele and Krikorian argue that in practice, the structure designed in this way *resulted in 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*.[374]

This contributed to basing the response to public health problems, such as the spread of infectious diseases, on the double premise, that (1) technological innovations are key to solving all health problems, and that (2) this can be done the most suitably by the private sector. Any occurring problems with access to these technologies are deemed to be punctual *market failures*. Fixing them is the role of the public sector which should provide additional incentives, grants or subsidies.

PPPs, international institutions and initiatives have been created to take responsibility for addressing various areas of public health in the Global South. They focus on financing, developing and/or procuring vaccines and treatments for, for example, tropical neglected diseases that are not profitable enough to attract private investment. In some cases, they have been able to garner political and financial support that has helped provide lifesaving medicines, diagnostics and vaccines to impoverished populations suffering from AIDS, malaria, tuberculosis and many other diseases that would otherwise go untreated. Undeniably, these organisations significantly contribute to filling the gaps in the development and accessibility of essential health technologies and to responding to some of the most urgent emerging health challenges in developing countries. As such, however, by doing so on an ad hoc basis, they allow the system to preserve the current pharmaceutical business model. Torreele and Krikorian further argue that they help silence criticism of the injustices of the pharmaceutical system and help ensure that the status quo is not effectively challenged, stating that *certain types of solutions intrinsically carry the conditions that enable scarcity, rationing, and inequity*.[375]

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[373] A. E. Birn, *Gates's grandest challenge: Transcending technology as public health ideology*, The Lancet, 366 (9484), 11 March 2005, p. 514–519. https://doi.org/10.1016/S0140-6736(05)66479-3 (27 May 2023).
[374] G. Krikorian, E. Torreele, *op. cit.*, p. 122.
[375] *Ibidem*, p. 119.

Many disease areas remain neglected, and the vast majority of the world's population is deprived of access to lifesaving products. It can be argued that the current focus of the discussed institutions and initiatives on disease-specific solutions is detrimental to the ability to implement a broader vision of public health development.

During the COVID-19 pandemic, this structure was once again activated to help the Global South countries access vaccines through the charity of rich countries and the voluntary engagement of pharmaceutical companies under the traditional market approach.

The result was inequality on an unprecedented scale.

6.6. Dependence and solidarity

6.6.1. Pledges and declarations of the pandemic's early days

The COVID-19 pandemic took world leaders by surprise. Health systems were unprepared, stocks of personal protective equipment were not replenished, response procedures were not working, and advances in R&D on medical countermeasures against coronaviruses were insufficient. After the initial shock and ensuing chaos, attempts to coordinate a global response to a once-in-a-generation health crisis began.

The prevailing approach was to work together to reduce the time it takes to develop vaccines, tests and treatments, and to maximise the ability to expand the infrastructure needed to produce and deliver them.

In early February 2020, policymakers and experts gathered at WHO agreed that the most effective way forward would be to exchange information, share knowledge and technologies and pool resources.[376] At the same time, promises of solidarity and statements that *no one is saved until everyone is saved* were repeated by virtually all political leaders, public health experts, industry executives and activists.

For example, the EU has repeatedly declared its commitment to equal access to COVID-19 technologies and portrayed itself as a leader in global efforts to combat the pandemic.[377] At the World Health Assembly in May 2020, European Commission

[376] WHO, Coronavirus press conference 11 February, 2020. See: https://www.who.int/docs/default-source/coronaviruse/transcripts/who-audio-emergencies-coronavirus-full-press-conference-11feb2020-final.pdf (27 May 2023).

[377] EU countries' statements at the WHA on 19th May 2020: Croatia, on behalf of the EU, voiced the need for emerging technologies related to COVID-19 to be treated as global public goods, and that should be

President von der Leyen firmly stated in her speech that *the coronavirus vaccine should not be a luxury of a few, but a universal common good*.[378]

On the same occasion, Croatia holding the presidency of the Council of the European Union at the time, voiced the need for emerging technologies related to COVID-19 to be treated as global public goods. Germany, among other countries, stressed that medical products and vaccines should be available to everybody. Slovakia called for an efficacious vaccine not to be commercialised in the first place but to serve the *general good*.[379] Resolution WHA73.1 on *COVID-19 Response* adopted at the same time and originally proposed by the EU, recognised that all countries should have timely and affordable access to diagnostics, therapeutics, medicines and vaccines as well as to essential health technologies and equipment to respond to COVID-19.[380]

6.6.2. Defying intellectual property barriers

In the early months of 2020, with no certain COVID-19 vaccine candidates in sight, countries were determined that no artificial barriers should stand in the way of developing, producing and using technologies that could bring the world closer to tackling the pandemic. This included the intellectual property regime.

In that sense, the pandemic upended the normal ways of doing business in the pharmaceutical sector.[381] For example, when Roche, a Swiss company, refused requests from the Dutch government to release the recipe for a test solution needed for COVID-19 testing units, the European Commission launched a preliminary investigation into the company's economic power in the Dutch market and began looking into possible abuse of

available to everybody. Germany, among other countries, voiced that medical products and vaccines should be treated as global public. Slovakia even called for an efficacious vaccine not to be commercialized in the first place, and serve the "general good". See: N. Syam, M. Alas, V. Ido, *The 73rd World Health Assembly and Resolution on COVID-19: Quest of Global Solidarity for Equitable Access to Health Products*, South Centre, Policy Brief, No. 78, May 2020.; https://www.southcentre.int/wp-content/uploads/2020/05/PB-78.pdf (27 May 2023).; Resolution WHA73.1 on "COVID-19 Response", originally proposed by the EU, recognizes that all countries should have timely and affordable access to diagnostics, therapeutics, medicines and vaccines as well as to essential health technologies and equipment to respond to COVID-19. See: https://apps.who.int/gb/ebwha/pdf_files/WHA73/A73_R1-en.pdf (27 May 2023).

[378] *Ibidem*.

[379] *Ibidem.*

[380] WHO Seventy-Third World Health Assembly, *COVID-19 response*, Resolution WHA 73.1, 19 May 2020.; https://apps.who.int/gb/ebwha/pdf_files/WHA73/A73_R1-en.pdf (27 May 2023).

[381] M. Palmer, D. P. Mancini, *Coronavirus puts Big Pharma's IP regime to the test*, Financial Times, 21 April 2020.; https://www.ft.com/content/5a364eb0-780c-11ea-bd25-7fd923850377 (27 May 2023).

the company's dominant position.[382] This, along with warnings from the Dutch government about the possibility of using a compulsory license for the patented technology, prompted the company to release the formula.

In Israel, the government issued a compulsory license for the patents on the U.S. company AbbVie's HIV drug Kaletra, which was identified as a potential COVID-19 treatment, to allow generic production. Instead of receiving the threat of lawsuits from the company or tariffs and trade repercussions from rich countries – as is often the case in such instances – AbbVie itself decided to give up its patents on the drug.

What is more, countries have been also changing their national intellectual property laws. In March 2020, several countries including Israel, France, Canada, Indonesia, Chile, Colombia and Ecuador reviewed their patent protection laws to facilitate patent limitations.[383]

This was also true for Germany.[384] Despite the belief that intellectual property is not a barrier, Germany amended its laws early in the pandemic to fast-track the issuing of compulsory licenses to override patents on health products, should there be a need.[385]

Noteworthy is the fact that at the time of the discussed legislative revision, no COVID-19 vaccine or therapeutic candidates had yet been under development, and

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[382] E. Van Ark, J-H Strop, *Roche releases recipe after European Commission considers intervention due to lack of coronavirus tests*, Follow the Money, 27 March 2020.; https://www.ftm.eu/articles/roche-releases-recipe-after-public-pressure-while-european-commission-considers-intervention-due-to-coronavirus-test (27 May 2023).

[383] The only country that has so far issued a specific compulsory license during the pandemic is Israel: by decree of 18 March 2020, the import of a generic version of Kaletra (AbbVie), a drug known per se as an HIV-active drug, was permitted for the treatment of Coronavirus patients. See: E. 't Hoen, *Covid-19 and the comeback of compulsory licensing*, Medicines Law & Policy, 23 March 2020.; https://medicineslawandpolicy.org/2020/03/covid-19-and-the-come-back-of-compulsory-licensing/ (27 May 2023).

[384] On 27 March 2020, Germany adopted the Epidemic Protection Act, which, among others, provides for measures to restrict patents. Under the Act, the Bundestag was authorised to declare a so-called *epidemic situation of national significance*, resulting in the Federal Ministry of Health gaining additional competences in the field of infectious disease prevention and control, including taking the necessary measures to ensure the supply of various medical countermeasures. See; T. Musmann, *German Government Plans Possibilities to Limit Patents In View of Corona Pandemic*, Kluwer Patent Blog, 24 March 2020.; https://patentblog.kluweriplaw.com/2020/03/24/german-government-plans-possibilities-to-limit-patents-in-view-of-corona-pandemic/ (27 May 2023). Most importantly, the Ministry of Health was authorised to issue so-called *use orders* for patents (pursuant to section 13 (1) of the Patent Act). The patented invention should be used in the interest of the public welfare, or security of Federation, and be required in order to ensure the supply of products in the event of a crisis, or be able to produce vital active substances or drugs. The concrete use of such an invention can, for example, be arranged by a license. See: Bird&Bird, *COVID-19: New German legislation to fight pandemic may affect granted German patents*, 10 May 2020.; https://www.twobirds.com/en/insights/2020/germany/covid-19-new-german-legislation-to-fight-pandemic-may-affect-granted-patents (27 May 2023).

[385] E. 't Hoen, *Covid-19 and the comeback*, op. cit.

Germany could not know whether or how it would be able to secure its supply once developed.

Taking such measures indicates the German government considered that strict intellectual property rights protecting medical innovations were likely to impede access to products needed to protect the public. Germany recognised a swift override of exclusivity rights as the best solution if this were to happen.

In the end, Europe's largest economy, joining forces with the other 26 EU countries and supported by additional EU funding, proved economically attractive enough to private companies to ensure an oversupply of all relevant products and the law has never been applied.

The fact that during the first months of the pandemic, compulsory licensing, an instrument traditionally regarded as an extreme, *nuclear option* has been normalised and presented as a prudent and reasonable policy choice has been considered a major development at the time. However, this has not resolved the broader problem of how medical countermeasures are developed and made available worldwide.

These deliberations were on the agenda of multilateral organisations around March 2020. For example, to make sure the stringent international intellectual property framework and the fragmentation of medical innovation do not stand in the way to end the pandemic, there were proposals to introduce a non-voluntary pooling mechanism for both, public and private actors *to ensure that the required technologies and data are made available, and that safe and effective medicines, vaccines and other products are manufactured on a large scale, distributed rapidly, equitably and affordably in all countries*. [386]

As pointed out by Zaitchik, such calls for non-voluntary measures were also based on the premise that a voluntary and temporary suspension of intellectual property rights for COVID-19 products would only affirm the legitimacy of the current unsuitable and ineffective regime.[387]

[386] See e.g.: South Centre, *Message from the South Centre at the Launch of the "Solidarity Call To Action" by the President of Costa Rica and The Director-General of the WHO*: https://www.southcentre.int/wp-content/uploads/2020/05/SC-Statement-SCTA-REV.pdf (27 May 2023).
[387] A. Zaitchik, *Owning the sun…, op. cit.,* p.237.

However, these discussions did not lead to a compulsory solution and indeed, a voluntary WHO mechanism, officially spearheaded by Costa Rica, materialised at the end of May 2020 with the launch of the WHO COVID-19 Technology Access Pool (C-TAP).[388]

As reported by Zaitchik, while at the World Health Assembly, held 11 days before the launch of C-TAP, 130 countries, including the EU, as discussed above, committed to *universal access*, only 34 of them (including only three high-income countries, Norway, Luxembourg and the Netherlands) supported the Pool.[389]

A study by Wemos, a Dutch non-profit organisation, stresses that as of the end of 2022, only Unitaid, a global health agency, Spain and Belgium have provided financial support for the mechanism. Similarly, only two public research institutes, the U.S. NIH and Spain's Research Council, and not a single private pharmaceutical company have shared some of their technologies with the Pool. The study shows that few countries have even made efforts to convince public research institutes and private companies to participate in C-TAP. The findings suggest that due to insufficient funding and political support, C-TAP has suffered from a lack of resources and strength from the beginning.

6.6.3. Shifting approach of wealthy countries

Two weeks before the official launch of C-TAP, U.S. President Trump announced *Operation Warp Speed*, a public-private partnership between the U.S. government and pharmaceutical companies outside of the international cooperation mechanisms, that included an estimated $18 billion public investment (mostly in late-stage clinical development and early production of COVID-19 vaccines) in exchange for 455 million doses delivered directly to the U.S..[390]

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[388] J. Hochberger, *Make Pooling Work to End Pandemics: a Qualitative Analysis of the Covid-19 Technology Access Pool*, Wemos, November 2022.; https://www.wemos.nl/wp-content/uploads/2022/11/Wemos_Make-pooling-work-to-end-pandemics_November-2022.pdf (27 May 2023).

[389] A. Zaitchik, *Owning the sun…, op. cit.,* p.236.

[390] S. Baker, C. Koons, *Inside Operation Warp Speed's $18 Billion Sprint for a Vaccine*, Bloomberg, 29 October 2020.; https://www.bloomberg.com/news/features/2020-10-29/inside-operation-warp-speed-s-18-billion-sprint-for-a-vaccine (27 May 2023).; See also: Lancet Commission on COVID-19 Vaccines and Therapeutics Task Force Members, *Operation Warp Speed: implications for global vaccine security*, The Lancet Global Health, 26 March 2021.; https://www.thelancet.com/journals/langlo/article/PIIS2214-109X(21)00140-6/fulltext (27 May 2023).

This was recognised by world leaders and experts as a clear departure from earlier promises of equitable access, cooperation and solidarity.[391] The U.S. decision has sparked a shift in rich countries' approach to access to vaccines, described as *vaccine nationalism* and *vaccine hoarding*.

The U.S. initiative was followed by other countries, including the EU, which adopted its *Vaccine Strategy* in June 2020. The strategy included a plan for the European Commission and EU countries to sign bilateral Advance Purchase Agreements – with upfront costs of €2.7 billion – with individual vaccine manufacturers to secure direct supplies of vaccine doses.[392]

In the end, wealthy countries have decided that the *business-as-usual* model can better serve their interests.

6.6.4. Breakdown of solidarity

The global response to the COVID-19 pandemic was based in practice on the promise of Global North-Global South cooperation and the dependence of the latter on the solidarity of the former.

The inadequacy of this dynamic was evident in past, during the Ebola, SARS, avian flu or HIV epidemics. COVID-19, however, highlighted to an unprecedented degree the failure of this dependency and a weak and underfunded institutional structure, lacking appropriate mechanisms to deal with global health crises of this magnitude.

This is exemplified by the EU's response to the pandemic, which, from hoarding vaccines to opposing the TRIPS waiver, fostered extreme global inequality.

The EU *Vaccine Strategy*[393] and subsequent vaccine purchases ignored the Fair Allocation Framework announced in September 2020 by the WHO calling for *an initial*

[391] The day before its announcement, 140 prominent individuals signed an open letter coordinated by UNAIDS and Oxfam, calling on governments to make the COVID-19 vaccine available to all people free of charge.

[392] See: European Commission, EU Vaccines Strategy: https://commission.europa.eu/strategy-and-policy/coronavirus-response/public-health/eu-vaccines-strategy_en#:~:text=It%20reserves%20an%20additional%201.8,an%20additional%20900%20million%20doses.

[393] European Commission, *Coronavirus: Commission unveils EU vaccines strategy*, Press Release, 17 June 2020.; https://ec.europa.eu/commission/presscorner/detail/en/ip_20_1103 (27 May 2023).

proportional allocation of doses to countries until all countries reach enough quantities to cover 20% of their population.[394]

This did not prevent the EU from issuing declarations of solidarity in the following months.[395] In November 2021, despite nearly 70 per cent[396] of adults in the EU being fully vaccinated, compared to just 8.6 per cent[397] in Africa, the EU maintained[398] that it was *at the forefront of ensuring global solidarity with the rest of the world*.

As of 2023, the vaccination rate with at least one dose in high-income countries is over 73 per cent compared to over 32 per cent in low-income countries.[399] Although vaccine distribution has evened out over time – largely due to the securing of major demand in rich countries – immunisations around the world have remained largely imbalanced.

This blatant lack of solidarity provokes a discussion about the international obligations of states to ensure the highest attainable level of health globally, including when responding to emergencies.[400]

Currently, international aid is understood as a charity, which loses out when confronted with the donors' own public health and often even economic interests. While the rich countries declared global solidarity, their politics undermined it. The questions remain open as to how, and where these commitments should be established or strengthened and whether the current multilateral structure including WHO and WTO provide adequate space for both developed and developing countries to protect their interests and cooperate on an equal footing.

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[394] WHO, *Fair allocation mechanism for COVID-19 vaccines through the COVAX Facility*, 9 September 2020.; https://www.who.int/publications/m/item/fair-allocation-mechanism-for-covid-19-vaccines-through-the-covax-facility (27 May 2023).

[395] For example, at the State of the European Union speech on 15th September 2021. See: https://state-of-the-union.ec.europa.eu/state-union-2021_en (27 May 2023); or at the Global Health Summit and in the G20 Rome Declaration on 21st May 2021. See: https://global-health-summit.europa.eu/rome-declaration_en (27 May 2023).

[396] See: The ECDC COVID-19 Vaccine Tracker: https://vaccinetracker.ecdc.europa.eu/public/extensions/COVID-19/vaccine-tracker.html#uptake-tab (27 May 2023).

[397] Oxfam, *Rich countries have received more vaccines in run-up to Christmas than African countries have all year*, Press Release, 24 December 2021.; https://reliefweb.int/report/world/rich-countries-have-received-more-vaccines-run-christmas-african-countries-have-all (27 May 2023).

[398] R. Birchard, *EU countries slammed for slow vaccine sharing*, DW, 26 November 2021.; https://www.dw.com/en/campaigners-slam-eu-countries-for-slow-vaccine-sharing-as-variant-sparks-panic/a-59946267 (27 May 2023).

[399] UNDP, Global Dashboard for Vaccine Equity: https://data.undp.org/vaccine-equity/ (27 May 2023).

[400] For example, what should the responsibility of rich countries look like in the light of human rights, which includes the universal right to health, in a situation of pandemics and limited supply of medical countermeasures? Would hoarding vaccine doses count as violating their international obligations?

6.6.5. Failing to stand up to *business-as-usual*

Pledges of ensuring fair access and commitments to make vaccines *global public goods* repeated in the first months of the pandemic could lead to upending the R&D model based on intellectual property and monopolies, in which companies control supply and price.

While the establishment of C-TAP as a voluntary mechanism has not contributed to embodying this ambition to the fullest, had it been supported by rich countries investing in medical innovation, it could have allowed the collaborative approach to gain momentum, leaving companies interested in the *business-as-usual* approach vulnerable.

Indeed, for the industry, there was a genuine risk that the system sustaining its lucrative model would be challenged. It, therefore, doubled down on the criticism of C-TAP. At a high-level panel composed of five senior executives from the leading pharmaceutical companies organised just a day before the official launch of C-TAP by the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA), the industry representatives dismissed the idea of sharing intellectual property, knowledge and technologies as dangerous and nonsensical.[401] At the event, the industry also assured of its commitment to providing equitable access to COVID-19 products under its control.

While objecting to using C-TAP, all executives supported another WHO mechanism introduced a month before with significant support from the Bill and Melinda Gates Foundation – the Access to COVID-19 Tools (ACT) Accelerator.[402]

Zaitchik points out that the creation of the ACT-A has particularly suited the industry's and rich countries' position by *provid[ing] a go-to answer for every question concerning access, equity, and intellectual property.*[403]

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[401] See the event's recording: https://www.ifpma.org/resource-centre/global-biopharma-ceo-top-executives-covid-19-media-briefing-28-may-2020/ (27 May 2023). See also: E. Silverman, *Pharma leaders shoot down WHO voluntary pool for patent rights on Covid-19 products*, STAT News, 28 May 2020.; https://www.statnews.com/pharmalot/2020/05/28/who-voluntary-pool-patents-pfizer/ (27 May 2023).

[402] At the IFPMA event on May 28 2020, Pfizer CEO Bourla stressed I *want to take the opportunity to emphasize the role that Bill Gates is playing*, adding *This man is an inspiration for all*. See the event's recording: https://www.ifpma.org/resource-centre/global-biopharma-ceo-top-executives-covid-19-media-briefing-28-may-2020/ (27 May 2023).

[403] A. Zaitchik, *Owning the sun…, op. cit.,* p.239.

6.7. Boxing developing countries into a corner – ACT-A

Tagmatarchi Storenga et al. describe the ACT-A as a *super public-private partnership* – a new, complex PPP with four separate pillars co-led by existing PPPs.[404] A structure built on and fit into global health architecture developed over the past decades.

ACT-A was created in April 2020 as a global public-private initiative for COVID-19 medical technologies. According to Yamey et al., its creation was a result of pressure from the Gates Foundation and the World Bank, which, while supporting health policymakers' efforts to establish a global coordination mechanism, argued that this could only be achieved with close engagement between existing global health PPPs and the private sector.[405]

Characteristically for the global health institutions and initiatives, ACT-A brought together actors from the public and private sectors to focus on (bio)medical solutions (diagnostics, treatments and vaccines) for a concrete disease.

Its new feature lies in the fact that ACT-A was an *alliance* of major, recognised PPPs, intended to benefit not only developing countries but the entire world.[406] ACT-A has been composed of separate pillars for diagnostics, treatment, vaccines and health system strengthening. These were overseen by the existing PPPs.[407]

Its largest and most funded pillar for vaccines, COVAX, is described as a *groundbreaking global collaboration* and *the only global solution* to vaccine equality. Thanks to COVAX, the supply of vaccines has reached 145 countries, many of which without its assistance might have had much more difficulties in accessing them.[408]

However, despite great promises, COVAX has been grossly inadequate, delivering only half of the promised 2.2 billion vaccine doses by the end of 2021.

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[404] K. T. Storeng, *COVAX and the rise…, op. cit.*

[405] G. Yamey et al., *Funding the development and manufacturing of COVID-19 vaccines*, Background paper for the World Bank/CEPI financing COVID-19 vaccine development consultation on February 20, 2020. The Center for Policy Impact in Global Health, Duke Global Working Paper Series No. 20, March 2020.; https://doi.org/10.2139/ssrn.3575660 (27 May 2023).

[406] K. T. Storeng, *COVAX and the rise…, op. cit.*

[407] ACT-A has been composed of separate pillars for diagnostics, treatment, vaccines and health system strengthening. They were overseen by the existing PPPs: Gavi and CEPI the vaccines pillar; Unitaid the therapeutics pillar; Find the diagnostics pillar; and The Global Fund the crosscutting health systems strengthening. They work alongside multilateral organisations (WHO, UNICEF, the Pan American Health Organization (PAHO) and the World Bank), as well as the largest global health philanthropic foundations (the Wellcome Trust, the Gates Foundation) and governments. See: WHO, What is the ACT-Accelerator: https://www.who.int/initiatives/act-accelerator/about (27 May 2023).

[408] Gavi, *COVAX explained*, 3 September 2020.; https://www.gavi.org/vaccineswork/covax-explained (27 May 2023).

Importantly, in its concept, the entire supply of COVID-19 vaccines should go through COVAX. However, even after enthusiastic support for global cooperation early in the pandemic, no rich country signed up for it, making it virtually exclusively for poor countries.

For example, since April 2020, the European Commission has expressed its support and contributed financially to COVAX.[409] However, soon after, the EU bypassed it through its regional procurement pool set up in June 2020, undermining the facility's solidarity principle and significantly weakening its effectiveness.

In this light, one can understand the frustration of countries seeking rescue through this mechanism. Strive Masiyiwa, head of the African Vaccine Acquisition Task Force expressing his views on how the cooperation has served African countries stated: *We were misled. […] We got to December 2020 believing the whole world was coming together to purchase vaccines, not knowing that we had been corralled into a little corner, whilst others ran off and secured supplies. That's what Covax was supposed to do for us.*[410]

Ignored by wealthy countries, COVAX suffered from the lack of collective ownership and funding. In practice, it had to compete for doses with the Global North.[411]

6.7.1. COVAX shortcomings

It is important to understand some of the key shortcomings of COVAX efforts so that they can be corrected while improving the international architecture and mechanisms needed to prepare for future health emergencies.

Tagmatarchi Storenga et al. argue that the mechanism proved ill-suited and doomed to failure from the outset. The roles of its eight co-conveners were unclear, transparency

[409] See: European Commission, EU Vaccines Strategy - https://ec.europa.eu/info/live-work-travel-eu/coronavirus-response/public-health/eu-vaccines-strategy_en (27 May 2023).

[410] See the recording: https://milkeninstitute.org/video/covid-vaccines-global-coordination (27 May 2023). *The people who bought the vaccines and the people who sold them the vaccines knew that there would be nothing for us (…). We had money, we were willing to pay upfront, in cash, we weren't asking for donations. And they said that all capacity for 2021 [had] been sold*. Masiyiwa said Covax's decision to procure vaccines primarily from the Serum Institute of India was fraught because the risks attached with sourcing from just one facility were too high. The problem is well illustrated by the production of AstraZeneca vaccine. The company licensed its vaccine to the Institute to manufacture it for poor countries. At some point India banned the export of vaccines to prioritise the needs of its citizens. The U.K. pressured the Indian government to lift the ban to enable the vaccine export to… the U.K.. Supply to poor countries stayed in place for months longer.

[411] R. Horton, Offline: *ACT-A—ça suffit* , The Lancet, 25 February 2023.; https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(23)00388-4/fulltext (27 May 2023).

was limited, accountability was weakened, and the participation of developing countries in its governance was non-existent.

COVAX leadership could and should have been more publicly critical of the pharmaceutical corporations that were failing to fulfil their contracts pushing the program to the end of the supply queue. Despite COVAX's spending large volumes of public resources on deals with pharmaceutical corporations, many of these contracts remained unmet, leaving it largely dependent on sporadic and unpredictable vaccine donations from rich countries. Ultimately, about 56 per cent of nearly 2 billion doses delivered by COVAX as of February 2023 came from individual country donations.

The COVAX failure was not caused by external forces and unexpected events but by policy choices and the constraints of the governance structure that allowed private interests to hijack its mission. The *institutional design and the nature of the super-PPP model itself* are to blame.[412]

COVAX has not put safeguards in place to prohibit rich countries' governments from undermining its goals through *vaccine nationalism*, i.e., prioritising the vaccination of its country's population without regard for multilateral efforts to ensure that all people are vaccinated based on needs, and *vaccine diplomacy*, which involves sharing surplus vaccine doses in pursuit of geopolitical interests (see Chapter 4.3.).[413]

COVAX's partners took advantage of the mechanism in different ways, contributing to its failure.

Based on a voluntarism and partnership model, it gave too much power to pharmaceutical companies, which used their privileged position to increase profits and shareholder value by maintaining a limited supply of vaccines.

6.7.1.1. Example of overreliance on Serum Institute

While supplies from production facilities located in the Global North were mostly reserved by rich countries, COVAX had to rely on generic drug manufacturers in the Global South. This resulted in an over-reliance on the largest of them, the Serum Institute of India.

[412] K. T. Storeng, *COVAX and the rise…, op. cit.*

[413] R. Furneaux, O. Goldhill, M. Davis, *How Covax failed on its promise to vaccinate the world*, The Bureau of Investigative Journalism, 8 December 2021.; https://www.thebureauinvestigates.com/stories/2021-10-08/how-covax-failed-on-its-promise-to-vaccinate-the-world (27 May 2023).

The way this happened is worth analysing to show the dynamics of power and interests in the existing pharmaceutical system.

As discussed in Chapter 3.1.5., the Jenner Institute at Oxford University, responsible for developing the ChAdOx1 vaccine candidate, stated at the beginning of the pandemic that it would license the rights to its technology in a non-exclusive manner so that manufacturers around the world could produce it. Before it changed its stance in April 2020 and decided to license exclusive rights to AstraZeneca, it had already signed a license deal with Serum Institute, the world's largest vaccine manufacturer.[414]

In the contract with AstraZeneca, the university demanded that the deal with Serum Institute remains in place. AstraZeneca and Serum amended the agreement so that the latter would produce the vaccine developed by the university for all poor countries normally eligible for the assistance of Gavi, the Vaccine Alliance, the international immunisation organisation that was responsible for buying the doses on behalf of COVAX. These 92 nations together counted for half the world, or nearly four billion people.

Given the difficulties of Gavi in obtaining vaccines from other sources, the supply for the mechanism ended up relying largely on this deal. The single company, however, struggled to supply a sufficient number of doses to meet the demand of that many countries. The situation for the Global South became particularly dire when the Indian government banned all exports of vaccines during the peak of COVID-19 deaths in the country.[415] As a result, for several weeks the Global South countries had virtually no access to any doses.

Importantly, while the Serum Institute has received the license to produce, it has not been in control over the allocation of the vaccine doses. While being the supplier for poor countries it also had to send millions of doses to the U.K. and Canada.[416]

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[414] A. Prabhala, L. Menghaney, *The world's poorest countries are at India's mercy for vaccines. It's unsustainable*, Guardian, 2 April 2021.; https://www.theguardian.com/commentisfree/2021/apr/02/india-in-charge-of-developing-world-covid-vaccine-supply-unsustainable (27 May 2023).

[415] C. Paun, *Vaccine supplier to the poor lands new clients: The rich*, Politico, 3 April 2021.; https://www.politico.com/newsletters/global-pulse/2021/03/04/vaccine-supplier-to-the-poor-lands-new-clients-the-rich-491980 (27 May 2023).; See also: https://twitter.com/adarpoonawalla/status/1363346341275967488?s=20 (27 May 2023).

[416] Both countries said they have *received assurances* from the company that its order won't affect other countries' procurements, *in particular its partnership with COVAX*. See: A. Isaac, J. Deutsch, *UK to import vaccine doses from India amid global jabs race*, 2 March 2021.; https://www.politico.com/newsletters/global-pulse/2021/03/04/vaccine-supplier-to-the-poor-lands-new-clients-the-rich-491980 (27 May 2023).

Although India has been called for years *the pharmacy of the developing world*, the shortfalls experienced during the pandemic make it necessary to rethink whether having one main supplier for half of the world can provide health security.

6.7.1.2. Missing manufacturing capacity and procurement policy

Indeed, among the factors contributing to unequal access to medical countermeasures is the lack of distributed production capacity in developing countries. Who controls the technology and where production takes place has a direct impact on who has access to the final product.

Currently, only about 1 per cent of all vaccines used in Africa are produced on the continent. The African Union launched its Partnerships for African Vaccine Manufacturing (PAVM) last year which aims for African nations to produce 60 per cent of all vaccines used in Africa by 2040 (see Chapter 7.7.5.3.1.).

The lack of solidarity and cooperation to diversify global manufacturing can be exemplified by the EU's stance. As discussed in Chapter 6.2., the EU *Vaccines Strategy* was centred around boosting development and production capacity in Europe. As a result, the EU has become the largest COVID-19 vaccine producer[417] and exporter[418], while African countries have been almost entirely dependent[419] on imports.

In May 2021, Team Europe pledged over €1 billion to foster the production and access to health technologies in Africa.[420] In March 2022, the EU also announced it would provide the African Union with €24.5 million to increase its vaccine manufacturing.[421] However, despite its financial support and calls for equity, solidarity and cooperation, the EU has never diverted from putting its political and commercial interests ahead of

[417] European Council, *"Impatience with vaccinations is legitimate, but should not blind us," warns President Michel*, 9 March 2021.; https://www.consilium.europa.eu/en/european-council/president/news/2021/03/09/20210309-pec-newsletter-6-vaccines/ (27 May 2023).

[418] European Commission, *EU replaces COVID-19 vaccines export authorisation mechanism with new monitoring tool*, Press release, 26 November 2021.; https://ec.europa.eu/commission/presscorner/detail/en/ip_21_6283 (27 May 2023).

[419] A. Irwin, *How COVID spurred Africa to plot a vaccines revolution*, Nature, 21 April 2021.; https://www.nature.com/articles/d41586-021-01048-1 (27 May 2023).

[420] European Commission, *€1 billion Team Europe initiative on manufacturing and access to vaccines, medicines and health technologies in Africa*, Press release, 21 May 2021.; https://ec.europa.eu/commission/presscorner/detail/en/ip_21_2594 (27 May 2023).

[421] European Commission, *EU strengthens partnership with WHO to boost local manufacturing and access to vaccines, medicines and health technologies in Africa*, Press release, 24 March 2022.; https://ec.europa.eu/commission/presscorner/detail/en/ip_22_1970 (27 May 2023).

improving developing countries' capacity. As noted above, the EU has not supported the WHO C-TAP mechanism and has consistently opposed proposals for compulsory technology transfer, most importantly the TRIPS waiver. While declaring its support for homegrown production in developing countries, the EU has persistently protected the ownership of EU-based industry over relevant technologies and promoted voluntary bilateral agreements between companies as the preferred way to scale up production. As a result, even though supporting developing countries in building manufacturing facilities, the EU ensures that control over the technology developed remains in the hands of European corporations.

While diversified production is a prerequisite for greater autonomy in the supply of medical countermeasures, it will only be able to succeed if supported by appropriate procurement policies making production facilities sustainable (see Chapter 7.7.6.). The procurement model used by COVAX, however, has been counterproductive in achieving this goal.

As discussed, COVAX has placed orders for 2.1 billion doses of COVID vaccines but not a single one has been ordered from Aspen Pharmaceuticals, the first company in Africa to produce COVID-19 vaccines. Although it shifted its production and achieved the capacity to produce more than 200 million doses of the one-shot Johnson & Johnson vaccine annually, it has been omitted by COVAX, according to its Senior Director.[422]

South African President Cyril Ramaphosa stated at the COVID-19 summit that progress in vaccine manufacturing on the continent *may be reversed* because international agencies *are not buying vaccines from African vaccine manufacturers even for vaccines that are destined for African countries*.[423]

6.7.2. Paying for undelivered doses

The far greater bargaining power of private companies than governments in the current system and the deep flaws in COVAX's structure, including having to compete with rich countries for vaccine doses, are evident in the aftermath of the procurement process and the situation in which Gavi found itself in early 2023.

[422] S. Jerving, *System 'skews' against African vaccine producers: Africa CDC deputy*, Devex, 5 May 2022.; https://www.devex.com/news/system-skews-against-african-vaccine-producers-africa-cdc-deputy-103181 (27 May 2023).
[423] *Ibidem*.

By 2023, nearly 1.9 billion doses have been delivered through COVAX. The manufacturers collectively made $13.8 billion in revenue from them. However, many of the doses were delivered with significant delays. In 2021, when COVAX began allocating them to developing countries, pharmaceutical companies ignored its orders and significantly undersupplied them.

In December 2021, the WHO's Independent Initiative on Vaccine Allocation Group (IAVG) confirmed that pharmaceutical companies not only failed to prioritise supplies to COVAX but actually violated their contractual obligations with it. IAVG stated that *not all expected doses from COVAX advance purchase agreements (APAs) have been honoured by vaccine producers according to contractual obligations*.[424]

Pharmaceutical companies have clearly under-delivered vaccine doses to COVAX at times when they were most needed. For example, Gavi ordered 150 million doses from Johnson & Johnson, but while it expected to receive a significant portion of that order at the peak of the pandemic, the company had delivered less than 4 million doses by the end of 2021.

Vaccines began to reach the mechanism in greater quantities only after the peak of the infections had passed. COVAX's often unpredictable, uncoordinated and unaccountable (to national governments) vaccine allocation process caused difficulties in the distribution and effectiveness of the immunisation campaigns.

Moreover, by not getting vaccines when they were most needed, but only when rich countries had many of them left unused, demand in the Global South weakened significantly, further depleted by waves of misinformation. This resulted in an oversupply to COVAX at a time when the pandemic had subsided, and demand had declined.

Gavi, therefore, made attempts to cancel pre-ordered doses and recover prepayments. However, some companies were not willing to renegotiate. As reported by the New York Times, Gavi wanted to recoup $2.3 billion for doses it no longer needed, but as of February 2023, pharmaceutical companies had refused to return $1.4 billion in

[424] WHO, *Achieving 70% COVID-19 Immunization Coverage by Mid-2022*, Statement of the Independent Allocation of Vaccines Group (IAVG) of COVAX, 23 December 2021.; https://www.who.int/news/item/23-12-2021-achieving-70-covid-19-immunization-coverage-by-mid-2022#_ftn11 (27 May 2023). In this case, it is also argued that such contractual violations would be less likely if the agreements would not be confidential, but publicly known and scrutinized – See: Human Rights Watch, *COVAX: Enhance Transparency, Share Intellectual Property*, HRW, 6 May 2021.; https://www.hrw.org/news/2021/05/06/covax-enhance-transparency-share-intellectual-property (27 May 2023).

advances for cancelled doses.[425] Some companies, such as the Serum Institute of India and several Chinese manufacturers, agreed to cancel unnecessary doses but retained some $700 million in prepayments. With Moderna, for example, Gavi has agreed, among other things, to retain a $58 million credit for future products, through 2030.

Other companies, however, have been far less receptive to Gavi's arguments. Johnson & Johnson, mentioned above in the context of supply delays, has been producing doses for COVAX even after Gavi informed the company that it would not need them and then demanded payment for them (over and above what was prepaid).

In this case, the company benefited from an advance purchase agreement with Gavi, delayed the delivery of vaccines to the mechanism to satisfy rich countries' markets in a quicker timeframe, and then forced the organisation to pay for pre-ordered doses that have no longer been needed.

This can serve as evidence of the advantage companies have under the existing model when negotiating contractual terms during crisis situations. Under contracts with Gavi, companies have not been required to refund prepayments for doses subsequently cancelled. Some contracts have also not included strict deadlines by which specific batches of vaccines should have been delivered.

6.7.3. A *go-to place* for the industry and Global North countries

Scholars identified three key features of the COVAX model as a *super-PPP* that primarily led to its failure.

First, it ceded the responsibility for the mechanism to existing PPPs, which operate in a fragmented global health field with very limited public representation, transparency and accountability. Second, it based the mechanism on a market model, dependent on donors and voluntarism, and scaled it to serve not just the least developed countries, but everyone, disregarding the divergent interests and powers of the Global North and Global South governments. Third, its level of complexity obfuscated the wide disparities in the mandate and public accountability among its constituent partners, leaving private companies with outstanding power.[426]

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[425] S. Nolen, R. Robbins, *Vaccine Makers Kept $1.4 Billion in Prepayments for Canceled Covid Shots for the World's Poor*, the New York Times, 1 February 2023.; https://www.nytimes.com/2023/02/01/health/covid-vaccines-covax-gavi-prepayments.html (27 May 2023).

[426] K. T. Storeng, *COVAX and the rise…, op. cit.*

The model of creating voluntary partnerships between public and private actors to solve public health problems has long been criticised. It can be argued that the failure of COVAX may lead to an effective questioning of the validity of this approach.[427] Lessons learned from the strengths and weaknesses of ACT-A should lead to a permanent, global, and inclusive platform based on a pre-negotiated system, as called for by the Independent Panel for Pandemic Preparedness and Response.[428]

It is often argued that COVAX was imperfect and riddled with various design and management flaws, but nevertheless, its creation was beneficial because without the mechanism the Global South countries would be even worse off.[429]

As discussed above, COVAX, and ACT-A as a whole, were conceived at a certain point in the pandemic when the need for any mechanism to accelerate research and development and production of vaccines, as well as to ensure equitable access to them, was evident.

Its creation, however, conflicted with other initiatives such as C-TAP (for R&D and manufacturing) and potentially other democratic and inclusive mechanisms that could have been created to ensure equitable access but did not materialise due to the formation of ACT-A. It can be argued that evaluating the results of COVAX is not a zero-sum game – COVAX has been able to provide some benefits to some countries but has also prevented other mechanisms from succeeding or even emerging.

As Zaitchik points out, COVAX has become a *go-to place* for pharmaceutical companies, enabling them to speak out against C-TAP and claim that there is no need to think about any other solution. If there were no COVAX, it would be much harder for the industry to argue against the voluntary sharing of patents and technologies, and for rich countries to claim there is no need to ease the existing international intellectual property rules as proposed in the TRIPS waiver. The fact that COVAX was created, allowed political

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[427] J. L. Ravelo, *Is COVAX part of the problem or the solution?,* Devex, 11 March 2021.; https://www.devex.com/news/is-covax-part-of-the-problem-or-the-solution-99334 (27 May 2023).

[428] The Secretariat for the Independent Panel for Pandemic Preparedness and Response, *Access to Vaccines, Therapeutics, and Diagnostics*, Background Paper 5, May 2021, p. 13.; https://theindependentpanel.org/wp-content/uploads/2021/05/Background-paper-5-Access-to-vaccines-Therapeutics-and-Diagnostics.pdf (27 May 2023).

[429] E.g., Dr Alakija, WHO Special Envoy for the Access to ACT-A: *As flawed as it was, it is the only mechanism that exists that was end-to-end. … What you need to do is look at the counterfactual, what would have happened if we didn't have the accelerator? It was flawed in its execution. But we got the products. But we failed on equitable access*. See: A. Buyatnal, *Dr. Ayoade Alakija: 'ACT-A is not winding down'*, Devex, 22 September 2022.; https://www.devex.com/news/dr-ayoade-alakija-act-a-is-not-winding-down-103976 (27 May 2023).

and industry leaders to point to it whenever they were asked what steps they were taking to ensure equitable access.

6.8. International intellectual property framework

6.8.1. The origins of the current regime

The failure of C-TAP and ACT-A arising from the structure prevailing in global health and driven by the forces of commercial markets demonstrates the inadequacy of the current system. Global inequalities in access to medical countermeasures are an inherent part of it with its policies and laws.

In order to understand how the latter, with the intellectual property regime at its core, is oriented towards the needs and interests of wealthy countries and the pharmaceutical industry they host, it is important to trace its development reflecting the power dynamics.

6.8.2. Brief history of empowering and weakening Global South countries

In the mid-20th century, the position of the Global South countries at the international level was much stronger than today.

In the 1960s, they were united and spoke with one voice as part of a coalition called the Group of 77 (G77), which emerged from the *Non-Aligned Movement* formed a decade earlier, reflecting the political identity of the Global South.

In the 1970s, Nehru-ruled India challenged the recognition of U.S. medicine patents, after American pharmaceutical companies were found to be charging the highest margins in the Global South countries, and began to develop its own, independent generic industry.[430]

As People's Health Movement campaigner, Prabir Purkayastha put it, *Nehru's vision represented an especially fearsome threat [to the Big Pharma companies]: A developing country with its own scientific institutions, cutting-edge capacity, no patent*

[430] A. Zaitchik, *Owning*, *op. cit*., p. 205.

protection, and factory lines that could provide pharmaceuticals to its own huge internal market and other developing countries.[431]

At the UN level, the G77 has pursued its agenda to facilitate technology transfer between rich countries and the Global South without intellectual property barriers. In 1974, the group spearheaded the adoption of a UN declaration calling for a *new international economic order*, stressing, among other things, that patents and knowledge monopolies are *the greatest obstacles to the full emancipation and progress of developing countries*. Four years later, the WHO called in the Alma-Ata Declaration for the establishment of a mechanism to help G77 countries become self-sufficient, spelling out the principle that *health as a human right based on equality and social justice*.

The progress toward greater access to medical technologies made by the Global South movement threatened to undermine Big Pharma companies' business model. Above all, it was of particular concern to the powerful U.S. pharmaceutical industry, which, led by Pfizer's CEO Edmund T. Pratt Jr., launched a campaign against this agenda. The industry hoped to counter the G77's calls for technology transfer by building support for the protection of intellectual property rights at the UN level and lobbied for the U.S. government to lead the effort.

While it succeeded in the latter (in 1979, U.S. President Carter named Pratt to the Advisory Committee for Trade Policy and Negotiation), it failed in the former. The U.S. was isolated on the matter in the 1970s. Zaitchik notes that *the U.S. patent lobby was taken aback by the unity and strength of the G77 negotiating position*.[432]

Big Pharma companies' internal lobbying in the U.S. gained significant momentum with the election of Regan as U.S. President and the creation of a joint industry-White House cooperation, which led to the desired policy shift at the international level.[433]

In the 1980s, the Regan administration working in tandem with the U.S. industry attempted to globalise the U.S. patent system. They realised that institutional changes in the architecture of the multilateral organisations might be necessary to achieve their goal. As noted by Zaitchik, *because the UN gave too much leverage to the G77 and its bureaucratic allies, a less democratic forum was needed. If such a forum did not exist, it*

[431] Cited after: A. Zaitchik, *Owning*, *op. cit*., p. 206.
[432] A. Zaitchik, *Owning*, *op. cit*., p. 209.
[433] A. Zaitchik, *Long, Strange TRIPS: The Grubby History of How Vaccines Became Intellectual Property*, The New Republic, 1 June 2021.; https://newrepublic.com/article/162527/long-strange-trips-grubby-history-vaccines-became-intellectual-property (27 May 2023).

would have to be created.[434] The U.S. has therefore begun calling for a new framework and a new global trade rule-setting body to better serve its interests.

These calls have been finding increasingly fertile ground. The group of developing countries was already much weaker in the 1980s than a decade earlier. The G77's position was heavily influenced by the debt crisis and the changing global economic order. Global South began to tie itself economically to wealthy countries through globalised trade, for example, by selling raw materials and textiles to the Global North. Zaitchik observes that more than 100 countries have increased their trade with the U.S. during this decade.[435]

The weakening position of the G77 has been aggravated by the policies of the World Bank and the International Monetary Fund, as well as the diminishing role of UN agencies such as the United Nations Conference on Trade and Development (UNCTAD), which has shifted from an advocate of structural reforms in the Global South to a limited technocratic role. Close economic ties and loss of institutional support have put developing countries in a vulnerable position.

This was to the advantage of the US, which in the 1980s was able to bring about changes in the global trade order by expanding the international intellectual property framework. It started with internal policies and regulations, for example, by amending Section 301 in the U.S. Trade Act of 1974, which created a new instrument, known as *Special 301*, that allowed the country to impose retaliation on their partners for non-compliance with intellectual property obligations.

This mechanism is meant to curb any attempt to not fully enforce intellectual property rights granted in the U.S. and is prominently used to this day.[436] For example, in 2016, the U.S. threatened Colombia with the cancellation of a bilateral trade agreement and withholding diplomatic and financial support for its peace deal with the FARC rebels if the country violated patents for an expensive cancer treatment marketed by Novartis.[437]

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[434] A. Zaitchik, *Owning, op. cit*., p. 209.

[435] *Ibidem*, p. 210.

[436] The U.S. pharma industry annually prepares the "Special 301 Submission" made at the *World Intellectual Property Day*, a holiday established by the industry-backed WIPO, pointing out any issues in the matter and calling out the U.S. government to pressure the countries. Interestingly, this is not only used against developing countries but halt any kind of measures that threaten the current system. In 2021, PhRMA pressured the U.S. administration *to continue to seek assurances that the problems (…) are quickly and effectively resolved*, referring to different measures included in the Commission's Strategy that the industry perceives as a threat to maintaining the current highly profitable status quo. See: PhRMA, Special 301 Submission 2021 p. 241-244.; https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/P-R/PhRMA_2021-Special-301_Review_Comment-1.pdf (27 May 2023).

[437] E. Silverman, *Colombia plans to proceed with price cut on Novartis cancer drug*, STATNEws, 16 September 2016.; https://www.statnews.com/pharmalot/2016/09/16/colombia-cutting-price-novartis-gleevec/ (27 May 2023).

The first major use of *Section 301*, however, was to weaken the position of the five main opponents to the projects of the proposed international Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement. The opposition was eventually broken, for example, by imposing tariffs on these countries' exports to the US.

Thus, the US, in the end, supported by other wealthy countries, led to the creation of the World Trade Organization (WTO) and the adoption of the TRIPS Agreement in 1994.

6.8.3. TRIPS Agreement

To outweigh the costs of the expanded intellectual property protection introduced in the Global South, the TRIPS Agreement was based on the promise of technology transfer from high-income countries to low-income countries and the creation of R&D activities in the latter. According to Article 66.2 of TRIPS, high-income countries *shall provide incentives to enterprises and institutions in their territories for the purpose of promoting and encouraging technology transfer to least-developed country Members in order to enable them to create a sound and viable technological base.*

The TRIPS Agreement was also based on the promise to create social benefits for all. At observed by ‘t Hoen, *Article 7 acknowledges that the protection and enforcement of IP should benefit society as a whole, not only rights holders. It describes the IP system as a social policy tool rather than a means to gather and hold on to assets. It refers explicitly to technology transfer and dissemination of technology*.[438]

Furthermore, Article 8 of TRIPS recognises the rights of countries to take measures to protect the public interest, particularly public health and acknowledges that countries may need to prevent abuse by intellectual property rights holders and any practices that restrain trade or adversely affect technology transfer.

[438] E. ‘t Hoen, *VIEWPOINT Protecting Public Health through Technology Transfer: The Unfulfilled Promise of the TRIPS Agreement*, HHR, Volume 24/2, December 2022, p. 211-214.; https://www.hhrjournal.org/2022/12/viewpoint-protecting-public-health-through-technology-transfer-the-unfulfilled-promise-of-the-trips-agreement/ (27 May 2023).

The former has been confirmed and reinforced by the Doha Declaration on the TRIPS Agreement and Public Health, adopted by the WTO Ministerial Conference in 2001.[439]

The reality brought about by the new international IP framework, however, turned out to be much different. According to the World Bank estimates, the implementation by developing countries of the stringent intellectual property protections required by TRIPS resulted in more than $20 billion in revenues being transferred to high-income countries (particularly the United States, Germany and France) between 1994 and 2002 alone.[440]

The first large-scale impact of the new law on access to medicines in the Global South became apparent during the HIV/AIDS pandemic in the 1990s.

In the late 1990s, HIV/AIDS was the leading cause of death in Africa, but access to affordable antiviral drugs was limited due to strict intellectual property laws introduced by TRIPS. Equipped with the new intellectual property framework, the pharmaceutical industry refused to lower prices for *azidothymidine* (known as AZT) and other antiviral drugs on the continent where the disease was most prevalent.

Reacting to the dire situation, in 1997, the South African government passed the Medicines Act, giving the Ministry of Health the authority to produce, purchase and import generic drugs, including the antivirals. The Indian company Cipla offered to supply generic versions of these drugs more than 10 times cheaper than Big Pharma companies.[441] In response, more than three dozen multinational pharmaceutical companies filed a lawsuit against the government, accusing it of violating its TRIPS obligations. South Africa was further pressured by the U.S. to withdraw the law.

However, as the health situation on the continent worsened, the Mandela government did not back down and allowed the case to go to court. Intense public outrage and a growing international scandal put the companies in a harsh light. Under pressure, the industry quietly withdrew its lawsuits. It was a symbolic win that shed more light on how

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[439] Fourth WTO Ministerial Conference, Doha Declaration on the TRIPS Agreement and Public Health, WT/MIN(01)/DEC/2 (2001); See: E. 't Hoen, *TRIPS, Pharmaceutical Patents, and Access to Essential Medicines: A Long Way from Seattle to Doha*, Chicago Journal of International Law 3, 2002.; https://chicagounbound.uchicago.edu/cjil/vol3/iss1/6/ (27 May 2023).

[440] World Bank, *Global Economic Prospects and the Developing Countries*, 2002.; https://documents1.worldbank.org/curated/en/285571468337817024/310436360_20050012014722/additional/Global-economic-prospects-and-the-developing-countries-2002-making-trade-work-for-the-worlds-poor.pdf (27 May 2023).

[441] D. G. McNeil Jr., *Indian Company Offers to Supply AIDS Drugs at Low Cost in Africa*, The New York Times, 7 February 2001.; https://www.nytimes.com/2001/02/07/world/indian-company-offers-to-supply-aids-drugs-at-low-cost-in-africa.html (27 May 2023).

TRIPS is a barrier to access and led to the adoption of the above-mentioned Doha Declaration in 2001.

6.8.4. Doha Declaration and TRIPS flexibilities

The Doha Declaration clarified the TRIPS Agreement's Article 30 on exceptions and Article 31 on licenses and expanded the tools, so-called *TRIPS flexibilities*, that allow countries to mitigate the negative impact of intellectual property on access to medicines in order to protect public health interests.

The Doha Declaration stresses that TRIPS *can and should be interpreted and implemented* to support the *right to protect public health [and] promote access to medicines for all*, including the sovereign determination of the grounds on which a compulsory license may be issued.[442]

These rules provide WTO members with a broad spectrum of tools that can be used to remove any intellectual property barriers that may frustrate their efforts to expand access to medicines.[443] These include, (1) the compulsory license system, including government use for non-commercial purposes (Article 31 TRIPS)[444]; (2) production for export exception (Article 30 TRIPS)[445]; (3) the parallel importation of products manufactured under a compulsory license (Article 6 TRIPS); (4) rigorous standards for the examination of patent applications in order to avoid excessively broad or unwarranted protection over products and manufacturing processes (Article 27 TRIPS)[446]; (5) public interest/public

[442] Declaration on the TRIPS Agreement and Public Health, WT/MIN(01)/DEC/W/2, adopted on 14 November 2001. See also: UNDP, *Good Practice Guide: Improving Access to Treatment with Flexibilities in TRIPS*, 31 October 2015.; https://www.undp.org/publications/good-practice-guide-improving-access-treatment-flexibilities-trips (27 May 2023).

[443] UNAIDS, *TRIPS flexibilities and access to antiretroviral therapy: Lessons from the past, opportunities for the future.* UNAIDS, Technical Brief, 2011.; https://www.unaids.org/sites/default/files/media_asset/JC2260_DOHA+10TRIPS_en_0.pdf (27 May 2023).; See also: J. Love, *The Quad WTO proposal on COVID 19 and TRIPS proposal is tied for the 5th best option for exports*, 16 March 2022.; https://jamielove.medium.com/the-quad-wto-proposal-on-covid-19-and-trips-proposal-is-tied-for-the5th-best-option-for-exports-dd8f165efdee (27 May 2023).

[444] See: C. M. Correa, G*uide for the Granting of Compulsory Licenses and Government Use of Pharmaceutical Patents*, Research Paper, No. 107, Geneva, South Centre, 2020.; https://www.southcentre.int/research-paper-107-april-2020/ (27 May 2023).

[445] See: C. M. Correa, J. I. Correa, *Manufacturing for Export: A TRIPS-Consistent Pro-Competitive Exception*, Research Paper, No. 155, Geneva, South Centre, 2022.; https://www.southcentre.int/research-paper-155-27-may-2022/ (27 May 2023).

[446] S. S. Ravi, *Patent Analysis for Medicines and Biotherapeutics in Trials to Treat COVID-19*, Research Paper, No. 153, Geneva, South Centre, 2022.; https://www.southcentre.int/wp-content/uploads/2022/04/RP153_Patent-Analysis-for-Medicines-and-Biotherapeutics-in-Trials-to-Treat-COVID-19_EN-1.pdf (27 May 2023).; See also: South Centre, South

health exception to trade secrets/confidential information (Article 39.2 TRIPS); or (6) exception to allow disclosure of manufacturing-related data (Article 39.3 TRIPS). In case of an emergency such as the COVID-19 pandemic countries can also use (7) the national security exception contained in Article 73(b) TRIPS, that would suspend the obligations in relation to any COVID-19 related products.[447]

In practice, however, the use of these tools is constrained by power and political dynamics.

6.8.4.1. Power dynamics in the use of *TRIPS flexibilities*

As discussed in Chapter 6.2., the political realities of rich and poor countries differ significantly, and while international rules may look equal on paper, the imbalance of power in global trade and in intellectual property rights ownership make their practical application incomparable.[448] Arguments that the TRIPS flexibilities provide all members with sufficient freedom to adapt their national laws so that IP rights do not have a detrimental effect on public health ignore these circumstances. The fact that rich countries, for example, are able to get access to relevant products through compulsory licensing, does not mean that other countries are also in a position to do so.[449]

Existing patent thickets, inconsistencies between patent laws, pharmaceutical regulations and data protection, the discouragement to use compulsory licences or even threats of trade sanctions, are the reality faced by developing countries.[450]

Centre and Patent Offices from developing countries gather to share experiences on intellectual property and public health, South News, No. 391, December 2021.; https://us5.campaign-archive.com/?u=fa9cf38799136b5660f367ba6&id=98a5ad03b9 (27 May 2023).

[447] See: F. Abbott, *The TRIPS Agreement Article 73 Security Exceptions and the COVID-19 Pandemic*, Research Paper, No. 116, Geneva, South Centre, 2020.; https://www.southcentre.int/researchpaper-116-august-2020/ (27 May 2023). In addition, the TRIPS Agreement exempts the WTO's Least Developed Countries (LDCs) from implementing its substantive provisions during an agreed transition period, which is extendable upon application. As of February 2023, there are 35 LDC Members of the WTO: https://www.wto.org/english/thewto_e/whatis_e/tif_e/org7_e.htm#:~:text=They%20are%3A%20Bhutan%2C%20Comoros%2C,%E2%80%9D%20or%20%E2%80%9Cdeveloping%E2%80%9D%20countries (27 May 2023). LDCs enjoy an extended transition period for granting and enforcing pharmaceutical patents and data protection, at least until 2033. See: E. 't Hoen, *Scaling-up Vaccine Production Capacity…, op. cit.*, p. 3.

[448] P. Patnaik, *Understanding…, op. cit.*

[449] *Ibidem*.

[450] See e.g.: Timeline for US-Thailand Compulsory License Dispute, Version 3, April 2009.; http://infojustice.org/wp-content/uploads/2012/11/pijip-thailand-timeline.pdf (27 May 2023).; See also: A. Oser, *The COVID-19 Pandemic: Stress Test for Intellectual Property and Pharmaceutical Laws*, GRUR International, Volume 70, Issue 9, September 2021, p. 846–854.; https://academic.oup.com/grurint/article/70/9/846/6323988?login=true (27 May 2023).

K. M. Gopakumar, a legal adviser on intellectual property, points out that *as soon as countries began to use the flexibilities, there was a pushback. (…) You can go down the list, from Thailand to Colombia, countries that seek to issue compulsory licenses face political pressure from the EU and the U.S., the legal wrath of the drug companies, and joint pressure demanding they ratchet up the TRIPS standards. It's a human rights violation that's all about defending the high prices on these patented drugs. For many countries, the Doha flexibilities only exist on paper*.[451]

An indication of how skewed the current system is and how far it has deviated from serving the public interest can be illustrated by the fact that during the COVID-19 pandemic, when the Dominican Republic government wanted to issue a compulsory license on Pfizer's patent on the best available treatment against the virus, the company argued that their intellectual property on the drug was a human right.[452]

6.8.4.2. Example of Biolyse case

One of the recent examples of failure to put the system of the *TRIPS flexibilities* into practice is the case of Biolyse, a Canadian manufacturer of sterile injectables, which contracted with Bolivia in May 2021 to produce doses of Johnson & Johnson's (J&J) COVID-19 vaccine.[453]

First, Biolyse requested J&J to license the rights to the vaccine so that it could be produced in Canada for 5 per cent royalties on shipments to developing countries.[454] The company, however, rejected the offer, refusing to negotiate.[455] Without J&J's permission to license the technology, Biolyse asked the Canadian government to issue a compulsory license, under a program called the Canadian Access to Medicines Regime, which allows

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[451] Cited after: A. Zaitchik, *Owning the sun, op. cit.*, p. 225.

[452] E. Silverman, *Pfizer faces criticism for arguing that intellectual property for its Covid-19 pill is a human right*, STATNews, 20 April 2022.; https://www.statnews.com/pharmalot/2022/04/20/patent-pfizer-covid19-patent-paxlovid-dominican-republic/ (27 May 2023).

[453] J. Crombie, *Intellectual property rights trump the right to health: Canada's Access to Medicines Regime and TRIPs flexibilities in the context of Bolivia's quest for vaccines*, Journal of Global Ethics, Volume 17, 2021, issue, 3, 10 September 2021, p. 353-366.; https://www.tandfonline.com/doi/full/10.1080/17449626.2021.1993452 (27 May 2023).

[454] See Biolyse's letter to Johnson and Johnson: https://www.dropbox.com/sh/zkzkialhe2jpxsj/AAD9sVMKTEOvvFpix7aMZI7Sa?dl=0&preview=2021-03-04+19.37.11.pdf (27 May 2023).

[455] Z. Brennan, *How to manufacture Covid-19 vaccines without the help of J&J, Pfizer or Moderna? Biolyse sees the difficulties up close*, EndpointsNews, 17 May 2021.; https://endpts.com/how-to-manufacture-covid-19-vaccines-without-the-help-of-jj-pfizer-or-moderna-biolyse-sees-the-difficulties-up-close/ (27 May 2023).

medicines and vaccines to be exported to low-income countries like Bolivia. However, the government refused to put COVID-19 on the list of diseases for which such a license can be issued. As put by Biolyse's EVP Fulton, *if a compulsory license system can't work now, during a worldwide pandemic, what's it for? What's the use?*[456]

Like Biolyse in Canada, companies such as Incepta in Bangladesh, Teva in Israel and Bavarian Nordic in Denmark offered to help produce vaccines during the pandemic but to no avail.[457]

As discussed in Chapter 5.5.7., there are various examples of the Big Pharma companies refusing to license their technologies, citing the complexity of the process, safety concerns and lack of time to carry out technology transfers.

6.8.5. TRIPS waiver proposal

Countries in the Global South facing a limited supply of COVID-19 medical countermeasures, the refusal of companies to share their technologies and IP rights to them, and the difficulty of using exceptions under the TRIPS Agreement to scale up production, have argued that international intellectual property rules should be temporarily waived.

Seeking waivers from certain WTO treaty obligations is possible under exceptional circumstances. If WTO members agree, they can then choose not to grant or enforce intellectual property rights related to certain, specific technologies.

A proposal for such a waiver has been submitted by India and South Africa on 2 October 2020.[458] It called for allowing all countries to choose to neither grant nor enforce certain kinds of intellectual property rights, including copyright, industrial design, patents or trade secrets related to all products relevant to tackling the pandemic, such as diagnostics, therapeutics, vaccines, medical devices, personal protective equipment, their materials and components for 3 years extended automatically unless there is a (consensus) decision to terminate the waiver.

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[456] *Ibidem*.

[457] A. Furlong, *Big vaccine makers reject offers to help produce more jabs*, Politico, 14 May 2021.; https://www.politico.eu/article/vaccine-producers-reject-offers-to-make-more-jabs/ (27 May 2023).

[458] WTO, *Waiver From Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment Of Covid-19*, Communication from India And South Africa, Council for Trade-Related Aspects of Intellectual Property Rights, 2 October 2020.; https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W669.pdf&Open=True (27 May 2023).

One of the arguments for the waiver raised by experts was that patents were never designed for use during global pandemics. Patents protect against competition and a pandemic requires global cooperation and sharing of technology to combat the virus with widely available vaccines and therapies.[459]

Greater cooperation on R&D and production scale-up would require the removal of legal as well as technological barriers. The waiver, if adopted, would provide the former. Freed from the legal threat, generic manufacturers could then seek technology and know-how from companies in the Global North (which could have been obliged to cooperate) or attempt to re-engineer products without their help (as the WHO's mRNA programme has done, see Chapter 7.7.5.1.).

However, under pressure from the pharmaceutical industry, high-income countries opposed the waiver.[460] The U.S. federal lobbying disclosures revealed that Pfizer spent at least $860,000 in 2022 on protecting the stringent intellectual property framework.[461]

For pharmaceutical companies, the main problem was not the waiver itself, which would allow circumventing IP rights on COVID-19 products (mainly because the Global North companies would still control the technology and know-how which would make it much harder for generic companies to compete effectively with them), but the precedent it would set.

Agreeing to override patents and other intellectual property rights in the face of a pandemic could put the entire international system built by wealthy countries since the 1980s in jeopardy. Adopting the waiver would amount to an admission that the existing regulations impede access to medicines, and it is reasonable to override them in order to protect public health. Although the waiver would apply only to the exceptional situation of a health crisis, any break in the current model could entail a domino effect.

The waiver proposal was supported by over 100 WTO members but blocked by wealthy countries such as the EU, the U.S., the U.K., Switzerland and Japan. In May 2021, the U.S. publicly supported a limited exemption only for vaccines, but then did nothing to achieve it.

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[459] See: https://twitter.com/ElsTorreele/status/1381731578552926209 (27 May 2023).

[460] WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) Waiver – See: https://s3.documentcloud.org/documents/20708987/trips-waiver-pharma-key-messages.pdf (27 May 2023).

[461] W. Bragman, *Pfizer Spends Big on IP Lobbying With Billions on the Line*, Sludge, 9 March 2023.; https://readsludge.com/2023/03/09/pfizer-spends-big-on-ip-lobbying-with-billions-on-the-line/ (27 May 2023).

A group of wealthy countries delayed and undermined the waiver proposal for more than a year and a half in the middle of the pandemic. Proponents of the waiver perceived it as a stonewalling tactic, aimed not so much at strictly opposing the waiver but at making sure it would not be adopted in its proposed form.

Corporate Europe Observatory revealed, based on minutes of the European Council meetings made available through a Freedom of Information request, that the EU's biggest concern during the negotiations was the potential PR repercussions of its opposition.[462] Countries such as Germany, France, Denmark, the Netherlands, Italy and Sweden, while agreeing with the EU's stance opposing the waiver proposal, were concerned about how it is received by the public, calling on the Commission to communicate *constructively* on the issue. At one meeting, the Netherlands praised the Commission for its engagement with members of the European Parliament, while Italy called for *more active external communication*.

After 18 months of negotiations, WTO members reached a very limited decision related only to vaccines in June 2022. [463] It addressed virtually only one barrier limiting generic vaccine exports and offered little to help with creating diversified vaccine production.

The decision has had very little impact on global vaccine manufacturing – in fact, no country has ever used it. However, experts agree that it could have had a much greater impact if it had covered therapeutics and diagnostic tests.

Although the outcome of the TRIPS waiver negotiations has been disappointing for the Global South countries and the access to medicines movement, the discussions in

[462] See: https://twitter.com/olivierhoedeman/status/1370019336694362121 (27 May 2023).

[463] See, e.g.: Medicines Law & Policy, *WTO Covid-19 TRIPS Decision: Some observations*, Medicines Law & Policy, 17 June 2022.; https://medicineslawandpolicy.org/2022/06/wto-covid-19-trips-decision-some-observations/ (27 May 2023); or J. Love, *The June 17, 2022 WTO Ministerial Decision on the TRIPS Agreement*, Knowledge Ecology International, 17 June 2022.; https://www.keionline.org/37830 (27 May 2023).
Read more about the negotiations: Third World Network, *Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of Covid-19* – See: https://www.twn.my/title2/intellectual_property/trips_waiver_proposal.htm (27 May 2023).; The Economist, *Mariana Mazzucato, Jayati Ghosh and Els Torreele on waiving covid patents*, The Economist, 20 April 2021.; https://www.economist.com/by-invitation/2021/04/20/mariana-mazzucato-jayati-ghosh-and-els-torreele-on-waiving-covid-patents (27 May 2023).; K. Perehudoff, E. 't Hoen, P. Boulet, *Overriding drug and medical technology patents for pandemic recovery: a legitimate move for high-income countries, too*, British Medical Journal, Volume 6, Issue 4, 2021.; https://gh.bmj.com/content/6/4/e005518 (27 May 2023).; MSF Access Campaign, *India and South Africa proposal for WTO waiver from intellectual property protections for COVID-19-related medical technologies*, Briefing Document, 18 November 2020.; https://msfaccess.org/sites/default/files/2020-11/COVID_Brief_WTO_WaiverProposal_ENG_v2_18Nov2020.pdf (27 May 2023).

multilateral fora, diplomatic meetings, media reports and private sector events that have taken place over the two years of its negotiations have brought about a significant change in the narrative on global access to medicines and intellectual property barriers to it. This has resulted in a consistent public outcry that has brought progress in understanding and talking about how IP rights impact global equality.

In the June 2022 decision, WTO members agreed to decide whether treatments and diagnostics should also be included in it by December 17, 2022. This deadline has, however, been missed as wealthy countries claimed they needed more time for internal investigations on whether to agree to the extension.

Delaying this agreement will continue until at least October 2023, when the U.S. International Trade Commission completes its own investigation into the need to extend the decision. Meanwhile, access to COVID-19 treatments remains out of reach for many in the Global South.

This shows that the approach of wealthy countries defending their own interests has not changed. A one-in-a-generation pandemic seems to have done little to change the perception among the leaders of these countries that the current system is not adequately adapted to ensure appropriate innovation and equal access worldwide.

6.9. Unmet hopes that COVID-19 pandemic will overturn the system

From broken promises of solidarity to choosing economic interests over expanding access to lifesaving medical tools worldwide, the global response to the COVID-19 pandemic has been a failure. Instead of becoming a watershed moment, leading to changes in the way things are done in the pharmaceutical sector, many leaders quickly reverted to their knee-jerk reactions and established habits.

Susan K Sell, a Professor of Political Science and International Affairs at George Washington University in the US, in an interview for the Geneva Health Files, admitted that she thought that *if there was a moment in time where we could really have the potential for a different approach to these issues, it was COVID-19. I was wrong*, adding that the outcome of the waiver negotiations has been *very disappoint[ing]*.[464]

[464] P. Patnaik, *Deconstructing the TRIPS Waiver Discussions: The Susan Sell Interview*, Geneva Health Files, 5 August 2022.; https://genevahealthfiles.substack.com/p/deconstructing-the-trips-waiver-discussions (27 May 2023).

In the same vein, Winnie Byanyima, the UNAIDS executive director stressed *COVID was the real moment for [breaking pharmaceutical monopolies, sharing of technology, IP and know-how]. It hasn't come…*

Similarly, Ameet Sarpatwari, an epidemiologist and lawyer at Harvard Medical School who studies drug-pricing regulation, notes that *if there were ever an opportunity* to change the economics of vaccine development, *this would have been it*. Instead, *it is business as usual*.[465]

While this crisis has provoked a great deal of debate and may bring tangible reforms in the long run, the inability to overthrow the status quo is certainly a missed opportunity.

[465] J. Hancock, *They Pledged to Donate Rights to Their COVID Vaccine, Then Sold Them to Pharma*, KFF HealthNews, 25 August 2020.; https://khn.org/news/rather-than-give-away-its-covid-vaccine-oxford-makes-a-deal-with-drugmaker/ (27 May 2023).

PART II – Reform proposals

Introduction

Transforming the medical innovation and access ecosystem

The public co-creates and is a major investor in health technologies but the market-based research and development model is by design unsuited to meet societal and medical needs. Governments, on their own and through multilateral initiatives, should therefore assume greater responsibility for defining directions for health innovation, ensuring access to it based on equity and human rights principles, and shaping the R&D ecosystem accordingly.[466]

This way, the public could reclaim its leadership in the development of and access to health technologies.

COVID-19 and previous pandemics have provided sufficient evidence that private economic interests should not drive global public health interventions. Public policies should resist the idea of continuing with the current system. Changing it must be an integral part of building effective health emergency preparedness and response mechanisms in the future.[467]

The public approach should no longer consist of handing out subsidies, monopoly protections and market commitments with no or few strings attached and limiting the role of states to *de-risking* and *fixing market failures*. The distinct roles, responsibilities, and liabilities of public and private actors should be reassessed[468] and the power dynamics between the two rebalanced, particularly given the unprecedented political influence achieved by the latter during the COVID-19 pandemic.[469]

While future health emergencies may look different than the COVID-19 pandemic, climate change and biodiversity loss are likely to make similar crises more frequent around the world in the future. It is, therefore, necessary to adopt a *just in case* model in the pharmaceutical sector (see also Chapter 5.5.2.), in which supply chains are resilient,

[466] M. Mazzucato, H. L. Li, *op. cit*., p. 2-4.
[467] E. Torreele, M. Kazatchkine, M. Mazzucato, *Preparing for the next pandemic requires public health focused industrial policy*, British Medical Journal Opinion, 1 April 2021.; https://blogs.bmj.com/bmj/2021/04/01/preparing-for-the-next-pandemic-requires-public-health-focused-industrial-policy/ (27 May 2023).
[468] M. Florio, *Biomed Europa: after the coronavirus, a public infrastructure to overcome the pharmaceutical oligopoly*, CIRIEC working paper 2020/08, April 2020.
[469] H. Kuchler, D. P. Mancini, D. Pilling, *op. cit.*

essential medicines stockpiled, and contingency plans and preparedness and response mechanisms developed by the public and private sectors.

In health emergencies, public response (including decisions on how and when vaccines and treatments are manufactured and distributed) cannot be based on the goodwill of private companies. While public-private cooperation plays an important role, it should be designed in a way that reflects the co-creation of value and a fair distribution of risks and rewards.[470]

Transforming this system can involve changing the ways in which health innovation is incentivised (putting an end to delivering unconditional financial gains to private companies whose investments diverge from public health needs and exacerbates global inequalities), knowledge is governed (reconceptualising the production and flow of knowledge[471]), and end products are manufactured, allocated, priced and accessed.

On the one hand, this includes changing the rules regulating the behaviour of private corporations operating in the pharmaceutical sector including by reforming their governance and altering their business model.

On the other hand, the state's capacity, approach and engagement in health innovation should be re-imagined, even including its direct involvement in the process, for example by creating public pharmaceutical companies.

Current discussions on enhancing critical pharmaceutical R&D and increasing access often limit to quick fixes (for example, by proposing to reserve a percentage of private companies' pandemic-related production for developing countries during health crises[472]). While short-term solutions are needed to quickly improve equitable access to medicines globally, the pharmaceutical system requires a profound overhaul to break the dependence of access to medicines on profit-driven strategies and charities.

One aspect central to all of the proposals is political leadership. The transformational changes must be based on the public sector's vision and commitment to take risks and invest significant resources to design and drive the work of public and private

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[470] M. Mazzucato, *Rethinking the social contract between the state and business: a new approach to industrial strategy with conditionalities*, UCL Institute for Innovation and Public Purpose, Working Paper (IIPP WP 2022–18), 2022.; https://www.ucl.ac.uk/bartlett/public-purpose/wp2022-18 (27 May 2023).

[471] Z. Rizvi, *Reclaiming Global Public Health*, Bill of health, Harvard Law, 20 September 2022.; https://blog.petrieflom.law.harvard.edu/2022/09/20/reclaiming-global-public-health/ (27 May 2023).

[472] WHO, Zero draft of the WHO CA+ for the consideration of the Intergovernmental Negotiating Body at its fourth meeting, 1 February 2023, Article 10.; https://apps.who.int/gb/inb/pdf_files/inb4/A_INB4_3-en.pdf (27 May 2023).

actors alike to create public value. Achieving this will also depend on the public sector's competence and strengthening the in-house capacity of public institutions (including decreasing reliance on external consulting companies and improving finance, governance, administrative processes and structures, monitoring and accountability).[473] The state would need to become an active, strategic investor and *creator and shaper of markets*.[474]

Strategic state's involvement in pharmaceutical R&D and access should be perceived as part of a broader health policy on universal access to quality health care.[475]

Mission-oriented policy

To achieve this goal, Mazzucato et al. propose a mission-oriented policy model.[476] Hekkert et al. define a mission-oriented approach as *an urgent strategic goal that requires transformative systems change directed towards overcoming a wicked societal problem*.[477]

Under this model, for pharmaceutical innovation, the state would set (through its specialised bodies and in consultation with experts and stakeholders) a public health agenda and R&D direction with clear and explicit objectives. This would include identifying unmet medical needs where innovation is of greatest value to the public, deciding on disease areas to be addressed and prioritised, allocating resources, setting milestones and targets and selecting – public, private or non-profit – collaborators (among multiple sectors) on pre-defined terms.

This does not only require setting the right strategies within public departments but also adapting the regulatory and policy framework to create the right environment for private innovation.

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[473] The WHO Council on the Economics of Health for All, *Governing health innovation for the common good*, Council Brief No. 1, 9 June 2021, p. 10.; https://cdn.who.int/media/docs/default-source/council-on-the-economics-of-health-for-all/councilbrief-no1_20210609_corr.pdf (27 May 2023).

[474] UCL Institute for Innovation and Public Purpose, *The people's prescription: Re-imagining health innovation to deliver public value*, IIPP Policy Report, 2018-10. London: IIPP, Global Justice Now, Just Treatment, STOPAIDS, October 2018, p. 31.; https://www.ucl.ac.uk/bartlett/public-purpose/sites/public-purpose/files/peoples_prescription_report_final_online.pdf (27 May 2023).

[475] The WHO Council on the Economics of Health for All, *Strengthening public sector capacity, budgets and dynamic capabilities towards Health for All*, Council Brief No. 4, 30 June 2022.; https://cdn.who.int/media/docs/default-source/council-on-the-economics-of-health-for-all/who_councileh4a_councilbrief4.pdf?sfvrsn=275a7451_3&download=true (27 May 2023).

[476] Understood as systemic public strategies to achieve specific goals with public value. See: UCL Institute for Innovation and Public Purpose, *The people's prescription, op. cit.* p. 24.

[477] M. P. Hekkert, *Mission-oriented innovation systems*, Environmental Innovation and Societal Transitions Volume 34, March 2020, p. 76-79.; https://www.sciencedirect.com/science/article/pii/S2210422420300010 (27 May 2023).

Medical innovation as part of broader economic and industrial policy

As observed by the WHO's Council on the Economics of Health for All, *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*.[478]

To achieve this, better coordination is needed between health and other policies to guide pharmaceutical R&D.[479] *Mission-oriented*, broad public policies may lay the foundations for economic growth that will have positive spillover effects across sectors.[480] A new *political economy* could deliver health innovation for the common good.[481] This requires a different public sector approach and a new narrative for health innovation.

The evident tensions between different policy objectives across sectors need to be identified, acknowledged and addressed, recognising that achieving health objectives may involve trade-offs. Too often, countries' trade or industrial policies sacrifice health goals for economic gain. This position should not continue. Trade policy should be based on health objectives, and potential risks of harm to the latter should be mitigated wherever possible.

When it comes to healthcare financing, a change in its conceptualisation should result in considering it a key long-term investment contributing to economic growth and resilience, rather than expenditure. This would require directing significant and sustainable public funding in a coordinated manner to productive investments[482] and enhancing mutually beneficial cooperation between public institutions, the financial sector, private industry, philanthropic organizations and academia that share a common understanding and purpose.

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[478] The WHO Council on the Economics of Health for All, *Governing health innovation, op. cit.* p.1.

[479] M. Mazzucato, H. L. Li, E. Torreele, *Designing Vaccines for People, Not Profits*, Project Syndicate, 1 December 2020.;https://www.project-syndicate.org/commentary/covid-vaccines-for-profit-not-for-people-by-mariana-mazzucato-et-al-2020-12 (27 May 2023).

[480] M. Mazzucato, Mission-oriented innovation policy: Challenges and opportunities, IIPP Working Paper 2017-01, September 2017.; https://www.ucl.ac.uk/bartlett/public-purpose/sites/public-purpose/files/moip-challenges-and-opportunities-working-paper-2017-1.pdf (27 May 2023).

[481] The WHO Council on the Economics of Health for All, *Governing health innovation, op. cit.* p.1.

[482] N. Lurie, *Urgent lessons from COVID 19… op. cit.*

Chapter 7. Redesigning the medical innovation system under current premises

7.1. Principles of public interest-based R&D model

A new approach to the development and access to health emergency-related medical innovation should address a lack of leadership in biosecurity R&D and the failure of the private sector to invest in this area (see, for example, Chapter 1.7.2.). In the current system, the industry works in silos, usually does not move beyond the use of its proprietary platforms and technologies (see Chapter 5.5.7.) and lacks mechanisms and practices for collaborative work.

Changing this requires an end-to-end system that, from basic research to clinical trials, manufacturing, procurement and the delivery of final products, is driven by the public interest and the goal of equitable and affordable access. It should shape the efforts of public and private actors, create a platform for cooperation, and ensure that technological advances are transformed into effective global health interventions in the most efficient manner. In the context of pandemics, the creation of such a system was recommended by the Independent Panel for Pandemic Preparedness and Response in May 2021.[483]

As countries have varying needs, preferences, capabilities, and political and economic systems, the models may differ in the way they organise activities, ownership and control of health technologies. In each case, however, public policy should be based on the following principles.

(1) Public governance and transparency.

The bodies responsible for the R&D of medical countermeasures should be fully publicly governed to ensure the identified directions of innovation will respond to real public health needs. Fully public governance allows for adequate cooperation with the private sector and coordination across the innovation chain to ensure the desired results are delivered and equally distributed.

[483] The Independent Panel for Pandemic Preparedness and Response, COVID-19: make it the last pandemic. May 2021.;https://theindependentpanel.org/wp-content/uploads/2021/05/COVID-19-Make-it-the-Last-Pandemic_final.pdf (27 May 2023).

To provide effective and equitably accessible medical innovation public policies should be guided by the principle of transparency in all activities. Transparency requirements should cover, among other things, the cost of R&D (including active pharmaceutical ingredients), manufacturing and marketing, public and philanthropic funding contributions, information on products' net prices as well as filed and granted patent and other forms of intellectual property protection. Another critical improvement of transparency is required for clinical trial data (including those with negative outcomes). It would improve patient safety, increase accountability among industry and investigators and protect the public's health and medical literature's integrity.[484]

Transparent (and participatory) management, democratic safeguards and decisions on, for example, public funding for research projects, interactions with private partners, or the selection of health threats to be addressed are essential to allow for public scrutiny, build trust and confidence in the R&D system and ensure accountability.

What is more, in the context of affordability, shedding light on the medicines' R&D costs and pricing would decrease information asymmetry between national authorities and pharmaceutical companies. It would increase governments' bargaining power and ultimately could lead to fairer prices. This can be achieved for example by including transparency conditions in procurement processes, public investments, and research cooperations. Adequate provisions obliging public bodies to include such conditionalities should be included in national laws, regional (like the EU) rules as well as at the international level (for example, in the *pandemic treaty* and other instruments addressing R&D beyond health emergencies).[485]

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[484] J. S. Ross, *Promoting Transparency in Pharmaceutical Industry–Sponsored Research, American Journal of Public Health*, January 2012, p. 72-80.; https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3319748/ (27 May 2023).

[485] What is more, research is usually published in academic journals behind paywalls. See more: S. Dattani, *The Pandemic Uncovered Ways to Speed Up Science*, Wired, 25 October 2022.; https://www.wired.com/story/covid-19-open-science-public-health-data/?utm_source=twitter&utm_medium=social&utm_campaign=onsite-share&utm_brand=wired&utm_social-type=earned (27 May 2023). Researchers tend to not share their data, which not only slows down the development but also makes it difficult to identify and correct errors – it takes around a year, on average, to retract a plagiarised paper. Greater access to data, for example by publicizing them in open access and collaboration between academics could have contributed to knowledge dissemination and accelerated innovation. See also: R. Dal-Re, C. Ayuso, *For how long and with what relevance do genetics articles retracted due to research misconduct remain active in the scientific literature*, Accountability in Research, Ethics, Integrity and Policy, Volume 28, 2021 - Issue 5, 30 October 2020, p. 280-296.; https://www.tandfonline.com/doi/full/10.1080/08989621.2020.1835479 (27 May 2023). Finally, better gathering, organising and analysing data in the pharmaceutical sector by strengthening contributions (from both public and private sources) to the WHO Global Observatory on Health Research and Development could increase and expand public capacities by providing

(2) A significant funding.

For such a mechanism to deliver on its expectations, it needs to be provided with substantial public resources. Only with a significant and flexible budget, can it be able to develop a long-term strategy, invest actively and widely in high-risk projects, terminate unsuccessful programmes, and reinvest.

Recognising that will be difficult to achieve a stable investment in R&D amid multiple economic and political crises, such as austerity, inflation and wars, to reserve a sufficient part of the public budget for this purpose, governments could agree at the international level, for example at the World Health Organisation (see Chapter 7.8.1.), to gradually increase their contributions in this area as an agreed % of their GDP.[486]

Beyond health emergencies and across borders, R&D joint ventures could be established to pool resources and undertake joint scientific initiatives. A network of regional funds guided by common principles, such as open access, knowledge sharing and providing access to end products as global public goods, could also be established, as suggested by Moon et al.

(3) The overarching objective of increasing health security should take precedence over any economic interests.

Increasing investment in and coordination of medical countermeasure R&D can have numerous positive economic impacts, such as a significant contribution to strengthening countries' or regions' overall competitiveness in health innovation and attracting private investment.

Undoubtedly, states should exploit the potential of increased R&D processes in this context. However, in no case must the economic objective take precedence over public health interest. The performance of the new mechanism must be judged by the benefits it brings to public health, not to business.

(4) Fair sharing of risks and rewards from the outset.

The R&D system should ensure equitable access to final end products. To make it possible, the sharing of risks and rewards of future innovations between the public and private actors must be fairly defined from the outset. Any agreement or partnership with

policymakers with a better overview needed to prioritise public investment and policy reforms. See: WHO, *Global Observatory on Health Research and Development*: www.who.int/observatories/global-observatory-on-health-research-and-development (27 May 2023).

[486] Global health committee suggested 0.01%. In 2017 Senator Bernie Sanders proposed a fund of 0.55% of U.S. GDP to reward researchers and developers for medical innovation for specific health objectives.

industry must be guided by the public interest and include conditions to ensure the availability and affordability of the developed technology, such as the provision of fair prices or broad access to technology and knowledge transfer.

7.1.1. Examples of public innovation institutes

Changing the innovation system based on these principles should be educated by previous and existing mechanisms across sectors.

These include the U.S. Defense Advanced Research Projects Agency (DARPA) and Biochemical Advanced Research and Development Authority (BARDA), which demonstrate how the public sector can steer and lead the development of ground-breaking innovation.[487]

For example, one aspect of DARPA's policy worth replicating is the agency's openness to *exploration of uncertain ideas* and risk-taking. Its scientists are encouraged to *conduct path-breaking research without pressure to produce results in the short term*.

The DARPA model was used in 2007 to create the Advanced Research Projects Agency-Energy (ARPA-E), leading the U.S. green investments. The agency does not conduct its own research but allows program managers (scientists and engineers on loan for 3-5 years from academia or industry) to fund technology development in the broader research community.[488]

BARDA, meanwhile, was established in 2006 to develop and procure medical countermeasures as part of U.S. public health emergency preparedness strategy. The agency funds R&D activities and stockpiles finished products ready for use in crises. During the COVID-19 pandemic, BARDA was responsible for leading the development of COVID-19 vaccines under the *Operation Warp Speed*.

BARDA is an example of a public authority that undertakes long-term, ambitious, joint ventures with private entities. One example of the agency's entrepreneurial activities is BARDA's Research, Innovation and Venture Division (DRIVe), which aims to strengthen the R&D of medical countermeasures also by investing in public and private companies. As part of DRIVe, in 2021, a new public-private partnership, BARDA

[487] UCL Institute for Innovation and Public Purpose, *The people's prescription, op. cit.* p. 32.

[488] E. R. H. Fuchs, *Cloning DARPA successfully: Those attempting to copy the agency's success in advancing technology development first better be sure they know how DARPA actually works*, Issues in Science and Technology, 26(9), 2009, pp. 65–70.

Ventures, was established between the agency and the non-profit organization Global Health Investment Corporation (GHIC), to accelerate development and commercialisation of technologies and medical products needed to prevent or respond to health crises.[489]

The risk of failure is built into the agency's operation.[490]

These examples show the face of a state that is able to act in an entrepreneurial manner, like a wise but bold investor. They also show that states do not have to limit their role to funding alone, but can foster collaboration, open access and knowledge sharing while identifying complementarities between different initiatives and policies.

Such an approach is supported by Moon et al., who also recommend that governments consider investing in small and medium-sized enterprises (SMEs), tying their financing to the requirement of fair prices and transparency.[491] As they further argue, SMEs are a particularly suitable target for the purpose of public investment because they are widely dispersed – unlike Big Pharma companies – and reliant on outside investors to undertake research and development, especially at a later stage.

The U.S. agencies' models have been analysed and replicated in other regions. For example, BARDA's approach has been mirrored by the EU in the creation of HERA, the EU Health Emergency Preparedness and Response Authority in 2021. The capacity, autonomy and budget of the latter are, however, much smaller.

While the U.S. agencies provide many positive examples of bolder action, greater investment and leadership on the part of the public sector, the rules governing their activities and internal practices are not well suited to sufficiently protect the public interest. Too often public investments and research developed by the agencies are privatised limiting their use. Similarly, there are times when state-led public-private partnerships do not fairly reflect public contributions.

While BARDA may be praised for its significant role in advancing biomedical innovation, it has failed in protecting public interests in the process. For example, although regulations grant the agency the *march-in* rights to the publicly financed technologies so that BARDA can take control of intellectual property rights to them if they are not made available on *reasonable terms*, the agency has never exercised this option despite various

[489] See: Drive's website: https://drive.hhs.gov/ventures.html (27 May 2023).
[490] An example of such a failure is the Innovation Centers for Advanced Development and Manufacturing (CIADM).
[491] S. Moon et al., *New Business Models, op. cit.,* p. 45.

situations that required doing so.[492] What is more, in the agency's contracts with pharmaceutical companies for the development and production of COVID-19 vaccines – despite record public funding – BARDA has even agreed to either remove or narrow the circumstances under which the *march-in* rights could be invoked.[493] Effectively, the current political and legal system in which the agency operates often results in the privatisation of public resources and knowledge.

Based on these lessons, for any R&D mechanism, an overarching policy for managing the innovation developed within its framework is critical to ensuring public return on investment, which should be measured by the suitability, efficacy, affordability, and availability of the final end products.

7.2. Subjecting all forms of public investment to concrete commitments

Although the public-interest objectives discussed above can be best achieved through an end-to-end system, a first step toward achieving them can be taken even without new structures or initiatives, but only by attaching specific and strict conditions to public funding for pharmaceutical R&D.

The public sector is already a major investor in medical technology (see, for example, Chapter 3.1.) and, based on the models discussed further below, its role in this area should grow even bigger. To ensure the effectiveness and sustainability of these investments, they must be targeted at clear goals and conditioned on recipients meeting requirements consistent with those objectives.[494] States should use conditionalities to shape and target public funding to maximise its public value.

Such conditions should ensure that products developed (entirely or partially) with public money are priced fairly so that people can afford the medicines they helped develop.

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[492] C. L. Treasure J. Avorn, A. S. Kesselheim, *What is the public's right to access medical discoveries based on federally funded research?*, JAMA, 2014;311(9), 5 March 2014, p. 907-908.; https://jamanetwork.com/journals/jama/article-abstract/1835510 (27 May 2023).

[493] J. Love, *KEI receives seven new contracts for COVID 19 research from BARDA and DOD…*, Knowledge Ecology International, 1 July 2020.; https://www.keionline.org/covid19-ota-contracts (27 May 2023).

[494] M. Mazzucato, *Rethinking the social contract between the state and business: A new approach to industrial strategy with conditionalities*, UCL Institute for Innovation and Public Purpose, Working Paper Series (IIPP WP 2022-18), 2 November 2022.; https://www.ucl.ac.uk/bartlett/public-purpose/wp2022-18 (27 May 2023).

In addition, the R&D costs of products that have benefited from public funding should be transparent and include a breakdown between private and public investment.

The public funders should also ensure that in times of crisis, all forms of intellectual property, data, know-how and biological resources required for the development of final end products are shared broadly through, for example, the Medicine Patent Pool (MPP) or mechanisms such as the WHO COVID-19 Technology Access Pool (C-TAP), to scale up their production.

Another potential condition could be a commitment to reinvest part of the company's profits from a publicly (co-)financed product in predefined activities or a public innovation fund.[495]

To protect public investment, states should create an effective framework for *march-in* rights and not hesitate to use them when needed, so that patents on specific technologies can be effectively overridden and additional licenses granted to other manufacturers, including in the Global South.

Lastly, public funding could be conditioned on putting all work related to the development of a product in open source.[496] It would result in research and data (including from clinical trials) being accessible by scientists (either within a country, a group of cooperating countries or around the world), who could build on them to make further innovations. Patents on publicly funded technologies could also be pooled (as could all follow-on patents on innovations derived from the original publicly funded technologies). This condition could be taken into account, for example, when selecting private entities to collaborate on public-private ventures. Companies agreeing to it could be favoured in the selection process.

Attaching conditions to public investment is certainly an under-used policy tool, but there are also examples of success in this area. In April 2023, the Drugs for Neglected Diseases initiative (DNDi), a non-profit drug research and development organisation (see also Chapter 7.5.1.) published its insights on how terms and conditions can be applied in R&D collaborations, presenting a template license agreements[497] based on two decades of

[495] M. Mazzucato, *The Entrepreneurial State*, *op. cit.*, p.164-166.
[496] D. Baker, *Vaccinating the World: If We Had Grown Ups in Charge*, CEPR, 23 May 2021.
[497] D. J. Moser, P. Boulet, M. Childs, M. Shieh, B. Pecoul, St*riking fair deals for equitable access to medicines*, ournal of Intellectual Property Law & Practice, Volume 18, Issue 4, April 2023, p. 323–335.; https://academic.oup.com/jiplp/article/18/4/323/7115852 (27 May 2023).

its experience in this area.[498] DNDi emphasises the importance of having *a deliberate strategy, backed up by conditions negotiated at the early stage of R&D* to ensure equitable access to end products.[499]

7.3. Breaking away from rewarding medical innovation with intellectual property rights

In line with the proposed reforms, the public sector should shape, drive and invest more in health innovation. Along with conditions on public funding, states should also change the ways in which they direct private efforts. How the state chooses to incentivise private engagement in pharmaceutical R&D has direct implications for the ultimate success of bringing relevant innovations to markets around the world and advancing technological progress.[500]

It is argued that the existing approach based on an intellectual property regime reinforced by various other tools that limit competition (such as regulatory exclusivities) and provide subsidies is ineffective, if not detrimental to the development and access to medical innovations.

Instead of continuing to rely on patent monopolies and exclusivities, states should more actively explore alternative models. The first step should be a critical assessment of the negative impact of a rigorous IP system on knowledge sharing and scientific progress.

The R&D model based on IP encourages developers to work in secrecy and isolation, leading to knowledge fragmentation and limiting the ability of science to be disseminated and translated into future innovation. It also results in wasted time, financial resources, and duplication.

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[498] See: DNDi, Pro Access Policies: https://dndi.org/advocacy/pro-access-policies-intellectual-property-licensing/ (27 May 2023).

[499] DNDi, *Publication demonstrates how equitable deals for access to medicines can be signed with pharmaceutical industry*, Press release, 12 April 2023.; https://dndi.org/press-releases/2023/publication-demonstrates-how-equitable-deals-for-access-to-medicines-can-be-signed-with-pharmaceutical-industry/ (27 May 2023).

[500] J. Love, *Alternatives to the Patent System that are used to Support R&D Efforts, Including both Push and Pull Mechanisms, with a Special Focus on Innovation-Inducement Prizes and Open Source Development Models*, CDIP/14/INF/12, Study, 19 September 2014.; https://www.wipo.int/meetings/en/doc_details.jsp?doc_id=287218 (27 May 2023).; See also: Unitaid, *An Economic Perspective on Delinking the Cost of R&D from the Price of Medicines*, World Health Organization, February 2016, pp. 13-45.; http://www.unitaid.org/assets/Delinkage_Economic_Perspective_Feb2016.pdf (27 May 2023).

There is a strong lobby that presents IP as the only way to stimulate innovation, but this is far from the reality. In fact, there are many alternatives that have been shown to work and that could work. The problem is not a lack of options, but insufficient political will to discuss and debate them properly. Particularly the regions with large R&D investments (such as the U.S., EU, U.K. or Japan) could contribute to this discussion by driving pharmaceutical innovation through various alternative approaches which include *push incentives*, which reduce R&D costs (typically used to incentivise early-stage research), and *pull incentives*, which increase developers' revenues from products (typically used to incentivise late-stage research and production).

7.4. Alternative medical innovation models

7.4.1. Exploring and fostering the use of alternative models

Various models seek to make R&D investments more cost-effective and responsive to public needs. Different disease areas and different products may require special ways of financing, incentivising and rewarding R&D activities. Similarly, different stages of the innovation process, such as medicine discovery and data sharing, licensing or late-stage development and broad marketing need to be treated distinctly.

Alternative models often include common features, such as being driven by global health needs, providing pooling mechanisms and broad collaboration opportunities or adopting some kind of open approaches to R&D.[501] They may, however, differ in terms of their potential public health impact or technical, financial and implementation feasibility.

In the following discussion, various of them are presented and analysed. To illustrate how they can be used, often jointly, in specific disease areas, the examples of their application in particular contexts are also described. Finally, conclusions are drawn about how these models can be used for the development of medical countermeasures and providing broad access to them.

The purpose of this discussion is not to provide a comprehensive overview of the available models but to explore the range of possibilities of selected ones that may prove

[501] S. Moon et al., *New Business Models*, *op. cit.*, p. 30; UAEM has recognised 81 such existing or proposed approaches based on these criteria, see: R. Kiddell-Monroe, A. Greenberg, M. Basey, *Re:Route A map of the alternative biomedical R&D landscape*, Report, 2015.; https://www.altreroute.com/assets/download/UAEM_Reroute_Report.pdf (27 May 2023).

most useful for improving emergency R&D and access to end products. Due to the lack of definitive evidence on which to base an objective assessment of the alternative approaches' adequacy, costs and benefits, this discussion is not intended to make conclusive recommendations for their implementation in different contexts. It does, however, offer suggestions as to which ones should be preferred in which situations and for what reasons.

7.4.2. Delinking model

Among different mechanisms, options based on decoupling investment in innovation from medicine sales volumes and high prices are likely to stimulate innovation while ensuring its affordability and accessibility the most effectively.

For example, if there is uncertainty about the end product's commercial application or if scientific progress is the main goal, grants can be used as incentives in all stages of research. Furthermore, if the medical need is pre-determined and well-framed, R&D towards it can be incentivised through prize funds.[502]

Importantly, the *de-linkage* model requires significant upfront public investments. Therefore, national governments should ensure a robust budget for that purpose. This can be facilitated through international cooperation and the creation of joint funds. Importantly, such upfront investments do not necessarily have to generate additional public spending, but can even be limited to the reallocation of resources that are already dedicated to encouraging innovation through the intellectual property system and paying high prices for final products over decades. The difference, however, is that, unlike IP-based incentives such as patents, which are granted regardless of the social value of the end product, prize-funded health technology always addresses a specifically identified medical need.

By including contractual conditions, the accessibility and affordability of the end products can be secured, as well as the sharing of knowledge resulting from publicly funded research. In this way, prize funds have the potential to progressively replace the granting of exclusive monopoly rights.

[502] Either at regular milestones or at the end of a project. One advantage of this incentive is that it allows multiple promising research proposals with different approaches to be undertaken simultaneously, rather than targeting only one proposal at a time, as in a grant-based model.

A number of multilateral initiatives have clearly demonstrated the value and potential of such approaches.[503] There are also examples of smaller public, private or public-private initiatives based on prizes which aim to incentivise pharmaceutical development.[504]

Delinking mechanisms can be introduced at different levels. In 2012, the WHO Consultative Expert Working Group on Research and Development recommended the creation of a global prize fund (as part of a global biomedical R&D treaty) to reward medical innovation, which would be financed by all countries in proportion to their GDP (at least 0.01%). The fund would allow to fund the creation of pharmaceutical technologies, which would then be made available in the public domain as global public goods.[505] The fund, however, like the treaty itself, has never been established.

7.4.3. Pooling intellectual property rights and technologies

To spark medical research and development in certain areas the value of collaboration is well represented by pooling mechanisms. Pooling can be defined as an agreement between two or more patent or technology owners to license it to each other or to third parties.[506] This approach can expand access to assets (such as IP rights, technologies, data and know-how, among other things) held by different entities and accelerate medical innovation development beyond the separate, proprietary platforms.

[503] For example, the need to address diseases that lack economic incentives has led to the creation of not-for-profit product development partnerships, such as the Drugs for Neglected Diseases initiative (DNDi) in which public and private contributions pay for the cost of R&D upfront, rather than through sales of the resulting products, allowing the initiative to identify priorities based on public health needs and to offer products at sustainably low prices while allowing knowledge and data to be broadly shared. Other initiatives based on this model include The Meningitis Vaccine Project (MVP), the Global Antibiotic Research and Development Partnership, the Medicines for Malaria Venture and the Global Alliance for Tuberculosis Drug Development. See: J. Arkinstall, *Lives on the Edge: Time to Align Medical Research and Development with People's Health Needs,* MSF Access Campaign, May 2016, p. 28-32.; https://msfaccess.org/sites/default/files/R%26D_report_LivesOnTheEdge_Updated29Sept_ENG_2016.pdf (27 May 2023).

[504] These include, Longtitude Prize Open providing ex-ante inducement prizes currently focused on competitive AMR innovation; X-Prize Foundation providing milestone inducement prizes to develop TB diagnostic tools; Prize4Life Foundation providing milestone inducement prizes to develop cures and treatments for amyotrophic lateral sclerosis (ALS); EU Vaccine Prize providing end product inducement prize for a vaccine cold chain innovation.

[505] WHO, *Research and development to meet health needs in developing countries: strengthening global financing and coordination*, Report of the consultative expert working group on research and development: financing and coordination, 1 January 2012.; https://www.who.int/publications/i/item/9789241503457 (27 May 2023).

[506] C. Grace, M. Pearson, J. Lazdins, Po*oled Funds: Assessing New Models for Financing Global Health R&D*, Technical Background Paper, Results for Development Institute, 2011.; https://www.r4d.org/wp-content/uploads/Pooled-Funding-Technical-Background-Paper-1.pdf (27 May 2023).

This could be arranged through bilateral and multilateral agreements or by using existing initiatives.

One example of patent pooling and voluntary licensing (See also Chapter 5.5.7.1.) is the Medicines Patent Pool (MPP), established in 2010 to increase development and equitable global access to pharmaceuticals (targeting medicines for HIV/AIDS and other products included in the WHO Essential Medicines List, but also COVID-19 medical countermeasures during the pandemic) in low- and middle-income countries. To date, it has concluded agreements with 18 patent holders for various products and entered into licenses with 57 sublicensees to produce their generic versions.[507] MPP estimates that $1.2 billion could have been saved through its licenses between January 2012 and December 2021. While MPP has significantly increased access to generic medicines globally, when assessing its impact on R&D, Moon et al. argue that *the extent to which [licenses] will result in successfully developed final products is not yet clear*.[508]

Another example of this approach is the WIPO Re:Search established in 2011 by WIPO and BIO Ventures for Global Health.[509] Through this mechanism, actors can share their assets (such as IP or know-how) relevant to early-stage medicine R&D, for example, for neglected tropical diseases.[510] Although in this case, sharing is not rewarded with royalties, over the decades of the initiative's operation, more than 150 entities have contributed to it.[511] The WIPO Re:Search has clearly facilitated many collaborations and is having an impact on pharmaceutical R&D. However, it still remains to be seen to what extent it will contribute to the development of end products.[512]

States could also encourage or oblige companies to share critical technologies, know-how and IP during a health crisis and use public investment and incentives for innovation as leverage to encourage their pooling through mechanisms established for this purpose, such as C-TAP during the COVID-19 pandemic.[513]

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[507] See: Medicines Patent Pool (MPP): https://medicinespatentpool.org/ (27 May 2023).
[508] S. Moon et al., *New Business Models, op. cit.*, p. 31.
[509] WIPO, *The First 10 Years of WIPO Re:Search*, 2021.; https://www.wipo.int/edocs/pubdocs/en/wipo-pub-rn2021-10-en-the-first-10-years-of-wipo-re-search.pdf (27 May 2023).
[510] S. Moon et al., *New Business Models, op. cit.*, p. 31.
[511] N. Ziegler, O. Gassmann, S. Friesike, *Why do firms give away their patents for free? World Patent Information*, 2013.; https://www.hiig.de/wp-content/uploads/2014/02/1-s2.0-S0172219013001592-main.pdf (27 May 2023).
[512] S. Moon et al., *New Business Models, op. cit.*, p. 31.
[513] See: COVID-19 Technology Access Pool: https://www.who.int/initiatives/covid-19-technology-access-pool (27 May 2023).

Another type of pooling can be established to gather funds to support R&D in line with jointly agreed priorities. Such pools can be created by governments (for example, at the regional or international level), but also by various partnerships, including non-profit public-private initiatives. The WHO Consultative Expert Working Group on Research and Development recommended in 2012 that *20-50% of funds raised for health R&D addressing the needs of developing countries should be channelled through a pooled mechanism which would also have a coordination function*.[514]

There are various examples of implementing this type of fund polling such as the Global Health Innovative Technology Fund (GHIT), a non-profit PPP that provides grants to encourage collaborative research on non-communicable diseases; the European Developing Countries Clinical Trials Partnerships (EDCTP), an international partnership that also provides grants and additional support for late-stage collaborative research on medicines against poverty-related and neglected infectious diseases in sub-Saharan Africa; or the Bridging Interventional Development Gaps Programme (BRIDGS), a program that provides in-kind resources to facilitate medicine development for both common and rare diseases.

Pooling should be used as part of the international cooperation frameworks. For example, if governments express a willingness to work together on pharmaceutical R&D but are unable to reach a consensus on the global, universal sharing of technology, know-how, IP and inventions, pooling mechanisms could be implemented on a *share-and-share-alike* basis, benefiting those members who join the pool.[515]

7.4.4. Advance market commitments

Advance market commitments (AMCs) are a type of incentive designed to guarantee a viable market for a product once it has been successfully developed (and met the specified criteria). In general, AMCs are used in circumstances where the cost of developing a product is too high to make it profitable for the private sector without guaranteeing a predetermined amount of purchases.

[514] WHO Consultative Expert Working Group on Research and Development: Financing and Coordination, *Report of the Consultative Expert Working Group on Research and Development: Financing and Coordination*, A65/24, 20 April 2012, p. 104.

[515] See e.g.: *EB152 – Constituency statement*, 31 January 2023.; https://www.keionline.org/38287 (27 May 2023).

One example of the use of this instrument is Gavi's 2009 advance market commitment related to pneumococcus.[516] For this AMC, Gavi has secured an initial funding commitment of $1.5 billion to supply 200 million doses of pneumococcal vaccine over a 10-year period. According to Gavi, the AMC has been a huge success over the past decade and has prevented the deaths of 700,000 children in 60 developing countries.[517]

As Moon et al. stress, while pneumococcal vaccines were already available on the market before signing the AMC, the Gavi initiative is *credited with securing the production and volume of supply for use in developing countries, but it seems to have had little or no impact in promoting R&D.*[518]

The analysis of Gavi's AMC by the Médecins Sans Frontiers pointed out that while it resulted in increased manufacturers' supply capacity and the availability of the vaccines in developing countries, it *failed in fulfilling all of its objectives*.[519] According to the evaluations commissioned by the Gavi AMC Secretariat, the mechanism has not accelerated R&D, failed to achieve transparency on costs, capacity and pricing decisions, did not result in meeting full PCV demand and did not spark the anticipated competition in the area.

In 2023, to support the African Union's goal of developing, producing and delivering more than 60% of the vaccine doses needed on the continent by 2040 (see also Chapter 7.7.5.3.1.), Gavi is working on a proposal for a new African Vaccine Market Accelerator or similar AMC that could support the sustainability of new manufacturers entering the African pharmaceutical sector and build resilience in vaccine supply.[520]

The AMC model was also used during the COVID-19 pandemic to de-risk R&D and production for vaccine manufacturers (see Chapter 4.1.1.).

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[516] See: Gavi, Pneumococcal AMC: https://www.gavi.org/investing-gavi/innovative-financing/pneumococcal-amc (27 May 2023).

[517] Gavi, *What is an Advance Market Commitment and how could it help beat COVID-19?*, 4 May 2020.; https://www.gavi.org/vaccineswork/what-advance-market-commitment-and-how-could-it-help-beat-covid-19 (27 May 2023).

[518] J. Plahte, *Is the pneumococcal vaccine advance market commitment motivating innovation and increasing manufacturing capacity? Some preliminary answers*, Vaccine, Volume 30, Issue 14, 23 March 2012, p. 2462-2466.; https://www.sciencedirect.com/science/article/abs/pii/S0264410X12000849?via%3Dihub (27 May 2023).

[519] MSF Access Campaign, *Analysis and Critique of the Advance Market Commitment (AMC) for Pneumococcal Conjugate Vaccines (PCVs) and Impact on Access*, MSF Briefing Document – Executive Summary, June 2020.; https://msfaccess.org/sites/default/files/2020-06/Executive-Summary_Gavi-AMC-PCV-critique_MSF-AC.pdf (27 May 2023).

[520] Gavi, *Expanding sustainable vaccine manufacturing in Africa: Priorities for Support*, November 2022.; https://www.gavi.org/sites/default/files/document/2022/Gavi-Expanding-Sustainable-Vaccine-Manufacturing-in-Africa-2022.pdf (27 May 2023).

All in all, while AMCs are effective in increasing access, questions remain about the extent to which they play a role in increasing innovation. There are also concerns about the cost-effectiveness of AMCs and whether they do not lead to overcompensation, providing manufacturers with revenues that far exceed their investments.[521] Similarly, AMCs often fail to ensure the affordability of end products, although this can be remedied by including appropriate contractual clauses.

7.4.5. Patent buyouts

Another way to increase the availability of pharmaceuticals by increasing the production of their generic versions is to buy out patents and other rights. Governments (individually or working together) can purchase and license them out to generic manufacturers or even place them in the public domain.

One of the key issues in implementing such buyouts is the assessment of the appropriate level of compensation for the rights holders. Experts suggest that this could be done in one of two ways. First, under a cost-based approach, the state(s) could cover the research and development costs incurred and provide a substantial additional sufficient premium, recognising the risks taken by the originator and incentivising further innovation. The second, arguably more difficult way, is a profit-based approach. In this case, the state(s) would estimate the value lost by the holder whose rights have been bought out. However, knowing how much, for example, a company can profit from medical countermeasures during pandemics, governments would also have to take responsibility for determining what is a fair price for a product protected by such rights and how much the company could earn from it, ensuring, for example, equitable global access, rather than being driven by a profit maximisation strategy.

The amount to be paid to the rights holders could be determined by a global commission informed by all interested parties.

There are no examples of effective use of this mechanism at scale in the pharmaceutical sector, but there have been proposals to encourage countries to include this option in the *pandemic treaty* being negotiated at the World Health Organisation.

[521] D. W. Light, *Saving the pneumococcal AMC and GAVI*, Human Vaccines, Volume 7, 2011, Issue 2, 1 February 2011, p. 138-141.; https://www.tandfonline.com/doi/abs/10.4161/hv.7.2.14919 (27 May 2023).

7.4.5.1. Revealing trade secrets by regulators

Even if the rights that impede access to critical technologies remain in the hands of private companies, there are proposals for changes in the way patent offices and other public agencies use their powers to access and share them. They include suggestions to review national laws, regulations and practices on trade secrets and confidentiality, arguing that stronger public interest doctrine and broader exceptions for protection of public health should be established in this context.[522]

For example, it is argued that U.S. federal and regulatory agencies have access to information that they claim cannot be disclosed since they constitute confidential commercial information. However, Morten disputes the view that trade secrets law limits the authority of public agencies to make private companies' confidential information public, arguing that regulatory agencies have the statutory and constitutional power to obtain and disclose this information (including even *bona fide* trade secrets) when it serves the public interest.

Morten proposes a solution called controlled *information publicity* that regulators can use to make secret information public in a way that maximises public benefit and minimises private harm. He suggests that regulators can effectively and selectively make trade secret information public to non-commercial users while thwarting commercial competitors. This way regulators could protect the integrity of trade secrets from the competition while unlocking new publicly valuable non-profit uses.

7.4.6. Tax incentives

As part of a broad spectrum of subsidies, states also provide companies with tax incentives for pharmaceutical innovation, allowing them to write off R&D expenses against taxable profits in the year the expenses are incurred.

For example, according to one study, tax incentives for European industry amounted to €872 million in 2016.[523] There are medical R&D initiatives based on tax

[522] MSF Access Campaign, *Pandemic Accord: MSF's Comments on Equity Provisions in Zero Draft*, Technical Brief, April 2023, Annex 1, p. 1.; https://www.msfaccess.org/pandemic-accord-msfs-comments-equity-provisions-zero-draft (27 May 2023).

[523] M. Vieira, *Research Synthesis: Public Funding of Pharmaceutical R&D*, Knowledge Portal on innovation and access to medicines, Graduate Institute Geneva, April 2019.

incentives. For example, the U.K. Vaccines Research Relief was established to encourage companies to increase investment in R&D for vaccines and treatments for certain diseases.

However, the evidence to date on the effectiveness of such mechanisms in increasing R&D in certain disease areas and improving the availability and affordability of end products is not encouraging. The efficiency of such schemes cannot be demonstrated.[524]

7.4.7. Regulatory and other non-financial measures

There are also non-financial measures that countries may introduce to facilitate the bringing of desirable products to the market.

Specific programmes can be applied to offer regulatory advice to drug developers on the most appropriate way to generate robust evidence of a product's clinical benefits and risks and on the best way to present them in a marketing authorisation application.

Public institutes and agencies can also facilitate the conduct of clinical trials, for example by providing access to patent registries. This, like any other support, should be conditional on the affordability and availability of the end products, among others (see Chapter 7.2.).

Another regulatory tool to encourage R&D for specific products is expediting the regulatory process, for example through rolling reviews or accelerated approvals, to allow them to reach the market faster. Importantly, this should mean providing more resources to regulatory agencies, so that they can speed up the process rather than applying not less rigorous standards for examination of efficacy and safety data.

7.4.8. Open-source model

While regulatory incentives can encourage some developers to increase their efforts in specific areas, a much more far-reaching alternative way to improve medical innovation is to make greater use of the open-source model.

Open-source research and development involve collaboration and sharing of data, technologies, platforms, or research results to accelerate the innovation efforts and improve

[524] WHO Consultative Expert Working Group on Research and Development: Financing and Coordination, *op. cit.*, p. 61.

access to final products. This approach can increase the number of researchers working on a single innovation, improve knowledge dissemination, accelerate scientific progress, and reduce duplication by applying open-source principles at every stage of the process, from initial ideas to clinical trials and data collection for authorisation purposes.[525]

For example, while the speed at which COVID-19 vaccines were developed demonstrates the potential of science and public-private collaboration, CEPI's analysis indicates that the first COVID-19 vaccine could have been developed even much faster if the available innovations had been combined.[526]

Greater use of an open-source approach to pharmaceutical R&D has been recommended by the WHO Consultative Expert Working Group. In fact, there are many private, public or PPP initiatives on pharmaceutical R&D of varying sizes based on open-source.[527] There are various initiatives to promote this model in the area of neglected diseases, such as the Open-Source Pharma Foundation or the Open-Source Drug Discovery.[528] Successful collaborative projects include Cambia's open patent database and Medicines for Malaria Venture's (MMV) Pathogen Box.[529]

Experts argue that to better assess the potential of this model for drug development, more projects should be tested, and existing ones scaled up.[530]

Given that the use of this approach focuses on the preclinical stages of drug development, especially due to the high cost of the late-stage trials, there are also proposals to combine the open-source model with the commercial one, by collaborating with Big pharma companies driven by commercial incentives on phase 3 clinical trials and bringing drugs to market.

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[525] T. Andreson, *Can open-source drug development deliver?,* The Lancet, Volume 387, Issue 10032, 14 May 2016.; https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(16)30518-9/fulltext (27 May 2023).

[526] A. Tong, *Covid-19 spurred a historic vaccine R&D effort. What does it mean for future pandemics?,* Endpoints news, 1 November 2022.; https://endpts.com/covid-19-spurred-a-historic-vaccine-rd-effort-what-does-it-mean-for-future-pandemics/ (27 May 2023).

[527] See e.g., Dream Challenges focused on diverse topics within biomedical discovery http://dreamchallenges.org/challenges/ (27 May 2023).; Incentives focused on (but not exclusively) rare diseases https://www.innocentive.com/ar/challenge/browse (27 May 2023).; Collaborative Drug Dsicovery (CDD) including work on neglected diseases https://www.collaborativedrug.com/ (27 May 2023).; The Structural Genomics Consortium (SGC) primarily in epigenetics https://www.thesgc.org/ (27 May 2023). For more exmples, see: R. Kiddell-Monroe, A. Greenberg, M. Basey, op. cit.

[528] See: Open Source Drug Discovery: http://www.osdd.net/ (27 May 2023).

[529] Medicines for Malaria Venture, About the Pathogen Box: https://www.mmv.org/mmv-open/pathogen-box/about-pathogen-box (27 May 2023).

[530] M. Balasegaram, *An open source pharma roadmap*, Plos Medicine, 18 April 2017.; https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5395155/ (27 May 2023).

In order to provide more insight into the open-source's innovative nature and the effectiveness of initiatives based on it, two of them, one relating to a product used on a daily basis and the other to a medical countermeasure, will be discussed in more detail below.

7.4.8.1. Example of the Open Insulin project

The first example is the *Open Insulin* project, an independent insulin production initiative taking place in the US.

Insulin is an essential drug for millions of people living with diabetes – one of the most common chronic diseases in the world. It was discovered more than 100 years ago and sold for a symbolic dollar by its innovators. Today, however, the drug's availability is a major challenge for health systems and individual patients, especially in the US, where three pharmaceutical giants, Novo Nordisk (see also Chapter 8.2.5.), Sanofi and Eli Lilly, have created patent thickets around it and are imposing ever higher prices.[531] Over the past 20 years,[532] the average price of insulin has risen by 1,000 per cent, and the average annual cost of insulin per person is nearly $6,000.[533] According to media reports, *one in six Americans with diabetes who use insulin say they ration their supply because of the cost*.[534]

Research on the cost of insulin R&D and production shows that the high price of the drug in the U.S. cannot be justified by companies' need for a return on investment. According to evidence presented in a BMJ Global Health study, insulin could cost less than $133 per year.[535]

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[531] I-MAK, *Overpatented, overpriced, How Excessive Pharmaceutical Patenting is Extending Monopolies and Driving up Drug Prices*, August 2018.; https://www.i-mak.org/wp-content/uploads/2018/08/I-MAK-Overpatented-Overpriced-Report.pdf (27 May 2023).

[532] See: T1International, 100 Years: From Gifts to Greed: https://www.t1international.com/100years/ (27 May 2023).

[533] T. O'Neill Hayes, J. Farmer, *Insulin Cost and Pricing*, American Action Forum, Research, 2 April 2020.; https://www.americanactionforum.org/research/insulin-cost-and-pricing-trends/ (27 May 2023). In 2023, after years of pressure and government reforms, the three companies announced they will lower the price of insulin in the US by 70 per cent and automatically cap out-of-pocket costs for their insulin products at US$35 at participating retail pharmacies. See e.g.: M. McConnell, *Insulin Manufacturer to Finally Lower Prices in the US*, Human Rights Watch, 1 March 2023.; https://www.hrw.org/news/2023/03/01/insulin-manufacturer-finally-lower-prices-us (27 May 2023).

[534] L. Searing, *Over 1 million Americans with diabetes rationed insulin in past year*, The Washington Post, 8 November 2022.; https://www.washingtonpost.com/wellness/2022/11/08/diabetes-insulin-rationing/ (27 May 2023).

[535] Dz. Gotham, M. J. Barber, A. Hill, *Production costs and potential prices for biosimilars of human insulin and insulin analogues*, British Medical Journal Global Health, 25 September 2018.; https://gh.bmj.com/content/3/5/e000850 (27 May 2023).

Against this background, there is a growing number of initiatives to produce versions of insulin whose patent protection has already expired, by non-profit foundations and even the public sector (see, for example, Chapter 9.2.3.1.).

For example, in 2015, the *Open Insulin* project was established in California.[536] It is supported by a foundation of the same name and managed by researchers and patients. The project aims to produce insulin locally on a small scale based on an open-source model.[537] It is an example of a bottom-up approach as a counterproposal to market control by big pharmaceutical corporations. The project currently attempts to solve the technological and economic challenges associated with production at scale, including securing authorisation for such manufactured drugs from regulatory agencies.

In this case, thanks to the open-source approach, the manufacturing process and technologies used to produce insulin are available and may be reused without prior authorisation. The initiative's scientists are also trying to develop devices – which are out of reach for small-scale production due to a price tag of more than $100,000 – needed for manufacturing and best practices in insulin production, which could reduce regulatory costs associated with safety and quality assessments.

In addition to the technological aspects, the *Open Insulin* project is developing an economic model for a network of small production facilities that could partner with pharmacies or hospitals.[538] Such a model would need to ensure sustainable production, timely delivery, and a reliable distribution network to become a viable counteroffer to large corporations.

For this type of projects to succeed, the support from the public sector, for example, through its procurement policies, is critical.

7.4.8.2. Example of Corbevax

A prominent example of applying the open-source model to health emergency-related medical innovation is Corbevax with its COVID-19 vaccine.

In 2021, researchers (led by Dr Peter Hotez and Dr Maria Elena Bottazzi, co-directors of the Center for Vaccine Development at Texas Children's Hospital) developed an affordable, open-source COVID-19 vaccine based on recombinant protein technology

[536] See: Open Insulin Foundation: https://openinsulin.org/ (27 May 2023).
[537] OTMeds, *Relocation of the Pharmaceutical Industry*, *op. cit.*, p. 42.
[538] *Ibidem.*, p. 44.

with the goal of making it accessible in developing countries.[539] The project aimed to make developing countries less dependent on Big Pharma companies and sped up their access to an effective and affordable medical countermeasure.

The technology behind the vaccine is not patented and can be produced by any company. In Botazzi's words, *Open science is very important to us. We want to enable countries in the Global South to develop their own vaccine manufacturing capacity instead of simply accepting something that was created by multinational pharma companies. We wanted this to be a collaboration, instead of 'Here are some leftover vaccines'*.[540]

An estimated 100 million people in India and Indonesia have received the vaccine by the end of 2022.[541]

According to Bottazzi and Hotez, cooperation with developing countries was also aimed at empowering local drug manufacturers and breaking with the *colonial mentality* (see Chapter 6.3.) applied by the industry. Companies from developing countries are free to use the technology to produce the vaccine but also to develop it further. They can also commercialise the vaccine under their own brand name (for example, the Indian company called it Corbevax while the Indonesian IndoVac).

For the development of the vaccine, the team at Texas Children's Hospital has received no funding from the U.S. *Operation Warp Speed*. It relied on previous grants for work on SARS and MERS vaccines, as well as a modest contribution from the U.S. NIH for the COVID-19 one. In the end, most of the funding has been provided by philanthropic organisations.

While the vaccine took less than two years to develop, if the public sector had provided this open-source project with similar support that the large pharmaceutical companies have received in the form of funding and regulatory streamlining, it could have succeeded even quicker. As Hotez puts it, *That could have been probably cut in half had we had the support to move faster*.[542]

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[539] That technology is well-known to producers in LMICs such as Bangladesh, India, Vietnam, Indonesia, Brazil, and many other places, which already use to make e.g., the hepatitis B vaccine.

[540] Texas Monthly, *The Best Things in Texas 2023: The Texans Vaccinating the World*, Texas Monthly, January 2023.; https://www.texasmonthly.com/being-texan/best-things-in-texas-2023-texans-vaccinating-world/ (27 May 2023).

[541] *Ibidem.*

[542] A. Tong, *op. cit.*

7.4.9. Vaccines as global public goods

During the COVID-19 pandemic and before, there have also been numerous calls for building economic activities and designing R&D models in which knowledge and health technologies are considered a common or even a public good, rather than private property. It is argued that vaccines, as critical medical countermeasures, are particularly well-suited to be considered such a good.

What makes vaccines different from other health technologies – and therefore arguably more suitable for becoming a public good – is that their value is both individual and collective. The vaccinated person is protected themselves, while at the same time protecting others, by increasing their immunity and reducing the risk of hospitalisation, thus not burdening public services. If the vaccine also reduces transmission, immunisation also reduces the spread of the virus.

This individual and collective value makes vaccines key medical countermeasures particularly important for public health.

What is more, while vaccines are one of the most cost-effective public health interventions, there is often no significant market for them, which can partly be attributed to a lack of sufficient political interest in prevention policies (not least because it is difficult to measure the economic value of preventing, for example, a spread of a disease). Since the case for investing in preventative intervention is sometimes difficult to make, vaccines tend to be undervalued.

For a long time, vaccines were not considered attractive to pharmaceutical companies (due to the lengthy and expensive research and development process, and costly trials requiring a larger scale than those for other medicines to prove efficacy in preventing rather than treating disease). Traditionally, the economic value of developing vaccines to companies has not been sufficient to undertake this process. The vaccine market (excluding for COVID-19) is currently estimated at $32 billion (representing about 2% of the total pharmaceutical market).

Compared to other pharmaceutical industry products, while about 15-20 new drugs enter the market each year, in the case of vaccines, the figure for vaccines is only about 4-5 per decade (excluding variants).

One other specificity of vaccines relates to technology. Vaccines use a so-called technology platform, such as mRNA or viral vector platforms. These platforms are based

on decades of basic research, most often (co-)funded by public investments and (co-) conducted by public institutes and universities. Subsequently, pharmaceutical companies make different variants of these platforms and patent them. This means that these different variations of collective technologies are then – through the IP system – privatised.

The level of innovation in the vaccine industry is relatively low. Once it is established that it is possible to produce immunity for a given disease using one platform, then there is a good chance that all manufacturers using their variants of this platform can develop an effective vaccine.

The above arguments make the case for having vaccines available to all who need them as public goods. For this to happen, the public sector (in partnership with private entities or through direct involvement in R&D and production by establishing public capacities, see Chapter 9.) should invest in and guide their development and production, while ensuring equitable access. Ideally, this would be done through an international mechanism for joint financing and development, or at least by pooling resources.

7.5. Alternative business models for specific disease areas

Over the past decades, different approaches have also been implemented for specific disease areas to address the shortcomings of the mainstream pharmaceutical R&D system within them. For example, they have been introduced to combat neglected tropical diseases, rare and paediatric diseases or antimicrobial resistance as well as emergency-related pathogens.[543]

It is worth looking into these different ways of financing, developing and making pharmaceutical innovations available. An analysis of their strengths and weaknesses and lessons learned from their implementations allow broader conclusions to be drawn on public sector leadership, allocation of public resources, return on investment, and modes of cooperation with private entities, among other things.

7.5.1. Neglected tropical diseases

A prime example of an area that has been largely abandoned by private entities because of the lack of sufficient profitability to justify research and development costs is

[543] S. Moon et al., *New Business Models, op. cit.,* p. 44.

tropical diseases.[544] For example, despite the fact that tuberculosis has been declared a global emergency in 1993, a person dies of the disease every 20 seconds.[545]

As Navarro and Moon observed, more than 20 public-private product development partnerships (PDPs) have been formed over the past decades to address the lack of innovation in the field. They have resulted in more than 50 product launches for malaria, HIV/AIDS and Ebola, among others, and provide vast evidence to evaluate the effectiveness of various approaches, including the delinking models described above, such as prizes and grants.[546]

The key example here is the Drugs For Neglected Diseases initiative (DNDi). DNDi does not operate its own research facilities to develop new treatments but functions based on a collaborative model bringing together partners from public, academic, philanthropic and private sectors, including large pharmaceutical companies such as Pfizer, GlaxoSmithKline, or Novartis.[547] According to the initiative's business plan, *the diversity of potential partners are such that DNDi cannot operate according to a single model (…). [It] chooses different partner categories, collaboration schemes, funding mechanisms, or advocacy activities [depending on the specifics of its activities], and adjust the intensity of its contribution*.[548] These activities range from investing in regional drug development platforms for specific diseases, developing new biomarkers to better understand them, or supporting non-exclusive licensing to increase access. The initiative identifies research opportunities with the potential to translate into improved treatment options, creates development plans, identifies and contracts with relevant partners, and manages project

[544] G-Finder, *Neglected Disease Research And Development: The Status Quo Won't Get Us There*, Policy Cures Research, January 2023.; https://policy-cures-website-assets.s3.ap-southeast-2.amazonaws.com/wp-content/uploads/2023/01/31195852/Embargoed-2022-G-FINDER-Neglected-Disease-report.pdf (27 May 2023).

[545] MSF Access Campaign, *Pandemic Accord: MSF's Comments on Equity Provisions in Zero Draft*, Technical Brief, April 2023, p. 1.; https://www.msfaccess.org/sites/default/files/2023-04/TechBrief_MSF-AC-Pandemic-Accord-Zero-Draft_EN_April2023.pdf (27 May 2023).

[546] M. Vieira, R. Kimmitt, D. Navarro, A. Bezruki, S. Moon, *Advancing innovation and access to medicines: the achievements and unrealized potential of product development partnerships*, In: *Partnerships for sustainability in contemporary global governance*, London - New York, NY, Routledge, 2022, p. 120-143.; https://repository.graduateinstitute.ch/record/300282?_ga=2.214710231.1179589478.1674228338-167871872.1674228338 (27 May 2023). PDPs are often non-profit organisations with public or philanthropic funding, which bring together all actors involved in the pharmaceutical R&D. Not being driven by commercial interests, they can focus on addressing health needs instead of perusing profits.

[547] J. Tuttle, *Drug Development for Neglected Tropical Diseases: DNDi and the Product Development Partnership (PDP) Model*, A thesis submitted to the Department of Global Health for honors, Duke University, 2016.; https://dukespace.lib.duke.edu/dspace/handle/10161/11869 (27 May 2023).

[548] See: DNDi, *DNDi 'S Alternative Business Model*, DNDi Business Plan 2011-2018 | Alternative Business Model, 2011, p. 8.; https://dndi.org/wp-content/uploads/2009/03/DNDi-s-model.pdf (27 May 2023).

progress.[549] For this purpose, DNDi set up a lead optimisation consortium for each of the major diseases in its portfolio.[550]

Other initiatives established specifically to address the lack of innovation in the area of neglected diseases include the Foundation For Innovative New Diagnostics (FIND) working on diagnostic tools for poverty-related diseases, Medicines For Malaria Venture (MMV) targeting medicines against malaria (also without in-house product development capacity), TB Alliance developing drugs for the treatment of tuberculosis, or Tuberculosis Vaccine Initiative (TBVI) focused on the development and delivery of a tuberculosis vaccine.

There are also PDPs established to work across different disease areas, such as the Infectious Disease Research Institute (IDRI), which is a biotech company and a PDP focused on developing drugs for infectious diseases, particularly tuberculosis, leishmaniasis, leprosy, malaria and Chagas disease, or MEDICINES Development For Global Health (MDGH) focused on developing drugs for infectious diseases such as onchocerciasis, with its own manufacturing capabilities.

Another key example of an organisation applying innovative models in this field is the Program for Appropriate Technology in Health (PATH), which collaborates with the private sector on R&D activities based on global health needs through five large programs dedicated to product development, including the Malaria Vaccine Initiative and the Meningitis Vaccine Project. PATH Global Health Innovation Hub directly supports innovators in India and South Africa and incorporates startups, impact equity investors and knowledge transfer from local to global levels.

A comparison of PDP and commercial R&D models developed by Viera et al. established that the direct costs and timelines of both are similar, while the former has various advantageous features.[551] Since affordability and accessibility, including intellectual property and data management strategies, are included in PDP initiatives from

[549] *Ibidem*.

[550] E. van Beek, J-F. Alesandrini, Drugs for Neglected Diseases initiative; Best Science for the Most Neglected, Health Action International, 2010.; https://haiweb.org/encyclopaedia/drugs-for-neglected-diseases/ (27 May 2023).

[551] M. Vieira, R. Kimmitt, S. Moon, *Non-commercial pharmaceutical R&D: what do neglected diseases suggest about costs and efficiency?,* F1000 Research, 2021.; https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8063537/pdf/f1000research-10-70804.pdf (27 May 2023).

the outset so as not to hinder the use of end products in poor countries, they yield better – from a public health perspective – results than commercial ventures.

Although the PDP model has been successful in drug development for neglected diseases, as pointed out by Moon et al, its prevalence in *lucrative* disease areas requires further study.

7.5.2. Rare and paediatric diseases

Another area that has historically been identified as a *market failure* is diseases that affect only a small group of patients or children. Given that research and development for medicines in these fields is risky and the ultimate market is small, alternative models mostly aim to attract private investment by reducing risk and increasing market size.

For these reasons, many countries and regions have adopted specialised laws containing special incentives for developers.

For example, the United States (Orphan Drug Act of 1983) and the EU (Regulation (EC) No. 141/2000 on orphan medicinal products - currently under review) have introduced market exclusivities for a product granted an orphan designation. Drug development in this area has indeed increased in recent decades. For example, 146 orphan drugs were introduced in the EU between 2001 and 2016. However, it is estimated that only 18-24 (12-16%) of these can be attributed to the EU law.[552] Most of them would probably reach the market even without additional public incentives.[553]

Although thanks to the existing incentive system, more companies are investing in the development of drugs for rare diseases and children, there are numerous shortcomings in the way it is structured. For example, the frameworks established to boost R&D on orphan medicines do not provide adequate safeguards to protect against their abuse nor sufficiently stimulate innovation in areas of real unmet medical needs and result in often unaffordable and unequally available treatments generating high profits.

Given the scale of the incentives implemented, which, however, have failed to provide a comprehensive solution to the problem, the flaws in the EU incentive system for

[552] Technopolis Group, *Study to support the evaluation of the EU Orphan Regulation*, Final report, July 2019.; https://health.ec.europa.eu/system/files/2020-08/orphan-regulation_study_final-report_en_0.pdf (27 May 2023).
[553] D. Marselis, L. Hordijk, *From blockbuster to "nichebuster", op. cit.,* p. 2.

orphan drugs will be briefly analysed to point out the various common shortcomings and ways to fix them.

The EU legislation has been in force for more than two decades. However, its evaluation points out that only 28 per cent of registered orphan medicines are for diseases for which there were no alternative treatments on the market, while 95 per cent of rare diseases remain untreated.

As Marselis and Hordijk describe, the EU law has created particularly lucrative markets for the industry, which has been enabled to generate more than a billion euros a year from products targeting only a small group of patients. As described in their study published in British Medical Journal, *since 2001, average annual sales of all orphans have multiplied by five, from €133 million to €723 million in 2019. Medicines treating rare cancers, like Revlimid, are particularly rewarding*.[554]

At the same time, Jayasundara et al. presented evidence that research and development costs for orphan drugs are, on average, much lower than for non-orphan ones.[555]

While the main reason for the adoption of the EU orphan regulation was the presumed lack of profitability of medicines for rare diseases, in practice the actual economic considerations are never examined in granting orphan incentives to the industry or afterwards.[556]

What is more, the EU regulation does not provide for the practical possibility of withdrawing market exclusivity if a company charges prices that the public cannot afford, or if its revenues from the orphan product excessively exceed the value of its investment in it.[557]

The described problems point out the importance of subjecting incentives to a transparency requirement that would enable evidence-based decision-making. For one, the terms used in the legislation such as *sufficient* (Article 8(2) of the EU Regulation) in the context of profitability could be defined with knowledge of the actual costs of R&D

[554] *Ibidem*, p. 3.

[555] K. Jayasundara et al., *Estimating the clinical cost of drug development for orphan versus non-orphan drugs*, Orphanet Journal of Rare Diseases volume 14, Article number: 12, 10 January 2019.; https://ojrd.biomedcentral.com/articles/10.1186/s13023-018-0990-4 (27 May 2023).

[556] Similar to the case of the Supplementary Protection Certificate (SPC) that was introduced based on the presumption that the period of product exclusivity after its marketing could not be sufficient to recoup the investment, the granting of a SPC is not dependent on the actual revenue or profit a pharmaceutical company obtains from that product.

[557] D. Marselis, L. Hordijk, *From blockbuster to "nichebuster", op. cit.,* p. 4.

incurred by developers to determine what is an *insufficient* or *excessive* return on investment.[558]

Another conclusion to be drawn from this example is that the assumptions under which certain incentives are introduced should be regularly re-examined and revised if necessary. In the case of rare diseases, there is compelling evidence that the presumption that a medicine developed for no more than about 250,000 people is not profitable is false.[559] Soaring orphan drug prices and extended periods of exclusivity through combining indications make orphan drugs among the most profitable in companies' portfolios.

These shortcomings also point to the weaknesses of implementing one-size-fits-all types of incentives such as granting market exclusivities for all medicines that meet the threshold of orphan designation and the importance of applying tailored mechanisms to spur the most relevant innovations.

7.5.3. Antimicrobial resistance

Novel R&D business models are also being introduced to tackle antimicrobial resistance (AMR).

AMR poses a unique challenge for the pharmaceutical sector. Rising resistance to existing antibiotics and a shortage of new ones mean that patients and healthcare professionals face diminishing treatment options. Because investment in medicines to be used as sparingly as possible is commercially unattractive, governments have recognised that new approaches are needed to support the development of new antibiotic classes while improving the prudent use of the existing ones. There is general agreement that both *push incentives* (subsidising the overall cost of development) and *pull incentives* (rewarding successful development) are needed to stimulate research in this area.[560]

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[558] P. Boulet, Ch. Garrison, E. 't Hoen, *European Union Review of Pharmaceutical Incentives: Suggestions for Change*, June 2019, p. 9-21.; https://medicineslawandpolicy.org/wp-content/uploads/2019/06/MLP-European-Union-Review-of-Pharma-Incentives-Suggestions-for-Change.pdf (27 May 2023).

[559] D. Marselis, L. Hordijk, *From blockbuster to "nichebuster", op. cit.,* p. 2-3.

[560] CH. Ardal, J-A. Rottingen, A. Opalska, A. J. Van Hengel, *Pull Incentives for Antibacterial Drug Development: An Analysis by the Transatlantic Task Force on Antimicrobial Resistance*, Clinical Infectious Diseases, Volume 65, Issue 8, Oxford University Press, October 2017, p. 1378-1382.; https://academic.oup.com/cid/article/65/8/1378/3862465 (27 May 2023).

Various models have been proposed to increase antibiotic innovation,[561] however, so far, they are mainly focused on early-stage research, while facilitating the transition of antibiotic products from early clinical phases to commercialisation is still insufficient. There are many examples of *pull incentives* that could be applied, and some countries have already started piloting them. [562] Of the various options, also in this area, delinking models seem to stimulate innovation most effectively.[563]

One such model proposes that governments pay a subscription or license fee for priority access to antibiotics at a certain price. Payments to the manufacturer would not be based on volume of consumption but rather would be tied to ensuring an adequate supply of the drug, including continued availability when needed. In this way, a disconnect between revenue and sales volume could be achieved.[564]

Another approach is the option market model for antibiotics, which could provide an effective early investment and risk-sharing mechanism while maintaining a credible purchase commitment and incentives for companies to eventually bring new antibiotics to market.[565] This mechanism, similar in logic to COVID-19 vaccine purchase commitments (see, for example, Chapter 4.1.1.), would allow, for example, governments to pay upfront and *hold options* on antibiotic candidates with the possibility of buying the end products if or when they enter the market at a discounted price. This way, R&D investment would be de-risked (at least partially) by upfront payments and the final price of the products would be closer to the marginal cost of production.

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[561] M. J. Renwick, D. M. Brogan, E. Mossialos, *A systematic review and critical assessment of incentive strategies for discovery and development of novel antibiotics*, The Journal of Antibiotics, 69, 14 October 2015.; https://www.nature.com/articles/ja201598 (27 May 2023).

[562] See examples from Germany, Sweden and the UK in: EU-JARMAI, *Incentivizing antibiotic access and innovation*, Policy Brief, January 2021.; https://eu-jamrai.eu/wp-content/uploads/2021/01/EUjamrai_policy-brief-hub-incentives_2020.12.11.pdf (27 May 2023).

[563] The application of a de-linkage system could directly benefit unmet public health needs by providing a predictable return on investment for products that satisfy predefined public health priorities. Moreover, it would promote the prudent use of antibiotics by allowing research and development investments in successful products without requiring high product sales. In addition, contractual clauses could assure the products are priced reasonably and widely distributed. One major challenge of this system is the need for substantial upfront public investment.

[564] M. J. Renwick, D. M. Brogan, E. Mossialos, *op. cit.*

[565] D. M. Brogan, E. Mossialos, *Systems, not pills: The options market for antibiotics seeks to rejuvenate the antibiotic pipeline*, Social Science & Medicine, Volume 151, February 2016, p. 167-172.; https://www.sciencedirect.com/science/article/abs/pii/S0277953616300053?via%3Dihub (27 May 2023).

Such delinking models, according to Moon et al., also have the potential to lead to equitable global access.[566] The latter can also be achieved, for example, by another approach that introduces market entry rewards contingent on ensuring equal access and affordability of the antibiotic worldwide.[567]

Based on alternative incentives, a number of initiatives have been created to increase R&D in this area, for example, the Combating Antibiotic-Resistant Bacteria Biopharmaceutical Accelerator (CARB-X), established in 2016 by the United States Department of Health and Human Services;[568] the Global Antibiotic Research and Development Partnership (GARDP), also established in 2016 with support from WHO and DNDi;,[569] or the industry-initiated AMR Action Fund[570].

7.6. Medical countermeasures – developing drugs and vaccines for health emergencies

An analysis of the available alternative models and their application in different disease areas allows to draw conclusions about their ability to increase R&D and the accessibility of drugs and vaccines to tackle health emergencies.

As discussed in Chapter 5.2.2., innovation in products against pathogens with pandemic potential is risky, and because the commercial market for them may be limited, the mainstream R&D system is particularly inadequate to achieve desired results in this area. Therefore, biosecurity R&D has historically been driven by public-private partnerships with significant military participation (see, for example, Chapter 1.4.).

Moon et al. describe the typical medical countermeasures innovation model.[571] It is shaped by the public sector, which is responsible for identifying risks, setting priorities and providing incentives for private actors to get involved in R&D efforts. Public agencies also invest public resources and even engage directly in the innovation process. Thus, although

[566] S. Moon et al., *New Business Models, op. cit,* p. 29.
[567] J. O'Neill, *Tackling drug-resistant infections globally: final report and recommendations*, London: Review on Antimicrobial Resistance, May 2016.; https://amr-review.org/sites/default/files/160518_Final%20paper_with%20cover.pdf (27 May 2023).
[568] See: https://carb-x.org/
[569] See: https://gardp.org/
[570] See: https://www.amractionfund.com/
[571] S. Moon et al., *New Business Models, op. cit,* p. 26.

R&D is run by the private sector, its involvement depends on public steering and funding, as well as on the favourable legal and regulatory environment.

The incentives for private companies (in addition to intellectual property rights, which protect all sorts of innovations) have already been put in place to increase R&D, including regulatory measures such as priority review vouchers (PRVs).[572] However, studies have shown no evidence that PRVs encourage early-stage research in this field.[573] One shortcoming of the PRVs is also the lack of availability and affordability conditions.

Among *push incentives*, states also provide subsidies to companies involved in vaccine development (for example by lowering the cost of quality control) and seek to foster cooperation to increase their R&D capacity and reduce risks in specific projects.[574] A drawback of this approach is that developers may inflate their investments to receive larger subsidies.[575]

Pull incentives, on the other hand, include grants, prizes, exclusivities and procurement contracts or advance market commitments (AMCs).[576] What is more, to increase demand, and thus overcome market failure, governments plan vaccination campaigns and oversee the delivery of vaccines. In this context, international collaboration also plays a key role in expanding the market for the products (see, for example, ACT-A during the COVID-19 pandemic in Chapter 6.7.).

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[572] Priority review vouchers (PRVs) were proposed to expedite the process of obtaining regulatory approval and so allow a product to enter the market quicker. Such vouchers can be granted for meeting certain goals set by public policies (e.g., marketing a drug for a neglected disease) and can be used by the developer for its another product or sold to another company and that way making a financial return on R&D investment. See also: T. Sunyoto, M. Vieira M, S. Moon, A. Bezruki, *Research synthesis: biosecurity research and development (R&D*), Geneva: Global Health Centre at the Graduate Institute, 2020.;
https://www.knowledgeportalia.org/biosecurity-r-d (27 May 2023). An example of an initiative based on PRVs is the U.S. FDA Priority Review Voucher, which encourages the development of medicines for neglected tropical diseases and rare paediatric diseases.

[573] N. Jain, T. Hwang, J. M. Franklin, A. S. Kesselheim, *Association of the priority review voucher with neglected tropical disease drug and vaccine development*, JAMA, Research letter, 25 July 2017, p. 388–9.; https://jamanetwork.com/journals/jama/fullarticle/2645091 (27 May 2023).

[574] F. Lobo, *Restructuring the Global Vaccine Industry…, op. cit.,* p.7.

[575] R. Mossialos, C. M. Morel, S. Edwards, J. Berenson, M. Gemmill-Toyama, D. Brogan, *Policies and incentives*
for promoting innovation in antibiotic research, European Observatory on Health Systems and Policies, 2010; https://apps.who.int/iris/bitstream/handle/10665/326376/9789289042130-eng.pdf (27 May 2023).

[576] See for example, DARPA Grand Challenge, funded by the Defense Advanced Research Projects Agency. See: J. Matheny, M. Mair, A. Mulcahy, B. T. Smith, *Incentives for biodefense countermeasure development*, Biosecur Bioterror, 5 September 2007, p. 228-238.;
https://pubmed.ncbi.nlm.nih.gov/17903091/ (27 May 2023).

To further protect vaccine developers, countries (especially the wealthy ones, although poorer countries were forced to also do so during the COVID-19 pandemic) limit the liability of private companies for product side effects or even exempt them from no-fault liability altogether.

Public-private partnerships (PPPs) and organisations have also been established to host innovative vaccine R&D processes. One example is the European Vaccine Initiative (EVI), a PPP focused on facilitating the entry of potential vaccine candidates into clinical trials and the availability of end products in low-income populations. What is more, EVI hosts TRANSVAC, a collaborative project to create a European network for vaccine R&D. TRANSVAC aims to implement a permanent research infrastructure for early vaccine development.

Other initiatives created to improve innovation in this context are the International Vaccine Initiative (IVI), a non-profit organisation working on vaccine development for cholera, typhoid and dengue or the International Aids Vaccine Initiative (IAVI), a global non-profit organisation working on AIDS vaccine development.

R&D of vaccines for neglected diseases receive instrumental support from the philanthropic sector. For example, the Bill and Melinda Gates Foundation has contributed more than $18 billion to the cause.[577]

In the context of equitable global access, Moon et al. point out that *biosecurity R&D has traditionally focused on invention, with almost no attention to ensuring global availability or access to the technologies that result*.

7.6.1. CEPI

To address this problem and increase funding for research projects to develop vaccines against emerging infectious diseases while guaranteeing their global availability during epidemics, a partnership called the Coalition for Epidemic Preparedness Innovations (CEPI) was launched in 2017 in the wake of the Ebola outbreak in West Africa.[578] It was co-founded by the Bill and Melinda Gates Foundation, Wellcome Trust, and the governments of India and Norway (later jointly the EU and the U.K.).

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[577] S. Murray, *Philanthropists play a crucial role in developing vaccines*, Financial Times, 22 May 2020.; https://www.ft.com/content/847a9052-6847-11ea-a6ac-9122541af204 (27 May 2023).

[578] See: CEPI, *A world in which epidemics and pandemics are no longer a threat to humanity*: https://cepi.net/about/whyweexist/ (27 May 2023).

CEPI's R&D program is based on WHO's *blueprint priority diseases*, which include MERS, Nipah virus, Lassa fever virus and Rift Valley fever virus, as well as Chikungunya virus and more recently SARS-CoV-2.[579] Even before the COVID-19 outbreak, CEPI was working on the hypothetical unknown pathogen *Disease X* and had built a portfolio of 19 vaccine candidates against five priority pathogens, with investments of up to $456 million.[580]

Given that CEPI's goal is to provide worldwide access to the developed products, thus making them global public goods, the foundation's early agreements with the pharmaceutical industry included provisions for fair pricing, intellectual property management, risk-benefit sharing, data transfers and transparency. However, under pressure from commercial partners, who were hesitant to cooperate with the foundation due to its *inflexibility*,[581] CEPI later introduced policy changes that compromised this criterion.[582] Currently, it negotiates access provisions individually with companies.

7.6.2. Gavi, the Vaccine Alliance

Another organisation established in the area of medical countermeasures in 2016 is Gavi, the Vaccine Alliance. Gavi is a Geneva-based, public-private partnership that works on a philanthropic basis to improve access to immunisation in poor countries. According to Gavi's website, the alliance *has helped vaccinate more than 981 million children in the world's poorest countries, preventing more than 16.2 million future deaths*.[583] Jaupart et al. assessing the realisation of Gavi's mandate on immunisation rates and child mortality concluded that the organisation *has had a substantial impact on the fight against*

[579] D. Gouglas, G. Christodoulou, S. A. Plotkin, R. Hatchett, *CEPI: Driving Progress Toward Epidemic Preparedness and Response*, Epidemiological Review, November 2019, p. 28-33.; https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7108492 (27 May 2023).

[580] See: CEPI annual progress report 2019, Oslo, 2019.; https://cepi.net/wp-content/uploads/2020/04/CEPI-Annual-Progress-Report-2019_website.pdf (27 May 2023).

[581] See e.g.: G. Posner, *Big Pharma May Pose an Obstacle to Vaccine Development*, The New York Times, 2 March 2020.; https://www.nytimes.com/2020/03/02/opinion/contributors/pharma-vaccines.html (27 May 2023).

[582] B. Huneycutt, N. Lurie, S. Rotenberg, R. Wilder, R. Hatchett, *Finding equipoise: CEPI revises its equitable access policy*, Vaccine, Volume 38, Issue 9, 24 February 2020, p. 2144-2148.; https://www.sciencedirect.com/science/article/pii/S0264410X19317190?via%3Dihub (27 May 2023).

[583] See: Gavi, *Gavi, the Vaccine Alliance helps vaccinate almost half the world's children against deadly and debilitating infectious diseases*: https://www.gavi.org/our-alliance/about (27 May 2023).

communicable diseases for improved population and child health in lower-income countries.[584]

During the COVID-19 pandemic, CEPI and Gavi, along with WHO, co-led COVAX, the vaccine pillar of the ACT-A (see Chapter 6.7.1.). Under this initiative, Gavi was responsible for vaccine procurement. The failure of negotiations with pharmaceutical companies, which led to insufficient access to vaccines in the countries Gavi was supposed to serve, led to criticism of the organisation by some groups for its shortcomings in protecting the public interest (see Chapter 6.1.7.).[585]

Following COVAX's unsuccessful effort to quickly deliver vaccine doses to countries in the Global South at the height of the pandemic, Gavi launched a new initiative, the Pandemic Vaccine Pool, aimed at raising funds before the next generation of vaccines becomes available so that they can be purchased by the organisation without delay.[586] However, it remains unclear how COVAX's structural flaws will be addressed so as not to repeat the failure of the previous initiative.

7.6.3. Conclusions

The models discussed here demonstrate the breadth of alternative approaches to increasing relevant medical R&D efforts and providing more equitable access to final products. Some of them also show the potential to go beyond the current mainstream, profit- and market-driven commercial model and their use would better position the public sector to actively shape innovation and the market.

Selecting the most appropriate models and implementing them according to specific circumstances and identified medical needs pose a significant challenge. Various instruments may in theory fill similar gaps or have comparable effects, but differences between them make their suitability dependent on specific contexts. Local conditions and

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[584] P. Jaupart, L. Dipple, S. Dercon, *Has Gavi lived up to its promise?*, British Medical Journal Global Health, 31 August 2019.; https://gh.bmj.com/content/bmjgh/4/6/e001789.full.pdf (27 May 2023).

[585] See e.g.: MSF Access Campaign, *COVAX: A Broken Promise to the World*, Issue Brief, 21 December 2021.;https://msfaccess.org/sites/default/files/2021-12/COVID19_IssueBrief_Covax_1708_ENG_21.12.2021.pdf (27 May 2023).

[586] S. Berkley, *We can stop the cycle of new variants continuing indefinitely with a pandemic vaccine pool*, Gavi, 21 January 2022.; https://www.gavi.org/vaccineswork/we-can-stop-cycle-new-variants-continuing-indefinitely-pandemic-vaccine-pool (27 May 2023).

existing strategies could result in the same policy choice having different effects when transferred across borders.[587]

Moreover, the still limited evidence base on the effectiveness of the proposed models in diverse environments results in informed decision-making being all the more difficult. Although various examples of the use of particular models have been presented, most of them have not yet been widely used.

Nevertheless, among the options available, it is possible to distinguish those whose application would have the greatest chance of increasing suitable health emergency-related R&D efforts and providing broad access to their products.

Innovation in this area would ideally be based on an *open knowledge* model, which could generate technological advancements free to use, with no legal restrictions.[588] An open approach to innovation, including open source and open access schemes, could maximise research potential, speed up the development process, increase the scale of production and consequently provide broad access to end products. Corbevax can be considered proof of this concept for medical countermeasures. The best approach would be for countries to jointly fund and develop products such as vaccines making them available to all as public goods.

When funding medical R&D, options based on decoupling investment in innovation from medicine sales volumes and high prices are likely to be most effective in stimulating innovation while ensuring affordability and accessibility. Prizes, including milestone prizes, patent pools and broad, equitable licensing also offer effective ways to stimulate R&D for medical countermeasures, overcoming difficulties in the early-stage research and translating them into final technologies. For private technologies protected by intellectual property rights, governments should consider buyouts of patents and other intellectual property rights.

Given that public interest-driven R&D and the provision of affordable products would require significant upfront public funding, the possibility to pool resources at regional and global levels is an important factor. The impact of such pools could be highly

[587] R. R. Nelson, *What enables rapid economic progress: what are the needed institutions?*, Research Policy Volume 37, Issue 1, February 2008, p. 36.; https://www.sciencedirect.com/science/article/abs/pii/S0048733307002314 (27 May 2023).

[588] See also: WHO Consultative Expert Working Group on Research and Development, *op. cit.*, p. 104.

cost-effective. Better mechanisms and coordination for this purpose should be put in place, for example, as part of an international treaty.

While the experience to date with AMCs in terms of their potential to increase R&D activities and provide equitable access is mixed (see for example Gavi's AMC on PVC and the EU's or US's on COVID-19), this approach can be explored further and improved. If based on transparency principles, not over-compensating participating companies and including affordability and availability conditions in contractual clauses to ensure broad access, this tool has the potential to yield results in terms of enhanced R&D and production in markets that are currently not considered sufficiently lucrative from a business perspective.

For the success of any of these approaches, the creation of an appropriate legal framework is a critical factor. Often, a new law plays a fundamental role in enabling and promoting the use of alternative business models.

Countries should be bold, visionary and proactive in testing these models, especially those that can provide global public goods. The application of these mechanisms can fall within a range of ongoing, public interest-driven initiatives (many of those mentioned above) at global, regional and national levels. As discussed above, implementing these models would require strong public leadership, robust institutions and investments. Although it requires a major overhaul and expenditures, the price is worth paying to improve the existing system.

A coherent global framework that brings together different models and mechanisms in a coordinated and effective way could prove to be the most effective solution and the best chance to improve R&D outcomes and ensure equitable access to them.

The implementation of alternative models can be facilitated through international cooperation. Multilateral institutions could, for example, play a supportive role to governments in deciding which incentives and rewards are appropriate for a given country, how to implement them, and how much they will cost.[589] Governments could also collaborate to establish a global incentive program that pools resources and avoids duplication.

[589] The current lack of such a support has been indicated in the EU-JAMRAI interviews with policymakers and AMR experts in ten European countries: EU-JARMAI, *op. cit.*

When it comes to the public sector, national and regional agencies and institutes should cooperate through expertise exchange, training, and joint research ventures. Forming networks, consortia or partnerships bringing together not only research institutions, but also universities, non-profit organisations and private companies, could improve the flow of information and data, increase technological capabilities and spread risk. Product development partnerships (PDP) could be used subject to strong public leadership and balanced risk and rewards sharing between participating actors.

Ultimately, moving beyond the rhetoric, increasing evenly distributed R&D and manufacturing capacities and improving collaboration between institutions and producers around the world as well as engaging in the sharing of intellectual property rights, know-how and technology between them would allow realising the full scientific and technological potential to provide equal global access to the most effective medical countermeasures.

7.7. Reducing global inequalities – making the pharmaceutical system work for all

7.7.1. Mechanism for equitable access to medical countermeasures

As discussed in the first part of the dissertation (see Chapter 6.), one of the major shortcomings of the current pharmaceutical system is the unequitable access to medical innovation worldwide, which is particularly detrimental to the Global South. The current donor-recipient model and emergency mechanisms, such as ACT-A, have failed to support developing countries to prepare for or respond to health emergencies, whether pandemics like influenza or COVID-19, or epidemics such as Ebola.

Disease outbreaks start locally and responding as quickly as possible with local capabilities is essential to prevent them from becoming pandemics. In this way, the public health (but also social, economic and political) value of health technologies can be maximised.

Particularly in the absence of fully established publicly driven regional R&D and production infrastructure in the Global South, a new global mechanism should be set up to coordinate the development of adequate technologies and ensure equitable access to

medical countermeasures during emergencies. Their allocation should be based on needs assessed using internationally agreed recommendations, such as the WHO Equitable Allocation Framework, developed in May 2020 for COVID-19, which identified priority groups.

The mechanism should apply to all disease outbreaks and emergencies (instead of being limited, for example, to pandemics only) and serve all countries (instead of excluding, for example, middle- or upper-middle-income countries, as is often the case in such instances). It should overcome the profit-maximising commercial strategies by using all available tools to increase the production and supply of relevant products, including mandatory sharing of critical technologies, information, and intellectual property rights by private companies to make medical countermeasures a global public good.

Such a mechanism should link and coordinate key aspects of the development and delivery of medical products, including (1) global and regional R&D, (2) regulatory capacities (including conducting clinical trials as well as harmonising and strengthening regional regulatory agencies and WHO prequalification service), (3) regional manufacturing, (4) market shaping, (5) procurement policies, and (6) local integrated delivery (including the coordination of national, regional and global stockpiles) and health systems. These should not be treated as sequential steps but as interrelated elements. For example, access issues should be considered from the very beginning of the R&D process and health systems integration should be taken into account in the context of the conduct of clinical trials.

This can be achieved through clear, inclusive, flexible and effective structures, transparency (including in terms of IP information, licensing and technology transfer agreements), accountability, and sufficient surge funding.[590] To make the mechanism effective, its functions should include strategic planning, budget allocation decisions, programme monitoring and product distribution. Although its roles may vary in crisis and inter-crisis situations, clear triggers for the whole system and its distinct activities should be identified. This could come about as a result of an international agreement developed through an inclusive process, for example involving all WHO parties.[591]

[590] This includes leadership and equal partnership of governments from countries with different levels of income as well as civil society representation and safeguards against undue influence from the private sector.

[591] Worryingly, in early 2023, WHO and a select group of countries started discussions on setting up a Medical Countermeasures Platform, a *multi-disease, multi-tool, end-to-end platform for coordinating the rapid development and equitable access to medical countermeasures for pandemics and major epidemics*. The

7.7.2. Building regional expertise and structural capacity

The mechanism discussed is an important step to ensure better access to medical technology around the world. Its creation, however, will not provide a sufficient solution. The current and previous pandemics have shown that access to medical countermeasures depends primarily on who controls the technology and where production takes place. Both of these aspects are crucial.

The WHO report on the global vaccine market provides clear evidence of this from the COVID-19 pandemic.[592] COVID-19 vaccine distribution was mainly concentrated in the regions where particular vaccines were produced. As a result, regions without vaccine manufacturing capacity were left dependent on others to meet their demands, often belatedly. High-income countries, in times of acute emergency, tend to prioritise their own citizens and use their power to secure products for their own population.

In addition, beyond COVID, market concentration leads to supply shortages, as seen in the response to recent emergencies such as Mpox and cholera. Diversified global production is therefore a key element to enable equitable access.

Production alone, however, is not enough.

Increasing the real resilience of the global health infrastructure should include reducing the structural dependence of developing countries on external aid and charity. Enabling them to develop, produce and deliver medical products must go hand in hand with improving their ability to exercise control over the relevant technologies and ensure that international regulatory frameworks (such as those established under WHO and WTO) are not a barrier.

process of its establishment and design seem to repeat most of the same mistakes made with ACT-A, including governance left to actors (the private sector, philanthropic foundations and international agencies), which do not have a formal role in leading the global health processes. A platform run exclusively by a few public, private and philanthropic actors is destined to the failure in achieving equitable access. Read more: P. Patnaik, *A New Medical Countermeasures Platform for Equitable Access: Implications for On-Going Negotiations*, Geneva Health files, 21 February 2023.; https://genevahealthfiles.substack.com/p/a-new-medical-countermeasures-platform?utm_source=substack&utm_medium=email (27 May 2023).

[592] WHO, *Global Vaccine Market Report 2022*, Geneva, 9 November 2022.; https://www.who.int/publications/m/item/global-vaccine-market-report-2022 (27 May 2023).

7.7.3. Investing in and prioritising regional capacities

While collaboration and external financing can be vital to building a robust ecosystem in developing countries, the latter will not be achievable without prioritising public health policy at the national level, including through increased domestic budgets for local capacity. Most African countries fund only 50% of their health care and rely on external donors to sustain their systems. To change this, policymakers should put health high on their priority lists. Political leaders should fund regional infrastructure and create the necessary conditions, including science funding, to attract further investment while maintaining public health goals.

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7.7.4. Research and development institutes

Importantly, countries in the Global South can pool their resources, capabilities and knowledge to create infrastructure such as R&D institutes and production facilities at a regional rather than national level. Local researchers could acquire specialised competencies through scientific cooperation and training with more advanced institutions.

Such regional cooperation could build on existing examples in other sectors, such as the Consultative Group on International Agricultural Research[593] or CERN, the European Organization for Nuclear Research.[594]

Countries should create R&D networks in which knowledge, experience, technologies and rights to them are shared with each other. In the case of technology sharing, the development of a mechanism to do so could be educated by the success of the Montreal Protocol in this area.[595]

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[593] J. M. Alston, P. G. Pardey, X. Rao, *Payoffs to a half century of CGIAR research*, American Journal of Agricultural Economics 104(2) p. 502-529.; https://cgspace.cgiar.org/handle/10568/119445 (27 May 2023).

[594] K. Naim, M. G. Pia, A. Kohls, et al., *Pushing the boundaries of open science at CERN: submission to the UNESCO Open Science Consultation*, UNESCO, July 2020.; https://en.unesco.org/sites/default/files/cern-unesco_consultation_jul_15.pdf (27 May 2023).

[595] The Treaty was adopted to ban the production and use of ozone-depleting substances (ODSs) to save the layer's protective effect. As the ODSs are phased out, technology transfer is critical to the deployment of their replacements. By way of its encouragement, the Treaty provides for a financial mechanism (*Multilateral Fund* - MLF) to support it. This framework has proved remarkably successful in delivering high-impact technology transfer: *It is possible that the Montreal Protocol experience is the only occasion so far when public and private stakeholders considered technology cooperation a matter of human survival, stepped out of their narrow self-interests and promoted actions that allowed humanity to survive on Earth*. One helpful contributory factor has been that intellectual property has not (yet) posed significant

The (network of) institutes may include both public and private actors, but the focus should be on developing state-controlled regional capacities. If technology transfer is limited to collaboration within the private sector, it is likely to have a limited impact on equitable access – these products will continue to be sold by profit-driven companies to the highest bidder – as happened during the COVID-19 pandemic.

Some joint ventures could bring together institutes from around the world (for example, advancing the mRNA platform to develop vaccines for COVID-19 and other diseases), while others would naturally focus on meeting local needs (for example, adapting technology to develop a dengue vaccine in Asia).

As various technologies central to the development of medical countermeasures are currently protected by intellectual property and other rights belonging to the private actors (although many have been derived from public funds and public research, see Chapter 2.4.), states, through various means available, such as the use of *TRIPS flexibilities* but also, for example, patent buyouts, could ensure that institutes are able to take full advantage of them.

On the other hand, managing the rights to developed technologies and protecting them from privatisation resulting in limited access is a critical aspect of the institutions' operations. The ability to address potential barriers to technology and product commercialisation posed by intellectual property rights can be essential to ultimate success.

For the production of complex technologies such as those behind mRNA vaccines, addressing a barrier posed by patent protection is likely to not be sufficient as it also requires access to know-how, cell lines, and regulatory data.[596] This can be delivered most efficiently through direct technology transfer from the entity that holds the knowledge and rights. This is why a collaborative approach among various R&D and manufacturing entities is the best option. The approach would likely speed up the technology transfer and ensure continued interaction to solve problems in the production process, accelerate regulatory approvals and contribute to capacity enhancement. The terms of such cooperation could be agreed, for example, through an international instrument (see Chapter 7.8.1.).

problems, partially because many technologies were cooperatively developed and administratively delivered to the public domain for unrestricted global use. See: S. O., Andersen, K. M. Sarma, K. N. Taddonio, *Technology transfer for the ozone layer: Lessons for climate change*, Routledge, 2007.

[596] E. 't Hoen et al., *Scaling-up Vaccine Production Capacity… cp. cit.,* p. 5.

7.7.4.1. Global North-Global South collaboration

While the emphasis in the above discussion is on developing countries' initiatives to increase the autonomy and self-sufficiency in the Global South, ideally these would not compete, but be complementary and collaborative with efforts in wealthy countries.

Cooperation between the Global North and the Global South countries is required to maximise the dissemination of knowledge and the development of new technologies in the public interest.

This is particularly relevant in the field of medical countermeasures aimed at tackling infectious disease outbreaks around the world. The exchange of experience, the sharing of knowledge and technologies, joint training, and R&D ventures that enable scientists from all regions to take full advantage of state-of-the-art technologies and modern processes, can greatly enhance the effectiveness of efforts in this area.

Previous emergencies have demonstrated that there are coordination challenges across the R&D ecosystem. An appropriate framework is therefore needed to strengthen WHO's role and bring relevant stakeholders together, provide guidance for R&D and funding priorities, improve efficiency and align national, regional and international research goals. The Global South countries should play a central role in this process. An instrument adopted at the international level can be helpful in coordinating efforts to strengthen cooperation and reduce duplication.

7.7.5. Appropriate infrastructure for local manufacturing

Along with R&D capacity, developing countries also need to set up manufacturing infrastructure. The creation and operation of local, independent medical production require a coherent strategy that takes into account legal, technical, political and financial aspects.[597] It should balance the development of manufacturing capabilities for older and newer technologies, and factor in production efficiency and strategic autonomy.

For some countries in the Global South, it would mean expanding their manufacturing infrastructure (for example, Senegal, Tunisia, Egypt or South Africa) while for others, building it from scratch (for example, Kenya or Nigeria).

[597] *Ibidem*, p. 2.

Establishing manufacturing capacities in developing countries can be a challenging endeavour for various reasons. One of them is economic constrains and limited public health and industrial budgets. Different models can therefore work well for different regions depending on their financial capacities, existing infrastructure, populations or needs. Countries can achieve different levels of production with certain investments and should determine which model suits them best.

According to some estimates, small countries with limited resources could develop a facility with the capacity to produce about 100 million doses per year for over $11 million. Clearly, balancing capital investment and operating expenditures is key. Keeping a facility warm and able to switch to producing medical countermeasures during an emergency typically costs between five and 10 per cent of the capital expenditure.

Building and maintaining capacity in developing countries must be done in such a way that it does not represent too great a cost to national governments so that they do not decide to shut it down in *inter-pandemics* times and revert to relying on external supplies.

Importantly, such production facilities need not remain idle. Established facilities can be responsible for routine production[598] while having the critical infrastructure, skills and expertise to switch to medical countermeasure production during an outbreak.[599]

Such projects are not merely theoretical. The R&D and manufacturing infrastructure in the Global South is growing rapidly. Sufficient domestic and international funding, scientific cooperation and technical assistance over the long term, based on solid frameworks and agreements, can enable regional resilience, independent of rich countries and Big Pharma companies.

[598] The so-called *active use* conversion, by contrast with *passive use* when a minimum readiness is kept for future use while no routine production is performed.

[599] Establishing such a routine production, demand, market etc. would take time. In the meantime, they would operate the same way that the US government operates its pandemic influenza preparedness, which is that the spoke in this case, the national pandemic vaccine producer would produce every year one batch or maybe two batches of a pandemic vaccine – that's COVID initially and to be something else later – which would be released, tested for quality and maybe stored for a couple of months. Then pour down the sink, which is what happens in the USA, to the doses prepared for pandemic influenza.

7.7.5.1. WHO mRNA Technology Transfer Programme

The most ambitious attempt to build a network of R&D institutes and manufacturing entities in the Global South that would work together based on the above principles was launched by WHO and the Medicines Patent Pool (MPP) in June 2021.

The long-term initiative called the mRNA Technology Transfer Programme aims to develop technologies (starting with the mRNA platform) and establish sustainable, locally-owned manufacturing capabilities in and for developing countries based on the collaborative approach.[600]

In its current, initial stage, it is based around a technology transfer *hub* hosted by a small biotechnological company Afrigen Biologics in South Africa. Its task is to develop the mRNA technology, which in practice means re-engineering Moderna's vaccine based on publicly available information (and in collaboration with the University of the Witwatersrand in Johannesburg), as the company has refused to work with the programme.[601] In 2022, Afrigen succeeded in developing the COVID-19 vaccine AfriVac 2121, which is currently being tested. Afrivac 2121 will be the first mRNA vaccine developed in Africa from concept to clinical studies and manufacturing.

The *hub* provides training in the use of the technology with the aim of transferring it to the programme partners. However, as stressed by Petro Terblanche, managing director of Afrigen Biologics and Vaccines, *the hub is just one tiny, tiny component of a much, much bigger wave that's going through the globe*.[602]

In the first phase, as of early 2023, there are 15 companies participating in the programme in low- and middle-income countries across the world.[603]

These participating companies, on their part, build or enhance their absorption capacity to receive the technology from the *hub* and then produce, seek regulatory

[600] See: Medicines Patent Pool: mRNA Technology Transfer Programme: https://medicinespatentpool.org/covid-19/mrna-technology-transfer-hub-programme (27 May 2023).; and WHO, The mRNA vaccine technology transfer hub: https://www.who.int/initiatives/the-mrna-vaccine-technology-transfer-hub (27 May 2023).

[601] In March 2022, Afrigen succeeded in producing a vaccine called AfriVac 2121. As of March 2023, it is tested in preclinical trials and clinical trials I/II phase is planned to start in September 2023.

[602] S. Jerving, *Moderna's patents stand in way of mRNA vaccine hub's grand vision*, Devex, 21 April 2022.; https://www.devex.com/news/moderna-s-patents-stand-in-way-of-mrna-vaccine-hub-s-grand-vision-103055 (27 May 2023).

[603] Currently companies which are getting ready to be prepared for receiving the technology are based in: South Africa, Kenya, Nigeria, Senegal, Tunisia, Egypt, Brazil, Argentina, Ukraine, Serbia, Bangladesh, Vietnam, Indonesia, India, and Pakistan.

approvals and sell the products. They should also be able to further develop the technology, adapt and improve it.

The initiative's transformative approach is also evidenced by its handling of the ownership of innovations and rights as well as access to them. Companies participating in the network have open access to all developments carried out by each other under the programme. Once a technology is developed and tested by a *hub*, it is transferred not on the basis of bilateral licensing, but in a multilateral, inclusive way. All recipients of it can continue to work on it, and the rights to any changes and improvements and the final products developed based on it should be shared back with the network.

When it comes to specific products, the mRNA programme leaders and participating companies recognise that by the time they are able to develop, test, validate and produce an mRNA vaccine against COVID-19, it is highly likely that such a vaccine will no longer be needed. Rather, the programme is about building the mRNA platform, establishing partnerships, training, investing in and strengthening infrastructure, and developing a culture and trust in collaboration. Thus, the development of the COVID-19 vaccine is more about proof of concept than the product itself.

The programme is designed to also encourage the development of other than COVID-19 mRNA vaccines and therapies. Its scope should expand to other technologies, including viral vectors or monoclonal antibodies and other important diseases threatening the Global South, such as HIV, Zika or measles (depending on the likelihood of technical success, and regulatory and market capacity).[604]

In this way, developing countries could create a portfolio of technologies and products that they own and control. Political leaders should, and many already do, recognise that any other approach will fall short of providing autonomy from a public health and national security perspective.

The overall budget to coordinate the project, cover the established mRNA *hub's* activities in South Africa and develop the local innovations and products needed to become self-sufficient is estimated at approximately $117 million for 2021-2026. In early 2023, the programme was already close to securing this funding (received also from the Global North

[604] Some of the existing partners might even decide to not opt for getting a COVID-19 vaccine approved and might proceed with other products for other diseases.

countries).[605] While the first vaccine against COVID-19 was about to enter the costly clinical trial process, and further products against various diseases are to be developed in the future, the financial needs of the programme will certainly increase.

The *hub* has also received scientific support from high-income countries. For example, U.S. researchers from the National Institute of Allergy and Infectious Diseases (NIAID) have agreed to collaborate with Afrigen to share technical expertise related to the development of next-generation mRNA vaccines and therapeutics.[606]

Yet, the biggest problem for this potentially ground-breaking initiative is neither money nor scientific capability, but the thickets of intellectual property rights on health technologies creating legal barriers around them.[607] The existing patents represent a legal risk associated with potential litigations for companies receiving technologies under the programme and wishing to manufacture and commercialise products based on them.

Although Moderna has announced that it will never enforce patents on its mRNA technologies during the COVID-19 pandemic,[608] it has already sued Pfizer and BioNTech for patent infringement in 2022.[609] The company has subsequently updated its pledge to not enforce COVDI-19-related patents only in certain countries in the Global South.[610] Moderna's new commitment applies to only 92 eligible countries under the Gavi, Vaccine Alliance immunisation programmes. South Africa, along with three other countries

[605] The project is currently funded by the African Union, Belgium, Canada, Elma Foundation, European Commission, France, Germany, Norway, South African Government and South African Medical Research Council (SAMRC).

[606] See: Afrigen press release: https://www.afrigen.co.za/2022/07/08/afrigen-and-nih-to-collaborate-on-mrna-vaccine-production-research/ (27 May 2023).

[607] In a Devex interview, Terblanche said: *The mRNA intellectual property landscape is a nightmare*, Terblanche said. *If youlook at the web of patents … it's mind-boggling*. Moderna's patents stand in way of mRNA vaccine hub's grand vision. See: S. Jerving, *Moderna's patents stand…, op. cit.*

[608] Moderna, *Statement by Moderna on Intellectual Property Matters During the Covid-19 Pandemic*, Statements & Perspectives Details, 10 August 2020.; https://investors.modernatx.com/Statements--Perspectives/Statements--Perspectives-Details/2020/Statement-by-Moderna-on-Intellectual-Property-Matters-during-the-COVID-19-Pandemic/default.aspx (27 May 2023).

[609] Moderna, *Moderna Sues Pfizer And Biontech for Infringing Patents Central to Moderna's Innovative mRNA Technology Platform*, News details, 26 August, 2022.; https://investors.modernatx.com/news/news-details/2022/Moderna-Sues-Pfizer-and-BioNTech-for-Infringing-Patents-Central-to-Modernas-Innovative-mRNA-Technology-Platform/default.aspx (27 May 2023).

[610] Moderna, *Moderna's Updated Patent Pledge*, Statements & Perspectives Details, 3 July 2022.; https://investors.modernatx.com/Statements--Perspectives/Statements--Perspectives-Details/2022/Modernas-Updated-Patent-Pledge/default.aspx (27 May 2023).

(Argentina, Brazil and Serbia) hosting companies under the mRNA programme, is not on this list.[611]

Importantly, Moderna does not provide guarantees of the programme's freedom to use mRNA technology beyond the pandemic. The company's commitment not to enforce patents applies only to COVID-19 vaccines; it does not cover projects to develop vaccines and other products for various diseases, which may eventually include HIV or tuberculosis.

It should perhaps come as no surprise that an initiative aimed at building the independence of the Global South's medical research and production from Big Pharma companies is being met with non-cooperation from the latter. The companies that based their commercial success on mRNA technology during the COVID-19 pandemic are attempting to discredit and even refute the programme.

Moderna CEO Bancel told a media outlet POLITICO that working with the hub *is not a good use of our time* and that the hub is *nice to have, not a must have*. According to a report published in the British Medical Journal, BioNTech has sent representatives to South Africa to actively dissuade the government from local production of the COVID-19 mRNA vaccine.[612]

Experts directly involved in attempts to create a regional, end-to-end R&D, production and delivery infrastructure in the Global South, based on the principle of freedom to research in the public interest, have reported on their efforts *being blocked by the pharmaceutical industry and private foundations – parts of the same global health elite that presided over ACT-A's failure*.[613]

[611] A. Furlong, *Moderna to share vaccine tech, commits to never enforce COVID-19 jab patents*, Politico, 8 March 2022.; https://www.politico.eu/article/moderna-share-vaccine-tech-never-enforce-covid19-patents/ (27 May 2023). Moderna said that South Africa would be covered by its patent commitment, but the company has apparently not provided written confirmation to the Hub.

[612] M. Davies, *Covid-19: WHO efforts to bring vaccine manufacturing to Africa are undermined by the drug industry, documents show*, British Medical Journal, 376, 2022.; https://www.bmj.com/content/376/bmj.o304 (27 May 2023).

[613] R. Horton, Offline…, *op. cit.*

7.7.5.2. Other existing initiatives to increase local manufacturing capacity

While the mRNA technology transfer programme is the prominent and perhaps the most ambitious initiative of its kind, it is hardly the only one. There are currently 30 projects aimed at strengthening production in Africa alone.[614]

There is certainly overlap between these initiatives (for example, four (of the 15) WHO mRNA Programme companies are also participating in the CEPI's 100 Days Mission), and collaboration between them can significantly improve their effectiveness. However, it is important to recognise that the principles on which they are based do not always coincide, and the interests they serve may even be competing.

7.7.5.3. Pharmaceutical companies' satellite production sites

In early 2023, for example, BioNTech sent the first containers to Rwanda to build a *BioNTainer* to produce its mRNA-based vaccines for African Union countries.

In parallel, the company continues to build its manufacturing facility in Kigali which will "host" the containers to allow their setup and vaccine production.[615] The facility should be capable of producing up to 100 million mRNA vaccines per year.[616]

Moderna, meanwhile, is finalising an agreement with the Kenyan government to establish a $500 million manufacturing facility that will supply the continent with up to 500 million doses of mRNA vaccines per year.[617]

It is not clear to what extent these private initiatives will complement or compete with other projects. It is to be seen if they will strengthen the continent's capacity and improve access to medicines, or will they merely be new commercial ventures, making

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[614] J. Lei Ravelo, *Devex CheckUp: Another vaccine initiative? Hold on, says Africa CDC*, Devex, 9 March 2023.; https://www.devex.com/news/devex-checkup-another-vaccine-initiative-hold-on-says-africa-cdc-105093 (27 May 2023).

[615] BioNTech, *Update on First BioNTainer for African-based mRNA Manufacturing Facility*, Press Release, 21 December 2021.; https://investors.biontech.de/news-releases/news-release-details/update-first-biontainer-african-based-mrna-manufacturing (27 May 2023).

[616] The facility will initially house two sets of BioNTainers for mRNA vaccine production in bulk. One container will produce mRNA vaccines while the second container will produce formulated bulk drug products.
The BioNTainers are expected to commence manufacturing vaccines approximately 12 to 18 months after their installation.

[617] Reuters, *Moderna to build mRNA vaccine manufacturing facility in Kenya*, Reuters, 8 March 2022.; https://www.reuters.com/business/healthcare-pharmaceuticals/moderna-build-mrna-vaccine-manufacturing-facility-kenya-2022-03-07/ (27 May 2023).

profits for private companies contributing to countries' industrial policy but doing little to improve health security.

All in all, attempts by big pharmaceutical companies to establish their presence in the Global South could be detrimental to the public sector initiatives creating a national infrastructure that would allow governments to control medical technologies and the end products.[618] Market size is crucial to the profitability of vaccine production, and satellite manufacturing facilities of Big Pharma companies in developing countries may reduce the chances of any competitor making their business profitable.[619] They can therefore be seen as market competitors against, for example, the WHO mRNA Technology Transfer Programme.[620]

On the other hand, for developing countries with no production capacity, private investment can provide infrastructure that might not have been possible to establish without it. Countries are in different situations and different models can have positive effects in their specific circumstances. BioNTech, for example, has announced that it has hired nine local scientists for its *BioNTainers* in Rwanda, with plans to increase the number of employees to at least 100 by next year and eventually have local staff running the entire plant. This could boost the country's biotechnological development, and provide the region with a trained, specialised workforce that could ignite more interest and investment in the sector.

7.7.5.3.1. Partnership for African Vaccine Manufacturing (PAVM)

The pharmaceutical companies' projects in Africa may align with the ambitions of a new African Union initiative, the Partnership for African Vaccine Manufacturing (PAVM) established in 2021, which aims to enable the African vaccine industry to develop, produce and deliver more than 60 per cent of all vaccine doses required on the continent by

[618] D. R. Walwyn, *WHO's Technology Transfer Hub in Africa*, Erongo, 7 September 2022.; https://www.erongo.com.na/mw-b7-main/who%E2%80%99s-technology-transfer-hub-in-africa2022-09-0730902 (27 May 2023).; U. Beisel, *BioNTainer – A Manufacturing Solution for Africa or Circumventing Capacity*?, Medizinethnologie, 9 May 2022.; *https://www.medizinethnologie.net/biontainer-a-manufacturing-solution-for-africa-or-circumventing-capacity/* (27 May 2023).

[619] L. Paremoer, A. Pollock, *"A passion to change the landscape and drive a renaissance": The mRNA Hub at Afrigen as decolonial aspiration*, Frontiers in Public Health, 2022.; https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9742483/ (27 May 2023).

[620] In this light, adequate public investment and procurement policies are therefore critical to ensuring the sustainability of national infrastructure.

2040.[621] It aims to develop a fully integrated ecosystem to generate investment in all steps of the vaccine manufacturing supply chain, including R&D, drug substance manufacturing and the fill and finish stage. It will prioritise the development of vaccines for 22 diseases identified as critical. In total, some 23 manufacturing facilities are expected to be established under the initiative. It is estimated that the overall cost of the projects will be around $30 billion (of which $5 billion is needed to fund capital expenditure and other one-off costs[622] and $25 billion to fund recurring costs over 20 years[623]). Participation in the programme is open to both, public and private sector actors.

As part of a comprehensive public policy approach, the project is also supported by development finance institutions. For example, the African Development Bank Group and the Islamic Development Bank have signed a joint partnership action plan for the development of the pharmaceutical industry sector within their African member countries.[624]

7.7.5.3.2. *Transatlantic bridge* – South-South cooperation

Another recent initiative to *develop and manufacture pharmaceuticals for global public health* was launched on the sidelines of the COP27 in November 2022. It will support the development and production of pharmaceuticals in the Caribbean, Latin America and Africa by 2040.[625] As such, the initiative explicitly excludes Asia, potentially damaging its effectiveness and overall global solidarity. This project seems to be led by Barbados Prime Minister Mia Amor Mottley with the support of the European Commission and WHO, among others.

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[621] Up from less than 1 per cent today (with interim goals of 10 per cent by 2025 and 30 per cent by 2030).

[622] Primarily the set-up of the required vaccine manufacturing plants, the related cold-chain infrastructure, and the operationalization of key programs. See: Africa CDC, Partnerships for African Vaccine Manufacturing (PAVM) Framework for Action: https://africacdc.org/download/partnerships-for-african-vaccine-manufacturing-pavm-framework-for-action/ (27 May 2023).

[623] Including investments into priority R&D diseases as well as R&D into continual process improvement for vaccine manufacturing, royalties paid out for technology transfers, and additional spending on increased vaccine procurement on the continent.

[624] African Development Bank Group, *AfDB, IsDB join forces to boost Africa's health defense systems through the pharmaceutical industry*, 17 February 2023.; https://www.afdb.org/en/news-and-events/press-releases/afdb-isdb-join-forces-boost-africas-health-defense-systems-through-pharmaceutical-industry-59084 (27 May 2023).

[625] The initiative is referred to as a *transatlantic bridge between the Caribbean, Latin America and Africa to develop and manufacture pharmaceuticals for global public health*. See a letter: Barbados' Prime Minister Mia Amor Mottley announces transatlantic bridge between the Caribbean, Latin America and Africa to develop and manufacture pharmaceuticals for global public health, 8 November 2022.; https://irp.cdn-website.com/4b9fd501/files/uploaded/Pharmaceutical%20Equity%20for%20Global%20Public%20Health%208-Nov-2022%20Final%20Press%20Release%20v20.pdf (27 May 2023).

Very little is currently known about its structure, funding and priorities in the context of public or private sector engagement. It may also be competing for resources and a market with the WHO mRNA Programme and other ventures. The fact that it is, at least, supported by the kENUP Foundation, which lobbied against the mRNA Programme on behalf of BioNTech, does not give cause for optimism.

7.7.5.3.3. 100 Days Mission

The initiative in this area has also been launched by a group of the most developed economies. In 2021, based on lessons learned from the COVID-19 pandemic, the G7 launched the 100 Days Mission initiative, which aims to develop diagnostics, therapies and vaccines against emerging infectious diseases within 100 days of the discovery of a new pathogen. For example, under this initiative, CEPI is responsible for the vaccine pillar.[626] While CEPI aims to engage manufacturers from low- and middle-income countries, it is unclear at this point whether this cooperation will include technology transfer enabling them to adapt existing platforms and exercise control over the vaccines they produce.

7.7.5.3.4. Manufacturing and Access to Vaccines, Medicines and health technology products in Africa (MAV+)

Attempts to improve local infrastructure in developing countries are also supported, to some extent, by the EU countries. The EU has launched the *Manufacturing and Access to Vaccines, Medicines and health technology products in Africa* (MAV+) initiative to increase local production capacity and strengthen pharmaceutical systems in sub-Saharan Africa.[627]

The initiative aims to enhance industrial and supply chain development, improve regulatory systems, and increase technology transfer and *intellectual property management.* It is backed by €1 billion to be allocated in the form of loans, grants and blended funding from the EU and EU countries' budgets.[628]

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[626] CEPI, *Delivering Pandemic Vaccines in 100 Days*, November 2022.; https://cepi.net/wp-content/uploads/2022/11/CEPI-100-Days-Report-Digital-Version_29-11-22.pdf (27 May 2023).

[627] European Commission, *Team Europe Initiative on manufacturing and access to vaccines, medicines and health technologies in Africa*: https://international-partnerships.ec.europa.eu/policies/team-europe-initiatives/team-europe-initiative-manufacturing-and-access-vaccines-medicines-and-health-technologies-africa_en (27 May 2023).

[628] As of July 2022, the initiative mobilised over €906.55 million including at least €643.80 million in loans.

Part of this money has been earmarked for the African Medicines Agency (AMA), the Africa Centres for Disease Control and Prevention (ACDC) or the WHO mRNA Programme as well as capacity building in Senegal, Rwanda, South Africa and Ghana.

The EU stresses that its efforts are complemented by private initiatives such as those led by Moderna and BioNTech. It is questionable to what extent this initiative aims to empower developing countries by improving their domestic capacities or simply helping the EU industry expand into the African market.[629]

A similar initiative, called the EU-Latin America and Caribbean Partnership was launched by the EU in June 2022.[630] Not much detail is known about it, but it claims to follow the same approach as the MAV+, including increased *private sector engagement*. Therefore, similar concerns may be raised about the impact of the initiative on public sector capacity in the LAC region.

7.7.5.3.5. The more the merrier?

As noted above, the sheer number of projects aimed at improving local infrastructure raises the question of their ability to coexist and complement each other. Dr Ahmed Ogwell Ouma, acting director of the ACDC even warned countries against launching too many projects that could saturate the market, stressing that *it is very important that we don't have too many manufacturing facilities for vaccines … because if you have a glut in the production of vaccines, then you end up with a very unproductive investment*.[631]

7.7.6. Improving local procurement policy

In light of the above discussion on the plethora of private and public sector initiatives, local as well as global procurement policies can play a decisive role in enabling preferable ones to succeed.

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[629] E.g., through bilateral licensing of its technologies to companies from the continent while keeping full control of it.

[630] Its full name: *European Union – Latin America and Caribbean partnership on local manufacturing of vaccines, medicines and other health technologies, and strengthening health systems resilience*. See: European Commission, *EU-Latin America and Caribbean Partnership: manufacturing vaccines, medicines and health technologies and strengthening health systems*, Press Release, 22 June 2022.; https://ec.europa.eu/commission/presscorner/detail/en/ip_22_3890 (27 May 2023).

[631] J. Lei Ravelo, *op. cit.*

The sustainability of local production facilities will depend on demand creation and market building. Procurement from them, even if at a higher price in the early stages of production, should be prioritised. Joint procurement, such as that established by the Pan American Health Organisation (PAHO) in Latin America, can serve as a good model that can be replicated in other regions.

Transparency of supply, demand and procurement data is necessary to improve coordination and demand-driven procurement at different levels and in various regions.[632]

7.7.6.1. Joint procurement

In this context, developing countries should also take advantage of joint procurement beyond products manufactured by local factories. Overall, such a practice can benefit their bargaining power and increase their ability to incorporate public interest considerations or demand high standards of transparency in contracts with private companies. Joint procurement and negotiations with large suppliers (for example, of raw materials in China and India) will greatly enhance the ability of developing countries to secure the required goods on more favourable terms.

As discussed in Chapter 4.1.3., joint procurement was used during the COVID-19 pandemic by different groups of countries, and lessons from this experience should be learnt by regions around the world. This approach can change the dynamics of negotiations, strengthening the bargaining power of governments.

Cooperation in pharmaceutical procurement can take many forms, from information exchange to joint negotiations. For example, there are intergovernmental regional initiatives in Europe, such as the Benelux and Valetta groups, which focus on sustainability and transparency, laying the groundwork for cooperation and information sharing among national governments. Countries should learn from these initiatives to benefit from increased cooperation.[633]

Furthermore, strategic national, regional and global stockpiling of medical countermeasures and maintaining surge capacities are key parts of the *just-in-case*

[632] The Secretariat to the Independent Panel for Pandemic Preparedness and Response as background for the Panel, *Access to Essential Supplies*, Background paper 7, May 2021, p. 15.; https://theindependentpanel.org/background-paper-7-access-to-essential-supplies/ (27 May 2023).

[633] Improving countries negotiating position can also be done through collaboration on health technology assessments increasing the capacity to analyse the safety of drugs, their effectiveness combined with economic analysis of their cost-effectiveness.

approach, which should be implemented at decentralised as well as international levels. This should be accompanied by a mapping of available manufacturing capacities, including of raw materials.[634] The Global South countries should be involved in designing and managing any mechanisms to govern stockpiles established at the global level.

7.7.7. Strengthening local regulatory capacity

Local production and availability of medical countermeasures do not yet mean they can reach patients. Lack of regulatory capacity or inadequate standards and procedures can further impede access. In order to be allowed to authorise medicine substances for commercialisation, a regulatory authority must achieve *maturity level 3* status awarded by the WHO, which measures the quality of health regulatory systems. However, this has not yet been achieved in most countries or even regions in the Global South.

Swift and robust approval of health technologies should be facilitated by clear and streamlined regulatory pathways based on cooperation and harmonisation among regulators. The role of the WHO prequalification system and collaborative registration procedures should be enhanced.

7.7.8. Creating specialised agencies

Beyond R&D and manufacturing capacities, regional capacity in Asia, Africa or Latin America needs to be strengthened in terms of technical, legal and market knowledge aspects. Developing countries need strong public institutions that have the resources and necessary expertise to effectively represent the public interest when establishing pharmaceutical infrastructure or working with private companies.

The lack of them was glaring in the context of the COVID-19 vaccine negotiations. A former health minister from a South American country stressed that *one important lesson is that we needed more information and knowledge. Dealing with the market on specific products is a highly specialized area. I did not have someone who could help me to assess*

[634] The Secretariat to the Independent Panel for Pandemic Preparedness and Response as background for the Panel, *Access to Essential Supplies, op. cit.,* p. 15.;

products and negotiate prices. I wish we had a specialised agency in the region to support us.[635]

Medicine price negotiations are a good example of areas where specialised agencies and greater cooperation could improve public health outcomes.[636] Under the current system, the industry takes advantage of secrecy around national pricing negotiations. Pharmaceutical companies disclose the official prices set in different countries. However, these prices may differ significantly from the actual ones paid by national health systems, as pricing authorities often receive discounts or rebates based on a medicine's sales volume or performance. Importantly, these reductions in official unit prices are subject to confidentiality clauses and are not publicly disclosed. Consequently, national governments cannot know the real net prices paid by other countries. This can result in some states paying more for the same medicines than others for no particular reason, resulting in inequalities in access.

7.8. Reforming the international legal framework

7.8.1. Pandemic treaty

When it comes to global equitable access to medical countermeasures and beyond, COVID-19 and previous pandemics have proved that the existing international legal framework is unfit for effective pandemic preparedness and response.[637] The international rules established at WHO and WTO to protect public health have fallen significantly short, either due to poor compliance and the lack of enforcement measures or their overcomplexity and political pressure.

Lessons learnt from the pandemic point to the need for structural interventions and fundamental changes. The new rules should fill critical gaps in leadership, coordination and funding at the global, regional and national levels as well as in monitoring and evaluation of the implementation of international norms and standards.

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[635] The Independent Panel for Pandemic Preparedness and Response as background for the Panel, *How an outbreak…, op. cit.*

[636] The Secretariat for the Independent Panel for Pandemic Preparedness and Response as background for the Panel, *Access to Vaccines, Therapeutics, and Diagnostics*, Background paper 5, May 2021.; https://theindependentpanel.org/wp-content/uploads/2021/05/Background-paper-5-Access-to-vaccines-Therapeutics-and-Diagnostics.pdf p. 11 (27 May 2023).

[637] E. Torreele, Business as usual…, *op. cit.*

A key attempt in this regard was made in December 2021, when the World Health Assembly passed a resolution to set up a process for 194 WHO state parties to negotiate a new legal instrument (often called a *pandemic treaty*) so that they can effectively, and equitably address future pandemics.

The negotiations of the *treaty* along with the revision of the International Health Regulations (2005) offer an opportunity to introduce measures and mechanisms addressing issues such as innovation and equitable access to medical countermeasures, sharing of data and technology, building resilient health systems, oversight, governance and transparency as well as funding for *treaty* implementation. A detailed discussion of all these aspects is beyond the scope of this dissertation. There are, however, publications that provide a comprehensive analysis of them.[638]

In the context of medical countermeasure R&D and access, the international instrument could contribute to changing the status quo by including concrete commitments by WHO countries to, among other things, collaborate on R&D projects, share technology and know-how with developers and producers in developing countries, improve regional capacity through commitments to support and fund technology and production sites such as the WHO mRNA Programme, or create a fair and equitable system of access and benefit sharing.

7.8.1.1. Incorporating TRIPS flexibilities into national laws

Furthermore, while the *treaty* is being discussed at the WHO, which does not have a mandate for regulating international intellectual property rules (these fall under the remit of the WTO and WIPO), there are ways through which states can address IP barriers in the negotiated instrument, leading to greater access to vaccines and medicines in health emergencies.

For example, under the WHO *treaty*, countries could commit to preparing their national laws to allow for the use of non-voluntary sharing of rights to patents, data, know-how and biological resources needed for pandemic response, ensuring, among

[638] See e.g.: M. Kamal-Yanni, *Key Issues and Recommendations for the International Treaty on Pandemic Prevention, op. cit.;* MSF Access Campaign, *Pandemic Accord…, op. cit.;* Knowledge Ecology International, *KEI analysis on the WHO INB zero draft,* 28 March 2023.; https://www.keionline.org/38587 (27 May 2023).

other things, that their domestic legislation incorporates the *TRIPS flexibilities* (see Chapter 6.8.4.).

States could also commit to making full use of these *flexibilities*. Although it is already at the discretion of countries, the imposition of such an obligation at the international level could, in practice, improve the ability of developing ones to enact them. On the other hand, given the existing pressure often exerted by high-income countries on the use of these tools by countries in the Global South, the *treaty* should commit states to not in any way obstruct or seek to discourage other countries from making full use of the *flexibilities*.

Even the wealthy countries that have implemented these mechanisms into their laws have brought upon themselves additional restrictions that limit their full use. For example, EU countries can only take advantage of this instrument in their domestic markets, as all of them declared themselves ineligible to import medicines manufactured in another country under a compulsory license by opting out of Article 31bis of the TRIPS Agreement.[639] They should opt back into the Agreement as importers.[640]

Lastly, in regard to intellectual property, the *pandemic treaty* could ensure that bilateral and multilateral agreements (such as Free Trade Agreements or other investment deals) do not constitute a barrier to access to medical countermeasures and technologies. The treaty should require that states not enforce provisions in those other agreements when they conflict with the treaty obligations, for example, to share technology and know-how or scale up manufacturing.

7.8.1.2. Novel approaches to financing medical innovation

Financing medical countermeasure R&D efforts is a major challenge in the current preparedness and response framework, as the resources allocated and mechanisms put in

[639] Ch. Garrison, *Never say never – Why the High Income Countries that opted-out from the Art. 31bis WTO TRIPS system must urgently reconsider their decision in the face of the Covid-19 pandemic*, Medicine law and policy, April 2020.; https://medicineslawandpolicy.org/2020/04/never-say-never-why-the-high-income-countries-that-opted-out-from-the-art-31bis-wto-trips-system-must-urgently-reconsider-their-decision-in-the-face-of-the-covid-19-pandemic/ (27 May 2023).

[640] See: Open letter asking 37 WTO Members to declare themselves eligible to import medicines manufactured under compulsory license in another country, under 31bis of TRIPS Agreement, April 2020.; https://www.keionline.org/32707 (27 May 2023).

place for this purpose are inadequate. Therefore, securing sufficient, sustainable and long-term public funding from all countries, according to their capacities, is essential for effective national and global action. Collective development of medical technologies and equitable control over and access to them requires a new funding and governance structure in which the *treaty* parties collaborate and share the outcomes openly, or at least among each other. Only when governments develop a framework that governs how medical R&D is funded and managed in the public interest, will the resulting end products have a chance to be available globally and even become common goods.

R&D funding should be based on a progressive and sustainable model. Global Public Investment (GPI), a system of international public finance in which governments work together to secure international public policy outcomes through fractional contributions from public sector revenues, may be most appropriate for this purpose. GPI is based on the principle that everyone contributes, everyone benefits, and everyone decides.[641]

International and regional financial institutions also have a role to play in enhancing national R&D and production capacity and stimulating collaboration by choosing the most appropriate types of R&D models in which to invest. Their funds should support alternative initiatives, such as the WHO mRNA Programme. When investing in private companies, they should prioritise those that collaborate with such initiatives, contributing to regional independence.

The *treaty* should also address research prioritisation processes by including measures to identify R&D needs and gaps and establish clear objectives through a transparent and inclusive process. This could be done, for example, through the WHO Observatory on Health Research and Development[642] and the WHO R&D Blueprint[643].

[641] M. Kamal-Yanni, *Key Issues and Recommendations for the International Treaty on Pandemic Prevention*, *op. cit.*, p.8

[642] See: WHO, Global Observatory on Health Research and Development: https://www.who.int/observatories/global-observatory-on-health-research-and-development (27 May 2023).

[643] See: WHO, WHO R&D Blueprint: https://www.who.int/observatories/global-observatory-on-health-research-and-development/analyses-and-syntheses/who-r-d-blueprint/background (27 May 2023).

7.8.1.3. Increasing regulatory capacity and harmonisation

Another key area that an international instrument, such as the *pandemic treaty*, should address to improve the development and access to medical countermeasures is regional regulatory capacity. As discussed above, not all countries have sufficiently strong medicine agencies to evaluate drugs and complex technologies such as those behind next-generation vaccines.

Mutual recognition arrangements between regulatory agencies globally and information sharing to avoid duplication and inefficiencies as well as enhancing access to a global repository of data, can have a direct impact on access, reducing unnecessary delays.

The *treaty* should also improve regulatory pathways for robust but rapid assessment and approval of medical countermeasures during health emergencies and the role of the WHO prequalification scheme and collaborative registration procedures.[644]

7.8.1.4. Adapting the design of clinical trials

The negotiation of a *pandemic treaty* could also be used to agree on clinical trials designed by public authorities and conducted through a ready-to-use network linked to R&D institutes, allowing for better comparison of products, prioritisation, facilitated communication between developers and regulators as well as transparency.[645]

States should also seek to increase collaboration between public health agencies at national, regional and global levels. The COVID-19 pandemic has highlighted the need and provided an opportunity to harness new collaborations among regulatory agencies, health technology assessment bodies and payers to ensure the timely generation of comparative

[644] Prequalification process is performed by the WHO for other UN agencies, for purchase by those agencies. WHO Member States also use the WHO prequalification information in procurement decisions as do donors of medicines procurement and NGOs.

[645] The Secretariat for the Independent Panel for Pandemic Preparedness and Response as background for the Panel, *Access to Vaccines, Therapeutics, and Diagnostics…, op. cit.,* p. 14.; E. Torreele, M. Kazatchkine, J. Liu, M. Dybul, M. Cardenas, S. Singh et al., *Stopping epidemics when and where they occur*, The Lancet, Volume 401, Issue 10374, 4 February 2023, p. 324-328.; https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(23)00015-6/fulltext (27 May 2023).

data on medicines.[646] Similarly, improved cooperation among public health agencies can lead for example to more informed pricing decisions.[647]

7.8.1.5. Other areas to be addressed in the *pandemic treaty*

In addition to the areas discussed above, which have a primary impact on developing, manufacturing and delivering medical countermeasures, there are additional aspects, such as efficient surveillance capacity, well-functioning and funded health systems or improved governance of health emergency preparedness and response framework, which can be critical points for an adequate and rapid development and equitable allocation of health products globally.

While they are not the focus of this dissertation, a brief discussion of how they should be addressed in the *treaty* is important to complete the overview of interventions in the context of preparing and responding to pandemics.

7.8.1.5.1. Surveillance

First and foremost, better national and regional surveillance with routine data collection is needed to respond quickly to new pathogens, limiting the spread of outbreaks.

For example, six months into the COVID-19 pandemic, over 30,000 genome sequences of the virus have been available.[648] However, disparities in the capacity of doing so around the world are stark. While the U.K. has been able to sequence almost 3 million coronavirus genomes, many countries sequenced a few thousand in total, and some even

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[646] H. Naci, A. S. Kesselheim, et al., *Producing and using timely comparative evidence on drugs: lessons from clinical trials for covid-19*, British Medical Journal, October 2020, p. 1-6.; https://www.bmj.com/content/371/bmj.m3869 (27 May 2023).

[647] Also beyond medical countermeasures, in the post-marketing period, regulators, with input from HTA bodies, should encourage companies to conduct randomised trials with an active comparator to demonstrate the added therapeutic benefit of their products. Furthermore, payers should use their negotiating power to incentivise the generation of better evidence on new and existing medicines, for example, by explicitly including proven added therapeutic benefit in pricing and payment decisions. Moreover, HTA bodies and payers across Europe should routinely disclose information on the comparative benefits and harms of new and existing medicines.

[648] A. Maxmen, *One million coronavirus sequences: popular genome site hits mega milestone*, Nature, 23 April 2021.; https://www.nature.com/articles/d41586-021-01069-w?utm_medium=affiliate&utm_source=commission_junction&utm_campaign=CONR_PF018_ECOM_GL_PHSS_ALWYS_DEEPLINK&utm_content=textlink&utm_term=PID100095187&CJEVENT=b0c89def94e811ed825f014c0a18b8fc (27 May 2023).

less than a hundred.[649] As of late 2022, about half of the genome sequences came from just five countries, with the largest gaps in sequencing occurring in the African and Middle Eastern regions.

The *pandemic treaty* should therefore enhance the capacity of developing countries to access technologies and training in the use of artificial intelligence and genomic sequencing to understand how the virus is spreading and to evaluate the effectiveness of interventions.[650] The international instrument should also provide incentives for countries to notify the WHO of detected pathogens and avoid penalising those who do so.[651]

The *treaty* could also lead to the establishment of a global system of surveillance that enables early detection and rapid response in line with the recommendation of the Independent Panel for Pandemic Preparedness and Response.[652]

Surveillance, genome sequencing and rapid pathogen sharing should be part of a broader *access and benefit sharing system*.

7.8.1.5.2. Access and benefit sharing system

Access to, and benefit sharing of, genetic resources – including microbial genetic biological material – was *expressly developed in international environmental law to tackle historical and ongoing colonial exploitation and extraction of genetic resources by wealthy nations that then benefited further from the use of those resources*.[653] The Pandemic Influenza Preparedness (PIP) Framework adopted in 2011 linked for the first-time access to pathogens to fair and equitable sharing of benefits arising from their use. [654] The PIP framework establishes a mechanism for sharing influenza viruses and access to vaccines and other benefits. It also recognises that the WHO members have a commitment to virus-

[649] See: GISAID Global Tracker of Submissions: https://gisaid.org/submission-tracker-global/ (27 May 2023).

[650] M. Kamal-Yanni, *Key Issues and Recommendations for the International Treaty, op. cit.*, p. 19.

[651] For example, West African countries were late in notifying Ebola for fear of economic and trade impact, which happened in the form of flight bans. South Africa and Botswana were also punished by many countries
via flight bans (thus obstructing movement of people and trade) following their swift notification of new COVID-19 variants.

[652] The Independent Panel for Pandemic Preparedness and Response, *About the Independent Panel*: https://theindependentpanel.org/about-the-independent-panel/ (27 May 2023).

[653] A. L. Phelan, *The World Health Organization's pandemic treaty,* British Medical Journal, 380, 28 February 2023.; https://www.bmj.com/content/380/bmj.p463 (27 May 2023).

[654] It builds on the legal principles of the Convention on Biological Diversity providing governments with rights to fair and equitable benefit-sharing and recognizes the sovereign right of states over their biological resources.

sharing and benefit-sharing on an *equal footing*, as they are *equally important parts of the collective action for global public health*. Accordingly, the framework sets out international rules governing the access to influenza viruses of pandemic potential (IVPP) and the benefit-sharing obligations of the recipients of IVPP.[655]

The *pandemic treaty* should draw on such mechanisms and establish a system whereby the sharing of technology, knowledge and intellectual property by manufacturers accessing pathogens and data, biological samples or patient specimens is mandatory during a pandemic to ensure equal access to all medical countermeasures. Benefits should also include training on technologies, affordable prices of products distributed globally, or joint research projects based on shared information. During *inter-pandemics* periods, manufacturers accessing the information and data should make monetary contributions to WHO. The fund established with these resources could be used for improving emergency preparedness capabilities in developing countries.

To ensure traceability and accountability, the origin of pathogens and other biological materials should be disclosed in patent applications.[656]

7.8.1.5.3. Resilience of health systems

Even before the COVID-19 pandemic, shortcomings in preparing health systems for emergencies in developing countries were exposed, for example in West Africa during the Ebola virus crisis.[657]

The international instrument should therefore lead to increased investment in holistic public health systems to achieve access to quality health care with the capacity to prevent and respond to future outbreaks.[658] Having efficient healthcare systems is an essential part of ensuring access to medical countermeasures. Countries should develop long-term costed plans to build and maintain resilient systems that can serve health needs and health security.

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[655] See: People's Health Movement, *Access and Benefit Sharing: The Pandemic Influenza Preparedness Framework*, PHM, July 2018.; https://phmovement.org/wp-content/uploads/2018/07/D8.pdf (27 May 2023).

[656] MSF Access Campaign, *Pandemic Accord: MSF's Comments on Equity Provisions in Zero Draft… op. cit.*, Annex 1, p. 5.

[657] M. Kamal-Yanni, *Never Again*, *op. cit.*

[658] M. Kamal-Yanni, *Key Issues and Recommendations for the International Treaty*, *op. cit.*

The Global North countries, multi-lateral institutions or philanthropic entities should support developing countries' plans for building their health systems as a global public good in line with the principle of common but differentiated responsibilities.[659]

7.8.1.5.4. Governance

Finally, the new international framework should establish inclusive, transparent, and coordinated governance of pandemic prevention, preparedness and response.[660] It should entail co-creation and decision-making by all WHO states.[661]

The representative inclusion of the Global South countries (for example, through WHO regions or other regionally agreed selection processes) in any global mechanism is critical to breaking the flawed donor-recipient model that dominates the development and health sectors. High-income countries should not be in the position to decide how the rest of the world is represented and what solutions may be best for it.

Global governance should also include civil society and other relevant stakeholders. In terms of the latter, countries should give consideration to the potential commercial interests of the private sector and so guard against conflict of interest and undue influence.

7.8.1.6. Operationalising equity

The balance between incentivising countries and setting binding obligations and commitments on them to invest, collaborate and coordinate their actions to strengthen the pandemic preparedness and response frameworks can be difficult to strike in practice.

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[659] *Common but differentiated responsibilities and respective capabilities* (CBDRRC) is the most significant guiding principle in the international climate change regime. This principle refers to the fact that the climate change problem *affects and is affected by all nations in common, if not to the same degree, and that the resulting 'responsibilities' ought to be differentiated because not all nations should contribute equally to alleviate the problem*. This entails that while pursuing a common goal, States undertake different obligations depending upon their socio-economic situation and their historical contribution to the problems at stake.
It is also a fact that developed countries bear the main responsibility for climate change, inasmuch as they've contributed to the largest share of historical GHG emissions. Therefore, the commitments of developed and developing countries on substantive, as well as procedural, rules occupy a bifurcated system that reflects their differing responsibilities and capacities. The ongoing negotiations on the WHO Pandemic Accord include the implementation of the principle in the global health area.

[660] M. Kamal-Yanni, *Key Issues and Recommendations for the International Treaty, op. cit.,* p. 15.

[661] The Global Fund's national coordination mechanisms can provide a model for decision-making based on national consultations.

As the negotiations of the *pandemic treaty* progress, a clear divide between the positions of Global North and Global South countries is evident in the subject matter of the provisions, but also in their binding effect and enforceability. For example, while the first drafts of the *treaty* presented in early 2023 recognise the need to develop multilateral mechanisms for technology and know-how transfer, the proposed language referring to the *promotion* of such actions and limiting them to *mutually agreed terms* weakens these provisions and may make them difficult to apply in practice. Using qualifiers or other limiting language such *as appropriate* or to *the extent necessary* would make the new measures merely aspirational.

In terms of countries' actions toward pharmaceutical companies, a commitment by WHO parties to only *encourage* originator companies to share technology and intellectual property rights with capable manufacturers around the world to increase the scale of production and availability of products would likely have little impact in reality. The lack of willingness of private actors to take such action during the COVID-19 pandemic clearly indicates that a change in the status quo can only be achieved through compulsory measures. Proposed encouragements to the private sector, when public health is at stake, should be transformed into obligations.

Chapter 8. Altering corporate governance and having new actors in the pharmaceutical sector

8.1. Changing the business model of pharmaceutical companies

The above proposals aim to transform public sector management and leadership, increase multilateral cooperation, shape the market, and influence the decision-making of private companies. These ways to improve the approach to medical innovation, however critical, do not exhaust the possibilities of changing pharmaceutical R&D and access ecosystem.

Given that the poor outcomes of the pharmaceutical system are a consequence of its current ineffective design, far-reaching options must also be considered such as altering the ways in which private actors operate on the market – or even changing the actors themselves – to promote corporate governance which considers aspects beyond profit and leads to better value creation.[662] It may involve limiting the practice of share buybacks, setting conditionalities of profits' reinvestment, or tying executive compensation not to stock value but to equal access to the produced goods, among other things.

Influencing the business models of companies in the pharmaceutical market is necessary to bring about a meaningful change in the system and could complement other public policy measures such as attaching conditions to public investments.

The solutions discussed below could be applied across sectors, but there is a particularly strong case for their introduction in the context of pharmaceutical R&D, given the significant public funding for it and the essential nature of its results.

8.1.1. Limiting or banning stock buybacks

The first proposed change is to limit or ban the practice of companies repurchasing their own shares on the public market.

[662] UCL Institute for Innovation and Public Purpose, *The people's prescription, op. cit.,* p. 42.

Stock buybacks are used by companies to manipulate the market in order to increase profits for their shareholders and are associated with what Mazuccato and others call *value extraction*.[663]

While share buybacks are supposed to benefit all shareholders, Lazonick and Tulum distinguish between two groups of them, arguing that this tactic does not pay off for everyone.[664]

The current financialisation of the industry mainly benefits shareholders who are professional stock market investors generating profits by buying and selling shares at the right time, sometimes taking advantage of non-public information.[665]

The other group of shareholders who buy pharmaceutical companies' shares on the stock market and hold them seeking dividends on the profits generated by the company should be opposed to buybacks and instead, call for reinvesting profits in R&D or production capacity of the company. That way, the company could develop new competitive products on which more income would be generated in the long run and a stable dividend would continue to be paid out.

From the public interest perspective, the latter group of shareholders is more desirable and should be preferred to hold shares in pharmaceutical companies. For companies that successfully invest in health innovations, their shares should grow over the long term, also allowing shareholders to sell their assets at a profit.[666]

Restricting or even banning the practice of share buybacks, along with other measures, could lead to greater reinvestment of profits in long-term R&D projects. By doing so, pharmaceutical companies would lose one of their main tools for manipulating the market in the interest of short-term profit and could use their money in relevant research leading to much greater efficiency in the sector.

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[663] *Ibidem*.
[664] W. Lazonick, O. Tulum, *Sick with "Shareholder Value", op. cit.*, p. 17.
[665] W. Lazonick and J-P. Shin, *Predatory Value Extraction: How the Looting of the Business Corporation Became the US Norm and How Sustainable Prosperity Can Be Restored*, Oxford University Press, 2020.
[666] W. Lazonick, *US Pharma's Financialized Business Model, op. cit.*, p. 17-18.

8.1.2. Decoupling executive compensation from stock-price performance

Another feature of the industry's management, which itself also encourages share buybacks, is the linking of executive compensation to the company's stock price.

Executives currently receive stock-based compensation (see also Chapter 5.4.) and are rewarded far more for short-term stock price increases – often inflated by speculation and manipulation, as evidenced by Lazonick and Tulum – than for innovation.[667] Recent studies suggest that such a system has not been able to encourage and reward value creation and desirable (from the public interest perspective) outcomes.[668]

To remedy this, experts point out that performance-based bonuses could be linked to broader outcome measures, such as bringing to market new compounds with additional therapeutic benefits.[669] Such a model could also help increase access to end products by linking executive compensation to equal access.

This idea has even found support from businesses in the face of inequities in access to COVID-19 vaccines. In January 2022, 65 large investors in vaccine makers Pfizer, Johnson & Johnson, Moderna and AstraZeneca (representing $3.5 trillion in assets under management) signed a joint letter calling for executive pay to be tied to vaccine equity.[670] They asked the companies to adopt the WHO roadmap to achieve equitable access and to link its implementation to executive compensation *in a meaningful, material, measurable and transparent way.*[671]

What is more, in the US, President Biden has expressed its support for legislation *that would align executives' interests with the long-term interests of shareholders, workers, and the economy by requiring executives to hold on to company shares that they receive for several years after receiving them, and prohibiting them from selling shares in the years*

[667] W. Lazonick, O. Tulum, *Sick with "Shareholder Value", op. cit.*, p. 18.

[668] J. McGregor, *CEO pay-for-performance model could be broken, report says*, Financial Post, 6 October 2017.; https://business.financialpost.com/executive/a-new-report-suggests-a-fundamental-idea-behind-ceo-pay-could-be-broken (27 May 2023).

[669] High Pay Centre, *No Routine Riches: Reforms to Performance-related Pay*, High Pay Centre, May 2015.; http://highpaycentre.org/pubs/no-routine-riches-reforms-to-performance-related-pay (27 May 2023).

[670] According to the news agency, firms including Nomura, Investec, Boston Common Asset Management, Candriam, GAM, Aegon and PGGM asked the drugmakers to commit to a World Health Organization roadmap on global vaccine access. See e.g.: T. Sterling, *Tie pharma CEO pay to fair global COVID-19 vaccine access, investors say*, Reuters, 6 January 2022.; https://www.reuters.com/business/healthcare-pharmaceuticals/investors-tie-pharma-ceo-pay-fair-global-covid-19-vaccine-access-2022-01-06/ (27 May 2023).

[671] One of the backers of the initiative admitted that *pharmaceutical companies have a duty to do their utmost on this but unfortunately we see that they are lagging behind*. Another supporting management company pointed the need to *make business sense for a vaccine manufacturer to aim to vaccinate the whole world*.

after a stock buyback.[672] Such legislation would discourage corporations from using profits to repurchase stock and enrich executives, rather than investing in long-term growth and innovation.

At the same time, it is argued that all corporate employees who contribute to innovation through organisational-learning processes should also be rewarded for corporate successes through stable and equitable compensation plans.[673]

8.1.3. Including stakeholder representatives on corporate boards

Another way to improve companies' consideration of the public interest is to include broader stakeholder representation on their boards and extend voting rights to them.

As Lazonick and Tulum argue, this should also include taxpayers, who collectively fund research (see, for example, Chapter 2.4.) and contribute to value creation.[674] In the case of pharmaceutical companies, to reflect their responsibility to respond to public health needs, it can be argued that their boards should also include representatives of patients who rely on the companies for access to lifesaving products.

8.1.4. Reforming the corporate tax system

As argued in Chapter 7.4.6., one of the public incentives for pharmaceutical companies to invest in R&D is tax breaks on their profits. It is argued that by saving money on tax payments, companies could increase their innovation budgets. However, as demonstrated in the U.S. during the debate over the Tax Cuts and Jobs Act of 2017, the main way corporations use the extra revenue generated by these credits is to provide additional cash dividends to shareholders and buy back company stock.[675]

In this case, it should be further analysed whether the system of tax breaks for pharmaceutical companies should not be reduced, or at least strengthened.

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[672] The White House, *Budget of the U.S. Government: Fiscal Year 2023*, Government Printing Office, 2022, p. 16.
[673] W. Lazonick, O. Tulum, *Sick with "Shareholder Value", op. cit.*, p. 18.
[674] W. Lazonick, *Investing in Innovation: Confronting Predatory Value Extraction in the U.S. Corporation*, AIR Working Paper, 26 September, 2022.; https://theairnet.org/melseerg/2022/10/Lazonick-Investing-in-Innovation-20220926.pdf (27 May 2023).
[675] R. Wartzman, W. Lazonick, *Don't let pay increases coming out of tax reform fool you*, Washington Post, 6 February, 2018.; https://www.washingtonpost.com/opinions/dont-let-pay-increases-coming-out-of-tax-reform-fool-you/2018/02/06/1271905a-06a6-11e8-94e8-e8b8600ade23_story.html (27 May 2023).

8.2. Changing the statutory form of pharmaceutical companies

To improve the performance of pharmaceutical companies in line with public health needs, changes in their context can go beyond governance and operations. As observed above, the inability of the current system to achieve public health goals stems from the shift of responsibility for meeting public health needs to corporations whose statutory purpose makes them particularly unable to fulfil this mission. The social contract between the public and the pharmaceutical industry has been broken and public policies should reform the operations of the latter.[676]

While the model of shareholder-owned corporations is currently dominant in the pharmaceutical market, it is not the only possible way to structure economic activity leading to the development and manufacturing of medicines.[677] To combine the ability to attract private capital with delivering on public health needs, public policies should encourage the involvement of corporations with other legal forms, such as non-profit or limited-profit companies and benefit or social purpose corporations in the sector. The statutory form of currently prevailing for-profit companies could be changed to one of the above to *alter their incentives from the inside* and to enable and require them to consider other interests beyond shareholder value.[678]

8.2.1. Non-profit or limited-profit companies

One alternative (or complement) to for-profit companies is non-profit or limited-profit research and development companies. These are most often established for a good cause, such as charitable, humanitarian or educational purposes. They can neither raise private capital nor distribute profits.

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[676] These ideas are far from being purely academic as it has been e.g., recognised in the EU Council Conclusions during the Slovenian Presidency. The conclusions' point 23 calls on the Commission and the Member States to examine the possibility of creating one or more European non-profit pharmaceutical undertakings which operate in the public interest to manufacture medicinal products of health and strategic importance for healthcare, in the absence of existing industrial production. See: Council Conclusions on strengthening the European Health Union, Official Journal of the European Union, 2021/C 512 I/02, 2 December 2001.; https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52021XG1220(01) (27 May 2023).

[677] UCL Institute for Innovation and Public Purpose, *The people's prescription, op. cit.* 43.

[678] Y. Heled et al., *Why Healthcare Companies Should…, op. cit.*

The first non-profit pharmaceutical company in the U.S. was the Institute for One World Health founded in 2000. [679] It successfully developed a drug (Paromomycin IM) for the treatment of visceral leishmaniasis and obtained regulatory approval for it. The treatment program has been broadly expanded in Asia.[680] In 2011, the company was absorbed by PATH, a PDP working on pharmaceutical innovation (see also Chapter 7.5.1.), to enable the One World Health to scale and accelerate drug development efforts. As part of the PATH's current drug development strategy, it is now targeting diarrheal disease, ensuring the supply of malaria treatments, and developing a new tool to stop the spread of HIV.

Non-profit pharmaceutical R&D efforts are not new and have long been seen as a potential way to provide innovative and affordable medicines.[681] Their ability to deliver medical innovation can be evidenced by the fact that it was non-profit organisations that led technological advances in gene therapies and rare diseases supported by the public and patient organisations at the turn of the 20th century. Many gene therapies currently developed by Big Pharma companies can be traced back to these organizations.[682] In Europe, examples of such companies include Genethon in France and the San Raffaele Telethon Institute for Gene Therapy (SR-Tiget) in Italy.

However, as noted by Jarosławski and Toumi using Genethon as an example, non-profit companies grapple with the problem of finding the right balance between the affordability of their products and generating enough revenue to be sustainable and competitive.[683]

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[679] See: Institute for OneWorld Health, Palo Alto, CA: Skoll Foundation, 2021: https://skoll.org/organization/institute-for-one-world-health/ (27 May 2023).

[680] It has also pioneered the use of synthetic biology to produce a reliable supply of artemisinin – a key component of malaria treatment – at an affordable price. Semisynthetic artemisinin (PMIM) has been registered with national drug development agencies of India, Nepal and Bangladesh and included on the WHO Essential Medicines List.

[681] See e.g.: V. G. Hale, K. Woo, H. L. Lipton, *Oxymoron no more: the potential of nonprofit drug companies to deliver on the promise of medicines for the developing world*. Health Affairs, 2005.; https://pubmed.ncbi.nlm.nih.gov/16012146/ (27 May 2023).

[682] Sz. Jarosławski, Non-profit drug research and development: the case study of Genethon, Journal of Market Access & Health Policy, 5 July 2018.; https://www.tandfonline.com/doi/full/10.1080/20016689.2018.1545514 (27 May 2023).

[683] *Ibidem*.

8.2.2. Benefit corporations

The scope of consideration of (potential) actors playing a role in the pharmaceutical sector should not be limited only to for- and non-profit corporations, as it wrongly presents a conflict between the pursuit of private profit and public interest objectives.

It is argued that the use of *hybrid legal forms* allows the realisation of both public needs and individual benefits, reducing the divergence between private and public interests.[684] Such forms of economic activity are becoming increasingly popular and more countries around the world have begun to recognise them.[685]

While it is unlikely that governments will stop relying on private companies to develop and deliver medicines, there are ways to keep them from being solely profit-driven.[686] Experts suggest that this can most effectively be accomplished through limited-profit companies, such as benefit corporations, which are for-profit enterprises whose legal structure requires them to balance their social mission with profit for shareholders.[687] They can reward efficiency and attract private capital while aligning with the public interest in meeting medical needs and providing innovative and affordable products.

For example, under U.S. law, benefit corporations must (i.e., are required, not just allowed) to pursue a *general public benefit*,[688] take into account the non-financial interests

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[684] Y. Heled et al., *Why Healthcare Companies Should…, op. cit.*, p.120.

[685] G. Shockley, D. R. Young, E. A.M. Searing, and C. Brewer (Ed.): *The Social Enterprise Zoo: A Guide for Perplexed Scholars, Entrepreneurs, Philanthropists, Leaders*, Investors, and Policymakers, Journal of Entrepreneurial and Organizational Diversity, Vol. 8, No. 2, 2019, p. 77-79.; https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3567854 (27 May 2023).

[686] A. R Eiser, R. I. Field, C*an Benefit Corporations Redeem the Pharmaceutical Industry?*, The American Journal of Medicine, Vol 129, No 7, July 2016.; https://www.amjmed.com/action/showPdf?pii=S0002-9343%2816%2930200-5 (27 May 2023).

[687] In other jurisdictions these forms of corporations can be called low-*profit limited liability companies* See: https://nonprofithub.org/ (27 May 2023). In some U.S. states and *community interest companies*. See: https://www.communitycompanies.co.uk/community-interest-companies-cic (27 May 2023). Or *multi-stakeholder co-operatives*. See: https://anserj.ca/index.php/cjnser/article/view/78/24 (27 May 2023). In the U.K., in general, they are also obliged to meet stricter standards of social and environmental performance, transparency, and accountability. See: M. O'Regan, *B Corp certification won't guarantee companies really care for people, planet and profit*, London: The Conversation, October 2019.; https://theconversation.com/b-corp-certification-wont-guarantee-companies-really-care-for-people-planet-and-profit-124459 (27 May 2023). The dissertation will continue referring to benefit corporations while meaning all sorts of legal forms that meet these criteria.

[688] In the US, in most cases this is understood as a *material positive impact on society and the environment*. Besides benefit corporations, in the U.S. there is also a legal form of *social purpose corporations*, which pursue specific social or environmental purposes (and not a general public benefit like benefit corporations). See: Benefit Corporation, *How Do I Create General Public Benefit?*, B Lab, 2018.; https://perma.cc/X8AY-XJ5A (27 May 2023).

of its shareholders and other stakeholders, and report on how they meet their social and environmental goals.[689]

European[690] and U.K.[691] laws require companies to practice sustainability reporting. In addition, British companies can, subject to shareholder approval, reflect their social responsibility in their articles of association.[692]

As Haled et al. point out, benefit corporations are often referred to as *triple bottom line companies* that focus their efforts on profit, people and the planet. They identified four characteristics that make this type of companies the best fit for health care sector: (1) an obligation to consider nonpecuniary purposes in decision-making, (2) protection of directors from liability for doing so, (3) requirements for reporting to be independently assessed, and (4) enforcement mechanisms.[693]

As such, benefit corporations combine features of both the private and public actors. They can sell equity to private investors and are accountable to them for generating profits and providing them with a return on their investment while at the same time focusing on the public mission of providing citizens with medicines that bring additional therapeutic benefits at a price they can pay.

Gray et al. argue that benefit corporations are able to generate a return on investment similar to that of other for-profit companies while more effectively realising social benefits. It is argued that benefit corporations provide the checks and balances that solely profit-driven corporations lack. Benefit corporations are an example of how public interest considerations regarding corporate responsibility can be applied to the pharmaceutical industry.[694]

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[689] See: *Model Benefit Corporation Legislation*, Version of April 17, 2017, § 201(A).; https://perma.cc/VPX9-EX8V (27 May 2023). Most state-benefit corporation statutes are based on various iterations of the Model Benefit Corporation Legislation published by B-Lab, the promoter of the *B Corp* designation and a third-party certifying agency, as contemplated by the new law. See: About B Lab, B-LAB: https://perma.cc/RYY4-Q63P (27 May 2023).

[690] Directive 2014/95/EU of the European Parliament and of the Council of 22 October 2014 amending Directive 2013/34/EU as regards disclosure of non-financial and diversity information by certain large undertakings and groups, Official Journal of the European Union, L 330/1, 15 November 2014.; https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32014L0095 (27 May 2023).

[691] PWC, *Making your reporting more accessible and effective*, Sustainability Reporting tips 2014–2015, 2014.; https://www.pwc.co.uk/assets/pdf/sustainability-reporting-tips-for-private-sector-organisations.pdf (27 May 2023).

[692] A. Watson, *What is the best structure for a social enterprise?*, Michelmores, 14 November 2020.; https://www.michelmores.com/news-views/news/what-best-structure-social-enterprise (27 May 2023).

[693] Y. Heled, A. S. Rutschman, L. Vertinsky, *The problem with relying on profit-driven models, op. cit., p.* 128-138.

[694] A. R Eiser, R. I. Field, *op. cit.*

Benefit corporations can coexist with other forms of companies, but the public policy could also consider requiring companies operating in the pharmaceutical market to use this legal form. Existing for-profit corporations would then have to restructure themselves as hybrid organisations if they wanted to remain active in the sector.

8.2.3. Creating the right environment

Changing the business form of pharmaceutical corporations can be a difficult task, but one that may be worth the effort. As with other major reforms, such as open source (see Chapter 7.4.8.) or the *public option* (see Chapter 9.), transformational changes to bring greater benefits to the public will require broad policy and regulatory action. Without the right environment, actors not driven by profit maximisation can be at a significant disadvantage, unable to compete in the current profit-driven capitalist market, unless other mechanisms are put in place to favour them.

Therefore, for benefit corporations to succeed in the pharmaceutical market, they should be adequately supported by targeted public policy measures. For example, they could be exempted (or at least subject to reductions or concessions) from certain types of taxes, requirements or regulatory provisos imposed on traditional for-profit companies. They could also enjoy *fast-track* approval by regulatory agencies or greater financial and non-financial incentives. Another way to promote this business form would be to give preferential treatment to benefit companies when publicly investing in research and development or seeking partners for joint ventures and public-private partnerships.[695]

As Helad et al. argue, a *critical mass* is needed for this change to succeed, i.e., their success may depend on shaping a supportive ecosystem through internationally coordinated policies and laws, making them widespread globally.

8.2.4. Keeping strict control over companies pursuing public interests

On the other hand, for companies whose statutory form would require them to pursue public interest goals, there must be robust enforcement laws put in place. As Heled et al. point out, the ability to hold benefit corporations accountable for adhering to their statutory objectives through rigorous oversight mechanisms is critical to effecting

[695] *Ibidem.*

meaningful change. Corporate law should be equipped with the right tools and laws to ensure that benefit corporations do not game the system. Enforcement mechanisms, for example, should give third parties the power to take action against corporations that fail to meet their obligations.[696]

8.2.5. No perfect solution

B Lab, a non-profit organisation that certifies benefit corporations, lists 39 such companies in the *pharmaceutical products* category.[697] To what extent such status has a practical impact on companies' approaches to research and development, pricing or commercial practices remains unclear and requires further analysis. B Lab itself is not free from criticism for the way it rates companies.[698]

One of the certified companies in the pharmaceutical sector is Danish Novo Nordisk, in which a foundation established to contribute to the treatment of diabetes holds a majority stake – and thus a decisive voice in corporate decisions.[699] According to the company's statutes, its goal, in addition to generating profits, is to promote social and humanitarian progress, as well as scientific progress.

At the same time, however, Novo Nordisk, along with two other pharmaceutical giants, Sanofi and Eli Lilly, have created patent thickets around the diabetes drug insulin resulting in slower generic market entry, keeping its price out of reach for many patients, especially in the US. Although Novo Nordisk has been introducing affordability programs to increase access to the product, such decisions can be perceived as a tactic to fend off any serious political backlash that might break the oligopoly, rather than a genuine prioritisation of patient access over profit maximisation.[700] It was only in early 2023 that the three

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[696] Under current law applying to corporations (traditional or benefit ones) consumers do not have powerful tools recourse available to hold them accountable H. Panossian, *Workers vs. Shareholders Under United States Corporate Law: Reforming Corporate Fiduciary Law to Protect Worker Interests*, University of Pennsylvania, 106, 2007.; https://scholarship.law.upenn.edu/cgi/viewcontent.cgi?article=1067&context=jlasc (27 May 2023).

[697] As of February 2023. See: Looking for a B Corp?: https://bcorporation.net/directory (27 May 2023).

[698] M. O'Regan, *B Corp certification… op. cit.*

[699] See: Novo Nordisk, Share and ownership structure.; https://www.novonordisk.com/investors/stock-information/share-and-ownership-structure.html#:~:text=Share%20capital%20and%20ownership,capital%20of%20nominally%20DKK%20343%2C512%2C800. (27 May 2023).

[700] J. Hancock, E. Lucas, *How a drug company under pressure for high prices ratchets up political activity*, STAT News, 30 April 2018.; https://www.statnews.com/2018/04/30/novo-nordisk-high-drug-prices-political-activity/ (27 May 2023).

companies including Novo Nordisk, lowered the price of insulin fourfold due to a new U.S. law.

Another example of the questionable principles guiding the company's actions can be the decision by a British pharmaceutical industry trade group to suspend Novo Nordisk for two years due to *serious violations* related to its promotion of a weight-loss drug that breached the group's code of conduct.[701] This means that Novo Nordisk's behaviour was judged by its peers to stand out among all the tactics and plays by other companies putting the industry in a bad light.

The example of the Novo Nordisk as a benefit corporation, points to the need for a specific law that would tightly regulate and monitor such companies, and an ecosystem that would allow firms that are able to truly balance private and public interests to sustain themselves on the market.

[701] E. Silverman, *U.K. trade group suspends Novo Nordisk for 'serious breaches' in promoting obesity drug*, STAT News, 16 March 2023.; https://www.statnews.com/pharmalot/2023/03/16/novo-nordisk-obesity-uk-saxenda-weight-loss/ (27 May 2023).

Chapter 9. *Public option*

9.1. Creating a *public option*

Besides changing the ways for-profit companies operate in the pharmaceutical sector and introducing corporations that have other statutory forms and hence could more efficiently serve the public interest on the market, it is also possible to bring another actor directly into the mix – the public sector.

The previous chapters have discussed the numerous ways in which the public sector contributes to medical innovation. However, all of them have served to steer, encourage or restrict the behaviour of external actors to deliver desired products and market and price them according to public needs.

Beyond that, however, there is also a strong case for implementing another systemic alternative in the pharmaceutical sector - a *public option* for pharmaceutical R&D and manufacturing. The development of an ecosystem of public companies could counterbalance private actors by diversifying the market. It could be complementary to other reforms or tested independently of them.[702]

Public companies would need to be based on the principles that should guide all public sector activity in pharmaceutical innovation, i.e., be fully publicly driven, transparent, and include safeguards against undue influence and conflicts of interest. They should always prioritise the public interest and be oriented toward public health goals.

The *public option* involves the creation of national public pharmaceutical R&D institutes, manufacturing, and wholesale and distribution companies. While they would not be obliged to maximise profits, they could have the flexibility that for-profit corporations lack in order to be more responsive to public needs and provide an overall better return on public investment.

As Brown envisions, the basic supply chain of a fully developed public pharmaceutical system would begin with (1) the development of a new product by a public R&D institute, (2) which would then license its production to public manufacturers (including for its testing and authorisation, and if the ambition is to achieve global access

[702] D. Brown, *Medicine for All: the case for a public option in the pharmaceutical industry*, Report, Democracy Collaborative, 2019.; https://thenextsystem.org/medicineforall (27 May 2023).

to the product, licensing could also be extended to public and private producers around the world). (3) Once the product is manufactured, the producer would sign contracts with public wholesalers, who in turn would sell it to retailers.[703] Brown's model is dedicated to the U.S. healthcare system and tailored to its institutions, but universal lessons can be drawn from it.

Although a comprehensive, full-fledged *public option* would involve various independent but interconnected entities at different levels, the model can be introduced in a stepwise manner. The creation of any such companies could add value for the public by improving access to medical products, even before a fully public system is established. For example, the model could be used first to produce off-patent drugs (as is already happening in some countries) before more resources are allocated to public R&D.

While some *public option* proposals assume the gradual elimination of for-profit corporations from the market in favour of public companies, a mixed system of public and private actors in the pharmaceutical sector could also function effectively.

While the proposed model may sound far-fetched, it is important to keep in mind that until recently, many countries, including the US,[704] kept key parts of pharmaceutical research and production under public control. Countries such as Brazil, Thailand[705] and Cuba[706] still have significant government involvement in their pharmaceutical sectors.

9.1.1. Public research and development institutes

As argued by Brown, there are a number of reasons why public R&D institutes are a particularly good fit for the pharmaceutical system. For one, given that the public sector is a major funder of basic research and generates knowledge that is often privatised in later

[703] In the model proposed by Brown, both wholesalers and retailers would charge a fixed percentage by sales/prescriptions processed volume rather than price. See: Ibidem, p. 38.

[704] A. Zaitchik, *No Vaccine in Sight*, *op. cit.*

[705] N. Ford, D. Wilson, G. Costa Chaves, et. al, *Sustaining access to antiretroviral therapy in the less-developed world: lessons from Brazil and Thailand*, AIDS, Volume 21 Issue, July 2007, p. 21-29.; https://journals.lww.com/aidsonline/Fulltext/2007/07004/Sustaining_access_to_antiretroviral_therapy_in_the.4.aspx (27 May 2023).

[706] WHO, *Cuban experience with local production of medicines, technology transfer and improving access to health*, ISBN 978 92 4 150971 8, 2015.; https://apps.who.int/iris/bitstream/handle/10665/336685/9789241509718-eng.pdf?sequence=1&isAllowed=y (27 May 2023).; J. Singh, *Cuba's COVID-19 vaccines: A journey of collaboration and revolutionary solidarity*, Peoples Dispatch, 17 June 2021.; https://peoplesdispatch.org/2021/06/17/cubas-covid-19-vaccines-a-journey-of-collaboration-and-revolutionary-solidarity/ (27 May 2023).

stages of pharmaceutical innovation, public institutes could ensure that the return on these investments yields maximum benefit to the public interest.

Such institutes could be established within national ministries of health and oversee end-to-end pharmaceutical R&D. Their innovation strategy could be shaped by the public sector and driven by public health needs. Initially, they could focus on drugs for (local) unmet medical needs and those of special interest from a public health perspective, such as medical countermeasures.

The institutes should be equipped with significant in-house capacity and employ their own researchers. At the same time, they would act as a coordinating hub bringing together various academic and industrial partners working on projects in partnerships funded by grants provided by the institutes and in accordance with the latter's strategies.[707]

Many public institutes (including the military ones) are already conducting some drug development projects or even their own clinical trials. R&D institutes could, therefore, be closely linked to already existing national research entities, such as, in the case of the US, the National Institute of Health (NIH).

Also in Europe, there are smaller-scale initiatives that an ambitious public R&D institute can benefit from and build on, such as the European Research Infrastructure, the European Molecular Biology Laboratory (EMBL) or the European Institute of Innovation and Technology (EIT) Health.

For their sustainability and protection of the public interest, a critical aspect of the institutes' activities would be the management of rights to the developed innovation. Various approaches can be taken to do so. For example, the institutes may choose to patent and license their technologies. In the case of partnerships with private entities or manufacturers, all rights to the innovation would have to remain in public hands so that the institutes retain control over pricing and access.

They could also benefit from licensing their patents to manufacturers outside the public supply chain in exchange for royalties. Contractual terms in such cases should ensure that these products remain equitably available and affordable.

Institutes could also support open science by choosing to place IP and clinical trial data in open access and make them as well as developed technologies available through

[707] E.g., over 84 percent of NIH's funding is awarded for extramural research (largely through almost 50,000 competitive grants to more than 300,000 researchers while around 10 percent (still around 2.5-3 billion annually) for in house research.

pools (see Chapter 7.4.3.). By choosing this approach, they could help spread knowledge that benefits innovation and reduces R&D costs over time (see also Chapter 7.4.8.).

Public entities could continuously participate in global patent pools, such as the WHO Medicines Patent Pool, not only in the context of public health emergencies but as part of their regular strategies. Such cooperation would be enhanced by an international agreement under which many countries would fund, develop and share health technologies with each other.

Since funding more late-stage development and clinical trials would require significant resources, public institutes should be equipped with significant budgets. Providing them with significant and stable resources would be required with the understanding that undertaking this model would not have to require additional public funds but can be limited to shifting them to the R&D process in order to benefit later from access to affordable drugs, resulting in more efficient spending from health budgets.

Experts estimate that, for example, a public R&D institute established at the EU level would need to have a budget of about €3.5 (similar to NIH's internal spending) or €7 billion (similar to the European Space Agency).[708] There are also estimates suggesting that it should be around €25-30 billion (NIH's entire annual spending in proportion to the size of the European pharmaceutical market).[709] Considering all public spending on pharmaceutical R&D, pooling existing funding mechanisms would allow raising money even at the upper end of the range.

The creation of public R&D institutes would also require adjusting the mandates of existing public agencies, such as, in the case of the EU, the European Medicines Agency, so that the former has all the necessary competencies to fulfil their role.[710]

The size of the market and sources of funding can make a big difference in the sustainability of public R&D institutes. They could therefore be established regionally and even internationally to combine resources, scientific potential and demand most effectively. This is even more important in the context of emergency preparedness and response, when the spectrum of pathogens is broad, and technologies developed to combat the diseases must be available worldwide to bring the greatest value to public health. Based on the

[708] M. Florio, et al., *European pharmaceutical research and development, op. cit.*
[709] See: T. Joye, W. De Ceukelaire, *Concept note European Salk Institute*, Working paper, February 2023.
[710] P. C., Gotzsche, *Patients not patents: Drug research and development as a public enterprise*, European Journal of Clinical investigation, February 2018.; https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5817403/ (27 May 2023).

cooperation of states, the institutes can be created by an intergovernmental treaty and be subject to international law in the same way as international organisations.

9.1.2. Public manufacturers

The second step in the public pharmaceutical supply chain is publicly owned manufacturing companies. Since production is much easier and less costly to set up than R&D infrastructure, the former could – and already is – suitable for establishing at the beginning of exploring the *public option* to test it and build trust in publicly run pharmaceutical entities.

In addition to producing pharmaceuticals developed by public R&D institutes, the manufacturers could supply essential off-patent drugs whose price is artificially kept high by private companies, for example through patent thickets. The products they sell could be distributed at cost price (for example, in the case of essential medicines or for certain populations that cannot afford higher prices) or with a limited profit margin so that the revenue generated from sales could be reinvested in the public drug supply chain or even used to fund separate public services. In this way, they could increase access and provide savings for the public health budgets and individual patients. Manufacturers could also contribute to solving the growing problem of drug shortages by producing those drugs that are overlooked by existing companies, for example, because of limited profit margins on their sales.

Public manufacturing capacity would also be essential for the production of medical countermeasures, either those developed by public R&D institutes or based on technology shared by other public or private companies or obtained through non-voluntary measures (such as compulsory licensing or patent buyouts). Creating public production of medical countermeasures will certainly take time, but given all the health and economic benefits, it is an undertaking worth pursuing.

Public manufacturers would have to establish a procedure for selecting drugs for production (in addition to those developed by public R&D institutes) based on public health needs, market conditions, regulatory contexts or access to suppliers of active pharmaceutical ingredients.[711] Once a drug is selected and in production, the manufacturers

[711] D. Brown, *Medicine for All, op. cit.* p. 49.

would seek regulatory approval to bring it to market (potentially also by licensing production further to public or private entities).

The manufacturing capacities could be established at the regional (for example in the Global South), national (for example in Thailand where the Government Pharmaceutical Organisation is also involved in pharmaceutical R&D) or subnational (for example in the US, Brazil or Argentina) level.[712] Central and state governments can also form joint ventures, as in the case of India's Rajasthan Drugs and Pharmaceuticals Ltd.

9.1.3. Public wholesalers and distributors

While large institutions can purchase drugs directly from manufacturers, smaller entities such as retail pharmacies rely on wholesalers and distributors. Wholesalers are also useful intermediaries from the point of view of manufacturers, who can ship products in bulk to several warehouses instead of delivering them to individual buyers.

Brown recommends creating such public entities at the regional level (because drug distribution is largely organised around regional warehouses, but also because such an arrangement would allow smaller regions to use public production more efficiently) and serve as an effective and transparent alternative to private entities that may be concentrated and use anti-competitive tactics.

It is also argued that public wholesalers could reduce the cost of retail purchases by charging a fixed percentage of sales volume (private companies currently charge a fee based on a percentage of a drug's list price, i.e., the price without discounts and rebates, which increases the cost of the final product).[713]

Brown suggests that distributors could work for example with the postal service to increase delivery efficiency. A good example of public distribution of pharmaceuticals organised in such a way is the Swedish system (see below in Chapter 9.2.4.).

[712] *Ibidem*, p. 48. In the US, in the 1990s, Michigan, Massachusetts, and New York City produced e.g., diphtheria vaccine, before the production was privatized. See: A. Sammon, *It's Time for Public Pharma*, The American Prospect, 25 July 2022.; https://prospect.org/health/its-time-for-public-pharma/ (27 May 2023).

[713] D. Brown, *Medicine for All*, *op. cit.* p. 49.

9.1.4. Importance of market shaping

Public enterprises should be robust, well-managed, sustainably financed and solvent to complement or replace private companies. Ultimately, however, their sustainability and competitiveness should be ensured by actively shaping the market through public policies.

Just as in the case of private corporations with non-commercial or hybrid legal forms, public entities that would prioritise the public interest over profit maximisation, might not be able to compete with for-profit companies in a free market that is driven solely by commercial considerations. The market should therefore be shaped by governments. Public companies should be favoured by states in a variety of ways, from subsidies to increased public investments and regulatory incentives.

9.1.5. Broader benefits

While the overarching goal of public companies is to effectively deliver affordable medicines to the market, attention should also be paid to the broader benefits that the *public option* brings to society in terms of job creation, strengthening public sector capacity and democracy through participatory mechanisms, increased transparency and accountability.

9.1.6. Potential drawbacks

Public pharmaceutical companies, like any public institution, can be prone to inefficiency and for example, used instrumentally in national politics (for example, by raising medicine prices to fill a budget gap caused by irresponsible fiscal policies, etc.) As Brown argues, the use of surplus income generated by public companies should also be strictly regulated. This could include investment in research and development and sustaining and extending the companies' budgets (making them more resilient to political changes).

Therefore, public companies should be protected to the extent possible from deviating from their mission and principles. The objectives and public duties of such entities would have to be written into their statutes, as would progressive transparency measures. As with public benefit corporations (see Chapter 8.2.2.), independent

monitoring, enforcement measures and penalties would need to be in place to ensure compliance.

9.2. *Public option* – case studies

There are numerous examples of thriving or emerging public pharmaceutical companies. Perhaps the best example of a robust, fully developed *public option* is Cuba's R&D and manufacturing infrastructure.

9.2.1. Public pharmaceutical R&D and manufacturing in Cuba

As a result of the U.S. embargo, which restricted the ability to import medicines from abroad, Cuba's entire pharmaceutical sector was nationalised in the 1960s.

Today, Cuba's pharmaceutical industry is entirely funded and managed by the state. It includes R&D institutes developing innovative therapies and manufacturing plants producing them along with low-cost generic drugs. In 2012, Cuba merged its R&D institute and production facilities to create BioCubaFarma. It can serve as an example of a comprehensive public infrastructure based on collaboration and the free flow of knowledge, spurring innovation in the public interest.[714]

The public industry is the main reason for the affordability of medicines in the country.[715] As argued by experts, if Cuba had to import drugs from private companies abroad, it would not be able to build one of the most efficient public healthcare systems in the world. A 2015 study, *Cuban Experiences with Local Drug Production, Technology Transfer and Improved Access to Health*, commissioned by the European Commission, PAHO and WHO, observed that national health infrastructure has been successful in improving health and quality of life in Cuba.[716]

[714] M. R. Jiménez, Cuba's pharmaceutical advantage, Nacla, 16 August 2011.; https://nacla.org/article/cuba%E2%80%99s-pharmaceutical-advantage (27 May 2023).

[715] As argued by experts, if Cuba would have to import medicines from pharmaceutical companies it would not be able to be one of the most efficient public health care systems in the world.

[716] An important aspect to which the study draws attention is the country's continuous political will that over five decades has systematically integrated different policies (such as education, health, industrial technology and IP) that have converged and enhanced one another as well as kept its regulatory and legal framework adapted to international requirements. See: WHO, *Cuban experience with local production of medicines*, *op. cit.*, p. 56.

In Cuba's example, prioritising the public interest goes hand in hand with revenue generation. The public industry covers most of the domestic demand for drugs and makes a profit from exporting them, providing a stable return on investment for the public.[717] State-owned companies hold more than 1,200 international patents, have received WIPO innovation awards (among many others) and sell drugs to more than 50 countries.[718] Cuban innovations are known around the world, such as the first lung cancer vaccine (CIMAvax-EGF), which is reported to have cured 5,000 patients worldwide and cost $1 to produce, with clinical trials conducted in the US, Canada, Japan and the EU.[719] State-owned institutions participate in technology pools and share their innovations with other low- and middle-income countries.

9.2.1.1. Example of vaccine development against COVID-19

The most recent success of Cuba's public pharmaceutical industry, in the area of medical countermeasures, is the development and production of COVID-19 vaccines.[720]

Instead of relying on international mechanisms such as COVAX (see Chapter 6.7.) to secure access to medical countermeasures during the pandemic, Cuba has decided to leverage its public infrastructure and invest in the development of independent vaccines.

This has been made possible because *the country had cultivated a brain trust of vaccine scientists and a workforce pipeline; built state-of-the-art manufacturing facilities [including a new high-tech manufacturing plant at the Mariel Biotech Industrial Complex]; established a national biomedical regulatory authority that interacts with PAHO/WHO and*

[717] A. C. O'Farill, *State and Innovative Enterprises: The Case of the Cuban Biopharmaceutical Industry*, Business ad Economic History, Vol. 12, 2014.; https://thebhc.org/sites/default/files/ofarrill.pdf (27 May 2023).

[718] A. C. O'Farill, *How Cuba Became a Biopharma Juggernaut, Institute for New Economic Thinking*, 5 March 2018.; https://www.ineteconomics.org/perspectives/blog/how-cuba-became-a-biopharma-juggernaut (27 May 2023).

[719] See: WHO, *Cuban experience with local production of medicines*, *op. cit.*; S. Jacobs, *Cuba has a lung cancer vaccine. Many U.S. patients can't get it without breaking the law*, USA Today News, 1 September 2018.; https://eu.usatoday.com/story/news/world/2018/01/09/cuba-has-lung-cancer-vaccine-many-u-s-patients-cant-get-without-breaking-law/1019093001/ (27 May 2023).; PharmaLetter, *CimaVax-EGF, the first vaccine against lung cancer, debuts in Cuba*, TPL, 8 September 2011.; https://www.thepharmaletter.com/article/cimavax-egf-the-first-vaccine-against-lung-cancer-debuts-in-cuba (27 May 2023).

[720] Among various candidates, three Abdala, SOBERANA 02 and SOBERANA Plus have received authorisation. See e.g., a video: https://twitter.com/ProgIntl/status/1627608241944526850?s=20&t=rmv8TpCpcb18oNqvrhYTSA (27 May 2023).

retains high-level certifications from both; and established a universal health system relying on strong primary care.[721]

Central to this process was regulatory oversight by the national regulator, the Center for State Control of Medicines and Medical Devices (CECMED).

A High-Level Fact-Finding Delegation to Cuba (MEDICC) (consisting of scientists and experts from the US, the Caribbean and Africa) examined the country's reasons for developing its own vaccines, their marketing, and the overall approach to science, including its implications for global access.[722]

According to MEDICC, the country's decision in March 2020 was motivated by three main reasons: (1) BioCubaFarma scientists and health officials believed in internal capacity (based on previous successes in childhood vaccine development) and the assumption that the public confidence in a domestically developed vaccine would increase its compliance in vaccination campaigns, (2) the anticipation that Cuba would not be able to secure enough doses of the vaccine developed by Big Pharma companies through COVAX in a timely manner, even if it paid millions to buy them (how correct these predictions were, see Chapter 6.7.), (3) the belief that domestically developed vaccines are the only way to ensure sufficient and affordable access in times of economic hardship and uncertain prices of Western vaccines.

Cuba's public pharmaceutical industry was able to develop and test two lines of COVID-19 vaccines (each safe and providing more than 95 per cent efficacy against severe disease and death). Although they required refrigeration, deep freezing was not necessary, which is also an important aspect in a resource-constrained environment. The vaccines were used in a national vaccination campaign in which 96 per cent of the population was fully vaccinated – well above the global average.[723] Cuba's COVID-19 vaccines have received emergency use authorisation from several countries that have also signed commercial contracts with Cuba, including Mexico, Iran, Vietnam, St. Vincent & the Grenadines, Belarus and Venezuela.

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[721] MEDICC, *Cuba's COVID-19 Vaccine Enterprise: Report from a High-Level Fact-Finding Delegation to Cuba*, Technical Report, October 2022, p. 21.; http://mediccreview.org/wp-content/uploads/2022/10/MEDICC-Cuba-COVID-19-Vaccine-Full-Report_2022.pdf (27 May 2023).

[722] *Ibidem*.

[723] See: Coronavirus (COVID-19) Vaccinations: https://ourworldindata.org/covid-vaccinations (27 May 2023).

One of MEDICC's conclusions is that Cuba's health innovation model can serve as an example of the advantages of local biotech capabilities for other low- and middle-income countries. The delegation recommended, for example, that the African Union and the African CDC work with and learn from Cuba in the context of initiatives such as the Partnerships for African Vaccine Manufacturing (see Chapter 7.7.5.3.1.).[724]

9.2.2. Public pharmaceutical manufacturing in Bangladesh

An example of the tangible benefits of having public and local private production in the pharmaceutical sector is Bangladesh.

Bangladesh underwent a revolution in this context in the 1980s. Previously, almost 75 per cent of the country's drug needs were met by external private for-profit corporations. The prices of imported products were unaffordable for the majority of the population. Even most of the remaining 25 per cent of locally produced drugs were owned by multinational pharmaceutical companies. At the time, external pharmaceutical companies controlled approximately 84 per cent of the domestic market.[725]

The Drug Control Ordinance adopted by the Bangladesh government in 1982 led to increased public and local private production (including raw materials and packaging) and lower prices. The government also established the Drug Administration Directorate, which provided technical assistance to local generic companies and introduced regulatory incentives for them. Two banks were even set up to provide financial support to the domestic industry, on top of tax breaks and favourable procurement policies.[726]

Thanks to legal and policy changes, local production in Bangladesh has increased from $40 million to $700 million in the 20 years since the ordinance was passed. Whereas in the early 1980s, only about 10 per cent of the population had access to modern medicine, by 2002 more than 45 per cent did.

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[724] Africa CDC, *Partnerships for African Vaccine Manufacturing (PAVM), op. cit.*

[725] Multinational Monitor, *Essential Drugs and Health for All: Healthy Innovations from Bangladesh*, Multinational Monitor, Vol 23, No. 6, June 2022.; https://www.multinationalmonitor.org/mm2002/062002/interview-chowdhury.html (27 May 2023).

[726] USP, *The next frontier for the public health medicines market: Priorities for local pharmaceutical production*, U.S. Pharmacopeial Convention Rockville, Maryland, 2019, p. 12-13.; https://www.usp.org/sites/default/files/usp/document/our-work/global-public-health/local-pharmaceutical-production-compressed.pdf (27 May 2023).

9.2.3. Public pharmaceutical R&D and manufacturing in other countries

Public industries in Cuba and Bangladeshis are not the only examples of a successfully implemented *public option*. Public pharmaceutical companies were also created in other countries to address high prices or shortages. They were often seen as part of a broader industrial policy.[727]

The prominent examples include China's and India's public companies that are the backbone of the production of active pharmaceutical ingredients and generic and biological drugs, a significant percentage of which are for export.

Large public R&D and manufacturing capabilities also exist in South America, particularly in Brazil.

In Europe, for example, Poland's public Polfa Tarchomin has been an important supplier of human insulin since the 1950s.

Also in the U.K., there are many public drug manufacturers that supply domestic hospitals and export abroad.[728]

9.2.3.1. California's plan to produce its own insulin

What is more, Brown and Latkowski give many examples of current public pharmaceutical production in the US, such as MassBiologics at the UMass Chan School of Medicine, which is a non-commercial vaccine manufacturer in the U.S. (the only one that obtained FDA approval).[729] It produces tetanus and diphtheria vaccines and distributes them nationwide.[730]

Perhaps the best-known case of public production in the US, however, is another recent initiative that is attempting to publicly produce insulin.

In California, the state passed a law in 2022 to create an authority to produce its own insulin and allocated $100 million to support the effort. In the short term, the authority is looking for existing companies that could produce insulin for the state as a subcontractor

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[727] D. Brown, T. Latkowski, *Public Pharmaceuticals, State Policy Kit*, Democracy Policy Network, December 2022, p. 19.; https://static1.squarespace.com/static/62f41050584b40607baef690/t/63992dceb17a723edcbb9d1e/1670983118927/PUB_Public+Pharmaceuticals+State+Policy+Kit.pdf (27 May 2023).

[728] See: The list of NHS Manufacturers: https://www.pro-file.nhs.uk/Manufacturerinfo/NHSManufacturerList.aspx (27 May 2023).

[729] See: UMass Chan Medical School, MassBiologics History: https://www.umassmed.edu/massbiologics/history?page_id=92 (27 May 2023).

[730] D. Brown, T. Latkowski, *Public Pharmaceuticals*, *op. cit.*

in the next few years.[731] Based on such cooperation, California plans to supply generic insulin as early as 2024.

The state's ultimate ambition is to create a fully functioning public infrastructure – government-owned insulin production facilities. The plan is to retrofit the existing production capacity for insulin, start the process and obtain FDA approval ensuring the quality, safety and interchangeability with other versions of the drug. If successful, much cheaper versions of insulin will enter the California market, resulting in significant savings for the public budget and individual patients. Public competition may also prompt private pharmaceutical companies to lower their prices.[732]

As Brown and Latkowski argue, public capacity increases countries' bargaining power in negotiations with for-profit companies.[733] California plants could sell their products to other states disrupting the industry's stronghold.

Such a commercial threat to the private sector business model makes it clear that California's *public option* can expect blowbacks from Big Pharma companies, which could potentially resort to lawsuits, accusations of patent infringement or fear-mongering campaigns questioning the quality and safety of generic drugs.

9.2.3.1.1. Long-term vision for the U.S. public pharmaceutical production

California's effort could be an important test case for the *public option* in the U.S. If it provides a proof of concept, other U.S. states and countries could follow suit for various types of drugs that can be produced cheaply but remain out of the public's reach due to companies' pricing and marketing strategies.

Two other U.S. states, Washington State and Maine, are already taking the first steps toward introducing public production.[734] Washington has authorised (but as of early

[731] According to media reports, the state considers the CostPlus Drug Company established by the U.S. businessman, Mark Cuban to provide at-cost medications. See more about the company: https://costplusdrugs.com/mission/ (27 May 2023).; or Civica, a collaboration between several hospital systems to produce cheap generic versions of essential medicines. See more: https://civicarx.org/about/ (27 May 2023).

[732] Should companies lower the prices of insulin in California to stay competitive with the publicly-produced options, then, it might be even difficult for them to charge the high price in other states the citizens and politicians of which will clearly see how much they overpay.

[733] D. Brown, T. Latkowski, *Public Pharmaceuticals, op. cit.*, p.19

[734] In addition, Massachusetts also provides funding to the UMass college for vaccines, which are distributed to state residents at no cost.

2023 not yet fully funded) the development of a public generic manufacturing program.[735] A state law passed in 2021, allows the healthcare authority to partner with other agencies to manufacture, distribute and purchase drugs.[736]

Maine has created a bipartisan commission to study the feasibility of public manufacturing.[737] There have been reports that Michigan may follow suit (the state had public manufacturing facilities and produced its own vaccines in the 1990s).

The positive effects of greater public involvement in pharmaceutical production could go far beyond the provision of affordable medicines. After decades of diminished public sector capacity in pharmaceutical R&D and production, the success of such initiatives could restore trust and confidence in the effectiveness of public institutions.

9.2.3.2. Cancer medicines and hospital production

Another example of an alternative approach to drug production outside for-profit companies is hospital manufacturing.

In the Netherlands, public health authorities decided to produce cancer drugs in public hospitals after their price negotiations with pharmaceutical companies failed in 2017.[738] At the time, Dutch pharmacies led by Erasmus Medical Center in Rotterdam began their own production.[739] However, the attempt has been hampered by a data exclusivity framework that prohibits generic manufacturers from using the originator's clinical trial data to authorise their generic versions.

Pharmaceutical companies have also attempted to discredit these attempts by questioning the quality and safety of the publicly produced alternatives – the same tactic they used in the context of the generic production of COVID-19 vaccines (see Chapter 5.5.7.).

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[735] E. Silverman, *Washington may become the second state to distribute its own generic drugs*, STAT News, 27 March 2021.; https://www.statnews.com/pharmalot/2021/03/17/generics-washington-california-legislation-drug-prices/ (27 May 2023).

[736] See: Engrossed Substitute Sente Bill 5203, State of Washington 67th Legislature 2021 Regular Session.; https://lawfilesext.leg.wa.gov/biennium/2021-22/Pdf/Bills/Senate%20Bills/5203-S.E.pdf?q=20210316064538 (27 May 2023).

[737] D. Scott, *Insulin is way too expensive. California has a solution: Make its own*., Vox, 7 February 2023.; https://www.vox.com/policy-and-politics/23574178/insulin-cost-california-biden-medicare-coverage (27 May 2023).

[738] While the drugs produced by hospitals were still patented, a patent exception for research purposes or clinical trials has allowed the public sector to overcome the barrier.

[739] OTMeds, *Relocation of the Pharmaceutical Industry, op. cit.,* p. 44.

9.2.3.3. Public military production

What is more, since the early days of the pharmaceutical industry, military public R&D and manufacturing have played a significant role in health innovations. Since the penicillin project during World War II (see Chapter 2.3.3.), various medicines have benefited from military research. Given that the development of medical countermeasures is directly linked to public safety, the interconnectedness between the public military and medical innovation initiatives is natural and widespread.

Military facilities established as part of the biosecurity policy for the production of medical countermeasures can also be used to produce non-health security-related medicines when they stay idle. To keep manufacturing facilities warm, military sites sometimes produce medicines that are then destroyed, such as in the case of a French army pharmacy.[740] This waste and inefficiency could be reduced by reorienting production to other everyday drugs that are either unavailable or unaffordable. In Germany, for example, a military pharmacy produces cancer drugs.

9.2.4. Public wholesale distribution in Sweden

As for public wholesale distribution, the best example of its successful implementation can be found in Sweden. In the early 1970s, much of Sweden's pharmaceutical sector was nationalised, and the state-owned Apoteksbolaget AB was created to serve as the country's sole wholesaler.[741]

Originally a single drug manufacturing and wholesaling company, it was split in 2009.[742] Since 2010, Apotek Produktion & Laboratorium (APL), the manufacturing entity, has been separated from wholesaler Apoteket AB.[743]

Apoteket AB had a monopoly on buying products from manufacturers and contracted with two other logistics companies (Tamro Distribution (TD) and Kronans

[740] R. Le Saint, *Plunge into the French army's antidote factory*, Mediapart, 26 August 2019.; https://www.mediapart.fr/journal/france/260819/plongee-dans-la-fabrique-antidotes-de-l-armee-francaise (27 May 2023).
[741] See: APL, Our history: https://www.apl.se/in-english/about-apl/our-history.html (27 May 2023).
[742] During the period of deregulation when it became no longer permissible for pharmacies to produce medicines simultaneously.
[743] See more: APL, About APL: https://www.apl.se/in-english/about-apl.html (27 May 2023). Currently, APL is still one of the largest manufacturers of speciality medicines in Europe with a portfolio of 2,000 products sold in 35 countries around the world. See also: D. Brown, T. Latkowski, *Public Pharmaceuticals*, *op. cit.*, p. 18.

Droghandel (KD)) to distribute them to nearly 900 pharmacies in the country. Although these two companies negotiated margins directly with manufacturers, the fact that they acted only as distributors, not wholesalers, meant that the margins earned by TD and KD were small compared to what wholesalers typically charge – their average distributor margin was among the lowest in Europe.[744] According to the OECD survey, the public and drug manufacturers were satisfied with the public monopoly.[745]

Today, Apoteket AB, the retail company, operates about one-third of all pharmacies in Sweden.

The company pays annual dividends to its sole shareholder, the Swedish state.

On the retail side, one other example of a successful *public option* is in Brazil, which has created the Popular Pharmacies program that provides low-income patients with drugs to treat the most common diseases for free or at greatly reduced prices.

9.2.5. Failure in creating public sector capacity

9.2.5.1. Example of the U.S. attempts to build public infrastructure

Attempts to create a public pharmaceutical capacity are also not free from failures.

Already in 21st century, there have been efforts to establish a public full-cycle vaccine manufacturing infrastructure in the US. The University of Pittsburgh Medical Center supported by a group of NIH researchers put forwards such a proposal to the White House, which agreed to further investigate the visibility of such a project.[746]

Its failure, however, was brought about by the Tufts Center, a private U.S. medical centre with close ties to the pharmaceutical industry. Selected by the Pentagon and the U.S. Department of Health and Human Services to evaluate the proposed *public option*, the Tufts Center assessed that state-led vaccine production would be the worst possible scenario.

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[744] P. Moise, E. Docteur, *Pharmaceutical Pricing and Reimbursement Policies in Sweden*, OECD, 26 July 2017, p.42.; https://www.oecd-ilibrary.org/docserver/135870415741.pdf?expires=1676115762&id=id&accname=guest&checksum=CD10FD115D920379DF80437DE0C20CCF (27 May 2023).

[745] *Ibidem*, p. 49.

[746] D. Willman, *Pentagon makes costly foray into biodefense drug business*, Los Angeles Times, 23 November 2013.; https://www.latimes.com/nation/la-xpm-2013-nov-23-na-biodefense-spending-20131124-story.html (27 May 2023).

Instead, it recommended increased support for private companies that could provide medical countermeasures *less costly and timelier*.

This example points to the political capture that actors who benefit from the existing system have. The potential conflict of interest of bodies with close ties to the industry or the consulting firms (that have them as clients) should always be carefully assessed when trying to implement transformational changes. Those who stand to lose from them will certainly use all their powers to discredit them. In such cases, as in many others, political leadership, genuine dedication and close oversight will be crucial to prevent projects in the public interest from being thwarted by commercial ones.

Another attempt to create a public infrastructure (but this time involving collaboration with the private sector) at the federal level in the U.S. took place in 2010 when the Obama administration proposed the creation of vaccine Advanced Development and Manufacturing (ADM) facilities.

The project designated four sites across the country and invited private sector entities to apply to build and operate vaccine research and emergency production facilities at these sites. Intake from industry was suboptimal, as large, capable companies were not interested in investing in surge capacity (although GlaxoSmithKline initially expressed interest in one of the facilities, it cancelled its commitment within the first year).

As a result, facilities operated by smaller private entities have fallen short of expectations, and the program has been evaluated negatively, particularly due to limited private sector involvement and insufficient public investment.[747]

As pointed out by Zaitchik, the failure of this attempt may serve as evidence of the inadequacy of the contractor model in the context of health emergencies.[748]

9.3. The value of the *public option* in the context of health emergencies

The *public option* for pharmaceutical R&D, production and supply can be of particular importance in the context of health emergencies. Having an independent public capacity that can effectively execute a preparedness strategy and, even more importantly,

[747] D. Willman, *Federal vaccine development sites ill-suited to counter covid-19 epidemic*, The Washington Post, 25 March 2020.; https://www.washingtonpost.com/investigations/federal-vaccine-development-sites-ill-suited-to-counter-covid-19-epidemic/2020/03/15/34e8586c-63c4-11ea-acca-80c22bbee96f_story.html (27 May 2023).

[748] A. Zaitchik, *No Vaccine in Sight, op. cit.*

respond quickly and efficiently during a crisis can greatly improve the way countries deal with disease outbreaks.

A long-term R&D strategies applied by public companies would allow to address the most relevant health needs (rather than be driven by potential profit) and prioritise research that is most critical for the public. The public sector's ability to adapt technologies and scale up their production, rather than trying to convince private companies to get involved through financial and legal incentives, would put it in the driving seat in terms of providing access to vaccines, tests, or treatments.

Consequently, during health emergencies, it would be up to the public sector to decide what technologies are advanced, who has access to them and under what conditions, where and. Private companies could, of course, take part in preparing for and responding to health crises, but in specific roles that the public sector would assign to them, such as, for example, scaling up production.

Public R&D institutes could complement existing agencies, like U.S. BARDA or EU HERA, enabling strategic projects on medical countermeasures. By pooling expertise and resources regionally or even at the international level and building large-scale infrastructures, they could provide the *critical mass* that can shape the global medical innovation agenda and even influence private sector priorities.

The assumption of control over the innovation, production and distribution of medical countermeasures by the public sector would not, in itself, have to lead to equitable global access. As discussed in the first part of the dissertation, it was not only private companies that prioritised the rich markets of the developed countries, but also the countries themselves showed a lack of solidarity with the Global South, prioritising their economic interests, over tackling the pandemic worldwide.

To ensure that health preparedness and response strategies contribute to reducing global inequalities, countries through their public R&D institutes and manufacturers should work closely together. By developing international mechanisms through political agreements and working out technical solutions within networks and joint projects, public companies from different parts of the world would be interconnected, exchanging expertise, skills and technology, and providing broad access to vaccines, medicines and tests in times of crisis.

This public-interest-driven process would break away from the current race to get a product to market first and fend off competition, in recognition that the most effective health policy in response to communicable diseases is to be prepared and able to respond to outbreaks wherever they occur locally. It is in the interest of all countries to ensure that the most effective technology, trained workforce and final products are available everywhere in the world, and the public pharmaceutical infrastructure can play a critical role in achieving this.

For developing countries themselves, increasing the public infrastructure capacity can make the difference between having access to affordable lifesaving technologies or not. An example of this is the local public production of low-cost HIV/AIDS drugs in the late 1990s in countries such as Brazil and Thailand.[749]

In Brazil, thanks to a national intellectual property law allowing for the effective use of compulsory licences and existing national manufacturing facilities, the country has been able to significantly lower the price of antiretroviral drugs improving the quality of life of people living with AIDS and saving an estimated $422 million in hospitalisation and medical care costs between 1997 and 1999. By 1999, Brazil purchased 47 per cent of its antiretroviral drugs (19 per cent of expenditure – the remaining 53 per cent of imported antiretrovirals accounted for 81 per cent of expenditure) from domestic companies, of which 92.5 per cent were from state laboratories and 7.5 per cent from private companies. In 2000 and 2001, the domestic share of this production further increased.[750]

Conclusions

As this dissertation demonstrates, the current research and development ecosystem is not able to deliver the most relevant medical innovations while ensuring sustainable, affordable, and equitable access to them. Many reasons for this are discussed, not least the handing over of responsibility for the development, production and supply of pharmaceutical products to for-profit companies which, due to their statutory form and

[749] M. Mazzucato, *Op-Ed: How taxpayers prop up Big Pharma, and how to cap that,* Los Angeles Times, 27 October 2015.; https://www.latimes.com/opinion/op-ed/la-oe-1027-mazzucato-big-pharma-prices-20151027-story.html (27 May 2023).

[750] Medecins Sans Frontieres, *US action at WTO threatens Brazil's successful Aids programme*, Press Release, 1 February 2001.; https://www.msf.org/us-action-wto-threatens-brazils-successful-aids-programme (27 May 2023).

intrinsic characteristics, are guided by profit-maximising strategies instead of providing the most needed and effective products to as many people as possible.

It is clear that the incentives that drive pharmaceutical companies' investment in the pharmaceutical sector are disconnected from public health needs. One example of this is pharmaceutical companies ignoring R&D efforts to address medical needs that, although crucial to the public, are unlikely to generate significant profits. As a consequence, the current R&D system is biased towards lucrative disease areas.

Importantly, the fact that the public sector has ceded much of its responsibility for pharmaceutical R&D and access to the private sector does not mean that it has ceased to engage in it. The public sector continues to fund the highest-risk research and is most likely to discover medicines that offer significant therapeutic benefits over the existing ones. Therefore, the dissertation analyses the roles of public and private actors in the pharmaceutical system and how these are shaped by states.

A number of technological breakthroughs – both health emergency- and non-emergency-related – were (and still are) funded by government programs and institutes. For example, the most effective COVID-19 vaccines developed by Pfizer/BioNTech and NIH/Moderna are based on mRNA technology that has been developed over 30 years of public and private research. While the amount of public funding was unprecedented during the COVID-19 pandemic, the patterns it followed are typical of the current model: the public sector provides significant funding, transfers the technology to private companies that further develop it and manufacture end products ultimately purchased by governments at a premium.

Pharmaceutical policies that allow public research and knowledge to be privatised and the resulting products to be supplied and priced based on market forces to maximise profits, rather than becoming the most effective public health tools, result in gross inefficiencies. This model is particularly lucrative for the private sector but has dire consequences for the public.

The root causes of the current system's failures and inefficiencies lie in its flawed design and misconceptions reflected in various aspects. The way the system is structured ignores the fact that the functioning of pharmaceutical markets differs from the neo-capitalist model. For one, due to limited competition guaranteed by strict intellectual property rights and exclusivities, pharmaceutical companies have considerable power to determine the availability and affordability of medicines. What is more, demand for drugs

is inelastic and pharmaceutical prices are opaque and do not reflect the value of products but what the market can bear. The discussion confirms the inadequacy of neo-capitalist markets to drive medical R&D and provide affordable access to its outcomes.

The pharmaceutical industry learnt how to exploit laws and policies. What is more, as a result of widespread political capture, it also has a significant impact on their design. Consequently, the system is not only the result of poorly thought-out public policy but also of the direct and indirect influence of those who profit from it.

While the divergence between public interest and private considerations driving medical innovation decisions is evident for all types of pharmaceutical products and circumstances, it is particularly pronounced in the context of pandemic preparedness and response. The current system does not prioritise the development of the most appropriate medical countermeasures and the race to get a product to market as quickly as possible and fend off competition is counterproductive for the public.

It is also evident that the system of rewarding medical innovation by monopolies guaranteed by a strict regime of intellectual property and market exclusivities leads to the hiding and fragmentation of knowledge, a lack of collaboration and less access to technologies and products. Consequently, this significantly reduces states' ability to effectively prepare for and respond to health emergencies.

Finally, the dissertation analyses one of the worst consequences of the current system's failure – global inequalities. The imbalance of power between states widens the gap in terms of access to expertise and products between high-income countries with the originator companies they host on the one hand, and developing countries with their generic manufacturers on the other.

Inequalities in access to medicines are the result of inherent conflicts in the global pharmaceutical system. The discussion on the evolution of the global health architecture shows how this directly stems from the ways the existing mechanisms and initiatives have been shaped and evolved, including the ubiquity of public-private partnerships, where the balance is significantly tilted in favour of private interests. The response to the COVID-19 pandemic is an example of this system's inherent flaws and the lack of solidarity that prolongs health crises, causing enormous suffering and preventable deaths.

From the massive public investment and direct involvement in medical innovation that do not provide an adequate return in terms of equitable and affordable access to end products, to the dependence of public health interventions on the willingness of private

companies to engage in them, the dissertation provides ample examples of how the current pharmaceutical R&D and access ecosystem is unable to effectively respond to public health needs. It is argued that the failure is neither accidental nor exclusive to health emergencies. The current pharmaceutical system is not fit for purpose.

Building on this analysis, the second part of the dissertation discusses how to change the way medicines and particularly medical countermeasures, are developed and accessed.

The overarching premise of the dissertation is that governments themselves should take greater responsibility for defining the direction of health innovation, ensuring access based on equity and human rights principles and shaping the R&D ecosystem accordingly.

This will require an end-to-end system that, from basic research to clinical trials, production, procurement and delivery of final products, is guided by these principles. It should be publicly and transparently governed as well as substantially funded while ensuring that the overarching goal of enhancing health security is embraced before any economic interests, and that risks and benefits are shared fairly between public and private actors from the outset.

Even before such an overarching system is put in place, states can improve access to health technologies by attaching specific and strict conditions to public funding for pharmaceutical R&D. These should include guarantees that products developed (entirely or partially) with public money are priced fairly so that people can afford the medicines they helped to develop. A key condition in the context of health emergencies should be that, in times of crisis, all forms of intellectual property, data, know-how and biological resources required to develop medical countermeasures are made widely available to scale up their production.

Whereas the first part of the dissertation argues that the current system of incentivising medical innovation through monopolies is grossly inefficient, the second part presents alternative options.

There are various models developed for the purpose of making investment in R&D more cost-effective and responsive to public needs. They are analysed in recognition that different disease areas and different products may require specific ways of funding, incentivising and rewarding R&D activities. A wide range of these models are presented and examined. To illustrate how they can be used, often together, in specific disease areas, the examples of their application in specific contexts are also described.

Different alternatives such as pooling of intellectual property rights, technologies and funds; advance market commitments; patent buyouts or regulatory incentives are discussed in more detail. Of the various mechanisms, options based on decoupling investment in innovation from drug volumes and high prices may most effectively stimulate innovation while ensuring affordability and accessibility.

What is more, in the context of neglected diseases, the strengths and weaknesses of product development partnerships are presented while various types of regulatory incentives are analysed using EU regulations on orphan and paediatric medicines as an example. In the context of attempts to increase innovation of new antibiotics and manage adequate access to them to limit antibiotic resistance, alternative models, such as offering governments to pay a subscription or licence fee for priority access to them at a certain price or an options market model for antibiotics are demonstrated.

Finally, special consideration is given to alternative models for the development and access to medical countermeasures. Innovation in this area would ideally be based on an open knowledge model, which could generate technological advancements free to use, with no legal restrictions.[751] An open approach to innovation, including open source and open access schemes, could maximise research potential, speed up the development process, increase the scale of production and consequently provide broad access to end products. Corbevax can be considered proof of this concept. The dissertation argues that the best approach would be for countries to jointly fund and develop products such as vaccines making them available to all as public goods. For this to happen, the public sector (in partnership with private actors or through direct involvement in R&D and production, known as a *public option*) should invest in and steer their development. Ideally, this should be done through an international mechanism for joint financing and R&D, or at least by pooling resources.

Following this discussion, the dissertation delves into how to reduce global inequalities in access to health technologies and make the pharmaceutical system work for all. It argues that to increase equitable access to medical countermeasures worldwide, it is necessary to expand R&D and production capacity in the Global South. The Global South countries need to develop the expertise, know-how, skilled workforce and infrastructure to absorb existing technologies, be able to adapt them and develop them further. The

[751] See also: WHO Consultative Expert Working Group on Research and Development: Financing and Coordination, *op. cit.*, p. 104.

technologies should be controlled by governments, who should also be in charge of the allocation and pricing of end products. The role of international cooperation, which can be strengthened through a new *pandemic treaty* and revised International Health Regulations, is key, and ways to achieve this were also discussed.

All these models and structural changes demonstrate the breadth of alternative approaches to increasing medical R&D activities and providing more equitable access to health products. Some of them also show the potential to go beyond the current mainstream, profit- and market-driven commercial system. Their use would allow the public sector to actively shape innovation and the market.

Selecting the most appropriate models and implementing them at the national or regional level according to specific circumstances and identified medical needs pose a significant challenge. Various instruments may in theory fill similar gaps or have comparable effects, but differences between them make their suitability dependent on specific contexts. Local conditions and existing models could result in the same policy choice having different effects when applied elsewhere.[752]

These proposals aim to transform public sector governance and leadership, increase multilateral cooperation, shape the market, and influence the decision-making of private companies. These actions, however critical, do not exhaust the possibilities of changing the pharmaceutical R&D and access ecosystem.

Given that the poor outcomes of the system are a consequence of its ineffective design, far-reaching options must also be considered, such as altering the ways in which private actors operate on the market – or even changing the actors themselves – to promote corporate governance which considers aspects beyond profit and leads to better value creation.[753]

In this context, solutions such as limiting the practice of share buybacks, setting conditionalities of profits' reinvestment, or tying executive compensation not to stock value but to equal access to the produced goods, among other things, are proposed.

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[752] R. R. Nelson, *What enables rapid economic progress: what are the needed institutions?*, Research Policy Volume 37, Issue 1, February 2008, p. 1-11.; https://www.sciencedirect.com/science/article/abs/pii/S0048733307002314 (27 May 2023).; J. Mestre-Ferrandiz, B. Shaw, Ch. Chatterjee, J. Ding, P. Singh, M. M. Hopkins, *Policy Instruments (Non-Price) for Medical Innovation*, Oslo Medicines Initiative Technical Report, WHO Europe, 2022, p. 36.; https://apps.who.int/iris/bitstream/handle/10665/361755/9789289058223-eng.pdf?sequence=1&isAllowed=y (27 May 2023).

[753] UCL Institute for Innovation and Public Purpose, *The people's prescription, op. cit.,* p. 42.

To improve the performance of pharmaceutical companies in line with public health needs, changes can also go beyond their governance and operations. While the model of shareholder-owned corporations is currently dominant in the pharmaceutical market, it is not the only possible way to structure economic activity leading to the development and manufacturing of medicines. The dissertation argues that to combine the ability of attracting private capital with delivering on public health needs, public policies should encourage the involvement of corporations with other legal forms, such as non-profit or limited-profit companies and benefit or social purpose corporations in the sector. The statutory form of currently prevailing for-profit companies could be changed to one of the above to *alter their incentives from the inside* and to enable and require them to consider other interests beyond shareholder value.

Changing the statutory form of pharmaceutical corporations can be a difficult task, but one that may be worth the effort. As with other major reforms, transformational changes to bring greater benefits to the public will require broad policy and regulatory action. Without the right environment, companies that are not solely driven by profit maximisation will be at a significant disadvantage, unable to compete in the current profit-driven capitalist market, unless other mechanisms are put in place to favour them.

On the other hand, it is also argued that for companies whose statutory form would require them to pursue public interest goals, there must be robust enforcement laws put in place. The ability to hold corporations accountable for adhering to their statutory objectives through rigorous oversight mechanisms is critical to effecting meaningful change. Corporate law should be equipped with the right tools and laws to ensure that corporations do not game the system.

Lastly, besides changing the ways for-profit companies operate in the pharmaceutical sector and introducing corporations that have other statutory forms and hence could more efficiently serve the public interest on the market, it is also possible to bring another actor directly into the mix – the public sector.

The *public option* involves the creation of national public pharmaceutical R&D institutes, manufacturing sites as well as wholesale and distribution companies. Public companies would need to be based on the principles that should guide all public sector activity in pharmaceutical innovation, i.e. they should be fully public interest driven, oriented toward public health goals, transparent and include safeguards against undue influence and conflicts of interest. The dissertation also gives consideration to how public

companies in each segment should operate, including examples of their successful implementation (as well as failures in this regard) around the world. It is noted that the *public option* can be complementary to other reforms discussed above or tested independently of them.

The dissertation argues that the *public option* for pharmaceutical R&D, production and supply can be of particular importance in the context of health emergencies. Having an independent public capacity that can effectively execute a preparedness strategy and, perhaps even more importantly, respond quickly and efficiently during a crisis can greatly improve the way countries deal with pandemics and similar crises.

All in all, the broad spectrum of alternative approaches to transforming R&D and access ecosystem in the context of health emergencies provides the opportunity to move beyond the existing mainstream model and create an efficient system meeting public health needs and increasing global equity.

As argued above, different alternative models will work in different settings and situations. When applied, they should be designed and adapted as well as mixed with each other on a case-by-case basis depending on specific needs and circumstances such as existing infrastructure, scientific and technological capacities, available resources, political environment, national priorities or local disease burdens, among many other things.[754] No *one-size-fits-all* solution should be expected, even for the same problem.[755]

Different models and policy choices affect each other in a way that can be complementary or contradictory. They can reinforce each other's intended effects, be a catalyst for one another or cancel their positive outcomes.[756] They can be implemented together as components of a single initiative, or be staggered in recognition that the order in which certain models and instruments are introduced can also affect their functioning and the effectiveness of the overall system.[757]

According to states' strategic priorities, existing capacities (and short- and long-term prospects of increasing them), resources and collaboration mechanisms, they should

[754] J. Mestre-Ferrandiz, B. Shaw, Ch. Chatterjee, J. Ding, P. Singh, M. M. Hopkins, *op. cit.*, p. 35.
[755] *Ibidem*, p. 36.
[756] K. Flanagan, E. Uyarra, *Four dangers in innovation policy studies – and how to avoid them*, Industry and Innovation, 2016, p. 177-188.; See also: *Ibidem*, p. 36.
[757] P. Cunningham, J. Edler, K. Flanagan, P. Laredo, *Innovation policy mix and instrument interaction: a review, Manchester: Manchester Institute of Innovation Research*, Nesta Working Paper No. 13/20, November 2013.; https://media.nesta.org.uk/documents/innovation_policy_mix_and_instrument_interaction.pdf (27 May 2023).

select, adapt, combine and implement concrete options, which would best serve the public interests by addressing specific barriers, weaknesses and identified gaps.

Understanding gaps and needs at the level at which the models are implemented is a prerequisite to building an environment in which they can succeed. Policy choices should also be influenced by underlying conditions, both within and outside the health and pharmaceutical sectors. The range of other determinants that may favour or limit the effectiveness of particular medical R&D and access instruments include the ambitions and prioritisation of health care and medical innovation at the local and national level. Similarly critical can be countries' willingness to choose joint solutions and cooperate at regional and international levels and the availability of funding and success in pooling resources. What is more, the choice of R&D and accessed models can be determined by states' capabilities for local policy design and implementation, including support from specialised agencies and expertise of skilled workforce, or openness to risk-taking and policy learning.[758]

Different initiatives and approaches can be implemented individually or jointly and undertaken on a global level or in regions such as the EU, or even only within several countries or states. Smaller ventures are easier to undertake, and they benefit from lower transaction costs. With limited resources, different models can be piloted in this way and then, if proved successful, applied on a larger scale at higher levels.

New R&D and access models to be implemented in specific circumstances should be costed, as far as possible.[759] On the basis of this analysis, states must be able to commit to their long-term financing by securing resources (also across sectors and public departments under a coherent public policy). Providing the resources for their design (including ancillary aspects such as training a skilled workforce or establishing collaborative networks), implementation, operation and monitoring is an essential conditions for their success.

Policymakers should be aware of and anticipate risks in the application of the discussed models and tools. For example, poor implementation of some instruments may lead to overcompensation of companies and the lack of return on public investment. The outcomes of some solutions can also be the most effective if they are combined with others and can rely on other measures. What is more success of some models can be reliant on gaining a *critical mass*, for example, the number of benefit corporations on the market.

[758] J. Mestre-Ferrandiz, B. Shaw, Ch. Chatterjee, J. Ding, P. Singh, M. M. Hopkins, *op. cit.*, p. 39.
[759] *Ibidem*, p. 38.

As discussed in the context of building local manufacturing capacities or allowing benefit corporations and public companies to compete in the pharmaceutical sector, market shaping, and demand-side policy interventions cannot be overlooked. A good understanding of markets, including their sizes, public and private buyers' interest, their ability to pay, public procurement policies as well as expertise within specialised agencies and adequate policy and regulatory measures can play a decisive role in the ultimate success of selected strategies.

Just as important as the choice and implementation of R&D and access models is the ability and approach to regular, systematic and broad (including across sectors) evaluations of selected instruments. Monitoring and assessment of their suitability (which can be challenging in practice, particularly in complex systems mixing different instruments), their adaptations or replacements, is necessary to maximise the value of public resources and deliver anticipated outcomes.

Research on and assessment of the discussed models could also have great value for informing future policy choices. While various examples of the use of different instruments have been presented in this dissertation, the wide implementation of many of them in different political settings and geographical regions is limited. Building evidence through robust appraisals of policy experimentation, prospectively and retrospectively, by policymakers and academics, and sharing lessons learnt is important to allow countries to take potentially most effective measures in their contexts.

One aspect central to all of the proposals is political leadership. The transformational changes must be based on the public sector's vision and commitment to take risks and invest significant resources to design and drive the work of public and private actors alike to create public value.

The implementation of most of the alternative models, including the *public option* and leading to changes in the statutory form of companies in the pharmaceutical market requires strong leadership and robust public sector's structures. Introducing them would be a major, costly and long-term commitment. Their full success will depend on resilience to frequent political changes.

However, only through bold and dedicated public policies implemented by visionary political leaders can universal access to medicines and the right to health as such become a reality.

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