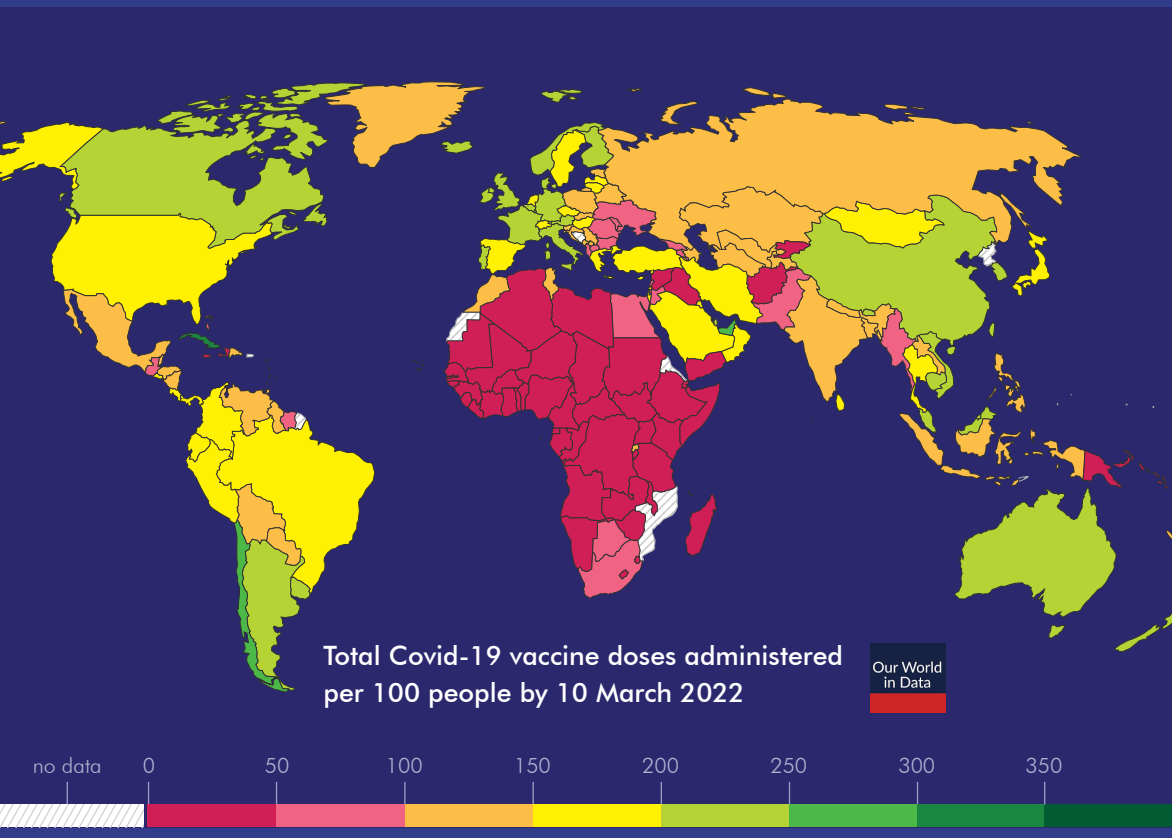
Pandemics and the illumination of "hidden things"

Lessons from South Africa on the global response to Covid-19



HEALTH JUSTICE INITIATIVE

Suggested citation: Health Justice Initiative *Pandemics and the illumination of "hidden things" – Lessons from South Africa on the global response to Covid-19*. Edited Volume. June 2023.

Editor: Laura Lopez Gonzalez
Project Lead: Marlise Richter
Proofreader: Sigwabusuku Mafu
Lay-out & Design: Jaywalk Design
Funding: The Health Justice Initiative is grateful to all its organisational and individual donors for funding and supporting its work. We would like to acknowledge the contributions of the Rockefeller Brothers Fund, the Joffe Trust and the Claude Leon Foundation towards funding this Compendium in particular.

Credit front-page image:

Adaption of *World in Data*. Image shows Total Covid-19 vaccine doses administered per 100 people, as of 11 March 2022 (two years since the WHO declared Covid-19 a "pandemic").

Credits for republished pieces and quotations:

Bhekisisa
Groundup
Spotlight
News24
People's Vaccine Alliance
Arundhati Roy
World Health Organization
Our World in Data
The Lancet

“The lockdown worked like a chemical experiment that suddenly illuminated hidden things.”

- Arundhati Roy:
‘The pandemic is a portal’

3 April 2020

ACKNOWLEDGEMENTS

The Health Justice Initiative (HJI) would like to thank everyone who made this Compendium possible.

Editor Laura Lopez Gonzalez was the shepherd of the Compendium project. She held the various threads of it together over many months and brought expert knowledge, skilful wordsmithing, and editorial wisdom to its wide spectrum of pieces.

The themes of the Compendium were informed by an extensive scoping exercise conducted by Laura. We would like to acknowledge the contributions of many advisors at the outset who helped us select key themes including the members of the HJI Board and Advisory Group and in addition: Madhukar Pai, Salome Meyer, Shuaib Manjra, Quarraisha Abdool Karim, Nick Dearden, Lisa Zhu, Fifa A Rahman, Jaume Vidal, Tom Moultrie, Maaza Seyoum, Peter Maybarduk, Gugulethu Ngubane, Kyle Aiden Cowan, Althea Adonis, Yanga Nokhepheyi, Gregg Gonsalves, Matthew Kavanagh, Francios Venter, Asia Russell and Ron Whelan.

The authors had the unenviable task of employing these themes to distil succinct lessons from a very painful pandemic that disrupted the global world order and caused immense hardship, suffering and death. We are grateful for their spirit of generosity.

We also acknowledge the contributions of the People's Vaccine Alliance that provided HJI with various images and materials, Sigwabusuku Mafu for proofreading, Gideon Engelbrecht and Lisa Stacey from Jaywalk Design for lay-out and design, and Althea Adonis for logistical and administrative support.

We are grateful to activists and frontline workers everywhere.

We dedicate this Compendium to frontline workers and activists in the Global South who advocated tirelessly against the health inequities exposed and exacerbated by the pandemic.

-Marlise Richter and Fatima Hassan
Cape Town, August 2023

TABLE OF CONTENTS

LIST OF FIGURES

LIST OF TABLES

ABBREVIATIONS

ACT-A	Access to Covid-19 Tools Accelerator
CDE	Centre for Development and Enterprise
CEPI	Coalition for Epidemic Preparedness Innovations
COVAX	COVID-19 Vaccines Global Access
CoVDP	Covid Vaccine Delivery Partnership
DG	Director-General
EU	European Union
GAVI	Previously Global Alliance for Vaccines and Immunisation. Current: Gavi, the Alliance
HJI	Health Justice Initiative
IEJ	Institute for Economic Justice
INB	Intergovernmental Negotiating Body
IP	Intellectual Property
MAC	Ministerial Advisory Committee
MCC	Medicines Control Council
MPP	Medicines Patent Pool
mRNA	messenger RNA
MSF	Médecins Sans Frontières
NDH	National Department of Health
NHI	National Health Insurance
NIH	National Institutes for Health
NISEC	National Immunisation Safety Expert Committee

OECD	Organisation for Economic Cooperation and Development
PHEIC	Public Health Emergency of International Concern
PHM	People's Health Movement
PPRR	Pandemic Preparedness Response and Recovery
PVA	People's Vaccine Alliance
SAHPRA	South Africa Health Products Regulatory Authority
SAMRC	South African Medical Research Council
SANDF	South African National Defence Force
SAPS	South African Police Services
SA	South Africa(n)
SARS	Severe Acute Respiratory Syndrome
SRDG	Social Relief of Distress Grant
TB	Tuberculosis
TRIPS	Trade Related Aspects of Intellectual Property Rights
UBIG	Universal Basic Income Guarantee
US	United States
VIRAT	Vaccine Introduction Readiness Assessment Tool
WHO	World Health Organization
WTO	World Trade Organization

11 March 2020

"We have therefore made the assessment that Covid-19 can be characterized as a pandemic.

Pandemic is not a word to use lightly or carelessly. It is a word that, if misused, can cause unreasonable fear, or unjustified acceptance that the fight is over, leading to unnecessary suffering and death. […]

We have never before seen a pandemic sparked by a coronavirus."

Tedros Adhanom Ghebreyesus
WHO Director-General

Foreword

Shuaib Manjra
Fatima Hassan

On 11 March 2020, World Health Organization (WHO) Director-General (DG), Tedros Adhanom Ghebreyesus, sat in front of a slew of cameras, journalists, and colleagues.

By then, cases of the newly discovered SARS-CoV-2 had increased by more than 13-fold in China, which first identified the virus that causes Covid-19. Less than three months after its discovery, Covid-19 had spread to 114 countries and killed more than 4,000 people.

Thousands more were fighting for their lives.

"WHO has been assessing this outbreak around the clock and we are deeply concerned both by the alarming levels of spread and severity and by the alarming levels of inaction," the WHO DG, Tedros Adhanom Ghebreyesus, said at the 2020 live press conference.

"Pandemic," he told the cameras, was not a word the organisation used lightly.

Still, the head of the world's highest-ranking health body assured the public that there was hope.

"There has been so much attention on one word," he continued. "Let me give you some other words that matter much more and that are much more actionable — prevention, preparedness, public health, political leadership and, most of all, people."

The WHO DG concluded: "We're in this together to do the right things with calm and protect the citizens of the world — it's doable."

Covid-19 was an unprecedented pandemic. Government lockdowns and shelter-in-place orders confined many to their

homes, if they had one. News reports related terrifying increases in cases of the new disease. Hospital queues stretched around city blocks during deadly waves of infections driven by seemingly ever-more infectious variants. Businesses closed, jobs and homes were lost, and people went hungry.

Friends and family died and often far from home. They were quickly laid to rest in line with strict protocols that limited gatherings for funerals and robbed us of the traditional ways we mark the passing of those closest to us.

Covid-19 changed how we lived, how we died, and how we mourned.

Meanwhile, many scientists worldwide carried the enormous weight of at once trying to understand the virus' basic science while simultaneously developing vaccines and treatments at breakneck speed. Ultimately, their efforts produced several safe and effective Covid-19 vaccines within a year.

Several critical factors accelerated parts of the pandemic response, including international scientific collaboration, massive but select public investments and private-public partnerships. Frontline workers, including community healthcare workers, bore the brunt of the pandemic's force — risking their lives to provide care in the face of a new disease in overrun hospitals and far-flung rural communities.

Open-source journals, the introduction of publicly available pre-print versions of studies and accelerated peer review created a common repository of ever-evolving knowledge during the pandemic. Genetic sequencing of the virus allowed the world to track SARS-CoV-2's evolution. These data were largely shared in real-time by most countries. The world owes scientists in South Africa and Botswana a particular debt of gratitude, experts there being the first to report several major evolutions of the virus. Unfortunately, the international community responded to their work with unscientific and ineffectual travel bans — and vaccine hoarding.

Massive public funding by several governments and a handful of private foundations ensured that initial efforts to develop Covid-19

vaccines and treatments were resourced. This funding permitted many scientists to pivot from existing work to Covid-19.

Public-private partnerships helped to ensure that novel findings could rapidly translate into practical outcomes, with upscaled production using existing manufacturing capacity for the benefit of the Global North first. Many regulatory agencies quickly reimagined approval processes to facilitate speedy public access, albeit with varying degrees of transparency, as is deftly described in this Compendium.

So too does this Compendium integrate the opaqueness in government policy that, in SA, led to a lack of transparency at key times, and also some irrational or insufficiently explained measures that even highly regarded scientists challenged, related to lockdown measures and vaccine eligibility criteria, during a time of growing state health sector corruption and also private sector pandemic gouging and profiteering (resulting in the appointment of three different Health Ministers in the pandemic) coupled with vocal anti-science and disinformation groups.

That line of questioning of decision makers left SA's Health Justice Initiative (HJI) facing the threat of legal action and a threat of adverse cost orders from the government and others.

The WHO demonstrated its usefulness as an international agency, playing the role of advocate, information source and conductor in a complex, multilateral world where many actors sought its blessing and bypass.

At the same time, many countries rolled out new social safety nets, such as far-reaching social grants, housing support and cash transfers to feed and shelter families and mitigate job losses caused partly by measures to contain Covid-19's spread. It was not enough.

But ultimately, the world was not, as the WHO DG had hoped early in the pandemic, "in this together".

Alongside documented cases of price gouging by private sector players, as early as December 2020, activists — many featured in this volume — warned that nine out of 10 people in poor countries were set to miss out on Covid-19 vaccines. Indeed, as late as April 2023, nearly three-fourths of people in high-income countries were

vaccinated, whereas only 59% of people in lower and middle-income countries had received a first dose. Vaccination rates in low-income countries were dramatically lower despite well-intentioned but weak multilateral initiatives to secure doses for the most vulnerable — essentially because vaccine supplies did not reach those most in need at the same time.

Billions in public funding to develop Covid-19 vaccines did not result in public goods. Instead, multinational corporations privatised access to life-saving vaccines, bankrolled by everyday people.

Intellectual property created with public funding — gene sequencing, vaccine technology, and therapeutics — was privatised through patents, these tools still unavailable to many middle and low-income countries.

Even communities at the heart of vaccine clinical trials were excluded from the benefits of such research. In SA, some of these same communities would eventually be given access to vaccines much later than people in the Global North, on a drip-feed basis, after SA negotiated agreements to purchase doses but at prices that, for some jabs, were more than twice that paid by the European Union.

Life-saving shots went to the highest bidder and begot new billionaires. This Compendium reveals the deep-seated and historical dynamics behind that.

Rich countries hoarded vaccines, often buying enough to vaccinate their populations several times over, even as poorer countries with healthcare workers and other people in greater need, went without. Wealthy nations and even the heads of some vaccine manufacturing companies consoled themselves with now debunked myths that poor countries were "spared" from Covid-19 — mistaking an absence of data on cases and deaths for evidence. This, as the same nations could not access the rapid tests that would have allowed them to diagnose and count Covid-19 cases in the first place.

Ultimately, research found that the prevalence and infection case fatality ratio of Covid-19 was far higher in developing countries than in high-income peers.

Poor and middle-income countries also fought for their existing rights under international trade agreements to temporarily waive certain intellectual property provisions to access Covid-19 vaccines, tests, medicines, and other tools during the pandemic. In October 2020, SA and India proposed a Trade Related Aspects of Intellectual Property Rights (TRIPS) "waiver" to this effect at the World Trade Organization (WTO) to ensure access, self-reliance and sovereignty. It was blocked.

SA and India's proposal stressed the need for "unhindered global sharing of technology and know-how in order that rapid responses for the handling of Covid-19 can be put in place on a real-time basis".

Ultimately, the TRIPS waiver — as it came to be called — was supported by more than 100 countries and many former world leaders, academics, researchers, activists, non-governmental organisations, Nobel Laureates and economists.

Almost two years later, staunch opposition from the EU, the US, the UK, and Switzerland resulted in a limited and inadequate deal, and only for vaccines. No waiver.

In all of this, NGOs and civil society groups mobilised to fight for equity, fairness, transparency and justice. HJI was one of those groups.

And indeed, small victories resulted. A spotlight was shone on vaccine apartheid and the greed of companies. The WHO mRNA Technology Transfer Programme, designed to research vaccines and build vaccine production capacity in low and middle-income countries was set up, first in SA, and is developing its own mRNA Covid-19 vaccine while working on vaccines for other diseases affecting the Global South.

Globally, among others, there is greater attention on the working conditions of frontline healthcare workers, the need to address equity in the entire pandemic countermeasures ecosystem, and on the need for fairness and transparency in clinical trials — including new demands for post-trial benefit-sharing agreements, and finally, a spotlight on the inadequacies of only relying on market-based solutions and "voluntary measures" or what are called "voluntary

licences" or charity.

On 5 May 2023, WHO DG declared that Covid-19 was no longer a "public health emergency of international concern". Although seven million deaths due to Covid-19 had been reported to the WHO, he said that the WHO knew that the death toll was at least 20 million people if not more. SA alone had recorded more than 300,000 excess deaths by March 2022 as compared to pre-pandemic years.

The virus, however, will remain with us.

Covid-19 was not the first pandemic, nor is it going to be the last. The global response did, however, repeat many mistakes of previous health emergencies — including HIV/AIDS — in which low and middle-income countries often waited as much as 10 years or more for the chance to access affordable life-saving medicines and vaccines.

As the world readies itself for the next and coming pandemics, and as it negotiates global treaties and accords and regulations to define the collective global management of the next pandemic, our past responses, and the greed and lack of solidarity in Covid-19, need not dictate our future.

This Compendium has been carefully curated by SA's HJI. It seeks to reflect on some key issues and moments in this pandemic, with a view to using some of the lessons we learnt in Covid-19 (set out here) to better inform our response to the next mass disease outbreak — to ensure that we always prioritise a just and equitable response that never forgets the millions of people lost too early and tragically in this pandemic.

A future in which, one day, we are truly "all in this together".

Dr Shuaib Manjra is the Chairperson of the HJI Board. He is a sport- and occupational-medicine physician and works with a range of non-governmental organisations, state- and private-sector institutions. He is also a senior honorary lecturer at UCT's School of Public Health and Chairperson of the Medical Committee of the International Netball Federation. He is an associate fellow and examiner of the College of Public Health Medicine (Occupational Health) (CMSA). He graduated in medicine from the University of Natal and did his post-graduate studies in sports medicine and occupational health at UCT and the University of Birmingham.

Fatima Hassan is a human rights lawyer and social justice activist and the founder and director of the HJI. She has dedicated her professional life to defending and promoting human rights in SA, especially in the field of HIV/AIDS and Covid-19. She is an Honorary Research Associate at the University of Cape Town School of Public Health and Family Medicine; she serves on the Board of Global Witness, is the Recipient of the 2022 Calgary Peace Prize and is a 2023 Echoing Green Fellow.

SECTION A

SOUTH AFRICA – STORIES FROM THE FRONTLINE

Safety nets during the height of the Covid-19 pandemic: SA's Social Relief of Distress Grant - A perspective from the Black Sash

Hoodah Abrahams-Fayker

The Covid-19 pandemic highlighted the economic fragility of SA and created an urgency to address the triple challenges of inequality, unemployment and poverty in the context of an economic and humanitarian disaster.

The United Nations Committee on Economic, Social and Cultural Rights (UNCESR) in a 2020 statement acknowledged that the Covid-19 pandemic had "devastating impacts across the world on all spheres of life — health, the economy, social security, education and food production". Lockdowns to curb transmission of the virus caused jobs losses, endangered livelihoods and heightened exposure to violence. States are under an obligation, within a human rights framework, to prevent or mitigate violations of economic, social and cultural rights and to reduce the suffering of the most marginalised

groups. Social relief and income-support programmes must be provided to ensure food and income security to all those in need.

SA offers several forms of social protection, including grants aimed at supporting citizens, permanent residents and asylum seekers with disabilities, the elderly, children and foster parents and war veterans, for example. As of January 2023, about three in every 10 South Africans relied on one of these grants.

The country responded to the pandemic by introducing further temporary social relief measures to provide a buffer against hunger and poverty. The initial package included R42 billion (US$2.3 billion) to increase the amount of money provided through existing social grants for an initial period of six months. The Child Support Grant was, however, excluded from these increases, but recipients of the Child Support Grant received an increased amount for a limited period in the form of a Caregivers Grant of R500 (US $28) for five months.

It also introduced an adult grant in the form of the Covid-19 Social Relief of Distress Grant (SRDG) of R350 (US$19) for an initial period of six months.

The Covid-19 SRDG is targeted at those between the ages of 18 and 59 years who have no income and did not benefit from other social grants or the Unemployment Insurance Fund (UIF). Introduced initially for six months, the grant has been extended on an *ad hoc* basis and, at the time of writing, was slated to continue until March 2024. The grant's introduction is a significant intervention, representing SA's first social grant to address a large portion of its population in need but otherwise not covered by the country's existing social grant system. In implementing the Covid-19 SRDG, the SA government is beginning to address a 2018 recommendation by the United Nations Committee on the International Covenant for Economic, Social and Cultural Rights to "ensure that those between the ages of 18 and 59 with little and no income have access to social assistance".

As of January 2023, the SRDG reached up to 10 million beneficiaries, or about one in six people living in the country.

However, almost three years after the Covid-19 SRDG's introduction, the eligibility criteria for the grant has become

narrower, despite provisions made to allow caregivers who receive the Child Support Grant to also qualify for the SRDG. For instance, the SA government announced that the income threshold to receive the grant has been increased from being zero rated to R624 (US$34), limiting who can qualify within the budget allocation despite the need.

Whilst the SRDG is a small step in the right direction, it is insufficient to respond to the SA context of significant high unemployment. The amount of the grant, R350 (US$19), is well below the food poverty line of R663 (US$37), meaning those who receive the grant still struggle to pay for their basic needs. Additionally, since its inception, the SRDG has been plagued with challenges *vis-a-vis* administration, technical glitches in processing applications, obstacles to apply for the grant through an exclusive online system, flawed eligibility criterion, a defective verification process and a fundamentally weak recourse and appeal process for those whose applications to receive the grant were denied.

Covid-19 has underscored the critical role of adequate investments in public health, comprehensive social protection programmes, dignified and decent work, and access to food, water, sanitation systems and housing. The pandemic has also intensified the intersecting forms of income and gender within SA, for which measures have to be put in place.

While the relief measures were a small step in the right direction, they were insufficient to meet the humanitarian crisis, both under lockdown conditions and today as many struggle to recover from the aftermath of Covid-19. Many poor families continue to go hungry.

The SRDG is a constitutional imperative that aids economic growth. It is an investment in our collective future given its proven positive benefits. As a human rights organisation, Black Sash believes that income support leads to better nutritional and educational outcomes, improved health, social cohesion, job-seeking behaviour and stimulates local economies. It encourages economic activity and helps to empower women who bear the burden of unpaid caregiving work and gender-based violence.

The Black Sash has therefore demanded and advocated that the SRDG be the first step towards the introduction of permanent

social assistance for those between 18 and 59 years with no or little income with the aim of working towards universal basic income, in anticipation of our government slowly moving towards the progressive realisation of "social security".

Hoodah Abrahams-Fayker has a legal background, which she has used to focus on advancing human rights. As the national advocacy manager for the veteran SA human rights organisation, the Black Sash, she advocates for the right to comprehensive social security with particular emphasis on social protection and social assistance to reduce poverty, inequality and unemployment. She previously used her expertise to advocate for access to justice and advance women's rights through impact litigation.

CONTEXT:
Basic Income Grant: What is the debate about?

Originally published: Vuyisiwe Mahafu "Basic Income Grant: What is the debate about?" *Groundup* 6 September 2022

The possibility that a Universal Basic Income Guarantee (UBIG) could be introduced in South Africa has sparked a lot of debate over the last two years.

Its advocates say this grant could address our extremely high rates of poverty and ensure that all people have an adequate standard of living. Its detractors say it would bankrupt the country.

In this three-part series from the Institute for Economic Justice (IEJ), we cover the basics of a basic income grant. In our first article, we gave an overview of what a universal basic income guarantee is and what transformative potential it could have. In this, our second piece, we cover the evolution and current state of the debate in South Africa. Our final piece will focus on how we could finance it.

The birth of the debate in South Africa

The idea of a basic income grant (BIG) in South Africa goes back to the late 1990s, when organised labour proposed that the idea should be investigated by the government at the 1998 Presidential Jobs Summit. In 2002, the report of the Taylor Committee of Inquiry into a Comprehensive System of Social Security for South Africa proposed a basic income grant of R100 per person, per month.

But then the debate disappeared for two decades. The recommendations of the Taylor Committee were ignored. The ANC was largely opposed to the UBIG during this period, influenced by concerns about "hand-outs" and dependency.

As successive governments pushed different growth agendas, there was less political interest in social

security as a developmental strategy. It took time for the ineffectiveness of these growth agendas to become clear: massive unemployment persisted, inequality worsened, poverty deepened.

Covid restarts the debate

When the Covid pandemic hit, the UBIG debate re-emerged. The temporary Social Relief of Distress (SRD) grant of R350 a month was introduced by the government as a response to the impact of the pandemic and related lockdowns.

This was the first grant that able-bodied adults between the ages of 18 and 59 could receive. Until then, even though a large proportion of this group had no other income and were shut out of paid work due to South Africa's structural unemployment crisis, they were not covered by the social grant system.

Civil society organisations began to call for a permanent UBIG to replace the temporary SRD grant, and the government listened.

In December 2021, a panel of experts commissioned by the Department of Social Development and the International Labour Organisation found that while the SRD grant had provided a lifeline for many, it had not made a sufficient impact on poverty because it was too small. In South Africa, four million households, comprising 11 million people, have income below the food poverty line (FPL), which was R595 per month in 2020.

According to the panel, a BIG introduced at scale, worth at least the FPL, would almost eliminate poverty in South Africa. The panel recommended that the SRD grant should be made permanent, and progressively increased over time. They said that "no alternative measures could reasonably address the widespread and urgent income support needs" of South Africans.

In January 2022, a coalition of civil society organisations met President Cyril Ramaphosa to argue that the SRD grant should be made into a universal basic income guarantee. They said that it should be increased first to the FPL and then by 2024 to the upper bound poverty line (R1,335 per month in 2021). These proposals were recently supported by a resolution of the ANC Policy Conference in July this year.

But support for a UBIG has not been unanimous.

Opponents of the grant, which include some groups in business and the National Treasury, have variously claimed that it is unaffordable,

that its costs would overshadow any benefits, that it is a "populist'" party-political tactic and that it would further a "culture of dependency".

A boost for the economy?

Critics of the UBIG say that it will cause the economy to slow down. The Centre for Development and Enterprise (CDE), for instance, argues that while the UBIG will "raise beneficiaries' consumption", causing a boost to the economy, this will come "at the cost of reduced consumption elsewhere". This argument does not account for the extent to which a UBIG can boost local economies. It is not just increased spending that will result, but it can allow more people to become active participants in the economy, which would grow as a result. UBIG beneficiaries will spend the money in their local communities, which stimulate these industries and increase tax revenues through increased VAT payments.

Informal sector workers would use a portion of their basic income to invest in self-employment and productive activities.

These types of positive spin-offs can, over time, resolve South Africa's pressing challenges such as inequality, unemployment and poverty. This means that the net cost to the government decreases.

The benefits of a UBIG are far greater than the initial cost of its implementation.

Populism or for the people?

The CDE also says that the only reason why a UBIG is now on the national agenda is that the governing party needs to shore up support. But in a democratic system we should expect parties to pursue policy platforms that they expect to have widespread support, and benefit their constituency. We should also respect voters' rights to judge the merits of such policies. The popularity of a policy is by no means an inherent argument against it.

This argument also ignores the pronounced and profound economy-wide impact of the Covid pandemic that led to the introduction of the R350 SRD grant. It also ignores the large number of civil society organisations and social movements that are calling for the adoption of a UBIG.

Dependency debates

Another line of attack from UBIG detractors, including the Minister of Finance, is to claim that providing grants will create a cycle of dependency. This argument is not based on evidence.

The evidence of a large number of studies on cash transfers in Africa and other low and middle-income countries demonstrates that UBIGs make people more productive.

Studies have shown that even meagre basic income support for vulnerable people increases autonomy and enables job-seeking, investment in productive assets, a transition from poor quality and exploitative jobs to more decent work as well as self-employment, small business creation, and women's economic empowerment.

As we mentioned in our previous article, basic income support helps people to join the formal labour market as it gives people money to look for a job.

The reality is, given the chance, people consistently seek ways to increase their economic participation and security.

Can we afford a UBIG?

Concerns about the affordability and sustainability of UBIG proposals have also come from the business lobby. The CDE and Intellidex argue that paying for a UBIG would require income tax increases or taking on debt that South Africa cannot afford. Income tax increases would lead to emigration and other destabilising economic effects, and South Africa already has a high debt-to-GDP (gross domestic product) ratio, they say. CDE and Intellidex argue that tougher taxes on the wealthy would compound the economic problems in South Africa.

They conclude that a UBIG is unaffordable.

But UBIG will act as a stimulus to the economy. Part of the cost associated with it will be recouped by the government through VAT. The remaining net cost can be sustainably financed through progressive taxation.

South Africa's income and wealth inequality is a destabilising factor in the economy. Taxing and redistributing income more progressively using a UBIG could shift persistent structural inequality in the economy, as argued by IEJ director Gilad Isaacs in response to the Intellidex report.

This argument has found unusual supporters. In August this year, the historically conservative Organisation for Economic Cooperation and Development (OECD) came out in favour of a UBIG as a safety net, and a more redistributive tax system.

The IEJ's analysis suggests that UBIG is achievable in South Africa in the short-

term and would carry little risk if it is phased in carefully and responsibly. We have proposed an initial UBIG valued at R624 per month (the food poverty line at September 2021) that would overtime be increased.

In the final part of this introductory series, we will look at how we could finance this.

Vuyisiwe Mahafu is a budget policy intern at the Institute for Economic Justice

Activist Q&A with Tinashe Njanji: "Information in the time of outbreaks"

Tinashe Njanji is a social justice, and human rights activist, and an educator with more than 10 years of experience in community mobilisation and working with grassroots organisations. He is the coordinator of the People's Health Movement South Africa (PHM) and a senior fellow at the Atlantic Fellows for Health Equity in South Africa (AFHESA) based at Tekano.

"When it came to responding to Covid-19, community healthcare workers around the world were often on the frontlines of the response but in SA, they were last in line for clear, basic information," says Njanji. Still, he reflects on ways in which the pandemic provided what he says is a golden opportunity to take the concept of intellectual property from the abstract to the real in communities and rethink community preparedness.

Question: Globally, community healthcare workers are on the frontlines of healthcare, including during disease outbreaks. What challenges did these workers experience in SA during Covid-19?

Answer: In SA, community healthcare workers are on the frontline of healthcare in policy but, in practice, they are still on the periphery in many ways. During the early Covid-19 response, they were the last people to get personal protective gear and, as a result, some contracted SARS-CoV-2 and died.

Similarly, there was a huge gap in the Covid-19 information community healthcare workers had compared to that given to nurses.

As the PHM (SA), we responded to both these gaps: sourcing and distributing personal protective gear for community healthcare workers and finding innovative ways to supplement their Covid-19 knowledge.

In our health system, many trainings are tick box exercises — they are not really meant to equip community healthcare workers with new information. If you look at the information they are being provided with, it is often not pitched at their level of education. Many community healthcare workers we spoke with said they received rushed information workshops by government or its partners.

Many of these training sessions left community healthcare workers with more questions than answers.

In response, we began asking them across the country, "what questions do *you* have?"

Every day, I received queries from community healthcare workers and, every day, we compiled a short, question-and-answer SMS message. The message might start with, for instance: "What is Covid-19?"

Then, we would provide a short, simple answer in the same message.

"How does Covid-19 spread?" might be the next day's SMS question and, again, we would answer it. We carried this on our social media as well: Facebook, Twitter, WhatsApp etc. We also developed informational posters covering symptoms, prevention, and why we needed vaccines.

Q: Were there any lessons learned about how we should be communicating about vaccines?

A: I am a father. I have been taking my kids for vaccinations their whole lives, but I only really took a moment to think about and understand the importance of immunisations because of the Covid-19 vaccine.

As parents and as a nation, we need to understand the importance of vaccines prior to a pandemic. As a society, we need to continue to invest in vaccine literacy and, for instance, include it in our education curriculum.

Q: How did the PHM help mobilise communities in SA to support the Covid-19 IP waiver proposal?

A: We also went politically into the issue of vaccine inequity, intellectual property, patents and why they were bad for health, for instance — and we talked about alternatives, like the Covid-19 waiver.

The pandemic was a golden opportunity to raise the issue of intellectual property because many communities understood that SA could not access vaccines early on. There was some awareness of the inequality we faced as the Global South and the injustice of the Global North skipping the queue for vaccine access.

SA began its public Covid-19 vaccination campaign in March 2021, four months after campaigns in countries such as the US and the UK kicked off.

It can be difficult to explain intellectual property rights [because it is technical] but we came up with creative ways.

Take KFC, the popular fast-food outlet. We would say: No one knows the recipe for KFC chicken, we would tell people. Even if

you work at KFC, you are not supposed to let that secret recipe out.

Patent protection is like that — a government gives an inventor the right to protect their inventions — or secret recipes, if you like, but for a limited period of time.

Q: What were some of the community challenges the PHM encountered?

A: Food insecurity in SA peaked in the initial phase of infections — when lockdown restrictions were harshest — but remained high throughout Covid-19's early years. About 10 million people were living in households affected by hunger as of May 2021.

Still, local community food gardeners in townships like Khayelitsha, for instance, were not considered essential workers — neither were informal traders that sell affordable fruit and vegetables.

Farmers like these were unable to tend their fields during hard lockdowns during which people were confined to their homes. They also did not receive dedicated government support. Still, both community farmers and traders like these form important parts of food security, particularly in poor urban areas.

In the future, governments need to rethink who is an essential worker during pandemics under lockdown rules.

SA's SRDG was introduced within months of the country's hard lockdown, partially in response to rising hunger. Because of the inequality we face in SA and its impact on social determinants of health, social support like this — and possibly a future basic income grant — should remain in place both during and outside of a pandemic as communities recover — and as they build resilience for future outbreaks.

What is the TRIPS, and why does it matter for public health?

TRIPS is an international legal trade agreement between countries as part of the WTO. It establishes minimum international standards for protecting intellectual property rights, including patents.

Still, the WTO and countries have recognised that patents can be a barrier to accessing vaccines and medicines. That is why TRIPS contains provisions — or flexibilities — that allow countries to bypass patents to protect the public health.

If countries need to access a vaccine or medicine but cannot because either the patent-holder cannot produce enough, or it is too expensive — for instance — they can use a TRIPS flexibilities to issue a compulsory licence. A compulsory licence allows another company to make the needed vaccine or medicine without the patent holder's permission.

The WTO notes that even threatening to use TRIPS flexibilities can help countries bargain with pharmaceutical companies for the products they need.

For instance, in the wake of the 11 September 2001 terrorist attacks, US officials began fearing attacks in which terrorists would use the mail to spread the bacteria that causes the potentially deadly infection, anthrax. The US then sought to stockpile medicines to treat anthrax but found that it could not afford the high price of drugs. Soon, it threatened to use a TRIPS flexibility, compulsory licensing, to allow other companies to produce the medication without a patent, citing a public health emergency.

Faced with the prospect of a compulsory licence, the original producer of the medicines chose to sell the drug to the US government at discounted rates.

Countries in dire need of affordable vaccines or medicines can also use a TRIPS flexibility called parallel importing. Parallel importing allows countries to import a cheaper patented product from another country without the patent holder's permission.

Although some high-income countries have dabbled in using TRIPS flexibilities, they have been less welcoming of some lower and middle-income countries use of these provisions.

Although high-income countries have dabbled in TRIPS flexibilities, some of their trade officials have been less welcoming of the use of flexibilities among poorer countries. This has often manifested in pressure during bilateral and multilateral trade talks.

But to use TRIPS flexibilities, countries must adopt laws locally to say how exactly they will do so and that has been challenging for many low and middle-income countries.

A dream deferred: The Covid-19 TRIPS waiver

The first three years of the Covid-19 pandemic were marked by highly inequitable access to Covid-19 vaccines, test kits and treatments, in particular.

SA and India proposed a Covid-19 waiver to the WTO in response to deadly inequalities in October 2020.

The waiver requested WHO members to temporarily waive four types of intellectual property rights: copyrights, patents, and protections around product designs or undisclosed information needed to make Covid-19 tools. The waiver would apply to Covid-19 vaccines, tests, medicines and other tools, such as ventilators but only until the majority of the world population received effective vaccines and developed immunity to Covid-19.

Although supported by more than 100 countries, the waiver was opposed by wealthier countries such as the US, the UK, and Canada. The EU — especially Germany, Norway and France — also worked to prevent the waiver from moving forward. Many of these countries are also home to strong pharmaceutical manufacturing sectors.

The US announced partial support for the waiver proposal in May 2021, and agreed to participate in negotiations. New Zealand, China and Ukraine subsequently indicated their support for the waiver proposal.

But by 2022, the original waiver proposal had been whittled down considerably. The WHO's final decision on the waiver in June of that year waived patent rights only for vaccines

and allowed for the use of protected clinical trial data solely for regulatory approval of vaccines.

As of March 2023, high-income countries had administered more than six times as many vaccine doses as poorer nations. Additionally, many low and middle-income countries still had no access to the Covid-19 antiviral treatment, Paxlovid, or the rapid tests needed to ensure the effective use of the medicine.

The fight for equity – One Country, One Plan: The role of the state and the private sector in procuring life-saving vaccines in a pandemic – some legal aspects

Leslie London

This is an extract of an expert affidavit submitted in the case the *Health Justice Initiative v Solidarity, Afriforum NPC, the Ministers of Health and others* Case Number. 3623/21. The matter concerned a challenge by Solidarity and Afriforum to the strategy and policy adopted by national government for a single procurement and distribution of Covid-19 vaccines for SA.

The HJI intervened in the case as a friend of the court (amicus curiae) in February 2021. It argued that the case sought to entrench a situation constituting vaccine apartheid in SA. All while major industry players and business groups including medical schemes in SA support a national allocation strategy in partnership with government.

The DG of Health (for the first and second respondents) agreed with HJI's expert evidence and relied on it in his replying papers. Afriforum and Solidarity withdrew the case on 2 March 2021.

For the full affidavit and other court documents, see https://healthjusticeinitiative.org.za/2021/05/12/solidarity-and-afriforum-vs-minister-of-health-and-16-others/

Professor Leslie London is Chair of Public Health Medicine in the School of Public Health and Family Medicine at the University of Cape Town. He leads the School's Health and Human Rights Programme and is active in the People's Health Movement South Africa. He serves on the HJI's Reference Advisory Group.

IN THE HIGH COURT OF SOUTH AFRICA

GAUTENG PROVINCIAL DIVISION, PRETORIA

Case Number: 3623/21

In the application of:

HEALTH JUSTICE INITIATIVE	Applicant for admission as an *amicus curiae*

In the matter between:

SOLIDARITY	First Applicant
AFRIFORUM NPC	Second Applicant
and	
MINISTER OF HEALTH	First Respondent
PRESIDENT OF THE REPUBLIC OF SOUTH AFRICA	Second Respondent
MINISTER OF CO-OPERATIVE GOVERNANCE AND TRADITIONAL AFFAIRS	Third Respondent
THE CHAIRPERSON OF THE COVID-19 SCIENTIFIC MINISTERIAL ADVISORY COMMITTEE	Fourth Respondent
MEMBER OF THE EXECUTIVE COUNCIL FOR HEALTH, WESTERN CAPE	Fifth Respondent
MEMBER OF THE EXECUTIVE COUNCIL FOR HEALTH, GAUTENG	Sixth Respondent
MEMBER OF THE EXECUTIVE COUNCIL FOR HEALTH, FREE STATE	Seventh Respondent
MEMBER OF THE EXECUTIVE COUNCIL FOR HEALTH, EASTERN CAPE	Eighth Respondent
MEMBER OF THE EXECUTIVE COUNCIL FOR HEALTH, NORTHERN CAPE	Ninth Respondent
MEMBER OF THE EXECUTIVE COUNCIL FOR HEALTH, LIMPOPO	Tenth Respondent
MEMBER OF THE EXECUTIVE COUNCIL FOR HEALTH, MPUMALANGA	Eleventh Respondent
MEMBER OF THE EXECUTIVE COUNCIL FOR HEALTH, NORTH WEST	Twelfth Respondent
MEMBER OF THE EXECUTIVE COUNCIL FOR HEALTH, KWAZULU-NATAL	Thirteenth Respondent
PHARMACEUTICAL SOCIETY OF SA	Fourteenth Respondent
COUNCIL FOR MEDICAL SCHEMES	Fifteenth Respondent
SOUTH AFRICAN MEDICAL ASSOCIATION	Sixteenth Respondent
PHARMACEUTICAL INDUSTRY ASSOCIATION OF SA	Seventeenth Respondent

---

EXPERT AFFIDAVIT: PROFESSOR LESLIE LONDON

I, the undersigned,

PROFESSOR LESLIE LONDON

do hereby make oath and say that –

1 I am a Professor at the School of Public Health and Family Medicine at the University of Cape Town (UCT). I attach a copy of my curriculum vitae marked **"LL1"**.

2 The facts contained in this affidavit fall within my own personal knowledge, except where I indicate otherwise. To the extent that I rely on information supplied by others, I believe that such information is true and correct.

6 I start by summarising Mr. Hermann's contentions as follows. Mr. Hermann contends that:

6.1 The COVID-19 epidemic is a major public health emergency and is an urgent health crisis (referred to as a life-threatening second wave in paragraph 57) that requires urgent measures to address the epidemic.

6.2 The discovery of vaccines that are effective against SARS CoV-2 provides the opportunity to address this health crisis and there is, therefore, an urgent need to vaccinate as much of the population as speedily as possible, "in order to achieve herd immunity as soon as possible". (I refer interchangeably to "herd immunity" and "population immunity" as the same concept in my affidavit, being a level of immunity to the virus SARS CoV-2 in the population sufficient to interrupt transmission of COVID-19 at a population level and thereby bring the epidemic under control.)

6.3 There is a restriction on the ability of private health care entities to procure vaccines in some places, Mr. Hermann refers both to a restriction on procurement of vaccines and on the distribution of vaccines being adversely affected.

6.4 This restriction on the ability of private health care entities to procure vaccines will (a) delay or protract the vaccine from reaching those who need it and (b) prevent South Africa from attaining herd immunity in as quick a fashion as possible.

6.5 Allowing the private sector to procure vaccines will enable the vaccine to (a) reach those who need it and (b) allow South Africa to attain herd immunity more rapidly than if the vaccination rollout were based on solely government procurement.

6.6 The restriction on the ability of private sector entities to procure vaccines is an unreasonable limitation on the human rights of the members of Solidarity, on members of various medical schemes, and on practitioners in private practice and provincial health departments.

6.7 I examine each of these arguments in turn below.

COVID-19 AS AN EXTRAORDINARY EMERGENCY

7 First, it is common knowledge that the COVID-19 epidemic is a major public health emergency and requires extraordinary efforts to address it. To the extent that Mr. Hermann recognises the COVID-19 epidemic as requiring urgent responses, I am in agreement. However:

7.1 As an emergency, the crisis cannot be dealt with through measures we would normally expect to be present in the South African health care system. The world has recognised this necessity in the World Health Organisation (WHO) declaring a global Public Health Emergency of International Concern (PHEIC) on 30 January 2020. A copy of the statement by WHO is attached marked **"LL2"**.

7.2 To the extent that existing health systems are stretched and disrupted by the epidemic, the WHO has provided guidance to countries in how best to cope with these extraordinary circumstances. In this regard, the WHO has provided extensive guidance on, amongst other matters related to COVID-19, the prevention and treatment of COVID-19, the protection of health systems, and most recently on how best to roll out vaccines for COVID-19 in the form of the '*WHO SAGE values framework for the allocation and prioritization of COVID-19 vaccination*' ('WHO Values Framework') and the 'WHO Roadmap for Prioritizing Uses of COVID-19 Vaccines in the context of limited supply' ('WHO Roadmap') A copy of the WHO Values Framework and the Roadmap are attached and marked **"LL3"and "LL4"** respectively.

7.3 The idea that what pertains under normal circumstances should necessarily pertain under emergency circumstances is therefore not plausible in the present epidemic.

7.4 Extraordinary measures have previously been adopted by nation states in relation to other global health crises such as Ebola, H1N1, and SARS.

7.5 The measures proposed by the South African government with regard to vaccine procurement and allocation are not in my expert view incompatible with the global recognition of the need for extraordinary measures. As I explain below, they are:

7.5.1 rationally based on understanding the need for equity in access to a life-saving health technology for COVID-19;

7.5.2 rationally based on the past experience of uncontrolled private sector procurement of scarce health technologies;

7.5.3 consistent with all the major global vaccine allocation guidance documents rooted in public health and epidemiological considerations that are currently available.

7.6 The measures proposed by Mr. Hermann essentially involve returning the control of the COVID-19 epidemic to the pre-COVID-19 scenario of the private sector paying for those who can afford medical supplies, while the public sector should 'focus on the vaccination of the most vulnerable members of society'. It is therefore a departure from what numerous jurisdictions around the world have recognised – that stewardship of the entire health system is needed to ensure a coordinated response to COVID-19. In this regard, I attach a copy of the '*WHO COVID-19 Strategy Update of 17 April 2020*' **("LL5")**.

7.7 Returning to the pre-COVID-19 scenario would only be justifiable if it could be shown that such an arrangement would expedite the goals of controlling this epidemic and minimise loss of life. As I explain below, there is no evidence that such an approach would benefit COVID-19 public health control measures. On the contrary, there is much evidence that such an approach would harm our capacity to survive the epidemic with the minimum loss of life and would exacerbate inequality in our country.

VACCINES CAN HELP US REACH POPULATION (HERD) IMMUNITY FASTER

8 We face a global crisis that requires scientific consensus and cooperation, using the best evidence and data available, given that severe acute respiratory syndrome coronavirus 2 ('SARS-CoV-2') presents many complex and scientific uncertainties, while we deal with imperfect scientific knowledge. This is why the integrity of any vaccine programme is critical to ensuring, over time, widespread access to vaccines that are safe and effective, and convincingly so for the public.

9 It is correct that several new vaccines for COVID-19 have been reported to be effective to varying degrees in providing protection against COVID-19 infection, severe disease, and death associated with COVID-19. However, there are a number of scientific uncertainties regarding the vaccines:

9.1 None of the vaccines available globally have been formally registered as yet in South Africa other than through a Section 21 authorisation by the regulatory body in South Africa, SAPHA, for Covishield and the authorisaton for the Johnson and Johnson vaccine to be 'rolled out' to health care workers through a research study (the Sisonke study).

9.2 Although much is said about many vaccines in the public domain and used in other countries, the producers of some of these vaccines have generally not approached the SAPHRA with their information dossiers, which slows down the registration process and which complicates assessments of efficacy, risk, and guidance for use. I attach a copy of the SAPHRA authorisation for Covishield, as well as a copy of a news article related to the rollout of the Johnson & Johnson (the Jansenn) vaccine (annexures **"LL6"** and **"LL7"** respectively).

9.3 In several cases, global vaccine manufacturers have pre-committed hundreds of millions of doses for certain governments first (including but not limited to the US, countries in the EU, UK, Canada, Israel, Australia, China, Russia, UAE), with limited immediate supplies for the COVAX facility and other regional blocs such as the African Union (AU). A recent academic article in the Lancet, published on 12 February 2021, illustrates the current status globally of inter alia vaccine approvals, COVAX participation, and forecasted supplies. A copy of the article, entitled '*Challenges in ensuring global access to COVID-19 vaccines: production, affordability, allocation, and deployment*', is attached marked '**LL8**'.

9.4 As yet, there is no consensus on how long immunity is conferred through vaccination;

9.5 The effectiveness of these vaccines varies, and it is unclear if effectiveness for the strain most prevalent in South Africa will turn out to be the same as that found to date in vaccine trials elsewhere in the world;

9.6 There is no current certainty regarding the effects of receiving multiple different vaccines;

9.7 Delivering a vaccine requires adherence to vaccination schedules, maintaining a cold chain, and ensuring quality control in the stocks and the administration of the vaccine.

9.8 Thus, while promoting the uptake of vaccines will, in general, be a positive development towards population levels of immunity that will interrupt transmission (also known as 'herd' immunity), an uncoordinated and poorly applied vaccination programme may hinder our country from attaining population or herd immunity. For example, if vaccinees do not receive a second dose of a two dose regimen, or receive it late, or receive a different vaccine the second time, or receive a vaccine that has expired or been damaged by the failure of the cold chain, then they will have been vaccinated, but ineffectively.

10 Furthermore, it is incorrect to assume that population or herd immunity can be achieved simply by vaccinating the highest number of people as quickly as possible.

10.1 It is an incontrovertible reality that there is an absolute shortage of vaccine supplies globally, at least at this early stage of the epidemic.

10.2 For this reason, it is widely recognised that rationing based on public health evidence, data and need, and the input of public health and scientific experts, will be necessary, at least at the early stages of the epidemic.

10.3 The 'WHO Roadmap for Prioritizing Uses of COVID-19 Vaccines in the context of limited supply' notes that "*sufficient vaccine supply will not be immediately available to immunise all who could benefit from vaccination.*" The guidance goes on to model three scenarios of constrained vaccine supply (different levels of availability). In all three models, it proposes strategies for vaccination of priority groups. In this regard, I refer to **"LL4"**.

10.4 Mr. Hermann's proposal that anyone who wants vaccination should be able to access vaccination is unscientific and contrary to global public health guidelines which also emphasise equity in access alongside an effective rollout.

10.5 As stated by the UN Committee on Economic, Social and Cultural Rights (UNCESR) in its Statement on Vaccines for COVID-19: '*It is impossible to guarantee that everyone will have immediate access to a vaccine for COVID-19, even if several vaccines are approved soon. The mass production and distribution of vaccines implies not only enormous financial costs but also complex administrative and health procedures. The prioritisation of access to vaccines by specific groups is unavoidable, at least in the initial stages, not only nationally but also at the international level. In accordance with the general prohibition of discrimination, such prioritization must be based on medical needs and public health grounds.* A copy of the statement by the UNCESR is attached to the affidavit by Dr. Tlaleng Mofokeng.

It is generally accepted public health practice to focus on those at high risk who can benefit maximally from vaccination. This meets both utility and justice principles. If one vaccinates *ab initio* fit and healthy adults or young people, who are low risk, even if one does reach high numbers, then one is doing so at the expense of individuals who have immediate health risk-based needs and who should be vaccinated first, on public health grounds. Thus, if a vaccination programme rolls out as proposed by the applicants there will be many persons at high risk who will be exposed to infection before they are vaccinated. This will result in preventable and unnecessary illness and death in the country because of failure to follow a common national strategy.

The pathway to population or herd immunity cannot be reached by disregarding the priority needs of those most at risk. This principle is enunciated in several international guidance documents on vaccine access. For that reason, vaccination of fit and healthy young adults is generally left for the last phase of vaccine rollout plans, as is reflected in the South African government's national plans. I attach a full copy of the *'WHO SAGE Roadmap for Prioritizing Uses of COVID-19 Vaccines in the Context of Limited Supply'* ("LL4" above)

Mr Hermann's affidavit appears to pay no attention to the fact that attaining population or herd immunity as rapidly as possible cannot be achieved at the expense of the health and survival of persons at risk of severe COVID-19 disease.

The 'rapid and effective' distribution of vaccines (as articulated in paragraphs 28, 36, and 59 of Mr Hermann's affidavit) will only contribute to the effective management of the COVID-19 epidemic if done in line with scientific principles. There is no evidence in his argument that he has taken account of any scientific principles, the most widely accepted of which is the *WHO SAGE Roadmap for Prioritizing Uses of COVID-19 Vaccines in the Context of Limited Supply*, attached above as **"LL4"**.

I also draw attention to the *WHO Values Framework* for guiding the allocation and prioritisation of COVID-19 vaccination attached above as "LL3". The framework articulates the aim of any vaccination programme as recognising that "COVID-19 vaccines must be a global public good. The overarching goal is for COVID-19 vaccines to contribute significantly to the equitable protection and promotion of human well-being among all people of the world". The document goes on to elaborate on six principles that should guide vaccine allocation, these being Human Well-Being, Equal Respect, Global Equity, National Equity, Reciprocity, and Legitimacy.

10.10.1 By promoting a vaccine programme that vaccinates on the basis of first-come, first-served, the applicants' proposed programme will fail to "protect and promote human well-being including health, social and economic security, human rights..."

10.10.2 If healthy adults secure vaccination earlier because they able to pay, then the applicants' proposed programme will fail the principle of recognising and treating "...all human beings as having equal moral status..."

10.10.3 The requirement to ensure "equity in vaccine access and benefit within countries for groups experiencing greater burdens from the COVID-19 pandemic" will be undermined by diverting vaccines to those who have lesser or no burden which will be a consequence of the applicants' proposed programme.

10.10.4 There is no recognition of reciprocity in the applicants proposals for private sector procurement.

10.11 Professor Keymanthri Moodley, head of Bioethics at the University o Stellenbosch, has noted that, with regard to COVID-19 vaccines "Rationing processes should be fair and based on transparent consistent criteria that can be subjected to objective scrutiny with the goal of ensuring accountability, equity, and fairness". A copy o Professor Moodley's article is attached marked **"LL9"**. The relie sought by the applicants will create inconsistency in who will receive the vaccine, inequity in distribution and unfairness in a situation o already extreme pre-existing inequalities.

10.12 The claim that South Africa is 'lagging' behind other countries in acquiring vaccines shows a lack of understanding of the problems facing countries classified as middle income – which are increasingly shouldered out of the market by richer and more powerful countries. Paragraphs 71 to 76 of Mr. Hermann's affidavit appear to attribute the entire responsibility to the South African government when many observers and commentators, including the Director-General of the WHO and the UN Secretary-General, have lamented the behaviour of richer nations and vaccine manufacturers in creating the conditions where less developed countries are disadvantaged in the global marketplace. A copy of an article highlighting the UN Secretary General's warning is attached marked **"LL10"**.

10.13 For example, in Paragraph 78, the applicant appears to think South Africa's inability to secure speedy supplies of safe and effective vaccines in a pandemic lies in the fact that it 'did not commit sufficien funds into COVAX'. However, it would seem that the applicants do not appreciate that given the design of COVAX, South Africa would not necessarily obtain any preferential supplies or better price by purchasing through COVAX and may even be substantially disadvantaged to do so. This is a serious design fault of the COVAX mechanism, amongst a number, which the applicants do not seem to appreciate.

10.14 COVAX depends on funding from donors and high-income countries but is still hugely underfunded. It also depends on voluntary participation by manufacturers and imposes tiered cost-recovery with Upper Middle-Income countries having to self-finance and pay higher prices. Only Low-Income countries will be supplied at a subsidised cost, and only some vaccine producers have put their products into COVAX. As a result, COVAX does not provide supplies of all efficacious vaccine candidates, is not yet transparent in the pricing of its vaccines, and procurement through COVAX involves forfeiture fees and penalties associated with transacting in a commercial arrangement. Further, COVAX is not accountable to any domestic institution in South Africa, including Parliament, as a result of which millions of Rands of public funds have to be spent with little or no oversight and accountability in the event that prices are excessive or supplies do not arrive on time, or at all.

10.15 In any event, South Africa has now seemingly secured supplies from other mechanisms, including bi-lateral negotiations for large quantities and through the African Union (AU) Vaccine Access Task Team.

10.16 Given the above scenario, the claim that South Africa's late payment was somehow responsible for delays in procurement appears to be irrelevant.

10.17 What is clear is that the procurement landscape is extremely complex. It is simplistic to contend that a free market would enable efficient private sector procurement and rational allocation of vaccines.

10.18 Moreover, it is now evident that some vaccine manufacturers are requiring governments to purchase vaccines on the basis that those governments indemnify the manufacturers against claims should vaccinees develop adverse reactions. Mr. Hermann gives no indication that private sector actors in South Africa would be willing to accept such liability. It is extremely unlikely that a private entity would do so.

10.19 It is therefore implausible that, in the current situation, a vaccine manufacturer will directly sell its vaccines to a South African trade union, a health insurance entity, a local pharmacy chain, or even a provincial government. I have not seen any evidence that a vaccine producer will do so.

RESTRICTING THE PRIVATE SECTOR FROM DIRECTLY PROCURING VACCINES IN A PANDEMIC

11 It is correct that the South African policy on vaccines is that the State shall be the sole procurer of vaccines with a negotiating team that includes representatives from business associations, the largest medical scheme in the country (Discovery Medical Scheme) and the National Treasury. I do not comment on the legal question of whether the policy imposes or proposes a legal prohibition on procurement by other entities. The policy is however in accordance with international practice. The affidavit deposed to by Ms Hassan of the Health Justice Initiative deals with the approach of foreign jurisdictions including India, the United States and the European Union. For the sake of brevity, I will not repeat those examples in this affidavit.

12 There are important reasons why this is the case.

12.1 This is a pandemic with global impact and consequences.

12.2 Vaccines for COVID-19 are not just any ordinary commodity that can be purchased by someone with the resources to do so. They are, as UN Secretary-General António Guterres articulated, "a global public good, affordable and available to all."

12.3 A global public good that should be affordable and available to all cannot be distributed through a private market or just by some provinces or nations. Mr. Hermann has said 'that a state monopoly should not exist' for the procurement of COVID-19 vaccines (paragraph 56). As a public health expert, I do not understand what this means as it is the obligation of the state to negotiate, select and procure vaccines for everyone in our country to meet the requirements of our Constitution. The private market in South Africa, which serves less than 20% of our people, cannot distribute a public good for reasons outlined below, nor should just one or two provinces.

12.4 Global experience, including our own experience in South Africa, has shown that private acquisition and allocation cannot be relied on to achieve equitable availability of health resources.

12.4.1 The huge divide between public and private health care sectors, which characterises South Africa's current divided health system, results in significant resources being inefficiently sequestered in the private sector.

12.4.2 Inequity arises because the private sector will service those who pay, be they members of a medical scheme or wealthier individuals but will not reach people in need who cannot afford private health care – the majority of people living in South Africa. Lack of access to private medical aid schemes is discussed in Dr. Mofokeng's affidavit.

12.4.3 As a result, South Africa has severe inequalities in health status by race, rurality, class, and gender. This inequality is associated with poor health outcomes for the amount of money we spend on health. It reflects inequalities in the distribution of both the determinants of health and in access to health care.

12.4.4 It is within this context that the COVID-19 epidemic hit South Africa in 2020. The epidemic has exacerbated inequalities, both in social conditions and livelihoods and in health outcomes.

12.4.5 An analysis of data from the National Income Dynamics Study (NIDS) in 2017 and the first wave of the NIDS-Coronavirus Rapid Mobile Survey (NIDS-CRAM) suggested that income-related health inequality in the COVID-19 era increased six-fold compared with what was obtained in 2017. For example, cumulative mortality due to COVID-19 was noted in January 2021 as approximately twice as high in poorer township areas of Cape Town compared with the rest of the city. This is partly explained by differences in access to care between the public and private sectors. A copy of the relevant portions of the data by the NIDS and article of the cumulative mortality in poorer areas are attached marked "**LL11**" and "**LL12**" respectively.

We also saw the impact of public-private inequality first-hand in South Africa in the last year. During the COVID-19 epidemic, disparate or unequal access to testing technologies (test kits) for diagnosis of COVID-19 was well documented. A copy of an article describing this is attached marked "**LL13**". As a result, many public sector patients could not be tested, or their tests were wasted as a result of long delays. The consequence in terms of missed infections, failure to prevent transmission, and any associated deaths have not been quantified. However, it was clear that the private sector laboratories did not always share scarce resources to ensure that there was equitable testing capacity across the health system, but deployed testing for those who were paying customers. Those who could not afford private care and who could, therefore, not access testing, were likely to have worse outcomes.

Even with the best of intentions, charities and major pharmacy chains that stepped in could only provide limited tests and, in some cases, carried out limited stop-start programmes with limited reach and an urban bias. These voluntary efforts are not sustainable unless coordinated through a national programme that prioritises equity in access.

12.7 Centralised procurement of a scarce resource thus ensures that there is the possibility of ensuring equity in its distribution. It does not guarantee equitable distribution, but it does make equitable distribution possible if it is an explicit policy objective of a vaccine programme, which is the case in South Africa and in almost all major democracies right now.

12.8 The converse of centralised procurement, in the form of uncoordinated and 'independent' procurement, makes equity in allocation impossible to achieve, as confirmed in a US National Academics of Science guideline referred to in the affidavit of Ms. Hassan from the Health Justice Initiative.. I note that this does not preclude all stakeholders, including those in the private, business or NGO sectors, assisting with the administration of a vaccination programme. The scale of the epidemic surely requires everyone's cooperation.

12.9 However, as Mr. Hermann implies in paragraph 84, it is unclear if all private sector providers will be able to administer vaccines or will want to administer vaccines to the maximum degree possible if vaccination is to be offered through private purchase or through a medical scheme. There is a very real possibility that stock purchased in the private sector could remain unused, sequestered within private contractual arrangements and unavailable to those who need it most.

12.10 Where there are multiple entities independently procuring a scarce resource, it is inevitable that there will be difficulties in ensuring adequacy of supplies and equity in distribution. This has been demonstrated at an international level in the uneven access to vaccines between countries, where according to the WHO, those with more economic and political power have purchased more vaccines than their population needs, at the expense of poorer countries.

12.11 Lastly, while Mr. Hermann asserts that centralised procurement of vaccines and 'stifling of the private sector ... can only result in unwarranted protraction in the distribution and administration of vaccines to the population,' he presents no evidence that this will be the case – only that the private sector has the capacity to deliver vaccination. Since the private sector, medical schemes and businesses will be involved in the distribution and delivery of vaccines and has been included in almost all relevant task teams including on the National Vaccine Acquisition Task Team, it is unclear on what basis Mr. Hermann makes this claim of central procurement delaying administration of vaccines to the whole population.

12.12 If one accepts that there is an absolute shortage of vaccines at this early stage of the epidemic, then it is clear that affording the private sector or some provinces the capacity to also procure vaccines and then decide whom to vaccinate and when to do so (i.e. outside of a national strategy of prioritisation and without central allocation) will mean that persons at low risk, with financial means, will be free to be vaccinated – assuming the regulatory authority, SAHPRA, approves a vaccine for use. At the same time, some of those at risk to severe COVID-19 disease will have to wait longer in other sectors / provinces, therefore risking their health and their survival and the country's ability to achieve population immunity safely.

12.13 The approach that the most rapid path to population immunity is through vaccinating the highest number of people as quickly as possible, irrespective of who is vaccinated, is therefore not justifiable on public health grounds, nor on medical and epidemiological practice and needs.

13 Mr. Hermann appears to conflate selection, regulatory approval, procurement, allocation and distribution when describing what is prevented by national policy, and as to what would be implemented, should the applicants be granted the orders which they seek.

13.1 I point out that there is nothing in the national strategy documents released thus far that precludes private practitioners from *participating* in the vaccine roll-out. To the contrary, Mr. Hermann himself cites evidence of government's commitment to *involve* the private sector in administering and delivering vaccines (paragraphs 43, 47).

13.2 The fact that the mining industry has health services capable of providing health care services to the members of Solidarity (Para 29) is irrelevant to the question of private procurement. On the contrary, it is entirely consistent with the state procuring vaccines and allocating vaccines to the mines to administer to its employees in line with a national policy focusing on priority groups based on risk, age, or co-morbidity status.

13.3 Further, Mr. Hermann provides no evidence that even if the private sector were to procure vaccines, the providers in the private sector would speedily vaccinate as many people as possible. Current evidence shows that private providers' behaviours are largely determined by financial incentives, and that they are unlikely to adopt behaviours that will specifically focus on maximising the numbers of persons vaccinated unless incentivised to do so. I attach, in this respect, the Competition Commission Health Market's Inquiry Report: An overview and key imperatives, marked **"LL14"**.

13.4 Even then, financial incentivisation of private sector providers to achieve population health goals has a weak evidence base internationally and in South Africa. I attach an extract from a discussion paper entitled 'Private sector involvement in funding and providing health services in South Africa: Implications for equity and access to health care' written by Professor Diane McIntrye. Pages 13 to 23 of the paper are attached, marked **"LL15"**.

13.5 It is therefore unclear how Mr. Hermann can deduce that private procurement and allocation will advance national vaccine coverage and support earlier attainment of population or herd immunity.

COULD PRIVATE SECTOR PROCUREMENT BE COMPATIBLE WITH PROMOTING ACCESS AND ACHIEVING POPULATION IMMUNITY?

14 Implicit in Mr. Hermann's argument is that allowing the private sector to procure vaccines will (a) enable vaccines to reach those need it and (b) allow South Africa to attain population or herd immunity more rapidly than if the vaccination rollout were based on solely government acquisition and

CONCLUSION

36. In summary: If provinces and some trade unions and private groups select, procure, and administer vaccines independently and outside of national processes and guidelines, there will be a lack of coordination, poor accountability and an inability to ensure equity in access, which will be at the cost of the health and survival of high-risk and vulnerable groups in our country. Such an approach has no support in any of the large body of technical, scientific, and ethical guidance presently available in the public domain.

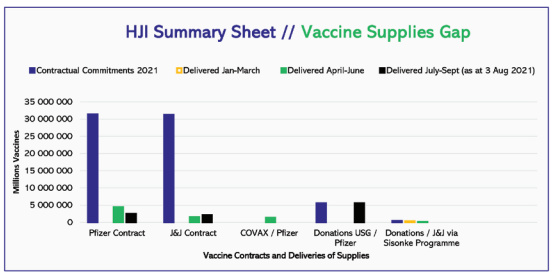
SECTION B

THE GLOBAL CONTEXT OF HEALTH EQUITY AND RESPONSE

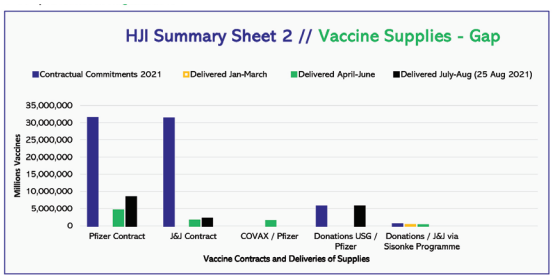
CONTEXT:
Covid-19 Vaccines supplies for SA: August 2021 – February 2022

HJI Supply Sheets

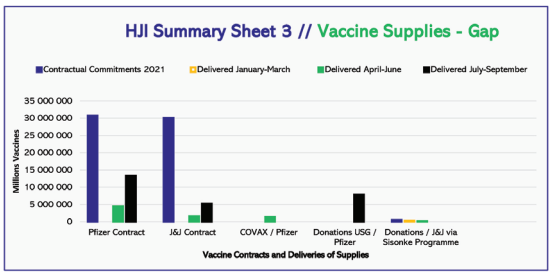
Last updated
//3 August 2021
//Summary Sheet 1



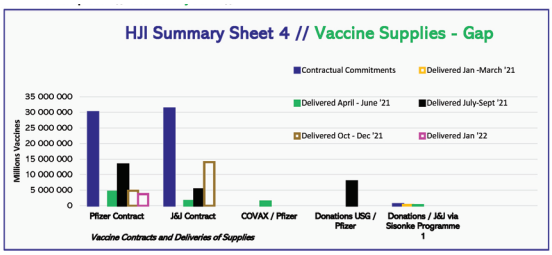
Last updated
//25 August 2021
//Summary Sheet 2



Last updated
//12 October 2021
//Summary Sheet 3



Last updated
//13 February 2022
//Summary Sheet 4



CONTEXT:

To enforce the Covid lockdown, did we wage a war on the people of SA?

Original publication:

Edwin Cameron: "To enforce the Covid lockdown, did we wage a war on the people of South Africa?" *News24* 6 March 2021

Soon a sombre anniversary will fall on our country. This week, it's a year since 11 March 2020, when the WHO first declared Covid-19 a pandemic.

On 15 March 2020, President Ramaphosa declared Covid a national disaster.

A couple days after our national Human Rights Day, on 23 March, he announced a nation-wide lockdown - among the strictest anywhere. The President's words were important - for they set the tone for what followed.

The nation, he explained on 23 April, was "forced to take aggressive action against an invisible enemy that threatened our lives and the lives of our loved ones".

This was war talk. Enemy. Aggressive action. Threats to life. It was not unique. Other countries, too, responded with war talk.

So did international bodies. The United Nations Secretary-General labelled the pandemic "the fight of a generation". We were plunged into war against a common enemy.

The President closed our borders, banned alcohol and tobacco sales, permitted only essential services and restricted our movements under strict curfew. To enforce all this, the government deployed more than 70 000 South African National Defence Force (SANDF) soldiers.

Fearsome spectres

For South Africa, a middle-income country already heavily

burdened by HIV/AIDS and TB, with a precarious public health system, the pandemic evoked fearsome spectres. What would happen to those who live in densely-packed under-serviced townships? What of children for whom school meals are their daily sustenance? And what of those without access to housing or proper sanitation? The pandemic undoubtedly demanded swift, decisive leadership.

This, President Ramaphosa, a person of accepted integrity, provided. More significantly, in doing so, he embraced medical expertise. In seeking to save lives, the government followed science and international guidelines.

Here, the President avoided the fatal mistakes President Thabo Mbeki made in the , in aggressively questioning science and medicine, at a terrible cost in lives and suffering.

But Covid plunged us into other, terrible mistakes.

In fighting contagion, we waged a war on our people. In the face of anguishing human needs, instead of doctors and nurses, we deployed the police and the military. Instead of improving social security, we created newly polished criminal laws. Under the lockdown regulations, we locked up tens of thousands. While communities pleaded for better opportunities to put bread on the table, we used pepper spray to disperse crowds queuing for the R350 Covid-19 grant. Instead of guiding our people through respectful example and instruction to safe and self-protective public health steps, we beat and brutalised them.

Words are never empty.

They frame a problem for us, providing a narrative for us to address it. Speaking about "war" and "the enemy" makes it easier to deploy the military, to incarcerate people, to roll back basic rights and infringe cherished liberties. And, perhaps it makes it easier to assault and even kill people.

Our still-fragile democracy knows this vocabulary - it has been called to earlier wars.

In the late 1990s the first and still-continuing war was declared, against crime and criminals. Since then, our democracy has been fighting many wars - against drugs and drug users, sex workers, cross-border migrants and unlawful occupiers. Too often, we frame the most vulnerable in our society as the greatest threat to our security, to job opportunities and to our values.

Yet all this war talk, all our aggressive counter-attacks, our "tough on crime" policies and mass incarceration have not brought us safety. Despite fearsome over-commitment to state-authorised force and

militarised policing, South Africa remains one of the most violent societies in the world.

This past dark year of Covid-19 seems to show that we have not learnt from our mistakes.

High density policing

After the first shock of the pandemic, we were shocked, even more, by the brutality with which our security forces responded to it. In addition to the SANDF deployment, the South African Police Services (SAPS) implemented its "high-density policing" approach.

This entails using forceful policing strategies to assert "the authority of the state". As Stellenbosch University Professor Guy Lamb noted, this quickly became "government's primary lockdown compliance strategy". Government made a major public policy– choice - to use securitised and militarised state force to address a public health issue. And its cost was to both human rights and human life.

Early in the lockdown, police imposed petty yet humiliating penalties on transgressors in Soweto - push-ups and squats. On the second day, some fired rubber bullets at a tight-packed crowd of shoppers outside a Johannesburg supermarket.

Then, people started getting killed.

In Alexandra, Collins Khosa, drinking beer on his stoep, was brutalised to death in his yard, by security forces seemingly enraged by his insolent attitude. The SANDF's first report told a disbelieving public that its soldiers had merely "pushed" and "clapped" Mr Khosa. A belated re-examination was more candid. It revealed that the soldiers violently beat Mr Khosa. He died of blunt force trauma to his head.

Chris van Wyk's apartheid-era poem – "In Detention" – sprang to mind:

"He fell from the ninth floor, he hanged himself, he slipped on a piece of soap while washing."

More tragedies ensued. A rubber bullet, seemingly randomly or inexpertly fired, killed nine-year-old Leo Williams inside his uncle's home.

Police beat Ntando Elias Sigasa. He died in his sleep. Petrus Miggels tried to buy alcohol. He was beaten with a hammer before being taken to the police station - he was returned home, only to die on his stoep.

Police killed Sibusiso Amos. He was shot in front of his family on his veranda. Adane Emmanuel was killed for illegally selling cigarettes.

Elma Robyn Montsumi, a transgender sex worker, died after the police locked her up on a charge of drug possession

in the Mowbray police cells. Why was she not released on bail under the lockdown regulations? She was "found hanging in the police cell alone, as she was in a single cell", investigators concluded. Once again' Van Wyk's poignant poetry came to mind.

And not only did central government's coercive measures trample on human rights. The Western Cape government plucked hundreds of homeless people from the city centre and placed them in a camp at Strandfontein, that soon became notorious.

Properly respectful obituaries are hard to offer. Names that did not reach media notice were swept into our statistics. In the first few weeks of the lockdown, the Independent Police Investigative Directorate (IPID) were investigating 199 Covid-related cases (five deaths as a result of police action, 37 discharges of official firearms, 152 assaults and five corruption complaints).

Corruption

All this created a grievous contrast. While police and military were deployed to discipline poor communities into submission, corruption and looting of public funds by public servants amid a public health crisis seemed to gain pace and force.

The Special Investigative Unit is currently undertaking the mammoth task of investigating 2 556 personal protective equipment (PPE) contracts valued at more than R13.3 billion. These hefty taxpayer funds "disappeared" through official malfeasance - by members of the elite - when early in the lockdown three million people lost their jobs - two million women among them.

Now, a year later, more than 49 993 people have been officially recorded as having died from Covid-19 in South Africa - but the actual toll, measured by the unusually high death toll overall ("excess deaths"), may be nearly three times higher.

The trauma of both the Covid-19 illness and death, and the securitisation and militarisation of this public health emergency, will for years be marked on bodies and communities. South Africa is not alone. Many countries followed this war-like approach. The United Nations Secretary-General recently noted that "our world is facing a pandemic of human rights abuses".

How did this happen?

The pandemic has exposed existing fault lines engraved in our society; the inequalities, indignities and fears. Illness and death from a new

contagion intersected with existing poverty, violence, femicide, mass incarceration, alcoholism and corruption.

It also highlighted a deeper problem. In tackling complex public health issues, we mistakenly take recourse to the blundering, blunt instrument of the criminal law. We coerce compliance with measures, designed to save the public's health, first through brutal force - and then through the stigma and shame that are criminality's inescapable companions.

But this was desperately wrong.

The AIDS epidemic taught us profound lessons. Our response to AIDS offered a choice - the harsh, misdirected criminal law approach or the benevolent human rights approach. The former penalises marginalised communities, perpetuates stigma and fear and impedes education and transparency and security. We know it simply does not work. The benevolent approach dispels unwarranted stigmas and fears. It inspires openness and places a premium on resourcing prevention, information and support.

In AIDS, we avoided the terrible criminal-law errors many African countries and states in the US made. We rejected new criminal penalties. We did not punish people through the law. Rather, we embraced the insight that protecting the rights of those at risk of and living with HIV grants better protection for everyone. We embraced the insight that a virus is not a crime.

We learnt first-hand that a public health crisis cannot be managed through fear and coercion and stigma. What it needs is human rights protections, leadership and role models, clear public messaging and education, social justice, compassion and empathy.

But the Covid emergency seems to have obscured these hard-learnt lessons.

War on drugs

When a crisis confronts us, we try to "nip it in the bud". All too readily, we turn to failed solutions that focus on the symptoms and not the underlying causes. We take far too ready recourse to punishing and stigmatising through policing and incarceration.

Perhaps the most grievous example is the misbegotten "war on drugs". We continue against increasing mountains of evidence to treat drug use as a crime issue, when it is a social and public health issue, managed effectively through public health education and

interventions.

We try to tell ourselves these problems are short-term, but - as with Covid-19 - they may be around for long.

Is this because we lack the imagination and determination to design and implement something different? Or is it because "tough on crime" approaches provide our politicians with an excuse for not thinking through and implementing more effective action?

Wisely, the President brought forward the parole dates of 18 000-19 000 inmates sentenced for non-violent offences. But the lockdown regulations worked directly against this, by creating more criminals, triggering more arrests, more over-crowding in correctional centres, and more stigma in vulnerable communities.

And our prisons serve as reservoirs for the spread of contagion increasing the risk for both those inside and the community beyond.

When I visited the Johannesburg correctional centre ("Sun City") in May 2020, we were told that awaiting trial detainees had burgeoned during the first month of the lockdown by over 10%. On the very first day of the lockdown, 55 people were arrested. The total arrested for lockdown regulations contraventions has swelled to 342 000.

The question for us is this: Do we keep anyone safe by treating Covid-19 as a security issue? By clamping down on the public with an iron fist, when what they seek is reassurance, food, healthcare and shelter?

Stalled economy

The answer is clearly No. The most vulnerable were disproportionately hit by the stalled economy, and then double-hit by the new lockdown crimes. Nor do we keep safe the people forcibly evicted and dragged out of their houses. Nor the women who were abused and brutalised. Nor the millions who are unable to socially distance on public transport, and who do not have regular access to running water.

This harsh reality does not affect me, nor others living in relative comfort and security. Most harshly affected were those already severely affected by injustice and dispossession.

The pandemic accentuated what most South Africans experience daily - that a culture of violence and impunity, with a long history, is not overcome simply by electing a democratic government or enacting a soaring Constitution.

In these communities, soldiers and police using sjamboks in Hillbrow to enforce overnight-enacted regulations are all too

reminiscent of the brutality we promised would end under the Constitution.

Brutal measures do not keep security personnel safe. While enforcing unpopular lockdown regulations, thousands of hardworking police contracted Covid-19 - and hundreds died "at a greater number than the combined total of SAPS deaths at the hands of criminals since 2016".

Our institutions also suffered a loss of elemental safety. The pandemic exposed the crisis of faltering reform and waning trust.

Take the SAPS. Police violence was pervasive during apartheid. The transition brought a welcome change - a human rights approach.

Professor Lamb observes that public trust and confidence in the police profoundly influences both legitimacy of the police and their actions.

In democracy, the central pillar is policing by consent.

This exists "where citizens recognise the authority of the police and the lawful right of the police to act in specific ways, and they consequently forfeit certain rights and freedoms (that they would typically enjoy in the absence of recognised authority), either explicitly or implicitly, in the interests of public order and peace".

In this way, "policing by consent" bolsters police effectiveness and the rule of law.

Eroded trust in police

The grievous reality is the opposite. Public trust in our police, already eroded, has drained away further in the pandemic.

A recent study even suggested that "the accountability chain in SAPS is broken". There has been a steady decline in internal discipline on SAPS members.

Professor Muntingh of Africa Criminal Justice Reform (ACJR) found that even when disciplinary action is taken, there is a 44% chance of not being held to account.

Lockdown corruption dragged national trust down even further.

And the blame does not lie with front line individual police personnel. Responsibility lies with leadership, within the police and nationally. This past, unnerving year, has done our still-nascent democracy no good. Our Constitution and Bill of Rights promised freedom, equality and human dignity. But the pandemic glaringly exposed our deficient follow-through.

The pandemic offered no warrant to suspend the rule of law, or for a moratorium on rights.

Lockdown measures, including physical-distancing, quarantining, masks and hygiene and education campaigns had widespread support and acquiescence. But hard-core coercive measures at a cost to human rights and dignity and human life exacted a high toll, particularly amongst the vulnerable.

Vaccine rollout

At this first anniversary, nearly coincident with Human Rights Day, equitable and effective vaccine distribution offer hope. The 1960 Sharpeville massacre anniversary invites us to renew commitment to human rights and to nurturing public health by measures healthy to the public - not by bullying coercion and brutality.

The pandemic is long not yet done with us. If we do not learn its lessons, deadlier waves may engulf us.

Much better is the promise embedded in our Constitution - that we encompass new and better ways of sharing our society's energies and opportunities and assets. That approach offers safety and prosperity.

Justice Edwin Cameron is the Inspecting Judge of the Judicial Inspectorate for Correctional Services (JICS).'

People's Vaccine Alliance Open letter

May 2020

MORE THAN 140 WORLD LEADERS, EXPERTS AND ELDERS HAVE MADE AN UNPRECEDENTED CALL FOR GUARANTEES THAT COVID-19 VACCINES, DIAGNOSTICS, TESTS AND TREATMENTS WILL BE PROVIDED FREE OF CHARGE TO EVERYONE, EVERYWHERE

4 May 2020

More than 140 world leaders and experts, including the President of SA and Chair of the African Union, Cyril Ramaphosa, the Prime Minister of Pakistan, Imran Khan, the President of the Republic of Senegal, Macky Sall, and the President of the Republic of Ghana, Nana Addo Dankwa Akufo-Addo have signed an open letter calling on all governments to unite behind a people's vaccine against Covid-19. The call was made just days before health ministers meet virtually for the World Health Assembly on 18 May.

The letter, which marks the most ambitious position yet set out by world leaders on a Covid-19 vaccine, demands that all vaccines, treatments and tests be patent-free, mass-produced, distributed fairly and made available to all people, in all countries, free of charge.

Other signatories include the former President of Liberia, Ellen Johnson Sirleaf, the former Prime Minister of the UK, Gordon Brown, the former President of Mexico, Ernesto Zedillo, the former United Nations Development Programme Administrator and former Prime Minister of New Zealand, Helen Clark.

They join notable economists, health advocates, and others, from the Chair of the Elders and the former President of Ireland, Mary Robinson, Nobel Laureate, Joseph Stiglitz, to Moussa Faki, Chairperson of the African Union Commission, Dr John Nkengasong, Director of African Centres for Disease Control and Prevention, and Dainius Puras, the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.

"Billions of people today await a vaccine that is our best hope of ending this pandemic," said Cyril Ramaphosa, President of SA, "As the countries of Africa, we are resolute that the Covid-19 vaccine must be patent-free, rapidly made and distributed, and free for all. All the science must be shared between governments. Nobody should be pushed to the back of the vaccine queue because of where they live or what they earn."

"We must work together to beat this virus. We must pool all the knowledge, experience and resources at our disposal for the good of all humanity," said Imran Khan, Prime Minister of Pakistan. "No leader can rest easy until every individual in every nation is able to rapidly access a vaccine free of charge."

The letter, coordinated by UNAIDS and Oxfam, warns that the world cannot afford monopolies and competition to stand in the way of the universal need to save lives.

"This is an unprecedented crisis and it requires an unprecedented response," said former President of Liberia, Ellen Johnson Sirleaf, "Learning the lessons from the fight against Ebola, governments must remove all the barriers to the development and rapid roll out of vaccines and treatments. No interest is more important than the universal need to save lives."

The leaders recognize that progress is being made and that many countries and international organizations are cooperating multilaterally on research and development, funding and access, including the welcome US$ 8 billion pledged on 4 May at the European Union's international pledging marathon.

However, as many countries and companies are proceeding with unprecedented speed to develop an effective vaccine, the leaders are calling for concrete commitments to ensure that it is made affordable and available to all in the quickest possible time. These include:

- A mandatory worldwide pooling of patents and sharing of all Covid-19-related knowledge, data and technologies in order to ensure that any nation can produce or buy affordable doses of vaccines, treatments and tests.
- The rapid establishment of an equitable global manufacturing and distribution plan for all vaccines, treatments and tests that is fully funded by rich nations and which guarantees transparent "at true cost prices" and supplies in accordance with need rather than the ability to pay.
    - ◊ This would include urgent action to massively increase manufacturing capacity to produce the vaccines in sufficient quantities and train and recruit millions of health workers to distribute them.
- A guarantee that Covid-19 vaccines, treatments and tests are provided free of charge to everyone, everywhere, with priority given to frontline workers, vulnerable people and poor countries with the least capacity to save lives.

"Faced with this crisis, we cannot carry on business as usual. The health of each of us depends on the health of all of us," said Helen Clark, former Prime Minister of New Zealand, "The Covid-19 vaccine must not belong to anyone and must be free for everyone. Diplomatic platitudes are not enough—we need legal guarantees, and we need them now."

"Market solutions are not optimal to fight a pandemic," said Nelson Barbosa, former Finance Minister of Brazil, "A public health care system, including free vaccination and treatment when that becomes available, is essential to deal with the problem, as shown by the Brazilian experience with compulsory licensing of antiretroviral drugs in the case of HIV."

A short history of a big problem: The undue influence of the pharmaceutical industry and profiteering in shaping the Covid-19 pandemic

Nick Dearden

The term "Big Pharma" has become nearly synonymous with profiteering. There is a public revulsion that anyone could make vast sums of money from life-changing or even life-saving medicines, diagnostics or vaccines. But during the Covid-19 pandemic, this underlying revulsion turned into an outpouring of anger when it became clear that the immense profits of a few corporations had only been possible thanks both to vast sums of public money and by controlling the supply of those medicines, overwhelmingly to the richest countries. This created an inequality of access so great that it became known as "vaccine apartheid".

But although Covid-19 was an extreme and very high-profile example of Big Pharma's exploitation, it was not unusual. The

industry's power over our political system, healthcare and academic institutions is vast. This power, of course, derives to some degree from the size of the industry's marketing budgets. But it goes much deeper.

In this chapter, I will explore the history of Big Pharma's entrenched power over governments and how it uses this power and influence to shape domestic and global trade policies in a way that set the stage for the vaccine apartheid and other inequities seen during the Covid-19 pandemic. The result was suffering for much of the world, but massive profits for Big Pharma.

In turn, this has created a reality in which the pharmaceutical sector does not simply profiteer off products that would not exist without those same companies. Rather, the sector, increasingly does not actually make these medicines in the first place. Instead, it privatises and monopolises public knowledge, and squeezes the maximum value out of it — even if that entails epidemic levels of overprescribing or leaving most of the world's health needs unmet.

Covid-19 should be a wake-up call, showing us the dangers of relying on a dysfunctional and monopolistic industry to deal with life and death issues.

How scientific breakthroughs became mass market consumables

In the middle of the 20th century, Big Pharma was making major medical breakthroughs that were rapidly transforming the way people lived, particularly in the West. Antibiotics, steroids, chemotherapy drugs, the polio vaccine, tranquillisers and antidepressants — medicines like these allowed us to imagine a world in which many forms of suffering might be consigned to history.

But there was a dark side to these products too, perhaps best shown by the way American psychiatrist Arthur Sackler devised methods of mass marketing medicines to doctors and patients. Sackler's firm, Purdue Pharma, would bear the "lion's share" of blame (Keefe, 2017) for the US's opioid epidemic, during which more than 564,000 people died from overdoses between 1999 and 2020 (US Centers for Disease Control and Prevention, 2022) — a

figure that includes both illicit opioids and prescription drugs and was fuelled, in part, by a wave of over-prescribing.

But the techniques that gave rise to that epidemic were invented much earlier and used to promote other medicines such as Valium — used to treat anxiety for instance — or the mental health medication, Lithium. The duo, although important drug developments, were massively over-prescribed across Europe and the US (Waldron, 1977).

The transformation of important scientific breakthroughs into mass market consumables relied on campaigns of misinformation and deception, kickbacks to doctors, dodgy marketing techniques and the medicalisation of the human condition in general. This generated a series of blockbuster drugs that made huge amounts of money for the industry, money that was used to further cement the power of that same industry.

The power of Big Pharma — more than money

Big Pharma's power takes multiple forms. Most obviously, its lobbying spend is vast.

In the US, the pharmaceutical industry donated to two-thirds of Congressional representatives in 2020 (Facher, 2020). Pfizer alone donated to 228 American lawmakers.

"Even after years of criticism from Congress and the White House over high prices, it remains routine for the elected officials who regulate the healthcare industry to accept six-figure sums," authors warned in a report (Facher, 2021).

But there are myriad other ways in which Big Pharma builds power, including direct marketing both to the health professionals and potential patients. In countries such as the US, this activity is extreme, with the industry providing doctors with honorariums, professional association funding or special "educational" conferences at high profile destinations and top restaurants, for example.

In 2012, the industry spent US$24 billion in marketing aimed at American doctors (Pew Charitable Trusts, 2013). The problem

persists in even more regulated markets, with drug companies spending around £40 million a year on British doctors in service fees, flights, hotel and other travel expenses (Boseley, 2013).

As one study recently concluded: "The power that lobbying and unconstrained political donations give the pharmaceutical industry is hard to overstate" (Humphreys et al., 2022).

But it is not just about the money.

In reaction to regulatory attempts to crack down on profiteering in the 1960s, the pharmaceutical industry developed a series of political arguments that appeared to align them directly with the interests of Western governments. Without new medicines — they contended — the US and other countries, risked being outcompeted by other economies.

"Your country is only as strong as its national champions," decision-makers were told in essence, "and therefore you better back these champions, whatever the cost".

University of Virginia Professor and writer Dominique Tobbell has documented how the industry's growing power was built through a network of influence that spanned medical science students, university administrations, health workers, patients, politicians and regulatory bodies. She presents Big Pharma less as an external actor exerting a powerful pull over Western governments, and more as a network of influence deeply intertwined in the state itself, undermining whatever regulation legislators manage to pass (Tobbell, 2011).

Public money, private patents

The power of the pharmaceutical industry helped it to secure new powers that made it even stronger. The US Bayh-Dole Act, passed in 1980, gave private bodies the right to patent their discoveries, for instance — even when those discoveries were contracted and funded by the government. The result was an explosion of patents (Hanna, T. et al., 2020). Then, in 1984, the Hatch-Waxman Act, although supposedly about making it easier to register generic medicines, actually gave patent holders a tighter form of market exclusivity and longer patent terms.

Heftier pharma monopolies help explain the eye-watering price of new medicines — prices that seem to bear no relationship to the costs of making or even researching the drugs.

Just look at AbbVie's cancer drug Imbruvica. While a standard three pill-a-day course in the US would have come to a cool US$98,000 a year in 2013, that price had nearly doubled eight years later (Higgins-Dunn, 2021).

During a 2021 congressional hearing, US congressional representative Katie Porter grilled AbbVie's CEO about how such a price jump could be justified.

"AbbVie took zero risk to develop this drug, you bought it approved for the market knowing it would be profitable," she said. "You hiked the price to pay for [research and development] but you haven't made the drug any better even as you doubled the cost" (US House of Representatives, 2021).

Indeed, AbbVie filed 165 patents for Imbruvica to keep competitors outside the market, giving the firm an additional nine years on what is considered a normal exclusivity period (I-MAK, 2020).

Bad policies for export: Pharma's influence on the global trade system

It is no wonder, that after winning change in the US, the pharmaceutical industry set about extending these monopolies to the rest of the world. This was done particularly through trade deals, especially the foundational agreement at the WTO known as TRIPS.

TRIPS extended very high, US-style intellectual property protection to the whole world. That meant, for example, every country implementing a minimum 20-year period of protection on patents.

Of course, there were patent laws before TRIPS, but in many countries they tended to be, at most, fairly weak. Patents on medicines were particularly controversial — even in countries like the UK — until well into the 20th century. Meanwhile, in much of the Global South, they did not exist at all until TRIPS.

University of Leeds Professor Graham Dutfield has detailed the history showing how patents on early pharmaceutical products in Germany were resented in Britain and the US, which had a less developed industry (Dutfield, 2020). In 1919, the American Pharmaceutical Association denounced "unfair monopolies on medicinal chemical and dyes" arguing patents should be "primarily designed to benefit the public at large". The First World War gave the US the excuse it needed to override German patents, opening up a world of technologies to their own industries. But many European countries did not allow the patenting of drugs until the late 20th century, and very few would have argued that developing countries needed to have the same patent laws as rich countries (Ibid, 2020).

Partly, this came from an understanding, embedded in the post-war system of regulated capitalism, that some countries required different rules from others, particularly those countries that needed to develop their economies. Many East Asian countries developed successfully by disregarding Western intellectual property rules, importing technologies and reverse engineering them — sometimes literally taking stuff apart, seeing how it all worked and copying it.

Although giant corporations would like to convince us today that this is "theft", the truth is that this is how pretty much all countries have developed new industries. In fact, in a system already stacked against poorer countries, the ability to learn from other, richer countries was always seen as one of the main reasons to engage in trade by the development economists of the 1960s and 1970s.

But TRIPS made this nearly impossible.

Journalist Alexander Zaitchik describes the TRIPS backstory as "almost impossibly shallow and grubby; its founding documents younger than Justin Bieber" (Zaitchik, 2021). He details a process of negotiations in which pharmaceutical giants Pfizer, Johnson & Johnson and Merck Bristol-Myers worked with computer and car manufacturers to lobby for TRIPS (Sell, 2001). Ultimately, TRIPS, was "born as a brute and profoundly undemocratic expression of concentrated corporate power" he writes (Zaitchik, 2021).

Although TRIPS came into force in January 1995, campaigners secured a moderate weakening of TRIPS' language in the Doha Declaration. The declaration reaffirmed countries' right to use TRIPS

safeguards such as compulsory licences or parallel importation to overcome patent barriers and promote access to medicines, for example. A compulsory licence allows another company to make the needed vaccine or medicine without the patent holder's permission but with a royalty payment, nevertheless. Parallel importing, meanwhile, allows countries to import a cheaper version of a patented product from another country without the patent holder's permission. Either could potentially be used to solve a lack of access to drugs, vaccines or tests.

Still, Big Pharma argued for rules that went beyond TRIPS to be inserted into new trade deals which Global North countries signed with the Global South. With backing from the US, the EU and Japan, this became known as the "TRIPS-plus" agenda and it included even longer patent terms that went beyond the 20-year minimum, and limitations on a country's right to use compulsory licences or encourage generic competition, for example.

The financialisation of Pharma: Why taxpayers, not industry, fund some of the most important drug developments

Patent monopolies did not only mean higher prices. They started to transform the nature of industry. Pharmaceutical corporations realised that what was most important to their profits — and the interests of their financial investors — was not so much their research or their manufacturing, but the intellectual property they held. Research and manufacturing were scaled back while scientists were replaced by lawyers and financiers.

"Financialisation" refers to the extension of the logic of financial markets to the economy as a whole, subjecting wider society to financial motivations, with investors and creditors effectively forcing companies to prioritise maximising high returns to shareholders over all other considerations. If higher profits come from trading derivatives, or buying up and asset stripping other companies, so be it.

And Big Pharma was one of the industries at the forefront of the process.

To give an example of how far this has gone, I examined the annual reports of five Big Pharma giants — AbbVie, Gilead, Pfizer, GSK and AstraZeneca — all returned more to their shareholders than their net income between 2016 and 2020, with AbbVie returning a huge 165%. A separate report confirms this trend, showing that shareholders' pay outs among the 27 biggest corporations increased by almost 400% from $30 billion to $146 billion annually between 2000 and 2018 (Fernandez and Klinge, 2020).

Far from investing in new medicines of the future, these corporations turned themselves into gigantic cash machines for financiers.

Research and development, meanwhile, is increasingly done by the public sector and by small businesses — particularly at early and most risky phases. But we are still dependent on Big Pharma's pipelines to get the resulting drugs manufactured. And while large quantities of this manufacturing does take place in countries such as India, ultimately Big Pharma ensures it retains full control over these drugs via patent monopolies.

Industry decides who produces medicines, who buys it and at what price. Big Pharma has us in a headlock, doing less of what made them useful in the first place but still remaining in control of the production of medicines.

This was the situation when the world encountered the worst pandemic in a century.

Covid-19 strikes

In 2016, the WHO had issued a warning "intended to be a call to arms for the world's largest pharmaceutical companies," healthcare journalist Charlotte Kilpatrick wrote in 2021 (Kilpatrick, 2021).

The WHO had identified 16 pathogens, including coronaviruses, that posed a serious threat to global health but said that all were seriously under-researched. "Two years later, in 2018, the pharmaceutical giants had zero research projects in development to fight coronaviruses," Kilpatrick noted.

Research into the medicines that could rapidly deal with such a

pandemic was minimal precisely because there was no guarantee that such work would produce profitable drugs.

Even today, while the coronavirus has obviously become a major concern for the industry, Big Pharma is doing almost nothing about the other emerging infectious diseases like Rift Valley Fever or the Zika Virus. Outside coronavirus, there are still only 15 projects targeting the other diseases on the WHO's priority list. Ten diseases languish with no research and development in the pipeline at all (Hazel, 2021).

In fact, vaccines of any sort — once a mainstay of the industry — had become uninteresting to Big Pharma until Covid-19. Out of the 20 largest pharmaceutical companies, only four of them still had major vaccine programmes of any sort. These four controlled some 80% of the vaccine market (Pluess, 2020).

Vaccines just do not make enough for the profit-maximising pharmaceutical industry, bringing in "only" $54 billion in 2019 (t'Hoen, 2020).

To deal with these market failures, governments and philanthropists began to pour money into pharmaceutical research. For instance, foundations including the Bill & Melinda Gates Foundation, the Wellcome Trust, and a host of governments in 2017 set up the Coalition for Epidemic Preparedness Innovations (CEPI) to finance research into vaccines against emerging infectious diseases. There would have been no reason to do this if the industry was responding to the world's needs.

Even Bill Gates, a fierce proponent of the pharmaceutical industry, admitted at CEPI's launch: "The market is not going to solve this problem because epidemics do not come along very often — and when they do you are not allowed to charge some huge premium price" (Cookson and Bradshaw, 2017).

The biggest spender on research is actually the US government, doing the bulk of work on coronaviruses until 2020 and without which we would have few medicines of any sort. By April 2020, it was clear this money would need to be multiplied many times over. The US government established Operation Warp Speed, a public-private partnership to facilitate and accelerate the development, manufacturing, and distribution of Covid-19 vaccines, medicines,

and diagnostics. Operation Warp Speed alone put US$18 billion forward to "incentivise" Big Pharma to pivot to this type of research. Although more than a billion dollars was given out to smaller companies, the biggest chunks went to Big Pharma, see Table 1.

US$2.5 billion to Moderna, US$2 billion to Sanofi and GSK for a vaccine, nearly US$2 billion to Pfizer and BioNTech, with Novavax getting $1.6 billion, Johnson & Johnson US$2 billion and AstraZeneca US$1.6 billion (Baker, 2020).

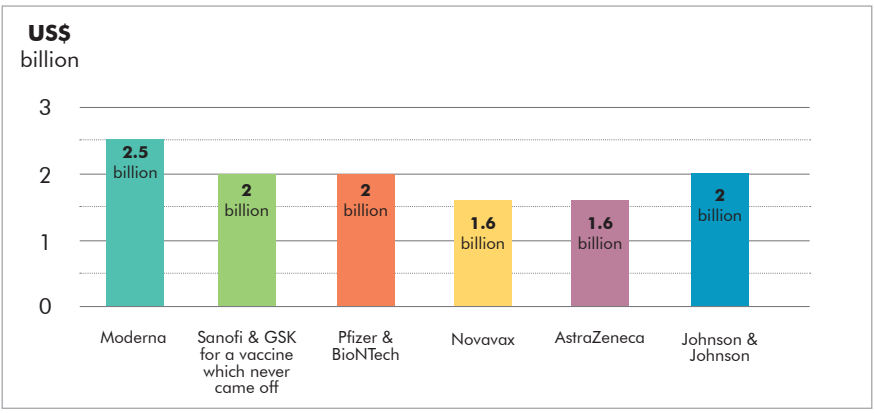


Table 1: Total amounts given to leading pharmaceutical companies as part of Operation Warp Speed.

One of the most inequitably distributed Covid-19 vaccines was overwhelmingly funded by taxpayer money.

But while Operation Warp Speed was necessary, it was not sufficient because it was still about trying to correct, rather than replace, the market. Money was thrown at Big Pharma with little transparency and seemingly, few conditions.

Big Pharma might be dysfunctional, but it was still the gatekeeper.

Moderna is perhaps the best example of the problem. Moderna specialises in mRNA technology, which has revolutionised vaccines and holds the possibility of cutting-edge treatment for a wide range of diseases including HIV, cystic fibrosis, and TB.

But the story of mRNA goes back decades before Moderna was established. As so often, the earliest and riskiest research was carried out in public universities with public backing, starting its

life in the 1990s as such a scientific backwater that it struggled to get any funding. One of the scientists who played a role in the mRNA revolution put it succinctly when talking about his own contribution to the mRNA delivery system: "You really can't claim credit, we're talking hundreds, probably thousands of people who have been working together" (Dolgin, 2021).

What is clear is that the US government, through the National Institutes of Health (NIH), played a critical role in the development of Moderna's vaccine, funded the overwhelming majority of the vaccine's development.

Public Citizen said of Moderna's vaccine, "This is the people's vaccine. The NIH's vaccine," (Public Citizen, 2021). Or, as economist Adam Tooze makes clear, "Given Moderna's heavy dependence on public funding, it is astonishing that the company should have any bargaining power whatsoever. It would not exist as a serious vaccine producer without public support of every kind" (Tooze, 2022).

And yet, Moderna and many of its executives made incredible fortunes. At one point during the pandemic, Moderna CEO, Stéphane Bancel, was worth more than US$12 billion, and while the stock on which that fortune is based has been volatile, he was still worth US$5 billion at the start of 2022 (Dearden, 2022a).

In 2021, PVA calculated that the Covid-19 vaccines had actually created nine new billionaires, with Bancel topping the list, but two of Moderna's founders and Moderna's chair were also included (PVA, 2021).

In early 2022, Moderna announced sales on its Covid-19 vaccine the previous year had brought in US$17.7 billion (Langreth, 2022). Of this, Moderna's US$13 billion pre-tax profit — around $36 million a day in 2021 — means it had a profit margin of around 70%, the kind of margin you should find on luxury goods, not essential medicines (Dearden, 2022b).

Does this matter? Yes, because despite this public funding, Moderna ultimately got to decide who could buy its vaccine. And it has proved to be one of the most inequitably distributed vaccines in the world. In September 2021, 85% of Moderna's total supply had been delivered to the richest countries, with almost no doses at

all going to the lowest income countries (Amnesty International, 2021). The company sold a tiny 3% to COVAX, but did not appear to have delivered them as of October 2021 (Malpani and Maitland, 2021).

As of March 2023, Moderna was engaged in numerous lawsuits in the US to protect its intellectual property, and had refused to collaborate with research facilities such as the mRNA Hub in SA, which could still ensure a rapid scaling up of vaccine production.

Vaccine apartheid

Thanks to the massive injection of public funding, effective vaccines and other treatments were produced fairly rapidly. But then, we hit the next problem: how to produce the quantity of vaccines the world needed in an equitable way?

The answer, according the decisions makers in the North, was COVAX (Covid-19 Vaccines Global Access) a partnership between the WHO, the Gavi vaccine alliance, and CEPI to provide poorer countries with vaccines.

COVAX failed, however, precisely because it, too, refused to stand up to the power of Big Pharma (MSF, 2021). Its founders refused to call for intellectual property to be waived and, instead, worked with Big Pharma to try to ensure a reasonable flow of vaccines went to the Global South. Ultimately, the body provided governments with less than half of the two billion doses it aimed to get out in 2021: 907 million vaccines (Unicef, 2021).

In fact, the situation was far worse than this figure suggests. COVAX was saved from utter disaster by US donations from its own supply, and by a massive increase in production only towards the end of 2021. A full third of the COVAX doses for 2021 came only in December 2021, creating its own problems, with many governments overwhelmed by bulk orders arriving all at once.

By and large, COVAX was a low priority for Big Pharma. In 2020, as major Covid-19 vaccine producers — Pfizer and Moderna — raced to get authorisation for their products, both companies had already sold the majority of their prospective vaccines to the richest countries (Global Justice Now, 2021a) (Global Justice Now, 2021b).

Even when you added in other leading vaccine candidates that had been sold somewhat more equitably, including the Oxford/ Astra Zeneca vaccine, the Russian Sputnik vaccine and the Chinese Sinovac vaccine, it was still the case that more than half of overall sales made had gone to the wealthiest countries, which account for less than 10% of the world's population (Oxfam International, 2021). Countries like the US , the UK and Canada had procured several times what they needed — hedging their bets to ensure they ended up with the best candidates, while most other countries had secured no vaccines at all.

By early summer 2021, G7 nations — which include the EU, Japan and Canada for instance — were vaccinating their citizens at a rate of 4.6 million people a day. Low-income countries were only able to manage 63,000 people per day. While the G7 was on track to have vaccinated almost all its citizens by the end of the year, low-income countries would be waiting 57 years if the current trend were to continue, (Oxfam, 2021).

Of course, vaccine nationalism and hoarding were a problem. But, at a deeper level, the real scandal of the pandemic was the refusal to countenance a proposal, supported by the majority countries in the world, to waive intellectual property (known as the TRIPS waiver) and allow all factories that could safely make vaccines to do so.

A single company in Bangladesh had already promised that it could produce between 600 and 800 million vaccines a year if it were given the know-how (Lerner and Fang, 2021). Bearing in mind the G7 countries had still only donated 865 million doses by February 2022, this could have made an enormous difference (Oxfam International, 2022).

Bangladesh was not alone. Indonesia also said it could produce 600 million a year. Meanwhile Indian activists identified 34 manufacturers who could have produced the Johnson & Johnson vaccine(Menghaney et al., 2021).

But intellectual property was at the heart of Big Pharma's profits. As such, it was regarded as sacrosanct.

In fact, the industry went into an all-out panic when US President Joe Biden moved to partially support the TRIPS waiver proposal in

May 2021, with industry lobby group the Pharmaceutical Research and Manufacturers of America (PHRMA), complaining, "multilateral organisations that once served as custodians of the international rules-based system increasingly are seeking to undermine and even eliminate intellectual property protections." Unsurprisingly, they urged the US to provide "leadership" to prevent the "weakening or even eliminating the intellectual property protections that drive America's innovation economy", (Pharmaceutical Research and Manufacturers of America, 2022).

Some might counter that one company, UK-based AstraZeneca, surely disproves the thesis. AstraZeneca did not create its vaccine, which was the product of the Jenner Institute at Oxford University. But the vaccine was sold widely in the Global South and it was "cheap", costing only a few pounds. Even here, there were problems, though, with reports emerging of SA being charged two and a half times what the EU was charged (Reuters, 2021). Uganda was asked to pay even more (Nakkazi, 2021) (Raghavan and Anil, 2021).

What is more, AstraZeneca's "no profit" pledge only lasted as long as they decided there was still a pandemic. In November 2021, the company decided that was no longer the case and they would start profiting from new sales (Espiner, 2021). Most fundamentally, AstraZeneca refused the one thing it could have done to make a greater difference: share the publicly created knowledge behind the vaccine. Ultimately, it seems, this was a step that Big Pharma is constitutionally incapable of taking.

AstraZeneca was ultimately locked in a no-win situation, with investors complaining that CEO Pascal Soriot was trying to do "politics, rather than business", with shares tumbling in value, and campaigners complaining the company was keeping vitally needed public research to itself (Jack, 2021) (Vardi, 2021).

It seems unlikely a Big Pharma company would go as far as AstraZeneca in future, and impossible to imagine any could take such steps for more than a short length of time in an extreme situation. So perhaps in this example we have the most that could possibly be expected of the industry — and it is not enough.

Meanwhile, the highest profits were made by Pfizer. In a single year, 2021, Pfizer's Covid-19 vaccine brought in US$37 billion,

making it easily the most lucrative medicine in any given year in history. Pfizer predicted that it would bring in US$54 billion in 2022 from both its vaccine and its Covid-19 treatment, Paxlovid (Mishra and Erman, 2022). Together these two medicines doubled the company's total revenue.

It is not hard to see where Pfizer's profits come from. Pfizer claims that the cost price of its vaccine is just under £5 (US$6) per dose. Others have suggested it could be much cheaper, with experts arguing Pfizer's doses could be made for as little as 76p (US$1) (Channel Four, 2021). But the UK government paid £18 (US$22) a shot for its first order, and £22 (US$27) for its later purchase (Global Justice Now, 2021c). Even taking Pfizer's cost price as the true one, that meant the British National Health Service has paid a mark-up of at least £2 billion (US$2.5 billion) — six times the cost of the pay rise the UK government agreed to give nurses last year (Siddle, 2021).

Pfizer would argue that it must cover development costs, not simply the actual cost of production. But if that is the case, it seems counter-intuitive that prices would increase over time. But Pfizer raised the EU price by more than a quarter between its first and second set of purchases: from €15.50 to €19.50 (US$19 to US$24) (Pilling, Kuchler and Mancini, 2021). Since then, Pfizer announced it would raise prices to between US$110 and US$130 a dose in the US (Erman, 2022). It is unclear what economic rule justifies the quadrupling of prices for a product several years old, except the rule of the monopolist. The People's Vaccine called the new price "daylight robbery" and that it would give Pfizer a 10,000% mark-up on its medicine (Johnson, 2022).

Conclusion

The scandal of Covid-19 vaccine inequality was not a once-off aberration. It was rather an inevitable consequence of our reliance on an industry that no longer does what made it useful in the first place, but whose power allows it to go on holding us to ransom. Big Pharma's power reaches deep into society, but its wealth is increasingly based on an intellectual property model which has helped financialise the industry — making it both more profitable

and less useful at the same time.

Such concerns have prompted governments in the Global South to begin building up their own medicine production capacity. In the most exciting case, mRNA research and development in SA is being shared with certain countries around the world. In the US, the government has given itself new powers to negotiate on drug prices, with the threat of public production even sending insulin prices tumbling. This is a good start, but more will be needed, including stricter conditions on research produced with public money, public manufacturing and the creation of new governance systems for intellectual property.

Covid-19 will not be the last global health emergency. All signs point to a similar story developing around other issues, for instance, the growth of antimicrobial resistance which could overwhelm the antibiotics on which so much of our medical practice depends. It is in the interests of nearly everyone that we break Big Pharma's stranglehold.

Nick Dearden is the director of Global Justice Now in the UK, since 2013, and a campaigner against corporate globalisation and for global economic justice for over 20 years. He was a leading voice in the UK and European movement against the now abandoned EU-US trade deal (TTIP), and subsequently against the US-UK trade deal, about which he wrote a short book, Trade Secrets.

References

Amnesty International (2021). A double dose of inequality: Pharma companies and the Covid-19 vaccines crisis. Available at https://www.amnesty.org/en/documents/pol40/4621/2021/en/ (accessed 18 Mar. 2023).

Baker S and Koons C (2020). Inside Operation Warp speed's $18 Billion sprint for a vaccine, *Bloomberg*, 29 October 2020.

Boseley S (2013). Drug companies pay doctors £40m for travel and expenses. *The Guardian*. Available at https://www.theguardian.com/society/2013/apr/05/drug-companies-pay-doctors-40m (accessed 15 Mar. 2023).

Cookson C and Bradshaw T (2017). Davos launch for coalition to prevent epidemics of emerging viruses. *Financial Times* Available at https://www.ft.com/content/5699ac84-dd87-11e6-86ac-f253db7791c6 (accessed 16 Mar. 2023).

Cookson C, Bradshaw T and Dutfield, G (2020). That high design of purest gold: A critical history of the pharmaceutical industry 1880–2020. World Scientific Publishing.

Dearden N (2022a). Moderna's profits: why we can't end the pandemic. *The Asean Post*. Available at https://theaseanpost.com/geopolitics/2022/mar/19/modernas-profits-why-we-cant-end-pandemic (accessed 18 Mar. 2023).

Dearden N (2022b). Moderna's profits show why Big Pharma can't meet our health needs. *Aljazeera.com*. Available at https://www.aljazeera.com/opinions/2022/3/16/modernas-profits-show-why-big-pharma-cant-meet-our-health-needs (accessed 18 Mar. 2023).

Dispatches (2021). Vaccine wars: Truth about Pfizer: Dispatches. *Channel Four Television Corporation*. Available at https://www.channel4.com/programmes/vaccine-wars-truth-about-pfizer-dispatches (accessed 18 Mar. 2023).

Dolgin E (2021). The tangled history of mRNA vaccines. *Nature*.597(7876): 318-324. Available at https://www.nature.com/articles/d41586-021-02483-w (accessed 18 Mar. 2023).

Dutfield G (2020). *That high design of purest gold: A critical history of the pharmaceutical industry, 1880-2020*. World Scientific.

Erman M (2022). Pfizer expects to hike U.S. Covid vaccine price to $110-$130 per dose. *Reuters*. Available at https://www.reuters.com/business/healthcare-pharmaceuticals/pfizer-expects-price-covid-vaccine-110-130-per-dose-2022-10-20/ (accessed 18 Mar. 2023).

Espiner T (2021). AstraZeneca to take profits from Covid vaccine. *BBC News*. Available at https://www.bbc.com/news/business-59256223 (accessed 18 Mar. 2023).

Facher L (2020). Pharma is showering Congress with cash, even as drug makers race to fight the coronavirus. *STAT*. Available at https://www.statnews.com/feature/prescription-politics/prescription-politics/ (accessed 15 Mar. 2023).

Facher L (2021). More than two-thirds of Congress cashed a pharma campaign check in 2020, new STAT analysis shows. *STAT*. Available at https://www.statnews.com/feature/prescription-politics/federal-full-data-set/ (accessed 15 Mar. 2023).

Fernandez R and Klinge T.J (2020). *Private gains we can ill afford. The financialisation of Big Pharma*. Amsterdam: SOMO. Available at https://www.somo.nl/nl/wp-content/uploads/sites/2/2020/04/Rapport-The-financialisation-of-Big-Pharma-def.pdf (accessed 15 Mar. 2023).

Global Justice Now (2021a). Pfizer's £2 billion NHS rip-off could pay for nurses' pay rise six times over. *Global Justice Now*. Available at https://www.globaljustice.org.uk/news/pfizers-2-billion-nhs-rip-off-could-pay-for-nurses-pay-rise-six-times-over/ (accessed 18 Mar. 2023).

Global Justice Now (2021b). Most of Pfizer's vaccine already promised to richest, campaigners warn. Available at https://www.globaljustice.org.uk/news/most-pfizers-vaccine-already-promised-richest-campaigners-warn/ (accessed 18 Mar. 2023).

Global Justice Now (2021c). 78% of Moderna vaccine doses already sold to rich countries. Available at https://www.globaljustice.org.uk/news/78-moderna-vaccine-doses-already-sold-rich-countries/ (accessed 18 Mar. 2023).

Hazel J (2021). R&D for Covid-19 has increased, yet other pandemic risks go unaddressed Access to Medicine Foundation. Available at https://accesstomedicinefoundation.org/medialibrary/loop-atm_2.mp4

Hanna TM, Brown D and Brett M (2020). Democratising knowledge: Transforming intellectual property and research and development. Common Wealth and Democracy Collaborative.

Higgins-Dunn N (2021). AbbVie repeatedly hiked Humira, Imbruvica prices and abused patents to keep competitors at bay: report. Fierce Pharma. Available at https://www.fiercepharma.com/pharma/abbvie-repeatedly-raised-prices-for-humira-imbruvica-and-abused-u-s-patent-system-to-extend (accessed 15 Mar. 2023).

Ellen 't Hoen (2020). Coronavirus: The Latest Problem Big Pharma Won't Solve Barron's. Available at https://www.barrons.com/

Humphreys K, Shover CL, Andrews CM, Bohnert ASB, et al. (2022). Responding to the opioid crisis in North America and beyond: recommendations of the Stanford–Lancet Commission. *The Lancet*.399(10324):555-604. Available at doi: https://doi.org/10.1016/s0140-6736(21)02252-2.

I-MAK (2020). Overpatented, overpriced: Imbruvica's Patent Wall. Available at https://www.i-mak.org/wp-content/uploads/2020/08/I-MAK-Imbruvica-Patent-Wall-2020-07-42F.pdf.

Jack S (2021). AstraZeneca vaccine - was it really worth it? *BBC News*. Available at https://www.bbc.com/news/business-56570364 (accessed 18 Mar. 2023).

Johnson J (2022). "Daylight Robbery": Pfizer condemned for hiking US Covid vaccine price by 10,000% above cost. Common Dreams. Available at https://www.commondreams.org/news/2022/10/21/daylight-robbery-pfizer-condemned-hiking-us-covid-vaccine-price-10000-above-cost (accessed 18 Mar. 2023).

Keefe P R (2017). The family That built an empire of pain. [online] *The New Yorker*. Available at https://www.newyorker.com/magazine/2017/10/30/the-family-that-built-an-empire-of-pain (accessed 15 Mar. 2023).

Kilpatrick C (2021). Covid-19 has shown how Big Pharma is broken. *Salon*. Available at https://www.salon.com/2021/02/20/COVID-19-patent-system-pharmaceutical-industry-delinkage/ (accessed 15 Mar. 2023).

Langreth R (2022). Moderna's 2022 shot orders edge up amid fading pandemic concerns. *Bloomberg*. Available at https://www.bnnbloomberg.ca/moderna-s-2022-shot-orders-edge-up-amid-fading-pandemic-concerns-1.1728049 (Accessed 18 Mar. 2023).

Lerner S and Fang L (2021). Factory owners around the world stand ready to manufacture Covid-19 Vaccines. *The Intercept*. Available at https://theintercept.com/2021/04/29/COVID-vaccine-factory-production-ip/ (accessed 18 Mar. 2023).

Malpani R and Maitland A (2021). Dose of reality: How rich countries and pharmaceutical corporations are breaking their vaccine promises. [online] The People's Vaccine. Available at https://www.oxfamnovib.nl/Files/rapporten/2021/A%20Dose%20of%20Reality-Briefing%20Note%20EMBARGOED%2000.01%20THURSDAY%2021%20OCTOBER.pdf (accessed 18 Mar. 2023).

Manas M and Erman M (2022). Pfizer's Covid product sales to top $50 billion this year, investors want more. *Reuters*. Available at https://www.reuters.com/business/healthcare-pharmaceuticals/pfizer-forecasts-54-bln-2022-sales-covid-vaccine-pill-2022-02-08/ (accessed 18 Mar. 2023).

Menghaney L, Kumar K and Prabhala A (2021). Letter from Indian civil society organisations to Johnson & Johnson -and- the Government of the United States Available at https://accessibsa.org/indian-civil-society-letter-jj/ (accessed 18 Mar. 2023).

Médecins Sans Frontières (2021).*COVAX: A broken promise to the world* December 2021. Available at msfaccess.org.

Nakkazi E (2021). Uganda defends price paid for AstraZeneca Covid-19 vaccine: New study suggests vaccine could cut transmission by two-thirds. Health Policy. Available at https://healthpolicy-watch.news/uganda-defends-astrazeneca-price-says-its-not-higher-than-other-countries/. (accessed 18 Mar. 2023).

Oxfam International (2021). More than a million COVID deaths in 4 months since G7 leaders failed to break vaccine monopolies. Available at https://www.oxfam.org/en/press-releases/more-million-COVID-deaths-4-months-g7-leaders-failed-break-vaccine-monopolies (accessed 18 Mar. 2023).

Oxfam International (2021). A shot at recovery. Available at https://oi-files-d8-prod.s3.eu-west-2.amazonaws.com/s3fs-public/2021-04/A%20Shot%20at%20Recovery%20April%202021%20Update_0.pdf.

Oxfam International (2022). Pandemic of greed: A wake-up call for vaccine equity at a grim milestone. Available at https://oi-files-d8-prod.s3.eu-west-2.amazonaws.com/s3fs-public/2022-03/Pandemic%20of%20greed-Oxfam%20media%20briefing-March2022.pdf (accessed 18 Mar. 2023).

People's Vaccine Alliance (2021). Covid vaccines create 9 new billionaires with combined wealth greater than cost of vaccinating world's poorest countries. Oxfam International. Available at https://www.oxfam.org/en/press-releases/covid-vaccines-create-9-new-billionaires-combined-wealth-greater-cost-vaccinating (accessed 18 Mar. 2023).

Pew Charitable Trusts (2013). Persuading the prescribers: Pharmaceutical industry marketing and its Influence on physicians and patients. Pewtrusts.org. Available at https://www.pewtrusts.org/en/research-and-analysis/fact-sheets/2013/11/11/persuading-the-prescribers-pharmaceutical-industry-marketing-and-its-influence-on-physicians-and-patients (accessed 15 Mar. 2023).

Pharmaceutical Research and Manufacturers of America (2022). Special 301 Submission 2022. Pharmaceutical Research and Manufacturers of America. Available at https://www.phrma.org/resource-center/Topics/Intellectual-Property/PhRMA-Special-301-Submission-2022 (accessed 18 Mar. 2023).

Pilling D, Kuchler H and Mancini D (2021). The inside story of the Pfizer vaccine: 'a once-in-an-epoch windfall. *Financial Times*. Available at https://www.ft.com/content/0cea5e3f-d4c4-4ee2-961a-3aa150f388ec (accessed 18 Mar. 2023).

Pluess JD (2020). *With no prospects for profits, big pharma neglects new infectious diseases*, SwissInfo. Available at swissinfo.ch.

Public Citizen (2021). Moderna vaccine belongs to the people. Available at https://www.citizen.org/news/statement-moderna-vaccine-belongs-to-the-people/ (accessed 18 Mar. 2023).

Raghavan P and Anil S (2021). Serum Institute's Rs 600/dose for Covishield in private hospitals is its highest rate the world over. *The Indian Express*. Available at https://indianexpress.com/article/india/serum-institute-covishield-price-india-world-7286635/ (accessed 18 Mar. 2023).

Reuters (2021). S.Africa to pay big premium for AstraZeneca Covid-19 vaccine from India's SII - Business Day. *Reuters*. Available at https://www.reuters.com/business/healthcare-pharmaceuticals/safrica-pay-big-premium-astrazeneca-covid-19-vaccine-indias-sii-business-day-2021-01-21/ (accessed 18 Mar. 2023).

Sell SK (2001). TRIPS and the access to medicines campaign. *Wisconsin International Law Journal* 20: 481.

Siddle J (2021). Pfizer made nearly £2bn in profit from cash-strapped NHS for its Covid vaccine. *Mirror*. Available at https://www.mirror.co.uk/news/uk-news/pfizer-made-nearly-2bn-profit-25545708 (accessed 18 Mar. 2023).

Tobbell D (2011) *Pills, power, and policy: the struggle for drug reform in cold war America and its consequences* (Vol. 23). Univ of California Press, Berkeley.

Tooze A (2022). *Chartbook #77: More than 7000 deaths per day … and we talk as though it is over.* Substack.com. Available at https://adamtooze.substack.com/p/chartbook-77-more-than-7000-deaths (accessed 18 Mar. 2023).

Unicef (2021) *Covid-19 Vaccine market dashboard.* Available at unicef.org.

US Centers for Disease Control and Prevention (2023). Understanding the Opioid Overdose Epidemic. Available at https://www.cdc.gov/opioids/basics/epidemic.html (accessed 15 Mar. 2023).

US Department of Justice (2020). Justice Department announces global resolution of criminal and civil investigations with Opioid manufacturer Purdue Pharma and civil settlement with members of the Sackler family. Available at https://www.justice.gov/opa/pr/justice-department-announces-global-resolution-criminal-and-civil-investigations-opioid (accessed 15 Mar. 2023).

US House of Representatives. Committee on Oversight and Reform (2021). Unstable drug prices (Part III): Testimony From AbbVie CEO Richard Gonzalez Available at https://www.govinfo.gov/content/pkg/CHRG-117hhrg44685/html/CHRG-117hhrg44685.htm (accessed 15 Mar. 2023).

Vardi N (2021). AstraZeneca's Pascal Soriotaas the hottest CEO in Pharma. Now he's in the hot seat. *Forbes*. Available at https://www.forbes.com/sites/nathanvardi/2021/03/19/astrazenecas-pascal-soriot-was-the-hottest-ceo-in-pharma-now-hes-in-the-hot-seat/?sh=5c20e01d10e6 (accessed 18 Mar. 2023).

Waldron I (1977). Increased prescribing of Valium, Librium, and other drugs—an example of the influence of economic and social factors on the practice of medicine. *International Journal of Health Services*7(1):37-62. doi:10.2190/FPJT-V9YE-VWM1-UXPA.

Zaitchik A (2021). Long, strange TRIPS: the grubby history of how vaccines became intellectual property. *The New Republic*. Available at https://newrepublic.com/article/162527/long-strange-trips-grubby-history-vaccines-became-intellectual-property (accessed 15 Mar. 2023).

18 January 2021

"As the first vaccines begin to be deployed, the promise of equitable access is at serious risk.

More than 39 million doses of vaccine have now been administered in at least 49 higher-income countries. Just 25 doses have been given in one lowest-income country. Not 25 million; not 25 thousand; just 25.

I need to be blunt: the world is on the brink of a catastrophic moral failure – and the price of this failure will be paid with lives and livelihoods in the world's poorest countries."

Tedros Adhanom Ghebreyesus
WHO DG

Activist Q&A with Leena Menghaney

“There had been hope… but ultimately nothing has changed from the HIV epidemic where we had to fight for access drug by drug.”

Leena Menghaney heads Médecins Sans Frontières (MSF) Access Campaign South Asia office. Menghaney began her work on access to HIV treatment with the Lawyers Collective, an India-based human rights organisation, as part of its legal aid unit assisting people living with HIV. In 2005, she and her colleagues helped organise a campaign to ensure that India’s new patent law included public health safeguards to limit the impact of patents on access to affordable medicines.

Menghaney reflects on access to medicines during the early Covid-19 pandemic, including the power of pharmaceutical companies, the ethics of voluntary licences, and how history repeated itself in unfortunate and tragic ways.

Question: MSF works in emergencies where the need is greatest. What were its critical concerns around access during Covid-19?

Answer: Early in the Covid-19 pandemic, MSF had hoped to play a role in providing Covid-19 vaccinations. Pharmaceutical corporations, particularly with the first-generation vaccines, were not directly providing the vaccines to humanitarian actors like MSF. Instead, they chose to work only through the COVAX facility.

In that context, MSF engaged with the COVAX facility — the vaccines pillar of the Access to Covid-19 Tools Accelerator (ACT-A). Even though it was supposed to be co-led by the WHO, the Gavi vaccine alliance, and CEPI to provide low and middle-income countries with vaccines, COVAX was more or less Gavi co-ordinated.

COVAX had set up a buffer for humanitarian contexts and promised to deliver about 155 million doses to this buffer. Still, as of November 2022, only about 2.5 million doses had trickled into complex humanitarian contexts like those in which we work.

The humanitarian buffer failed to support people who did not have access to Covid-19 vaccinations in humanitarian emergencies, such as those caught in conflict zones.

Our interactions with COVAX to try to obtain vaccines highlighted the complex liability issues involved in accessing the vaccines. Pharma corporations were pursuing excessive liability indemnity requirements. These indemnity clauses forced countries or humanitarian actors to accept any liability from serious adverse events following immunisation. Companies expected non-governmental organisations — which did not have the resources, governance, or means — to take on this risk.

To start with, MSF was denied access to some of the documents framing procurement that were necessary for us to assess the risks we were being asked to accept in terms of liability arrangements.

We ultimately could not obtain the vaccines in time. One of those reasons was the liability requirements from pharmaceutical corporations, the legal complexities that this led to, and the contractual wrangling that happened around accessing vaccines from the humanitarian buffer.

We welcomed the concept of COVAX's humanitarian buffer, but the system failed in its purpose and, more importantly, the people it is meant to serve.

Q: How did vaccine inequality play out in Asia, where you are based?

A: Globally, there was a lot of talk about easing vaccine supply challenges using India's manufacturing capacity.

One of the first vaccine licensing deals we saw was for Oxford University's Covid-19 vaccine, COVISHIELD. India's Serum Institute was the only Indian manufacturer that received a sub-licence from Oxford's licencee AstraZeneca, so Serum had an exclusive deal to produce the vaccine for low and middle-income countries. That licence could have been given to more vaccine manufacturers capable of producing in India.

So, we saw that India's potential ability to manufacture vaccines in time for the big waves that came in 2021 there and globally did not materialise.

This created a significant bottleneck in April 2021. India's Serum Institute had just started to export the vaccine to other countries. India faced a deadly wave of Covid-19, driven by the Delta variant, starting in March 2021. That wave alone is estimated to have killed about 240,000 people in India. At the time, the Indian government took the difficult decision to roll out the vaccine for its entire population — not just the 20% of the population that had been set as an earlier WHO target.

And when — in that wave — India's healthcare system started to collapse, the Indian government made the decision that all of Serum Institute's COVIDSHIELD vaccine manufacturing capacity would be reserved for India's own needs.

Even the vast manufacturing capacity that the Serum Institute had was not enough to meet India's demand, let alone all low and middle-income countries.

AstraZeneca's agreement to allow the Serum Institute to produce COVISHIELD was heralded as a game changer. Still, it was limiting because it only allowed one Indian company to manufacture the vaccine.

It was a major miscalculation by multilateral actors.

Q: Do you think the COVISHIELD deal showed the promise of philanthropy but the ultimate power of pharmaceutical companies?

A: Absolutely. Our initial information was that Oxford University, which developed the vaccine, was willing to license the vaccine to manufacturers in countries like India directly.

But within a few months, you had a major pharmaceutical company, AstraZeneca, controversially come on board. AstraZeneca became Oxford's main licencee and subsequently sub-licensed it to manufacturers in Brazil and India, for instance.

The dynamics completely changed once AstraZeneca came into the picture because AstraZeneca was then choosing its exclusive partners.

In the past, we have seen that licensing to several Indian generic manufacturers is not only beneficial in that it meets India's demands but also demands globally.

Until today, we are not able to fathom why they would just choose only one manufacturer in India.

Q: How was access to Covid-19 tools more broadly restricted for the Global South, and how did that change between year one and year three of the pandemic?

A: It became very clear that manufacturing was extremely verticalised. Very early in the pandemic, countries with that manufacturing capacity — or companies in those jurisdictions — controlled the whole manufacturing capacity. They were also deciding to withhold supplies.

As a result, certain countries — particularly high-income countries — controlled manufacturing capacity, whether it was for testing reagents or vaccines. Similarly, low and middle-income countries with their own manufacturing capacity, like Bangladesh and India, were doing better at accessing products. Bangladesh, for instance, could produce its own drugs. Meanwhile, India had the ability to produce not only its own vaccines but also molecular Covid-19 tests to compete with molecular testing manufacturer Cepheid.

But between year one and year three of the pandemic, the political speak completely changed. In year one, you saw a lot of political and government leadership announcing that Covid-19 medical tools were going to be public goods.

By year three, you could very well see that this was just doublespeak: Testing reagents, therapeutics, mRNA vaccines, mRNA technology transfer for the WHO's mRNA Hub were not going to be made easily available.

You could just see the shift in what political leaders and governments in high-income countries were saying and what they were doing.

Q: Is there anything that surprised you about the response from governments in the Global North and international organisations — especially given your long-standing work on access to medicines for HIV/AIDS, cancer, and TB, for instance?

A: When you compare the HIV experience with Covid-19, it is heartbreaking to see how different it was.

HIV brought governments, the WHO, and many other stakeholders — particularly very poor and marginalised communities — together to fight for the right to access basic essential medicines like Fluconazole, to treat opportunistic fungal infections, and, subsequently, antiretrovirals.

In the Covid-19 struggle, you saw disempowerment creep into the accepted norms or realities of communities and low and middle-income governments. One of the classic examples was ACT-A to improve timely, equitable access to Covid-19 tools. Certain donors, institutional organisations, and high-income countries backed it. Still, it lacked transparency and had no meaningful involvement of communities and governments in low and middle-income countries.

It is also very striking with ACT-A that while they said that they were there to help with procurement and supply, you could see that the pharmaceutical corporations had tied them up in chains. For example, they had signed non-disclosure agreements with pharma, so they could not share the pricing available from these companies. You could also see that ACT-A could do little to push back on the indemnity clauses.

India, meanwhile, refused to sign indemnity clauses and, as a result, could not access mRNA vaccines from Pfizer. But still, ACT-A could not push back on those clauses.

Lastly, ACT-A did not help humanitarian actors to procure

treatments. MSF had a tough time procuring the first generation of Covid-19 medicines like the monoclonal antibody treatment Tocilizumab. MSF spent over a year trying to get even a tiny amount of the drug from the manufacturer Roche.

ACT-A could do very little to help procure those medicines for MSF's medical operations. By the time MSF could get Tocilizumab, other therapeutic options had already replaced it and MSF could not use the drug.

ACT-A, as a multilateral platform, completely failed and did not draw from the lessons of the HIV epidemic.

Q: How were these access struggles further undermined or advanced at the WTO?

A: In October 2020, SA and India put a proposal for a waiver on intellectual property for all Covid-19 medical tools, which included diagnostics, drugs, and vaccines. It was a historic step.

During year one of the pandemic, everyone was talking about Covid-19 medical tools being public goods. At the inception of SA and India's proposal, there was a feeling that there would not be much opposition to this proposal.

By year two, even at the peak of the big waves in Brazil and India, it became very evident that the waiver proposed by India and SA — and backed by more than 100 countries — would not see the light of day.

Pharmaceutical companies would say, "Well, intellectual property waivers would not be enough to allow countries to produce the vaccines." At the same time, they denied mRNA technology to the mRNA Hub (established by mid-2021).

It was very evident that this was a political game that was being played by certain high-income countries and that they had created

a narrative that vaccine technology was the bottleneck. All the attention regarding the waiver was on vaccines.

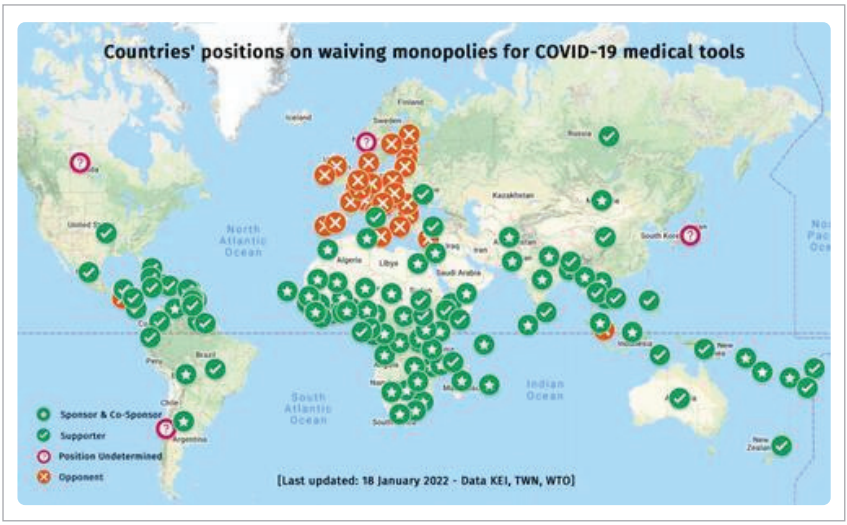


Figure 1: Countries' positions on waiving monopolies for Covid-19 (MSF)

Still, at that point in time, a lot of us who had worked on access to medicines felt that the intellectual property waiver would have been particularly useful for therapeutics, especially the oral antivirals that were in the pipeline at that time. Those medicines could potentially have saved millions of lives.

We watched a lot of people — friends, family, people we were close to — pass away due to lack of access to effective Covid-19 therapeutics.

We knew waiving patent barriers could have been a game changer in potentially saving millions of lives. We also knew that Brazil, India, Bangladesh, Thailand, Egypt — many countries had the capacity to make those therapeutics.

But it became clear then that high-income countries, the negotiators, and Big Pharma and its associations had made up their minds that they would block the waiver and prolong the negotiations.

It was a deliberate attempt at undermining access.

Ultimately, nothing changed from the HIV epidemic — where we had to fight for access drug by drug — to the Covid-19 pandemic, during which we have still been fighting for access drug by drug.

Q: Was the outcome of the waiver something that you expected?

A: There had been hope things would be different. Again, initially, countries had again said medical tools were going to be public goods and there was a kind of cheer.

People like me said, "Okay, at least acknowledge they are going to be public goods. We will not have to fight the battle the way we fought it in HIV, drug by drug."

But if you look at the medicines that came out for Covid-19, there was a clear divide between high-income countries, middle-income countries, and, of course, low-income countries.

High-income countries were the ones buying these medicines at very high prices.

No one blinked an eye at the fact that in middle-income countries, only the rich could access them or that low-income countries might possibly never get to use these drugs because they were not seen as lucrative markets.

Then we saw the so-called voluntary licences come out for Covid-19 antivirals. Still, countries were simply treated as markets and the licences excluded countries that could still be lucrative markets for Big Pharma. Following this, licences included low-income countries but excluded China, Brazil and many other middle-income countries that could have benefited from affordable, generic Covid-19 medicines.

Nothing changed in pharma's strategy: They kept the most lucrative markets for their own profiteering.

Q: What should the WHO and multilateral organisations be thinking about how to do better in the future?

A: We need to have a discussion about the ethics of granting licences to manufacture in a country but not allowing the people to benefit from that manufacturing that happens in their **own** country. This is something that we, as people who work on rights and public health, need to start bringing to the forefront with WHO, the Medicines Patent Pool (MPP), pharmaceutical corporations and anybody who is involved in voluntary licensing.

For instance, China made an enormous contribution to manufacturing the Covid-19 antiviral medicines, but people in China were themselves left out of accessing affordable treatments, which my Chinese colleagues have written about.

In December 2022 and early 2023, a surge in cases in China contributed to severe shortages of Covid-19 medicines across the country, particularly the WHO-recommended oral antiviral treatment nirmatrelvir/ritonavir for high-risk populations. Chinese companies were already positioned to manufacture the drug for export to low and middle-income countries through the existing voluntary licence agreement but **could not** supply domestically under the same agreement.

Each treatment course was nearly US$300 from Pfizer. Generics could cost a tenth of that cost. Meanwhile, with cases surging and millions affected, China was struggling to provide the medication to all eligible patients.

Essentially, Chinese manufacturers were part of the voluntary licence to manufacture the Covid-19 therapeutics, but they were

not allowed to supply China itself — people in China could not access these treatments.

Secondly, the Covid-19 pandemic and the access to medicine issues show just how powerless institutions like WHO are when it comes to challenging rules that have been set by high-income countries and the pharmaceutical industry, which together command most of the space and the power.

The WHO really supported an intellectual property waiver; it pushed for the creation of an mRNA Hub and technology transfer; and it spoke strongly to high-income countries and industry to do more on both. None of those calls were respected.

We have got a long way to go to reform the power imbalances between the WHO, on one side, and the pharmaceutical industry and high-income countries on the other side.

Lastly, one thing that really struck a lot of us who work on rights and public health was how the Covid-19 pandemic undid a lot of the rights-based lessons that we learned from other diseases — the need for consent for testing and a move away from mandatory testing, for instance.

We learned from HIV that stigma and discrimination drive people underground, away from healthcare services, and have a chilling effect on early care and treatment. Yet, we saw a repetition of these problems during the Covid-19 pandemic.

Similarly, we also saw these very severe lockdowns in which people were confined to their homes and they had huge social and economic impacts on people. People could not reach healthcare facilities.

Lastly, it brought up the point that we need more resources and public funding for health systems. At the same time, already scarce human resources for health were diverted away from HIV,

TB, and other illnesses and into the Covid-19 response, which impacted testing and treatment.

We need to fund our public healthcare systems rather than, in many countries, allowing the privatisation of healthcare.

Q: What should we be hopeful about?

A: The positive point, perhaps, about the Covid-19 pandemic is that it made access to vaccines and diagnostics more mainstream. It highlighted that the lack of manufacturing capacity in the African region was an important challenge that leaders needed to address. It made the hoarding by rich countries and pandemic profiteering by pharma corporations a mainstream issue. It raised awareness that the current system is not based on justice.

Many younger activists have started to enter the movement and are now putting their energies into making these issues even more mainstream.

We lost a lot of battles, but you could see clearly that people started to understand the politics of the pharmaceutical industry and the politics behind international negotiations. In that sense, the People's Vaccine Movement became a strong contender to also unite people and movements worldwide.

That has been a very positive thing to come out of the Covid-19 pandemic.

People's Vaccine Alliance Open letter

September 2021

LETTER FOR HEADS OF STATE CALLING FOR A SEA-CHANGE IN THE COVID-19 PANDEMIC RESPONSE AT THE VACCINE SUMMIT

Dear leader,

We are writing as organizations, academics, activists and Covid-19 survivors in support of a People's Vaccine. We are part of a global movement fighting for equitable access to Covid-19 vaccines and other health tools for all. Today just 2% of people living in the poorest developing countries have been vaccinated and 10,000 people are dying each day of the virus. On the eve of the United Nations General Assembly and related Vaccine Summit, we call on you to use this moment to take immediate and bold actions to control the virus everywhere.

The grotesque inequity in access to COVID-19 technologies is depriving people in developing countries of life saving vaccines and is responsible for unnecessary loss of life. This inequality has resulted from the lack of global focus on maximizing the production of doses to cover the majority of people in all nations; on ensuring affordable pricing; and on forestalling nationalist hoarding of available doses. Even now, having achieved high vaccination rates within their borders, rich country governments are unforgivably blocking the solutions most needed to ramp up vaccine production and supply in developing countries. Vaccine inequality prolongs the pandemic and all its suffering; increases the risk of vaccine resistant variants, and, according to the IMF will cost the global economy trillions of dollars and dramatically increase inequality.

Several rich country governments, most notably Germany and the EU, the UK and Switzerland are blocking the approval of a temporary suspension of intellectual property (IP) rules called for by over 100 other countries. The Waiver proposed by India and South Africa would lift World Trade Organization (WTO) IP restrictions on the production of vaccines and other COVID-19 health technologies for capable manufacturers across the world. Rich country governments are also failing to exert influence over pharmaceutical companies to share critical technology and know-how to enable independent, wide-scale vaccine production by capable companies in developing countries.

Having vaccinated the majority of their people, rich countries are also purchasing millions more doses for boosters while failing to reallocate excess doses to redress vaccine inequality. In some cases, they have even taken doses from COVAX — the international mechanism on which many developing countries depend. Of the insufficient doses promised for reallocation by the G7 and EU only 15% have been delivered to date. In some cases, redistributed doses arrive too close to their expiry date to save lives.

Developing countries also have responsibilities to use all legal tools available to override IP barriers to COVID-19 health technologies; to expand and support regional manufacturing capacity; to raise domestic resources to procure vaccines, medicines, tests, and personal protective equipment at affordable prices; and to strengthen health delivery systems.

We are appealing to your collective humanity; your duty to protect people from even more deadly vaccine resistant variants; your responsibility to uphold the right to health worldwide; and to your economic self-interest, to use this summit to correct the mistakes that have been made by taking immediate and bold actions:

1. **Commit to a global plan to vaccinate 70% by the middle of 2022.**

The WHO called for vaccinating 40% of every country population by December 2021 and 70% by mid-2022. The plan must turn these goals into a reality

2. Share vaccine technology and know-how and require pharmaceutical companies to do the same.

Mandate knowledge sharing and require and facilitate biopharmaceutical companies and other originators of COVID-19 medical-products to engage in technology transfer in order to allow scale-up of independent manufacturing capacity, to achieve more affordable pricing, and to accelerate equitable access. In addition, governments should support the WHO to operationalize the COVID-19 Technology Access Pool (C-TAP) and the mRNA and other vaccine technology transfer hubs, to further facilitate sharing vaccine technologies, know-how and IP.

3. Waive IP and override intellectual property barriers.

Immediately support the proposal by India and South Africa at the WTO to temporarily waive relevant IP rules under the Agreement of Trade-Related Intellectual Property Rights (TRIPS) for COVID-19 vaccines and other medical technologies until pandemic control is achieved. Once the Waiver is agreed, countries will also have to operationalize it in national law and thereafter coordinate with others to use global supply chains to manufacture and distribute COVID-19 vaccines and other health products.

4. Invest public funding to increase vaccine R&D and manufacturing capacity in developing countries.

This investment will build a global distributed network capable of and governed to deliver affordable vaccines as global medical public goods to all nations including but beyond COVID-19

5. Reallocate vaccine doses now.

Countries with vaccine over-supply that have already achieved high vaccination coverage must urgently redistribute COVID-19 vaccines via COVAX or other regional procurement mechanisms. They must publish a transparent timeline, to achieve the WHO target of vaccinating 40% of the population in low- and middle-income countries before by the end of 2021.

We urge you to rise to the huge responsibility of saving millions of lives from this pandemic by urgently taking the above 4 actions to ensure that all people in all countries have access to COVID-19 vaccines and other essential medical tools.

Published in English on The Indepedent.

Spanish language version available at Publico.

Lessons from the ACT-Accelerator: Into Future Pandemic Countermeasures Platforms

Fifa A Rahman

The ACT-Accelerator and its components have been described at different times as:

"the global solution we are looking for"
(United Nations, 2020)

"anti-democratic, because it's extraordinarily non-transparent, and opaque"
(Banco, et al., 2022)

"a blueprint of how to deliver vaccines at scale in an emergency"
(Berkley, 2022)

"naively ambitious"
(Furneaux, 2021)

The complete truth is somewhere in the middle. Not the global solution; certainly not a blueprint. Not as opaque as some claim. Definitely naïve in its failure to predict the limits of high-income country solidarity. A platform that delivered 80% of tests deployed in Africa in the first year of the pandemic (WHO, 2022a) and mobilised US$1 billion worth of oxygen supplies to more than 90 low and middle-income countries (Unitaid & Every Breath Counts, 2022). A platform with ultimately smart and good people from multiple agencies fighting for self-tests for low and middle-income countries at the same time as high-income countries but held back by ideological errors and failures by certain agencies. A platform with unprecedented collaboration between senior leadership of global health agencies and civil society meeting weekly on Thursdays to unpack the toughest weekly issues arising in the global Covid-19 response. A platform that birthed the Covid Vaccine Delivery Partnership (CoVDP) that delivered important work to integrate gender-inclusive vaccination approaches and increase uptake, in collaboration with countries. At the same time, a platform that did not know what to do on health systems. And a platform with poor intellectual ownership and expertise by and for low and middle-income countries.

In this chapter, I unpack the ACT-Accelerator from an insider-outsider perspective, drawing upon my insights and experience as a civil society representative within working groups and in high-level ACT-Accelerator meetings and working directly with colleagues within global health agencies on guidelines and responses, and as an outsider responsible for gathering and representing civil society feedback on the response through to global health agencies. I have grounded my analysis in data, in my own notes from meetings in crucial ACT-Accelerator working group and decision-making meetings, and secondary analysis from observers and stakeholders — and hopefully presenting to you, the reader, an illustration and analysis of power dynamics and neo-colonialism, structure and governance, efforts towards equity, and what key reforms are needed for future pandemic countermeasures mechanisms.

Introduction: The beginnings of the ACT-Accelerator

The Access to Covid-19 Tools Accelerator (ACT-Accelerator) was a global pandemic countermeasures platform — a group of loosely organised global health agencies, experts, and civil society that worked together to deploy and co-ordinate the global response to SARS-CoV-2. By and large, these were representatives of WHO, FIND, the Global Fund, the World Bank, Unitaid, Wellcome Trust, Gavi, CEPI, and later, civil society and community representatives meeting weekly to discuss, contextualise, and deploy SARS-CoV-2 commodities and work on health systems deficits affecting uptake of those commodities.

Formed less than three months after the WHO announced that the novel coronavirus (which we now recognise as SARS-CoV-2 or Covid-19) was a Public Health Emergency of International Concern (PHEIC), the ACT-A consisted of four pillars — the vaccines pillar (which housed the COVAX delivery mechanism), diagnostics pillar, therapeutics pillar, and the health systems connector — and was launched in April 2020 at an event co-hosted by WHO's DG, the President of France, the President of the European Commission (EC), and the Bill & Melinda Gates Foundation (WHO, 2020a). In the coming days and weeks, pillar co-lead agencies (Global Fund and FIND for the diagnostics pillar; CEPI and Gavi for the vaccines pillar; Unitaid and Wellcome Trust for the therapeutics pillar, and WHO/World Bank for the health systems connector) worked to draw up some parameters and goals for 2020.

At around the same time as priority-setting activities, the pillars worked to incorporate civil society representation. This proved easier in pillars led by agencies with more of a robust history working with civil society. Civil society was first integrated into the therapeutics pillar, after one of the co-leads, Unitaid, approached several Community Service Organisations about representation. Global Fund Advocates Network and STOPAIDS co-ordinated the appointment of interim representatives while a selection process was devised. Similar processes were initiated and quickly adopted in the diagnostics pillar, then the health systems connector (later revised to the Health Systems and Response connector), and finally — after much back and forth — the vaccines pillar, which would

later house the COVAX, which would procure and deliver vaccines to some countries.

The priority- and target-setting process began. A 28 May 2020 call on the diagnostics pillar among all partners (dubbed the "Dx Partnership Calls") was held and was attended by, inter alia, Soji Adeyi who was the then-Director of Health, Nutrition, and Population Global Practice at the World Bank; Peter Sands, Executive Director of the Global Fund; Greg Widmyer, Director, Health Product Delivery and Market Dynamics at the Gates Foundation; the French Ministry of Foreign Affairs; and civil society representatives (myself, representing Health Poverty Action); and Carolyn Gomes (representing the Global Fund Developing Country delegation). This call discussed several strategic objectives, including the development of 2-3 fit-for-purpose affordable antigen RDTs, the need to procure 500 million tests over 12 months, and the need to increase country preparedness and readiness in terms of capabilities for both automated and manual PCR tests. At this meeting, Widmyer raised an important point — that there was a need for a joint Vx-Dx and Vx-Tx strategy, that is, "test and vaccinate" and "test and treat" strategies: "We need to ask: how does diagnostics drive smart action in other pillars?"

His observation was astute and necessary; whether it was heard and translated into action was a completely different matter which I will revisit later in this chapter.

Also at this meeting, I took the floor to raise my concerns about the Global North/Global South imbalance in these calls. Attendees were predominantly those with Global North passports from global health agencies based in the North. This was intuitively a problem for me and other key experts precisely because of the neocolonial nature of the global health architecture — the notion and practice of Global North Geneva/New York-based bureaucrats operating without the technocratic and real-world knowledge that Global South experts have — and how in numerous other spaces this often had translated into a distortion of priorities, poorly informed execution, and a lack of buy-in from Global South governments. The chairperson agreed to receive nominations for Global South expert membership. However, through its operation, the ACT-Accelerator

was plagued by geographic imbalance and decision-making that was insufficiently inclusive of LMIC experts and country input.

COVAX was set up in April 2020 (Loft, 2022), and over the next few months began target setting, country discussions, and procurement for deployment. It was in these initial meetings that the "20% coverage in COVAX Advance Market Commitment (AMC) countries by the end of 2021" target was set. In one COVAX call held on 8 September 2020, civil society and COVAX leads, including Seth Berkley (the then-Executive Director of GAVI), Soumya Swaminathan (the then-WHO Chief Scientist), and Richard Hatchett (the Chief Executive Officer, CEPI). Seth Berkley provided the first presentation — commenting on the high risk of failure in vaccine development and the need to scale up processes to industrial scale before clinical trials begin.

Soumya Swaminathan then presented the proposed vaccine Allocation Framework, that health and social care workers and high-risk adults be prioritised at country-level for vaccinations, and that countries were to receive additional doses to cover 20% of their population. Countries would be invited to join the COVAX either as self-financing members or AMC facility members, the LMIC members of the latter of which would receive vaccines financed through donor contributions, as well as enter into binding financial commitments that would take them to 20% coverage. Swaminathan also presented indicative prices of the Covid-19 vaccines. It was at this point that Brook Baker — who is a professor of law at Northwestern University in Boston and Senior Policy Advisor at Health GAP, a CSO working on global access to medical technologies, and who always had astute observations and questions that dissect the nitty-gritty details of policy proposals — took the floor to ask what considerations, data, and studies had been done which brought the COVAX to 20%. Crucially — Baker was concerned about potential inequity, profiteering by industry, and potential vaccine nationalism. He may have been clairvoyant.

After a conversation with a diplomat from Palau, I was extremely concerned about the prices offered to small island states, raising a question as follows: "Some small island states have indicated that vaccine prices indicated to them are high-income prices. Why

is COVAX taking the restrictive World Bank definition of income levels? This is just one example of the injustice resulting from tiered pricing approaches."

I do not recall having received an answer for this question — nor was any answer scribbled in my notes. I can only offer my interpretation on this point — that as CSOs we certainly offered a perspective from countries which lent nuance and contextualisation to high-level targets, and that the architecture at that stage had not done that independently. We also raised concerns as to why ACT-A CSOs had not been asked to input or co-create these documents, and we were told that feedback was welcomed on final versions of documents. This certainly points to the tokenistic engagement of civil society on many parts of the ACT-Accelerator — ultimately successful interventions leverage upon the value and diversity of civil society expertise, and this will need to be integrated and elucidated in responses for future pandemics.

During this call, my CSO colleagues asked whether there would be transparency around agreements with manufacturers, including whether — for accountability purposes — they would be publicly available. Richard Hatchett responded stating that "appropriate levels of discussion" could be held due to specific levels of "commercial confidentiality" in the agreements. To his credit — he reached out to me after the meeting stating that he would be happy to continue conversations on the matter and was committed to communication and conversations with CSOs, and while we did not always agree — Hatchett was always more accessible to me and other CSO colleagues compared to Seth Berkley.

On 8 December 2020, we (ACT-A CSOs) attended a vaccines pillar briefing chaired by Susan Brown, the then-Director of Public Policy Engagement at GAVI, and attended by CSOs (including Red Cross Afghanistan, Health GAP, Population Services International (PSI)), academics, and key technical leadership of the COVAX, including Ann Lindstrand, head of the vaccine and register unit of the WHO. Among the key updates were that there were 97 countries and territories that were fully self-financed and 92 AMC countries that a Vaccine Introduction Readiness Assessment Tool (VIRAT) (WHO, 2020b) would be rolled out to. These countries would also be

provided a guidance package on acceptance and demand and a detailed supply and logistics guide. The VIRAT contained fields where countries could indicate "yes" or "no" as to whether they had, *inter alia*, identified a master list of service providers who could effectively deliver Covid-19 vaccines to various target populations, assessed dry storage and cold chain capacity at all levels, and had designed a demand plan to generate confidence, acceptance, and demand for Covid-19 vaccines which included advocacy, communications, social mobilisation, community engagement, and so forth (WHO, 2020b).

We were also informed during this call that countries could apply for cold chain infrastructure support through World Bank or GAVI funding, which precipitated a question from me on how many countries had thus far asked for cold chain infrastructure support. Mike Brison, the then--Lead for Covid-19 Vaccine Delivery on the Health Support and Infrastructure Services team at GAVI responded, stating that "UCC (ultra cold chain) technical assistance is a key challenge. There is a growing body of experts we are looking to draw expertise from to figure out how to mobilise to help these countries. Because the window has only opened yesterday for UCC support, only five countries have applied so far. The process is ongoing, and we expect more (applications) and the specific nature of those requests will be clarified in 2-3 months' time. We are looking at a lead time of 3-6 months to deploy equipment, and we will be prioritising cold chain support towards 56 GAVIi-eligible participants." His comments illustrate the monumental challenge that existed in vaccine delivery, occurring while flight routes were shutting down, but also to the infrastructure and health systems challenges that pre-existed the Covid-19 pandemic.

2021: Inequity abounds

The ACT-Accelerator was a platform pieced together in haste. At various times in meetings numerous actors, including CSOs, sheepishly admitted to riding the bicycle that was the ACT-Accelerator while trying to fix it. The result is a keen understanding that we must be more prepared for the next pandemic and more realistic about the realpolitik around how rich countries behave,

and how corporations behave. The following are illustrative examples of key equity issues that unfolded in the ACT-Accelerator *vis-à-vis* vaccines and self-testing, albeit there were also numerous inequities that occurred *vis-à-vis* Paxlovid, oxygen access, and the failure of the ACT-Accelerator to integrate a strong health systems approach.

Vaccines: Supply constraints, hoarding, and a failure to account for local context

In January 2021, the AMC Engagement Group on the COVAX, chaired by Lia Tadesse, the Minister of Health for Ethiopia, held its first meeting, beginning with co-chairs stating their priorities for COVAX and vaccine access. Of note was the intervention by the then-Minister of Foreign Affairs of Indonesia, who underlined three priorities, namely 1) transparency, inclusiveness and ensuring transparent processes within the AMC Group; 2) certainty on key issues such as the number of vaccines available, timelines and regulatory issues; and 3) solidarity and international cooperation to ensure a fair and equitable access to the Covid-19 vaccine for all (GAVI, 2021). The story that unfolded is well-known — in March 2021, the Serum Institute of India needed to reserve its supplies for India and suspended its supply to COVAX (Findlay et al., 2021) (Agencies, 2021). Throughout 2021 it became clear that rich countries were hoarding much more vaccines than they needed, to the detriment of the Global South. According to one article:

> The G7 and European Union combined have 769.8 million vaccines to spare this year, even if 75% of the population is vaccinated and 20% gets boosters (which assumes a three-fold increase in the daily vaccination rates), plus 10% is set aside for waste
>
> (Goldhill, 2021).

Many countries had had enough. The Malaysian Minister of Health in a June 2021 World Bank event slammed rich countries for hoarding

and said that the COVAX was an "abysmal failure" (Zahiid, 2021). Countries derided poor transparency on the platform, with one Latin American country stating that GAVI stated that they were having issues with producers but that no precise answers were given as to when vaccines would be delivered (Furneaux et al., 2021). Libyan officials said a meeting request to Seth Berkley was met with silence. A Pakistani official said that COVAX would "sometimes not pick up the phone", and Sabin Nsanzimana, the DG of the Rwanda Biomedical Centre and now the Rwandan Minister of Health, said COVAX had given his country just a days' notice of a shipment arriving. An external evaluation of the ACT-Accelerator would later find that "accountability and transparency were not sufficiently promoted by the ACT-A model" (Open Consultants, 2022). Seth Berkley would later say that he suspected that companies were prioritising their wealthy customers over COVAX and that activists "should have invested more effort into asking companies to be more transparent on their vaccine supply rather than asking for a TRIPS waiver" (Ravelo, 2023).

And while supply was a massive issue, there was also a fundamental issue contained in the architecture of the ACT-Accelerator that had not been addressed. In April and May 2021, news emerged of the Democratic Republic of the Congo (DRC) (Jerving, 2021) and South Sudan returning vaccine doses to the COVAX. The question is, why would countries return vaccine doses to the COVAX right in the middle of the acute phase of the pandemic? One colleague based in DRC told me that the COVAX had not engaged provincial health leadership and had not sufficiently leveraged the expertise of community health workers that had been mobilised and trained for the Ebola response. One article pointed to "strong levels of vaccine hesitancy and gaps in the DRC health system that limit the country's capacity to roll out vaccines quickly" (Jerving, 2021). And while the term "hesitancy" does not sit well with me because it was a narrative pitched by Pfizer's Albert Bourla (Hossain et al., 2021) amplified by Global North entities, and eventually co-opted by Global South entities to explain away a situation where communications campaigns simply had failed to address the legitimate concerns and questions that people had about vaccines, it became clear

that there were multiple contextual factors that were preventing vaccine uptake. The next question was, did DRC's VIRAT indicate to the COVAX that it was not ready to deploy?

VIRATs (readiness assessments) were rolled out to more than 100 LMICs in November 2020, and according to a March 2021 World Bank publication, the majority of countries had not developed processes to train vaccinators, nor had they developed social mobilisation and public engagement strategies to encourage people to get vaccinated. An excerpt from the report reads as follows:

> The assessments reveal that while 85% of countries have developed national vaccination plans and 68% have vaccine safety systems, only 30% have developed processes to train the large number of vaccinators who will be needed for the campaign and only 27% have created social mobilization and public engagement strategies to encourage people to get vaccinated. Given the worrying vaccine hesitancy levels, strategies to generate confidence, acceptance and demand for the vaccine are urgently needed
>
> (World Bank, 2021).

It was clear that a predominantly commodities-based approach to vaccines was not going to work. Any mechanism that had sufficient Global South expertise integrated and present throughout meetings would have been able to communicate this. This was something I kept saying in multiple meetings, like a broken record. This allows us to segue into the next section of this chapter — on the key elements needed in future pandemic mechanisms, including the proposed WHO Medical Countermeasures platform.

Self-tests: Ideological failures and poor co-ordination

Self-tests remained largely inaccessible in the Global South, owing to a combination of conservatism and paternalistic attitudes at

the global, regional, and national decision-making levels and poor regulatory capacity at the regional level. As self-testing became widely available in the Global North — including in the UK where I live from 9 April 2021 for free on the NHS (UK Government, 2021) — progress on self-testing on the ACT-Accelerator was progressing extremely slowly, and not for want of trying. WHO Guidelines for self-testing needed to be issued before large procurers like Global Fund and UNICEF could make purchases for the countries they work in, or risk rejection/non-acceptance of supplies. The reality was that many countries in the Global South remain reliant on the WHO for regulatory approval and quality assurance of products (including self-tests). While the WHO has robust technical expertise on quality assurance, the responsible unit on product prequalification is small and underfunded, and especially during a fast-moving pandemic, lacked capacity to review the large number of dossiers from diagnostics manufacturers, many of which were of poor quality (PVA, 2023).

Throughout 2021, ACT-Accelerator civil society and community representatives, the Global Fund, FIND, the Gates Foundation, and even key actors within the WHO, were pushing against a select few diagnostics decision-makers within WHO and who were concerned about whether communities in the Global South knew how to "link to public health action" (Rahman et al., 2022) after a self-test and concerns about the "trustworthiness" of WHO in recommending self-tests without comprehensive studies into feasibility, acceptability, and public health value of self-testing in communities. Some officials were concerned that there was a lack of randomised controlled trials and meta-analyses on Covid-19 self-tests — and we argued against this rigid and binary view of what constituted scientific evidence — drawing them to examples of self-testing in HCV and HIV, and in pregnancy. Notably, we would not be paternalistically gatekeeping access to pregnancy tests fearful of women not knowing what the next steps were.

While meetings pushing for self-tests occurred throughout the year, a pivotal meeting occurred on 11 November 2021 with key decision-makers in global health agencies and with WHO officials involved. The above points were raised by assorted WHO technical

staff members, precipitating angry responses from multiple agencies and from civil society. In the Zoom chat, I typed (verbatim):

> So I think what's important here is to ask how trustworthiness is impacted by delay. In the start of the pandemic, we obviously heard WHO's own Mike Ryan say that "speed trumps perfection" in the pandemic response - and while I understand why systematic processes like this exist, the implication of this delay is that self-testing is OK for Germany and UK but not for LMICs. Also concerned about some of the language coming out from WHO staff on this that "we don't know whether people will link to treatment". And we do in the global north? People should be allowed to self-test even for managing their own risk to their families, as what is happening in our homes in the UK. Some of this language mirrors some of the language of distrust in the HIV world as well - and it is really quite racist. Third is that I hope that equity is taken *really* seriously on this because the approach is really quite stark. We have self-tests in our homes in the UK. But not in Zambia, in Laos, in Peru. That's problematic.

Crucially, at that stage, many across rich countries still did not know how to access Paxlovid but were not prohibited access to self-tests on account of this fact. Communities across the Global North were allowed access to self-tests because their governments and scientific decision-makers believed they had the right to know their status and take measures within their own homes to protect their families.

An op-ed written by key members of ACT-Accelerator CSOs precipitated a bilateral meeting with the WHO DG, Tedros Adhanom Ghebreyesus, who agreed with us. Culminating from this meeting and immense pressure from multiple other agencies, the WHO released Covid-19 self-tests guidelines in March 2022 (WHO,

2022b), enabling large procurers to begin purchases and supplies. Many countries in the Global South had to wait for supplies from large procurers, and that was contingent on WHO guidance. Strengthened regulatory capacity at regional levels will enable greater agility, and better adherence to equitable access principles as applied to testing and the right to know one's status.

The issue of accessibility of self-tests could have probably also benefited with cross-pillar discussions and co-ordination. Earlier in this report, it was discussed how Greg Widmyer from the Gates Foundation suggested the need for joint pillar discussions to drive "smart action" in other pillars in May 2020. While joint pillar discussions eventually became more frequent, the first joint therapeutics and diagnostics meeting was only held for the first time on 23 September 2021, a full year and four months after the first time it was suggested.

What is needed for the next pandemic: Lessons from the ACT-Accelerator

Equal intellectual partnership of LMICs in a revamped and inclusive governance structure

In February 2022, CoVDP was established. Led by Ted Chaiban from UNICEF, the CoVDP would work in partnership with countries, CSOs, INGOs, and UNICEF country offices. As time passed, it became clear that the CoVDP was what was needed for uptake but what should have been established at the inception of the ACT-Accelerator. Work under the CoVDP established that in the DRC, for example, trusted influencers were church leaders and that when church leaders were engaged, people would want to get vaccinated, but because vaccination centres were often too far away from homes, there was a need for mobile vaccination centres to be placed right outside the churches (Matahari Global Solutions, 2022). CoVDP work by UNICEF South Sudan, for example, unearthed why women were not getting vaccinated — it was because Covid-19 vaccinations were rolled out in large hospitals far away from where women congregated and that there were gendered/patriarchal factors at play, such as women still needing permission from male partners

and guardians for any healthcare decisions. UNICEF South Sudan and the Ministry of Health then put in multi-layered interventions to increase vaccine uptake among women.

All these require equal intellectual partnership of LMICs in the architecture of any pandemic response mechanism. One cannot have an effective deployment with a predominantly Global North-led platform. Democratisation of expertise and geographic parity in governance of any mechanism is not a function of "wokeness", whatever that means, or tokenism or something global health entities do to tick their diversity, equity and inclusion (DEI) boxes. If your platform is not diverse and does not leverage the expertise within countries, it will fail on grounds of inefficiency, poor political buy-in, and poor local contextualisation.

This was well-documented by Global South actors. Devex quoted me as follows: "Fifa Rahman, a civil society representative with ACT-A, says a key drawback of the mechanism is the failure to integrate LMIC expertise in equal intellectual partnership." (Byatnal & Ravelo, 2022). In The Lancet, Pascale Ondoa, Director of Science and New Initiatives at the African Society of Laboratory Medicine, headquartered in Addis Ababa, Ethiopia, said, "the current format of the consultations could be improved to provide the right enabling environment for LMICs to bring their priorities forward and shape the agenda." The article further said that Ondoa hopes that the participation of LMICs and indigenous African health institutions becomes more prominent in the ACT-A decision process (Usher, 2021). In another article, Olusoji Adeyi, former senior adviser for human development, World Bank said that "in the fullness of hindsight, it is now eminently clear that the power structures have favoured the Global North over the Global South" (Banco et al., 2022).

Ultimately, this is an issue related to entrenched colonialism in global health architectures and governance, and something different is needed for the next platform on pandemic response. It should be noted here that in the ACT-A Evaluation: "Two-thirds of survey respondents (66.0%) agreed that ACT-A's operating model was the best possible structure at the time of the launch… For the next pandemic, only 34.7% of survey respondents would replicate

ACT-A's operating model –that is, four pillars and an informal coordination structure" (Open Consultants, 2022).

Geographic parity in the platform as well as regional implementation can also go a long way in mitigating paternalistic attitudes towards communities in the Global South –- as presented in the section on self-testing.

Co-creation of decisions with civil society

Integration of civil society occurred more seamlessly in some pillars of the ACT-Accelerator versus others. The therapeutics pillar included interim civil society representatives in some of their earliest working group meetings, largely an informal initiative of Unitaid staff members who believed that CSO opinions were necessary to ensure effective therapeutics interventions. Then diagnostics, health systems, and after much wrangling, vaccines. It is my reading that the ease of integration of CSOs into working groups depended greatly on the character of the co-lead organisations and the nature of their own experience with CSOs. I remember clearly one of the members of the senior leadership of one of the vaccines pillar co-leads stating he was worried CSOs "would be disruptive" — illustrating to me that he had a binary perception of civil society as rabble rousers and troublemakers — which we are, although some of us do this through strategic influencing and research, and others by loud and critical interventions. We also build meaningful partnerships with our colleagues in global health agencies and contribute intellectually — and it remains quite shocking to me that some view our ways of working as acutely different than theirs, or that it shocks them that we went to the same schools that they did. The work of CSOs is valuable and necessary, and they operate as a check and balance to binary viewpoints.

I asked Karrar Karrar from Save the Children, a CSO representative on the ACT-Accelerator, why the inclusion of civil society in the COVAX occurred so slowly. In his words:

> In achieving speed and scale of COVAX operationalisation, effective CSO integration took a little longer than other pillars of ACT-A. The early phase of COVAX operations surrounding contract negotiations and other politically sensitive decisions with governments, donors and industry required a huge degree of trust and confidentiality on the part of all partners. I suspect given the critical response of some sections of the CSO community towards COVAX's design and model of operation, this naturally led to reservations as to whether CSO's could be trusted with that information. I believe this led to an underlying tension which meant that we never really achieved truly effective CSO integration. In my opinion this was a shame as the voice of CSO's as an accountability mechanism could have been used strategically by COVAX leads early on when that public pressure could have eased some of the early supply bottlenecks.

Co-creation of ACT-A decisions with civil society largely depended on personal relationships with co-lead agencies and senior management within them. Future pandemic countermeasures mechanisms must ensure that documents and positions are not fully curated before they come to civil society, but that CSOs are viewed as technical and intellectual partners from the outset. At the same time, we acknowledge our faults — CSOs too need to invest more time in identifying and investing in representatives who are able to centre local expertise, deconstruct poor arguments, encourage accountability in CSO engagement, and understand how strategic influencing works.

A new TRIPS order

Access to pandemic tools was compromised by maximalist intellectual property and the actions of countries who were intent on delivering a TRIPS decision that was not as effective as it should

be. In addition, some of the co-lead agencies simply did not believe intellectual property was a factor in access to pandemic tools, (Ravelo, 2023) contrary to the testimony of experts with centuries of cumulative experience on intellectual property. The European Commission too was against any kind of TRIPS waiver, "suggesting that sharing intellectual property would not immediately speed up manufacturing" (Human Rights Watch, 2021).

Managing the corporate loyalties of certain actors will be impossible without the shifting of the IP power dynamic to the Global South. Before the next pandemic arrives, countries will need robust strategies on both ensuring Global South development of pandemic tools and in establishing a new TRIPS order at the national level with levels of IP that makes sense for the country.

A true equity and access lens

There is not one actor on the ACT-Accelerator that did not believe they were all focused on equity and access. However, the inequity of structures and biases inherent to all our backgrounds means that there were many blindspots. With self-tests, many laboratory-trained experts were overwhelmingly focused on the accuracy of tests over and above access. This often meant these decision-makers would deprioritise rapid tests, whether professional use rapid tests or self-tests. I dubbed these individuals PCR fundamentalists because they were pro-PCR at all costs, even though there were nomadic populations who by nature could not wait until the next day to get the PCR result and did not have an address or phone that you could forward results to. They were pro-PCR at all costs even for mums of six in South Sudan who lived a 40 minutes bus ride away from their nearest centre for PCR testing and faced the added obstacle of having to ask a male partner for permission to access healthcare. PCR fundamentalists and especially Global North PCR fundamentalists are viewing tests from a very binary worldview and thus cannot deliver real equity in access no matter their intentions.

The same applies to Paxlovid. An August 2022 report documented that doctors in rural healthcare centres in Haiti, Madagascar, and Nigeria having never heard of Paxlovid, despite it having received emergency authorisation at the US Food and Drug Administration

in December 2021 (Pfizer, 2021) and WHO calling for "wide geographical distribution" of Paxlovid in April 2022 (WHO, 2022c). An equity lens means several things here — that sufficient volumes be reserved for LMICs, that any intellectual property be waived instantly to enable generic competition and cheaper pricing, and that there is democratisation of information at the local level in languages people understand so that demand creation can come from the grassroots.

These examples illustrate how a true equity and access lens is not just closely related to ensuring diversity in expertise that you have in decision-making groups, but how diversity and geographic parity of experts is equally important and is not a function of some tokenistic tick in the box fanciful DEI process.

More agile and decentralised regulatory processes and guideline development

Regulatory and quality assurance processes at the international level, while technically robust, worked too slowly for fast-moving pandemic times. In addition, rigid processes for self-tests guidelines at WHO, a prerequisite for procurement by large procurers, focused heavily on what evidence specifically existed on Covid-19 self-tests, rather than self-tests for all diseases. Systematic analyses and meta-analyses were prioritised. While these studies hold value, this approach under pandemic times created additional bureaucracy for what was already an extremely late approval process for a document that was the single biggest barrier to large procurers making purchases. They also were largely irrelevant — at that stage there were many highly sensitive and specific self-tests being used in the Global North, having been approved by their stringent regulatory agencies.

More agile regulatory processes and guideline development processes require decentralisation. This means building capacity and establishing stringent regulatory authorities at regional bodies such as the nascent African Medicines Agency — and for large procurers being able to rely on guidelines developed by regional entities. In the meantime, WHO should also revise its guideline development processes during pandemics. While the quality of

evidence is extremely important, it should establish more agile processes and approaches to knowledge that take into account decisions made by stringent regulatory agencies, considerations of equity, and established knowledge about similar tests in other disease areas.

Health systems as a core investment

The ACT-Accelerator Health Systems and Response Connector was a failure. The ACT-Accelerator External Evaluation stated that "most key informants described the pillar as largely dysfunctional throughout 2020 and 2021" (Open Consultants, 2022) and indeed it was. Its working groups sat infrequently, and its scope initially focused predominantly on oxygen and PPE, which Hipgrave criticised in 2021 as "better described as components of clinical care" rather than fitting within the domain of health systems (Hipgrave et al., 2021).

In May 2021 my intervention at the 6th convening of the Facilitation Council, the body to which WHO Member States could — if they so desired — interrogate the inner workings of the ACT-Accelerator or share updates and concerns about their national responses, I pointed out the poor co-ordination and investments in health systems in the ACT-Accelerator, calling out specifically the return of vaccines from DRC to the COVAX due to "inaccurate assessments in vaccine readiness and insufficient engagement of local communities" (Rahman, 2021). Ultimately, health systems investments need to look at cold chain support, logistics, the mobilisation of community health workers, data systems that track who has been vaccinated and that can analyse which communities are being missed out, electrification of facilities, and reimbursements for community transport to vaccination facilities, among many key investments.

The next pandemic countermeasures mechanism must ensure a health systems focus. Commodities dumped in-country without health systems investments will result in the same story — commodities deployed in a suboptimal manner and with inequity for the most intersectionally marginalised communities.

Dr Fifa A Rahman PhD was the Civil Society Representative for the Access to Covid-19 Tools Accelerator Facilitation Council and Principals Group from 2020-2023. She is presently the Interim CSO Representative for the WHO Medical Countermeasures Platform Prototype Working Group for Future Pandemics.

References

Agencies (2021). Coronavirus India: Serum Institute's vaccine export halt a "nightmare" blow to Covax plan. *South China Morning Post*. Available at https://www.scmp.com/news/asia/south-asia/article/3134002/coronavirus-indias-vaccine-export-halt-deals-nightmare-blow.

Banco E, Furlong A and Pfahler L (2022). How Bill Gates and partners used their clout to control the global Covid response — with little oversight. *Politico*. Available at https://www.politico.com/news/2022/09/14/global-covid-pandemic-response-bill-gates-partners-00053969.

Byatnal A and Ravelo JL (2022) Devex CheckUp: What ACT-A's new strategy can't ignore. Devex. Available at: https://www.devex.com/news/devex-checkup-what-act-a-s-new-strategy-can-t-ignore-101834

Berkley S (2022). With #COVAX the world now has a blueprint of how to deliver vaccines at scale in an emergency to low-income countries, guided by a fair allocation framework developed with the @WHO to prioritise those most at-risk. Available at Twitter https://twitter.com/GaviSeth/status/1600626277253357569.

Findlay S, Peel M and Mancini DP (2021). India blocks vaccine exports in blow to dozens of nations. *The Financial Times*. Available at https://www.ft.com/content/5349389e-8313-41e0-9a67-58274e24a019.

Furneaux R, Goldhill O and Davies M (2021). How COVAX failed on its promise to vaccinate the world. *The Bureau of Investigative Journalism*. Available at https://www.thebureauinvestigates.com/stories/2021-10-08/how-covax-failed-on-its-promise-to-vaccinate-the-world.

Jerving S (2021). DRC to return 1.3M COVAX vaccine doses before expiry. *Devex*. Available at https://www.devex.com/news/drc-to-return-1-3m-covax-vaccine-doses-before-expiry-99792.

GAVI (2021). COVAX Facility Advance Market Commitment ("AMC") Engagement Group Meeting. Available at https://www.gavi.org/sites/default/files/covid/covax/governance/COVAX-AMC-Engagement-Group-2021-Mtg-01-Approved-Minutes.pdf.

Goldhill O (2021). We have enough Covid vaccines for most of the world. But rich countries are stockpiling more than they need for boosters.

STAT. Available at https://www.statnews.com/2021/12/13/we-have-enough-covid-vaccines-for-most-of-world-but-rich-countries-stockpiling-more-than-they-need/.
Hipgrave D B, Kampo A and Pearson L (2021). Health systems in the ACT-A. *The Lancet* 397(10280): 1181-1182.
Hossain A, Asiimwe S and Ivers L (2021). Claims of vaccine hesitancy in African countries are at odds with the reality on the ground. *STAT*. Available at https://www.statnews.com/2021/12/21/claims-of-vaccine-hesitancy-in-african-countries-are-at-odds-with-the-reality-on-the-ground/.
Human Rights Watch (2021). Seven reasons the EU is wrong to oppose the TRIPS waiver. Available at https://www.hrw.org/news/2021/06/03/seven-reasons-eu-wrong-oppose-trips-waiver.
Loft P (2022). COVAX and global access to COVID-19 vaccines. House of Commons Library. Available at https://commonslibrary.parliament.uk/research-briefings/cbp-9240/.
Open Consultants (2022). External evaluation of the Access To Covid-19 Tools Accelerator (ACT-A). Available at https://www.who.int/publications/m/item/external-evaluation-of-the-access-to-covid-19-tools-accelerator-(act-a).
People's Vaccine Alliance (2022). Study on the availability and affordability of diagnostics for Covid-19 and MPOX in low and middle-income countries. Available at https://matahari.global/wp-content/uploads/2023/02/Study-on-the-Availability-and-Affordability-of-Diagnostics.pdf.
Pfizer (2021). Pfizer receives U.S. FDA Emergency use authorization for novel Covid-19 oral antiviral treatment. Available at https://www.pfizer.com/news/press-release/press-release-detail/pfizer-receives-us-fda-emergency-use-authorization-novel.
Matahari Global Solutions (2022). Mapping access gaps in Covid-19: Results from 14 Countries and territories. Available at https://matahari.global/wp-content/uploads/2022/08/Mapping-Access-Gaps-in-Covid-19.pdf.
Rahman F, Baker B and Gomes C (2022). Covid testing equity: A reflection based on 1.5 years in the ACT-Accelerator. Speaking of Medicine and Health, Plos Blogs. Available at https://speakingofmedicine.plos.org/2022/01/24/covid-testing-equity-a-reflection-based-on-1-5-years-in-the-act-accelerator/?fbclid=IwAR376wMFRO1nBj54TsMuQ9vOEumtj2GVj1ClgG100mv8tEMjhMf6NsB5c5A
Rahman F (2021). 6th WHO Facilitation Council: Dr Fifa Rahman on investing in health systems during the pandemic. Available at https://www.youtube.com/watch?v=1OGxWgr6oHs.
Ravelo JL (2023). TRIPS waiver "did nothing' for vaccine access," Gavi's Seth Berkley says. Available at https://www.devex.com/news/trips-waiver-did-nothing-for-vaccine-access-gavi-s-seth-berkley-says-105091.

UK Government (2021). Twice weekly rapid testing to be available to everyone in England. Available at https://www.gov.uk/government/news/twice-weekly-rapid-testing-to-be-available-to-everyone-in-england.

Unitaid, Every Breath Counts (2022). The ACT-A oxygen emergency taskforce…one year on. Every breath counts. Available at https://stoppneumonia.org/wp-content/uploads/2022/03/ACTAOxygenTaskforceAnniversaryStatement17March2022.pdf.

United Nations (2020). Secretary-General hails efforts by ACT-Accelerator partners to end pandemic, calls for financial infusion so that research, therapeutics roll-out can continue. Available at https://press.un.org/en/2020/sgsm20240.doc.htm

Usher A D (2021). Health leaders criticise limited ACT-A review. *The Lancet* 398(10301): 650-651.

World Bank (2021). Assessing country readiness for Covid-19 vaccines: First insights from the assessment rollout. Available at https://documents1.worldbank.org/curated/en/467291615997445437/pdf/Assessing-Country-Readiness-for-COVID-19-Vaccines-First-Insights-from-the-Assessment-Rollout.pdf.

World Health Organization (2022a). ACT-Accelerator launches six-month plan as world transitions to long-term COVID-19 control. Available at https://www.who.int/news/item/28-10-2022-act-accelerator-launches-six-month-plan-as-world-transitions-to-long-term-covid-19-control.

World Health Organization (2022b). Use of SARS-CoV-2 antigen-detection rapid diagnostic tests for COVID-19 self-testing. Available at https://www.who.int/publications-detail-redirect/WHO-2019-nCoV-Ag-RDTs-Self_testing-2022.1

World Health Organization (2022c). WHO recommends highly successful Covid-19 therapy and calls for wide geographical distribution and transparency from originator. Available at https://www.who.int/news/item/22-04-2022-who-recommends-highly-successful-covid-19-therapy-and-calls-for-wide-geographical-distribution-and-transparency-from-originator.

World Health Organization (2020a). Launch of the Access to Covid-19 Tools (ACT) Accelerator. Available at https://www.youtube.com/watch?v=70cB03pbxrA

World Health Organization (2020b). Covid-19 vaccine introduction readiness assessment tool. Available at https://www.who.int/publications-detail-redirect/WHO-2019-nCoV-Vaccine-introduction-RA-Tool-2020.1.

Zahiid SJ (2021). Minister Khairy tells World Bank to speak out against vaccine inequity, calls Covax 'massive failure.' *The Malay Mail*. Available at https://www.malaymail.com/news/malaysia/2021/06/23/minister-khairy-tells-world-bank-to-speak-out-against-vaccine-inequity-call/1984309.

CONTEXT:
An inconvenient truth: The real reason why Africa is not getting vaccinated

Originally published:

Tian Johnson, Tom Moultrie, Gregg Gonsalves, Fatima Hassan "An inconvenient truth: The real reason why Africa is not getting vaccinated" *Bhekisisa 12 October 2021*

Only 2.5% of the world's COVID vaccines have gone to African countries.

As a result of vaccine hoarding by rich countries, more than 100-million Covid doses could go to waste this year.

Rather than focusing on the high levels of vaccine equity, pharmaceutical companies are trying to shift the blame onto vaccine hesitancy on the continent.

Albert Bourla, the CEO of the US-based pharma giant Pfizer, recently claimed the slow uptake of COVID jabs in Africa is because of vaccine hesitancy, which, he said, would be "way, way higher than the percentage of hesitancy in Europe or in the US or Japan".

But he conveniently misses the truth. It's not because people in Africa are hesitant that they're not getting their shots; it's because they're simply not getting stock.

Of the approximately 6.4-billion vaccine doses administered globally so far, only about 2.5% have been in Africa. If we consider that Africa has close to 1.4-billion people, this ratio translates to only a country the size of Ghana being vaccinated on the entire continent.

A "grotesque" gap: How rich countries are controlling Covid vaccine supplies

Bourla's statements about vaccine hesitancy perpetuates

a far too common narrative, grounded in racism and which paints people in Africa as being science shy and resistant towards vaccines and other medical advances. Quite to the contrary, a team of leading researchers reported in Nature Medicine in July this year that Covid vaccine acceptance is higher in several low and middle-income countries, including a number in Africa, than in richer countries such as the US and Russia. The results were remarkably consistent across countries, suggesting that people in poorer countries are willing to get their shots – if only vaccines were available to them.

While many African countries are still waiting for supplies, richer countries have in effect bought up the lot for 2021. The situation is so unequal that the WHO DG, Tedros Ghebreyesus, warned already in March this year that the vaccination gap between rich and poor countries would become "more grotesque every day".

The world was not fooled by a press briefing of some of the big pharmaceutical companies on 7 September – the same one where Bourla aired his views – proclaiming they are confident of having enough vaccines for everyone.

The next day, COVAX – the international initiative set up to ensure global access to Covid vaccines – announced a sobering outlook: it had to cut its forecast of deliveries to low income countries by 25% for 2021–2022 because of a constrained supply chain. This comes on the back of many countries in the North starting to consider rolling out third shots, despite the WHO repeatedly having called for a moratorium on booster shots to first get healthcare workers and the elderly in low-income countries vaccinated. A call which has thus far been ignored.

The WHO was not impressed either. "[B]ecause manufacturers have prioritised or been legally obliged to fulfil bilateral deals with rich countries willing to pay top dollar, low-income countries have been deprived of the tools to protect their people," Ghebreyesus said at a press briefing the same day. "I will not stay silent when the companies and countries that control the global supply of vaccines think the world's poor should be satisfied with leftovers."

A vaccine glut vs a desert: Why we need redistribution of the doses

Although vaccine hesitancy is real, it is shaped by a history of medical research not

always having the best interest of participants – especially from minority communities – at heart.

There has been the notorious Tuskegee Syphilis Study, in which infected Black men in the US were observed but not treated over four decades. During apartheid, we saw medical experimentation leading to chemical and biological weapon programmes being set up by the SA government to develop substances that could poison, sterilise or kill Black people.

The roll-out of injectable contraception between the 1950s and the 1970s by then minority, \undemocratic governments in South Africa and Zimbabwe raised concerns about these programmes being a mechanism to curb fertility rates among black communities.

And it's reared its head again recently. Reports that Covid-19 patients at an Arkansas jail were given Ivermectin – approved for treating parasitic worms, not Covid, and which the US Food and Drug Administration specifically advised against – sparked outrage.

Contrary to Bourla's "evidence-free" view, the WHO recognises that almost every low-income country has "extensive experience in large-scale vaccination campaigns". Every country in Africa has successfully eradicated smallpox, all but a few have effectively immunised their populations against polio and most are making steady progress in immunising their children against vaccine preventable childhood diseases.

Many countries in the North are also struggling with vaccine uptake, despite having started their programmes in the first quarter of 2021 already and having ample supplies – because they were allowed to buy them all up and continue to be "priority customers". Pharmaceutical companies do not hesitate to continue to prioritise supplying vaccines to wealthy countries, despite their glut possibly leading to many more than 100-million doses destined to go to waste by the end of 2021 if they are not urgently and equitably redistributed.

Bourla and his ilk clearly do not understand the broader context of how public health is realised in Africa, with their desire to profit driving supply decisions while Africa faces multiple waves of Covid-19 in a vaccine "desert".

A complex history: What's behind vaccine hesitancy in Africa

We've been here before.

During the early years of the

Aids crisis, the tardiness in giving Africa affordable and equitable access to ARV drugs was laid unfairly at Africa's door.

Scores of people died prematurely, yet then USAID administrator, Andrew Natsios, declared that the agency was opposed to giving Africans ARVs as people "do not know what watches and clocks are" and would not be able to take their medicines at the right time each day.

As a consequence of neocolonial economic and social policies in Africa, fragile health systems impact communities' access to health services in much of the continent. In this context, African civil society, the private sector and governments grapple daily with the complexity of vaccine hesitancy and work diligently to build vaccine confidence.

But it is more convenient for a fully vaccinated Bourla to glibly cite "hesitancy" as the reason for the low number of vaccinations in Africa than to engage with the ongoing supply crisis and the complexity of historical mistrust, exclusion and inequitable access.

Greed and glut: How rich countries are helping sustain Covid in Africa

Africa will become known as the continent of Covid-19 – not because of vaccine hesitancy but because of the inequity, greed and inaction of pharmaceutical companies and political leaders of the North.

Far from Bourla's self-serving narrative, Pfizer has not materially contributed to vaccine equity.

Instead, for the past year both Pfizer and its German partner BioNTech have refused to share vaccine know-how with other manufacturers around the world.

And not by coincidence, the German government publicly declared their opposition to a proposal, initially raised by the South African and Indian governments in October 2020, that the World Trade Organisation waive certain conditions of intellectual property rights with regard to Covid technologies.

So far, Pfizer has also not been willing to partner with the WHO's mRNA Hubs being set up around the world – including South Africa – and which could help to supply much-needed additional vaccine doses rapidly.

Rather, the company alone decides which countries it wishes to supply, with how much, by when and at what price – all factors that contribute to a sizeable and lucrative revenue stream for Bourla and his shareholders. But contracts are not

transparent and reports of disconcerting indemnity terms and pricing negotiations in supplying vaccines have again highlighted concerns about contractual agreements contributing to "vaccine nationalism".

Bourla cunningly side-stepped the issue of knowledge sharing at the manufacturers' joint press conference. Instead he referred to a recent "deal" with South African biotech firm Biovac, but which – incredulously – is not in any way linked to the first WHO mRNA Hub established in South Africa, of which Biovac is a partner.

The "deal" is in fact not a full manufacturing licence, but rather just a "fill and finish" arrangement – the final stages of production during which the product is put into vials, sealed and packaged for shipping. This means the process of mRNA production will remain in Europe and keep Africa dependent, unless a radical shift is seen in holding pharmaceutical companies accountable.

"I'm not sure what the point of transferring technology is … it is going to take years to transfer," he continued. Yet several medicine access advocacy groups, and even the WHO, have laid out realistic plans to establish technology transfer efforts, with far more ambitious timelines than Bourla will admit.

Turning "hesitancy" into a scapegoat: The moral crime of vaccine hoarding

Bourla's opinions on (not) sharing knowledge highlight larger structural issues. Rather than big pharma confronting their own complicity in blocking reasonable access to vaccines, "hesitancy" is increasingly made the scapegoat.

And while African countries are waiting for vaccines, which have not been delivered on time or not at all, wealthy countries continue to hoard supplies, some to the point of expiry. Little has come of their promises to donate vaccines to Africa, with the WHO stating that less than 15% of the one billion pledged doses have materialised.

By refusing to treat Covid-19 vaccines and other essential technologies as products for the public good – especially when those technologies were funded by public money – big pharma are sustaining the pandemic in low and middle-income countries.

It might be naive to expect consciousness, courage or even shame from an industry that has a long history of putting profits before people. But we

will not stand by in silence; instead, we will remind them at every opportunity that they will, for generations, be known as those who stood in the way of an end to Covid-19.

The current situation of vaccine inequity and racist tropes being flung about to justify knowledge hoarding and a dire lack of vaccine supplies is sadly shameful. It is also a moral crime.

SECTION C:

THE WORLD TRADE ORGANIZATION

People's Vaccine Alliance Open letter

March 2022

CALLING FOR A PEOPLE'S VACCINE AGAINST COVID-19

Two years since the WHO declared Covid-19 a global pandemic – and faced with disturbingly unequal access to Covid-19 vaccines – we urge world leaders to do what is necessary to end this crisis and unite behind a People's Vaccine.

For over two years, Covid-19 has ravaged the world, upending billions of lives and livelihoods. While some in wealthy countries become complacent about this unprecedented crisis, billions of people in the global south remain vulnerable to this terrible disease, facing the threat of severe illness and death. Many are suffering hunger and destitution as a result of lockdowns and continued economic hardship. While the huge social impact of children missing many months of school and women facing increased domestic violence are yet to be fully comprehended.

Sadly, despite what some leaders in wealthy countries would like

us to believe, the pandemic is not over. But it is within our grasp to end it and ensure everyone is protected. That requires giving everyone, everywhere access to safe and effective vaccines and other life-saving Covid-19 technologies. This is possible, thanks to the incredible advances of science and the public investment of governments around the world.

However, the cruel reality is that self-defeating nationalism, pharmaceutical monopolies and inequality stand in our way. We did not need to reach the milestones of two years and an estimated twenty million deaths from Covid-19. This was avoidable.

We ask world leaders to come together and coordinate a response to solve this unprecedented crisis of historic proportions. We urge them to commit to sharing the economic burden required to fund the next stages of vaccines, treatments, testing, and the medical oxygen and PPE needed by healthcare workers around the world. The commitment of world leaders according to each country's ability to pay is crucial. Nations must urgently come forward and provide their share of the long-term, sustainable finance that will enable us to make the whole world safe.

The EU, the UK, and Switzerland continue to block the lifting of intellectual property rules which would enable the redistribution and scale-up of Covid-19 vaccines, test and treatment manufacturing in the global south. The transfer of largely publicly funded vaccine technology and know-how from pharmaceutical corporations would fast track production to a matter of months. Yet still today, a handful of these corporations retain the power to dictate vaccine supply, distribution and price – and the power to decide who lives and who dies. World leaders, and particularly rich nations, have the responsibility to change this situation and ensure the publicly funded vaccine technology and know-how is available to the global south.

The current approach is immoral, entirely self-defeating and also an ethical, economic and epidemiological failure. The virus is mutating all the time. Existing vaccines are less effective against the Omicron variant, and although vaccines continue to protect

against severe disease and hospitalisation, there is no guarantee this will continue in the face of future variants. At the same time, the cost to the global economy of failing to vaccinate the world is estimated to be $9 trillion dollars.

Twenty-two months ago, we first united behind a call for a People's Vaccine. We knew the painful lessons from a history of unequal access in dealing with diseases such as HIV and Ebola. And we remembered the ground-breaking victories of health movements, including AIDS activists and advocates who fought for access to affordable medicines for all. But world leaders did not listen and failed to heed the warning that "Those who do not remember the past are doomed to repeat it."

Now we are reuniting, in greater numbers, and with utmost urgency repeating our call for a People's Vaccine. We appeal to world leaders to end this strategy of counter-productive nationalism and of protecting pharmaceutical monopolies and to finally act with international solidarity. Now is the time to renew the commitments made at the founding of the WHO, where all states agreed to deliver "the highest attainable standard of health as a fundamental right of every human being."

Specifically, we call on governments to take these urgent five steps:

1. Urgently agree and implement a global roadmap to deliver the WHO goal of fully vaccinating 70% of people by mid-2022, and beyond this ensure sustained, timely and equitable access worldwide to Covid-19 vaccines, treatments, tests and other medical technologies, including next generations effective and safe Covid-19 vaccines and medical technologies.
2. Maximise the production of safe and effective vaccines and other Covid-19 products by suspending relevant intellectual property rules and ensuring the mandatory pooling of all Covid-19 related knowledge, data and technologies so that any nation can produce or buy sufficient and affordable doses of vaccines, treatments and tests.

3. Invest public funding now in a rapid and massive increase in vaccine manufacturing as well as research and development (R&D) capacity to build a global distributed network capable of and governed to deliver affordable vaccines as global public goods to all nations.
4. Make Covid-19 vaccines, treatments and tests available to governments and institutions at a price as close to the true cost as possible, and provided free of charge to everyone, everywhere, and allocated according to need.
5. Scale up sustainable investment in public health systems to ensure that low and middle-income country governments have adequate resources to get shots into arms and save lives. These investments will pay dividends in the global economy and help restore economic and development gains which the global Covid-19 pandemic has partially reversed.

We stand ready to support world leaders in their joint response to achieve vaccine equity and are confident the lessons learned from previous crises will serve to guide us and avoid repeating old mistakes. Every life lost now to vaccine apartheid is avoidable. Only a People's Vaccine – based on the principles of equity and solidarity – can protect all of humanity and create a fairer, safer, more prosperous world.

Signed by 114 signatories including a range of presidents, prime ministers, heads of international and research bodies. For a full list see https://peoplesvaccine.org/wp-content/uploads/2022/03/Vaccine-Open-Letter-March-2022.pdf

Letter to President Ramaphosa

Date: 21 March 2022
via email

Send	From...	Jayati Ghosh, Joseph Stiglitz and Peter Kamalingin
	To...	President Ramaphosa, South African Presidency
	Subject:	Letter to President Ramaphosa

Dear President Ramaphosa,

We support and commend your tireless leadership on the Trade Related aspects of Intellectual property (TRIPS) Waiver proposal with respect to COVID-19 products and technologies including diagnostics, therapeutics, and vaccines at the World Trade Organization (WTO).

Despite your clear articulation of the need for a comprehensive waiver of all blocking intellectual property barriers, not just patents, and the need for access to treatments and other medical countermeasures, not just vaccines, the recently leaked draft text does not waive the IP barriers necessary to deliver any meaningful access to vaccines, treatments, or tests. We support you fully in rejecting this misleading and ineffectual proposal, which represents the European Union's belligerent blockade of any actual waiver of IP barriers and the United States' insistence that the IP waiver it supports be limited to vaccines.

Developing countries have experienced the worst effects of COVID-19. The crisis is far from over as infections and deaths continue all over the world. New variants are

also expected to emerge, with the potential to further devastate countries socially and economically. A meaningful outcome on the TRIPS Waiver proposal holds the key to promoting equitable access to the COVID-19 medical tools that can facilitate and sustain socio-economic recovery and protect the lives and livelihoods in South Africa, India and many other developing countries. It is for this reason, your waiver proposal is co-sponsored by 65 WTO Members and has received widespread support from the international community.

In contrast to your inspiring leadership for a meaningful waiver of IP barriers, this text reflects the interests of multinational pharmaceutical companies in preserving the deadly status quo.

The text leaked earlier this week:[1]

- Only covers vaccines, not lifesaving treatments or the diagnostics for testing COVID-19 which are a crucial part of an arsenal to prevent, treat and contain COVID-19.
- Largely restates the existing limited flexibilities to overcome only patent barriers that already exists in Article 31 of the TRIPS text. This has proved unfit for boosting production of COVID-19 vaccines. And this text adds new burdensome conditions not now required by WTO rules that would impose additional limits on countries using non-voluntary licensing.
- It also continues to require product-by-product authorization, meaning no simplified pathway for follow-on manufacturers to produce and enter the market.
- The leaked text also does not waive other forms of IP barriers that thwart COVID vaccine production, including protection of undisclosed information (Article 39). This is essential for the production of COVID-19 vaccines.

We strongly support South Africa not agreeing to this proposal. We are keen to work with you as you lead the world to obtain a useful and meaningful outcome that facilitates diversification and expanded production and supply. Like civil society groups around the world, we believe a bad deal is worse than no deal. We want to work with you to support an outcome at WTO that will make a difference in battling COVID. The leaked text fails that test.

Yours sincerely,
Jayati Ghosh
Professor of Economics, Jawaharlal Nehru University, New Delhi

Joseph Stiglitz
University Professor, Columbia University, New York
Awarded the 2001 Nobel Prize in Economics

Peter Kamalingin B.L
Pan-Africa Director, Oxfam

1 https://www.statnews.com/pharmalot/2022/03/15/covid19-vaccine-patents-wto/

Doc avail: https://drive.google.com/file/d/1h5JHQrqa9nsnH4PbEPChOSWg_rSzBla0/view?usp=sharing

Explainer: the WTO TRIPS "deal"

THE **WTO** AND THE WAIVER PROPOSAL

- The WTO is an institution of 164 members that is meant to operate on the basis of decision-making by 'consensus'.
- That is not always possible when richer countries exercise so much political and economic power over other countries, so that they can dictate the terms of any agreement.
- Despite over around 100 countries supporting the ***waiver proposal*** including 63 countries co-sponsoring the India-South Africa the ***waiver proposal***, a handful of powerful, rich countries were allowed to scupper it with the help of the WTO secretariat. They delayed a response for 20 months, and bullied the majority of countries into accepting an inadequate ***deal.***
- This was contrary to the considerable global support for the ***waiver proposal*** by former world leaders, the Vatican, Nobel Laureates, scientists, UNAIDS, WHO, academics, researchers and activists, INGOS, trade unions and community groups, among others.

UNFAIR DISCRIMINATION

APRIL 2022

The UN Committee on the Elimination of Racial Discrimination statement on global vaccine inequity stated that:

> *...a pattern of unequal distribution within and between countries replicates slavery and colonial-era racial hierarchies; and deepens structural inequalities affecting vulnerable groups...*

13 JUNE 2022

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.

> *The pandemic has had disproportionate impacts on Africans and people of African descent, Asians and people of Asian descent, indigenous peoples, stateless persons, migrant workers, women, people discriminated against on the basis of their sexual orientation, gender identity or sex characteristics, persons with disabilities and many other marginalized groups. I share the conclusion, articulated by several other international human rights experts, that unequal access to COVID-19 prevention, containment and treatment technologies ("COVID-19 technologies") violates the fundamental human rights principles of equality and non-discrimination.*

THE **WTO** MINISTERIAL CONFERENCE: JUNE 2022

After several postponements of the Ministerial Conference of the WTO ('MC 12') since 2020, it was held in June 2022 in Geneva, the head-quarters of the WTO.

On 15 June 2022,

because there was no agreement on the waiver proposal and on other MC 12 issues, it was extended by a further two days.

On 17 June 2022,

in Geneva, it was announced that countries rich and poor, including South Africa, agreed to a deal.

- The deal is not a comprehensive waiver: ***critics call it 'weak', and a 'slap' in the face of poor countries.***
- As a result, we now face a future where access to life-saving technologies and recipes to produce them will remain uncertain and possibly out of our reach, where equitable access to testing and treatments for disease will remain a distant prospect, for many people in developing countries but especially in poorer countries.

https://drive.google.com/file/d/19IvfYGLQbSvAdFWjPrtewPq2v54NYUxs/view?usp=sharing

Decoding the TRIPS decision of June 2022

Sangeeta Shashikant

Arguably the most pressing need facing WTO Member States at the WTO's 12th Ministerial Conference in June 2022 was to reach an agreement on lifting intellectual property-related barriers for the supply of Covid-19 medical products. Blunted by developed countries' intransigence, the eventual decision was a major disappointment that could end up costing lives.

The WTO's decision on the TRIPS Agreement (WTO document WT/MIN(22)/30)) gavelled in the final hours of 17 June 2022 may perhaps best be described as a bittersweet outcome for developing countries (Hassan, 2022) (HJI, 2022a) (Vawda et al., 2022).

Bitter for — even after 20 months of intensive discussion and negotiation — the outcome falls severely short of the comprehensive TRIPS waiver proposed by India and SA in October 2020 and discussed widely through this Compendium. That proposal sought to temporarily waive at least 35 articles of the WTO's TRIPS Agreement covering patents, protection of undisclosed information, and copyright and industrial designs in relation to health products and technologies for the prevention, treatment, and containment of Covid-19.

This chapter begins by briefly outlining the motivation for the waiver before discussing its aim. Next, it goes through the key features of the TRIPS Decision, highlighting in particular how the aggressive opposition and rigid positions of developed countries (the EU, US, UK and Switzerland) led to a limited diluted outcome. Finally, it discusses considerations for developing countries in implementing and using the TRIPS Decision.

SA and India's waiver proposal was motivated by the "growing supply-demand gap" early in the Covid-19 pandemic, arguing that "[t]he rapid scaling up of manufacturing globally is an obviously crucial solution to address the timely availability and affordability of medical products to all countries in need." The proposal went on to stress the need for "unhindered global sharing of technology and know-how in order that rapid responses for the handling of Covid-19 can be put in place on a real time basis".

At its core, the comprehensive TRIPS waiver proposal sought to create the "freedom to operate" on a temporary basis, to scale up and diversify global manufacturing to address the global inequity in access to Covid-19 health products and technologies for the benefit of the Global South. "Freedom to operate" being a term to describe in this case, the freedom to manufacture, use, sell or distribute a Covid-19 product, without any restrictions.

The TRIPS waiver proposal, which was co-sponsored by 65 WTO members and supported by many others, received tremendous backing from individuals and international organisations such as the WHO, as well as intellectual property experts, parliamentarians, and Nobel laureates (Third World Network, No date) (HJI, 2021) (UNAIDS, 2021).

However, persistent opposition and the uncompromising positions of developed countries, especially the EU, the US, the UK, and Switzerland — amply supported by the WTO Secretariat's manoeuvring — ultimately resulted in a very limited and conditional Ministerial Decision on the TRIPS Agreement at the June 2022 WTO conference.

This outcome was inevitable once negotiations commenced on the basis of a narrowly draft text communicated by the WTO DG to the WTO's TRIPS Council on 3 May 2022. The DG's text — already

public following a leak in March 2022 was globally criticised for its "TRIPS-plus" elements — or intellectual property protections that go beyond TRIPS Agreement requirements — and for its inadequacy in times of a global pandemic (Third World Network, 2022a) (Third World Network, 2022b).

The WTO Ministerial Decision reflects the obstructive positions of the EU, which could agree only to a decision framed in the context of a compulsory licence of patents. Similarly, the outcome reflects the US's insistence that the Decision should cover only Covid-19 vaccines, excluding therapeutics and diagnostics, and set criteria limiting which WTO members could use the Decision, in particular, excluding China. This exclusion is discussed in detail later in this chapter.

While the Ministerial Decision on the TRIPS Agreement that was eventually adopted does not deliver the desired comprehensive TRIPS waiver, it is nevertheless a marked improvement over the WTO DG's proposed text (see above). This is worthy to note in view of the vicious hostility of developed countries that had been observed during the course of the negotiations leading to the Decision's adoption. The UK and Switzerland, in particular, relentlessly sought to narrow the scope and application of the Decision (Third World Network, 2022c) (Third World Network, 2022d).

Making sense of the Ministerial Decision

The Ministerial Decision on the TRIPS Agreement is built on the existing compulsory licensing flexibility under Article 31 of the TRIPS Agreement, and only waives the limit on quantities of vaccines that may be exported when produced under a compulsory licence issued to override patent barriers for the manufacture of Covid-19 vaccines.

Article 31 of the TRIPS Agreement already allows governments to issue a licence to authorise a third party to use and exploit a patented product or process without the consent of the patent holder. This important flexibility is often referred to as a non-voluntary or compulsory licence. Where a compulsory licence is issued for public non-commercial use, it is also commonly known as a "government use" licence.

The use of a compulsory licence is ordinarily subject to various conditions. Among these, Article 31(f) of the TRIPS Agreement states that compulsory licences must be used predominantly for supplying the domestic market, thereby limiting the quantities of the licensed products that may be exported. Now, paragraph 3(b) of the Ministerial Decision on the TRIPS Agreement waives this condition alone, allowing most or all of the production to be exported. This is actually the only "waiver" contained in the Ministerial Decision on the TRIPS Agreement.

Previously, a mechanism to waive the Article 31(f) condition was adopted on 30 August 2003, and in 2005 it was translated into a permanent amendment of the TRIPS Agreement as Article 31bis. But this mechanism has mostly proven to be ineffective and unworkable due to the numerous rigid procedures attached to its use (MSF, 2006) (WTO TRIPS Council, 2021). The Ministerial Decision on the TRIPS Agreement in effect offers a mini-version of that mechanism.

Another interesting element in the Ministerial Decision on the TRIPS Agreement is paragraph 4, which relates to Article 39.3 of the TRIPS Agreement concerning protection of test data. Historically, developed and developing countries have held different interpretations of Article 39.3, which reads as follows:

> Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary toprotect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use.

Developed countries have typically argued that Article 39.3 requires the granting of exclusive rights for a specified timeframe over test data submitted by the originator pharmaceutical companies to regulatory authorities for purposes of obtaining marketing approval, thereby delaying the entry of generic and other follow-on manufacturers.

Developing countries maintain that such an interpretation is not supported by Article 39.3 and most developing countries do not implement such a requirement at the national level. However, often due to pressure exerted especially through free trade agreements, some developing countries have implemented data exclusivity at the national level. Evidence suggests that the implementation of data exclusivity delays generic competition, enabling the originator company to charge monopoly prices with significant implications for public sector budgets and access to affordable medicines (Malpani, 2009) (Gamba et al., 2012).

Against this background, paragraph 4 of the Ministerial Decision on the TRIPS Agreement confirms developing countries' interpretation of Article 39.3 that undisclosed test data submitted by originator companies to regulatory authorities may be relied on and used for purposes of granting rapid regulatory approval. Article 39.3 also allows disclosure of data in certain circumstances.

Paragraph 4 of the Ministerial Decision on the TRIPS Agreement reinforces that flexibility in the context of "timely availability of and access to Covid-19 vaccines". Towards that end, paragraph 4 states that Article 39.3 does not prevent a Member State from "enabling the rapid approval for use of a Covid-19 vaccine", which also supports the disclosure of undisclosed test data for the purpose of rapid approval for use of a Covid-19 vaccine produced under this Decision.

Paragraph 3(a) of the Ministerial Decision on the TRIPS Agreement reinforces the existing flexibility in Article 31(b) of the TRIPS Agreement that an eligible WTO Member State may grant a compulsory licence without first having to make attempts to get a voluntary licence from the patent holder.

Paragraph 3(d) of the Ministerial Decision on the TRIPS Agreement adds elements that may be considered when determining payment of adequate remuneration to the patent holder under Article 31(h) of the TRIPS Agreement. Payment of adequate remuneration is in any case subject to national discretion under the TRIPS agreement.

Still, use of the Ministerial Decision on the TRIPS Agreement is subject to several conditions that are not normally applicable when using the compulsory licensing flexibility under the TRIPS Agreement. Hence, these can be said to be TRIPS-plus conditions, for example:

- Paragraph 3(c) of the June 2022 Ministerial Decision on the TRIPS Agreement prevents the re-exportation of products manufactured under the authorisation in accordance with the Decision that have been imported under the Decision, with a footnoted exception for situations of "humanitarian and not-for-profit purposes". In a public health emergency, there is no logic or basis for such a condition. Still, despite the opposition of most developing countries to the barring of re-exportation, the EU insisted on maintaining this paragraph, only making leeway for the small exception in footnote 3 for humanitarian and non-profit purposes. However, this condition is only applicable when both the manufacturing and importing countries are using the Decision.
- Paragraph 5 and footnote 5 require countries to notify the WTO's TRIPS Council, which monitors the implementation of the TRIPS Agreement, as soon as possible after the adoption of the measure. Footnote 5 of the Decision states that the council "shall be notified as soon as possible after the information is available". On several occasions during the negotiations, the UK had insisted on pre-shipment notification, which was not ultimately agreed to by WTO members.
- The eligibility criteria in footnote 1 reflects the US intent that China legally commits to *opting out* of using the Decision. The DG's text had reflected the US proposal

> that, "for the purpose of this Decision, developing country Members who exported more than 10% of world exports of Covid-19 vaccine doses in 2021 are not eligible Members". China was not agreeable to this formulation, which was clearly targeted at singling it out. A counter-proposal was reflected in the DG's text: "For the purpose of this Decision, all developing country members are eligible Members. Developing country Member States with capacity to export vaccines are encouraged to opt out from this Decision."

On 10 May 2022, China formally announced to the WTO General Council that it was opting out of using the Decision. However, the statement was insufficient for the US. Due to US's domestic anti-China sentiment, the US sought a binding commitment that would exclude China, although China has significant production capacity that could support greater access in developing countries.

The final text of footnote 1 states:

> For the purpose of this Decision, all developing country Members are eligible Members. Developing country Members with existing capacity to manufacture Covid-19 vaccines are encouraged to make a binding commitment not to avail themselves of this Decision. Such binding commitments include statements made by eligible Members to the General Council, such as those made at the General Council meetingon 10 May 2022, and will be recorded by the Council for TRIPS and will be compiled and published publicly on the WTO website.

Ultimately, this final footnote was the outcome of a bilateral negotiation between the US and China. Most WTO members had not even seen the text of footnote 1 even as the Decision was gavelled. Although the stated objective of the Decision is "production and supply of Covid-19 vaccines", footnote 1 of the text discourages

developing countries with manufacturing capacity from using the Decision, revealing the absurdity, irrational power politics and Big Pharma interests that influenced the textual negotiations.

In implementing the Decision, paragraph 2 may be useful for it presents a simplified approach to implementation and reads:

> For greater clarity, an eligible Member may authorize the use of the subject matter of a patent under Article 31 without the right holder's consent through any instrument available in the law of the Member such as executive orders, emergency decrees, government use authorizations, and judicial or administrative orders, whether or not a Member has a compulsory license regime in place. For the purpose of this Decision, the "law of a Member" referred to in Article 31 is not limited to legislative acts such as those laying down rules on compulsory licensing, but it also includes other acts, such as executive orders, emergency decrees, and judicial or administrative orders.

This paragraph makes clear that the "law of a Member" referred to in Article 31 of the TRIPS Agreement is not limited to legislative acts, such as those laying down rules on compulsory licensing, but also includes other acts, like executive orders, emergency decrees, and judicial or administrative orders.

Paragraph 6 of the Ministerial Decision on the TRIPS Agreement provides that the duration of the Decision is five years. The duration effectively applies to the waiver of Article 31(f) of the TRIPS Agreement contained in paragraph 3(b) of the Decision, as the other elements of the Decision are mere clarifications and reiterations of existing TRIPS Agreement flexibilities.

Importantly, nothing in the Decision prevents any member country from issuing a compulsory licence for a period beyond five years.

Paragraph 7 safeguards against "non-violation and situation" complaints for the duration of the Decision. Until WTO's 13th Ministerial Conference, there is a moratorium on non-violation complaints with respect to the TRIPS Agreement. The Decision does not, however, stop challenges under the usual WTO dispute settlement mechanism for violating the TRIPS Agreement pursuant to Article XXIII.1(a) of the General Agreement on Tariffs and Trade.

Paragraph 9 clarifies that except for the granted waiver lifting the restriction on export of vaccines, the Decision does not affect the rights and flexibilities of WTO Members provided by the TRIPS Agreement.

Not perfect, but an improvement over leaked texts

As noted above, the final Decision is an improvement over the DG's text for several reasons, including:

- reference in the DG's text to "patented subject matter" was changed to "subject matter of a patent", ensuring consistency with Article 31 of the TRIPS Agreement and that the Decision is applicable not only in situations where the subject matter to be licensed is patented but also to subject matter at the application stage, that is, pending patents;
- deletion of the requirement to list all patents to be covered by the compulsory licences, which if maintained would have been difficult to comply with, given the uncertainty over the patent landscape of a particular product and process;
- addition of a humanitarian and non-profit exception in footnote 3 to the re-export restriction in paragraph 3(c) of the Decision, as discussed above.

What next for developing countries?

Footnote 1: Setting the record straight

Footnote 1 of the Ministerial Decision on the TRIPS Agreement states:

> For the purpose of this Decision, all developing country Members are eligible Members. Developing country Members with existing capacity to manufacture Covid-19 vaccines are encouraged to make a binding commitment not to avail themselves of this Decision. Such binding commitments include statements made by eligible Members to the General Council, such as those made at the General Council meeting on 10 May 2022, and will be recorded by the Council for TRIPS and will be compiled and published publicly on the WTO website.

On 22 June, the WTO Secretariat issued a WTO document IP/C/W/690 entitled, "Record in accordance with footnote 1 of the Ministerial Decision of 17 June 2022." It states: "This document provides a record of developing country Members that have made a binding commitment not to avail themselves of the Ministerial Decision on the TRIPS Agreement of 17 June 2022. This record will be updated as appropriate." China's opt-out statement at the May General Council meeting is mentioned.

The WTO Secretariat's approach of unilaterally creating such a record is inconsistent with the text in footnote 1, which lists a two-step process whereby commitments will be recorded by the TRIPS Council and published publicly on the WTO website. Footnote 1 requires that any intention to opt out of using the Decision should officially be communicated to the TRIPS Council by the Member State concerned, for only then can it be recorded by the TRIPS Council. The WTO Secretariat's role is to compile and publish it publicly once it has formally been recorded by the TRIPS Council. WTO Members should set the record straight with the secretariat.

Therapeutics and diagnostics

WHO has said that "it is simply not acceptable that in the worst pandemic in a century, treatments that can save lives are not reaching those that need them", calling the inequitable access a "moral failing" and adding that the world was "playing with a fire that continues to burn us" (WHO, 2022a).

By 29 June 2022, WHO DG, Tedros Adhanom Ghebreyesus, noted that Covid-19 cases were on the rise in 110 countries, causing overall global cases to increase by 20% and leading to rising deaths in three WHO regions. He stressed that countries should be integrating testing and antivirals into clinical care to ensure people receive prompt treatment (WHO, 2022b).

The crucial role of therapeutics and diagnostics in controlling Covid-19 is undisputed. They are recommended by WHO as well as by national strategies, increasingly as part of test-and-treat strategies.

Yet timely, affordable access remains a challenge in most developing countries.

Most of the limited supply of Covid-19 therapeutics has been procured by wealthy countries, which represent a mere 16% of the global population. Even when available, they are unaffordable to most developing countries. Voluntary licences are often put forward as the solution to the challenge of access in developing countries. However, as the licences are "voluntary", there is no guarantee that a patent holder will make available such a licence for supply to developing countries. And where voluntary licences exist, they exclude supply to many developing countries and contain other unjustified terms and conditions that delay or hinder generic production (MSF, 2022) (MSF, 2020).

Expanding supply options requires lifting the intellectual property barriers to the entry of generic manufacturers, especially as patent filings related to therapeutics considerably outnumber those on vaccines by some four-fold. Extending the scope of the TRIPS Decision beyond vaccines to cover therapeutics and diagnostics could have secured the availability of compulsory licences to override the patent barrier to production and export. It is a no-

brainer from a public health perspective and yet it was one of the most contentious aspects of the negotiations on the Decision.

Paragraph 8 of the Decision states: "No later than six months from the date of this Decision, Members will decide on its extension to cover the production and supply of Covid-19 diagnostics and therapeutics."

This two-track approach of "vaccines first, therapeutics and diagnostics later" reflects the US's obstinate position during the negotiations. Even when US concerns were addressed with the two-track approach, paragraph 8 was bitterly disputed until the end of the negotiations as the UK and Switzerland unsuccessfully attempted to dilute the definitive commitment to address therapeutics and diagnostics, proposing that the text regarding an extension give States six months to decide "whether to extend this Decision" instead to decide "on its extension".

At the time of writing, the six-month time period for extension of the Decision to Covid-19 therapeutics and diagnostics had been postponed indefinitely (Patnaik, 2022).

Implementing and using the Decision

Compulsory licensing is one of the most important tools that developing countries have to address patent barriers to production and access. The Decision could motivate the greater use of compulsory licences for Covid-19 vaccines in the Global South. The main beneficiaries of the Decision are developing countries manufacturing or planning to manufacture Covid-19 vaccines with the intent to export the majority or all of the vaccines but who are facing existing or potential patent barriers. Countries that are importing vaccines or exporting a non-predominant portion under a compulsory licence need not use the Decision. These countries may continue to import or export under Article 31 of the TRIPS Agreement.

Least developed countries enjoy full exemption from TRIPS Agreement obligations at least until 1 July 2034 and should utilise this exemption to import, export or use any patented products (Shashikant, 2022). They do not need to use compulsory licensing,

including under the decision, to address potential/existing patents or other intellectual property barriers.

For other products beyond Covid-19 vaccines, developing countries that wish to import and export may continue to use compulsory licences under Article 31 of the TRIPS Agreement to override any patent barriers. Article 31 limits neither the products that may be compulsorily licensed nor the duration of the licence, which may be for the duration of the patent term. Apart from compulsory licensing under Article 31, developing countries may also use other TRIPS Agreement flexibilities to address patent or other intellectual property barriers to access.

At the global level, the process that began in October 2020 with SA and India's proposal for a TRIPS waiver provided a platform for developing countries and the international community to highlight the challenge of timely and affordable access, exposing the hypocrisy of developed countries and their failure to deliver on promises of global solidarity and equitable access. Most notably, it has brought immense global visibility and awareness to the intellectual property monopolies that underpin and enable highly concentrated supply chains that are unsuitable for addressing public health needs in developing countries especially during a public health emergency, and consequently the need for greater freedom to operate for local manufacturers to diversify production and expand supply options.

Sangeeta Shashikant is a legal advisor to the research and advocacy organisation, Third World Network, and co-ordinator of its Development and Intellectual Property Programme. She obtained her Masters in Laws from the University College London in 2003. She also writes for the South-North Development Monitor (SUNS).

References

Duke Global Health Innovation Center (no date). Launch and scale speedometer: Covid-19 therapeutics. Available at https://launchandscalefaster.org/covid-19/therapeutics.

Gamba, M E C, Francisco, R B. and Damaris, V S M (2012). Impacto de 10 años de protección de datos en medicamentos en Colombia. Ifarma. Available at https://www.ifarma.org/publicaciones/impacto-de-diez-anos-de-proteccion-de-datos-en-medicamentos-en-colombia

Hassan, F (2022). A new and weak WTO deal on TRIPS is not fit for purpose. Think global health. Council on Foreign Relations. Available at https://www.thinkglobalhealth.org/article/new-and-weak-wto-deal-trips-not-fit-.

Health Justice Initiative (2021). Frequently asked questions: The TRIPS waiver and the WTO. Available at https://healthjusticeinitiative.org.za/2021/06/04/frequently-asked-questions-the-trips-waiver-and-the-wto/.

Health Justice Initiative (2022a). The WTO deal explainer. Available at https://healthjusticeinitiative.org.za/2022/06/30/the-wto-deal-explainer/.

Health Justice Initiative (2022b). TRIPS waiver negotiations - leaked text. Available at https://healthjusticeinitiative.org.za/2022/06/23/trips-waiver-negotiations/.

Malpani, R. (2009). All costs, no benefits: how the US-Jordan free trade agreement affects access to medicines. *Journal of Generic Medicines*, 6(3), 206-217.

Médecins Sans Frontières (2006). Neither expeditious, nor a solution: The WTO August 30th decision is unworkable. Available at https://msfaccess.org/neither-expeditious-nor-solution-wto-august-30th-decision-unworkable

Médecins Sans Frontières (2020). Voluntary licenses and access to medicines. Available at https://msfaccess.org/voluntary-licenses-access-medicines.

Médecins Sans Frontières (2022). Latin America: How patents and licensing hinder access to COVID-19 treatments. Available at https://msfaccess.org/latin-america-how-patents-and-licensing-hinder-access-covid-19-treatments.

Shashikant, S (2022). Lessons from the pandemic for LDCs: Implementing intellectual property flexibilities. Third World Network. Available at https://www.twn.my/title2/briefing_papers/twn/LDC%20IP%20flexibilities%20TWNBP%20Mar%202022%20Shashikant.pdf.

Third World Network (No date). Waiver from certain provisions of the TRIPS agreement for the prevention, containment and treatment of Covid-19. Available at https://www.twn.my/title2/intellectual_property/trips_waiver_proposal.htm.

Third World Network (2022a). Proposed TRIPS waiver outcome not yet agreed among the Quad. Available at https://www.twn.my/title2/health.info/2022/hi220305.htm.

Third World Network (2022b). WTO DG's proposed solution unsuitable for global public health crisis. Available at https://www.twn.my/title2/health.info/2022/hi220501.htm.

Third World Network (2022c). WTO: UK & Switzerland attempt to limit scope of Covid-19 TRIPS Decision. Available at https://www.twn.my/title2/wto.info/2022/ti220605.htm

Third World Network (2022d). Intense IP Negotiations are Underway, resolution on Eligibility Criteria Outstanding. Available at https://www.twn.my/title2/wto.info/2022/ti220623.htm.

UNAIDS (2021). Former heads of state and Nobel laureates call on President Biden to waive intellectual property rules for Covid vaccines. Available at https://www.unaids.org/en/resources/presscentre/featurestories/2021/april/20210414_letter-waive-intellectual-property-rules-COVID-vaccines.

Vawda Y, Hassan F. and Johnson T (2022a). New WTO deal is a slap in the face for poorer countries. *News24*. Available at https://www.news24.com/fin24/opinion/opinion-new-wto-deal-is-a-slap-in-the-face-for-poorer-countries-20220618.

World Health Organization (2022a). WHO press conference on Covid-19, Ukraine and other global health issues. Available at https://www.who.int/multi-media/details/who-press-conference-on-covid-19--ukraine-and-other-global-health-issues---4-may-2022.

World Health Organization (2022b). WHO Director-General's opening remarks at the media briefing – 29 June 2022. Available at https://www.who.int/director-general/speeches/detail/who-director-general-s-opening-remarks-at-the-media-briefing---29-june-2022.

World Trade Organization TRIPS Council (2021). Response to questions on intellectual-property challenges experienced by members in relation to Covid-19 in document IP/C/W/671, 42 WTO Doc. Communication from The Plurinational State Of Bolivia, Eswatini, India, Kenya, Mozambique, Mongolia, Pakistan, SA, The Bolivarian Republic of Venezuela and Zimbabwe, IP/C/W/673. Available at https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=Q:/IP/C/W673.pdf.

SECTION D:

SOUTH AFRICAN INTERVENTIONS

Regulatory approval in a public health emergency: Lessons from Covid-19 vaccines

Andy Gray

One of the Covid-19 pandemic's defining features has been the speed with which a wide variety of vaccines were developed, appraised and approved by national and regional regulatory authorities and the WHO, procured by governments and then, finally, administered to more than two-thirds of the world's population (Mathieu, 2023). Understandably, there has also been keen interest internationally in the adverse events associated with the use of the different vaccines given their novelty.

However, as always, aggregated data hide all manner of inequities. In low-income countries, as discussed in several chapters here, less than a quarter of the population had been fully vaccinated by February 2023 (Mathieu, 2023). Regulatory decision-making has varied between countries and the extent to which safety data have been gathered, analysed and shared publicly has also differed between settings.

This chapter briefly reviews the evolution of regulatory approaches towards Covid-19 vaccines globally, including how

national medicine regulatory agencies balanced gaps in data with the need to address a rapidly moving public health emergency. Next, it describes processes in SA to streamline approvals and ways in which the country monitored and reported adverse events following immunisation. Lastly, it argues that SA made important strides in transparency regarding medicine regulation that bode well for continent-wide efforts to harmonise regulation but that entrenching these ways of working will be key moving forward.

Covid-19 vaccines – a long time coming

The perception that Covid-19 vaccines were developed from scratch after the identification of SARS-CoV-2 ignores a long process of technological refinement. Those Covid-19 vaccines that contain attenuated or weakened forms of the novel coronavirus relied on a well-developed process. Still, of the 11 vaccines that had received WHO emergency use listing or prequalification by November 2022, only three relied on a traditional development approach (WHO, 2022). Of these, two were developed in China and one in India. As shown in Table 2, two vaccines were based on recombinant spike proteins, four used viral vectors to deliver spike protein antigens, and two used mRNA. India has become an important source of vaccines, particularly for low and middle-income countries. Indian companies also produced a viral vector vaccine, under licence from a developer in a high-income country, and a recombinant spike protein vaccine.

Vaccine	Vaccine Type	Manufacturer
Comirnaty, including original and subsequent versions for omicron sub-variants	mRNA	BioNTech Manufacturing GmbH
Vaxzevria, previously the Oxford / AstraZeneca vaccine	Viral vector	AstraZeneca
Covishield	Viral vector	Serum Institute of India (licensed from AstraZeneca)
Covid-19 Vaccine Janssen (Ad26.COV2-S [recombinant])	Viral vector	Janssen–Cilag International
Spikevax	mRNA	Moderna Biotech
Sinopharm	Inactivated virus_	Beijing Institute of Biological Products
CoronaVac	Inactivated virus	Sinovac Life Sciences
Covaxin	Inactivated virus	Bharat Biotech International
Covovax	Recombinant spike protein	Serum Institute of India
Nuvaxovid	Recombinant spike protein	Novavax
Convidecia	Viral vector	CanSino Biologics Inc.

Table 2: List of WHO emergency use listed/prequalified Covid-19 vaccines as of November 2022.

It is the last of these technologies, mRNA Hub, that had never been used in a vaccine outside of clinical trials. However, it could also be considered a maturing technology, having been the subject of intensive research and development efforts over many years (Fauci, 2022). The basic science work around mRNA immunisations was partially based on the immense efforts to develop an HIV vaccine, but was also behind the development of other as-yet experimental vaccines, such as that for respiratory syncytial virus (RSV), which causes lung and respiratory tract infections (Graham, 2020).

Data dilemmas: Regulatory challenges within a public health emergency

Despite somewhat long histories, Covid-19 vaccines initially posed significant challenges for national medicines regulatory agencies which approve vaccines for use in countries. During the pandemic's early years, agencies were expected to take decisions quickly given mounting Covid-19 cases and deaths. Different regulatory agencies took diverse routes to vaccine approvals, some based on early phase immunological data rather than placebo-controlled efficacy studies.

Immunological data rely on the detection and quantification of an antibody response to vaccination, with the assumption that the detected antibodies will be protective. Still, these studies are not designed to prove whether a vaccine works to reduce the risk of a disease, in part because sometimes there is no controlled comparison group, that is, a number of people who did not receive a vaccine, received a "dummy" vaccine containing no active ingredients or received another vaccine without an effect on Covid-19.

Conversely, randomised placebo-controlled efficacy studies are considered the "gold standard" for clinical trials and are designed to prove whether a medicine or vaccine is effective. In these studies, people are randomly assigned to receive a vaccine or a placebo. Next, results are compared between these two groups. Randomisation ensures that any trait among participants that could affect results is equally distributed among groups and so cannot affect results.

Chinese authorities, for example, approved locally developed vaccines without randomised efficacy clinical trials and, instead, relied on immunological data. Manufacturers did, however, conduct subsequent randomised efficacy studies outside of China. Similarly, Russia's domestically produced vaccine — which has yet to receive WHO approval — was also reportedly deployed prior to completion of randomised controlled efficacy studies.

A careful balance of rigour and agility

The International Coalition of Medicines Regulatory Authorities (ICMRA) is a voluntary association of nearly 40 national medicine regulators, including the South African Health Products Regulatory

Authority (SAHPRA). Together, these regulators — with the WHO as an observer — work to enhance collaboration, communication and approaches to common challenges.

Early in the pandemic, ICMRA and WHO recognised the need for a co-ordinated approach to assessing Covid-19 vaccine efficacy and safety data (ICMRA/WHO, 2020). In a joint November 2020 statement, the ICMRA and WHO emphasised regulatory authorities' obligation, warning that Covid-19 vaccines and treatments could only be rapidly approved if applications were supported by robust and sound scientific evidence that allowed medicine regulators to conclude that products were effective enough to outweigh any potential risks associated with their use.

But they also stated a clear preference for the kind of evidence that should support Covid-19 vaccine approvals: "Robust and reliable data on efficacy and safety to support market approval of medicines and vaccines are best collected through randomised controlled clinical trials which control for bias, meet Good Clinical Practice standards, respect the rights, autonomy and safety of clinical trial participants, and can be audited."

While highlighting the need for "regulatory agility", the ICMRA and WHO also called for "full transparency of clinical trial results to support regulatory decisions", and cited the need to safeguard the public's trust in authorities and vaccines. In the statement, both organisations pledged to monitor Covid-19 vaccines following approvals to identify, communicate and mitigate any possible safety or efficacy issues. Lastly, they recognised the need to "reduce the risks associated with unproven treatments, potentially fraudulent and false claims which endanger patients' lives".

Building consensus: Setting the benchmarks for new vaccines

Subsequently, in May 2021, the ICMRA developed consensus documents to guide Phase 1, first-in-human trials for Covid-19 vaccines, but most critically, it set the global standard for Phase 3 vaccine efficacy studies in June 2020 (ICMRA, 2020).

Although expressed as a desirable level, not an absolute minimum,

vaccine efficacy of at least 50% was required, as measured in a placebo-controlled randomised trial that enrolled sufficient participants, which the ICMRA and WHO advised was "generally, at least 10,000 and usually about 30,000" people and included the elderly.

Efficacy was carefully defined: "Clinical trials should show that a candidate vaccine very significantly reduces Covid-19 in people who are vaccinated, compared to a control group of people who do not receive the vaccine, through a reduction in numbers of laboratory confirmed SARS-CoV-2 infections."

The ICMRA and WHO also produced a series of statements to provide healthcare professionals with the needed confidence in Covid-19 vaccines. The most recent of these, issued in May 2022, has updated the approach to assessing efficacy, allowing for "appropriately designed" immuno-bridging studies (ICMRA/WHO, 2022).

After a vaccine has been proven to be effective, immuno-bridging studies allow scientists to use existing efficacy data to infer how well a vaccine would work in different circumstances, for instance, if it was given to different population groups or alongside other immunisations. These kinds of studies are most often done to supply regulatory authorities with additional data to approve vaccines for wider use or to allow extension to age groups not initially included in the efficacy studies.

Recent work may also help pave the way for more immuno-bridging studies as recent work claims to have found a *de facto* correlate of protection for Covid-19 vaccines, in the form of target levels of neutralising antibodies (Gilbert et al., 2022). Correlates of protection define the immune response, via a vaccine or natural infection, needed to protect one from future infection. Once scientists confirm a correlate of protection, it may become a measure by which future vaccines are tested.

Local regulatory decision-making in SA

Covid-19 struck SA just *two years* after SAHPRA replaced the country's previous regulator, the Medicines Control Council (MCC) in 2018.

SAHPRA's immediate priority then had been to address the backlog in applications for registration of medicines that it inherited from the MCC. That backlog has finally been cleared, but only when using the definition initially applied: "Applications submitted prior to February 2018" (SAHPRA, 2022).

Meanwhile, a new backlog was being generated, with the majority of uncompleted reviews being for generic medicines. While considerable resources were devoted to addressing SAHPRA's inherited backlog, less attention was paid to revising what were termed "business-as-usual" processes.

Nonetheless, SA's decision-making model for regulatory approvals faced a major change in the transition between the two bodies (Gray, 2018).

Previously, under the MCC, technical reviews of dossiers submitted for registration were considered by a series of committees, which then presented proposals for decision. In the interests of continuity, the identity and composition of these technical advisory committees has been left largely untouched in the transition to SAHPRA. Under SAHPRA's new model, however, the final decision now rests with SAHPRA staff, nominally with the chief executive officer.

Read literally and simplistically, SA's medicines legislation (RSA, 1965; Minister of Health, 2017) does not contemplate the submission of an incomplete application for registration, nor does it enable an emergency or conditional registration of a medicine, including a vaccine. A complete dossier is assessed and either rejected or accepted, with conditions attached to every registration. There is, nonetheless, a process for enabling access to unregistered medicines for individual patients or groups of patients, via an electronic portal. This process, allowed for under section 21 of the country's medicines legislation, was initially adapted during Covid-19 to allow for the prompt initial approval for importation of the first Covid-19 vaccine, AstraZeneca. Thereafter, registration with specific conditions was relied upon.

By June 2021, SAHPRA had approved the AstraZeneca, Pfizer and Janssen (Johnson & Johnson) vaccines, and was considering applications for the Sinovac and Gamaleya vaccines.

SA and a more agile regulator

More importantly, SAHPRA adopted one of the "agility" mechanisms promoted by the ICMRA — rolling reviews — during Covid-19. In a rolling review, data are presented to the regulator as they become available, shortening the time to reach a decision, once the "full" dataset is presented. Equally importantly, the conditions to registration included obligations to submit missing data that would traditionally be required before a full-fledged dossier could be accepted, such as longer-term safety data or data on particular sub-populations, such as children and adolescents.

During Covid-19's initial years, there were internal debates about whether to rely on the section 21 pathway or use conditions to registration as a form of conditional approval to expedite access to vaccines. As a result, SAHPRA developed a guideline on enabling availability of medicines for use in a public health emergency (SAHPRA, 2022a). Under the guideline, SAHPRA envisages two scenarios: one in which the unregistered medicine needed has already been authorised or registered for use under comparable circumstances by a national medicine regulator recognised by SAHPRA and a second instance, where no such authorisation exists.

In the first case, a section 21 application would be possible; in the second, a rolling submission of an application for registration — in terms of section 15 of the same legislation — would be required.

In every rolling review, technical appraisal of the evidence is still needed, drawing on the capacity of SAHPRA's multiple committees, which must co-ordinate to consider evidence of quality, efficacy, and safety while also developing an appropriate risk management plan. In the case of the Covid-19 vaccines, a dedicated working group was also created to address the complete set of evidence. The decision-making power, however, remains vested in SAHPRA's chief executive officer and her staff.

Safety monitoring and public reporting in an emergency

Regulatory decisions are based on consideration of the available evidence for product quality, efficacy and safety. In the case of the Covid-19 vaccines, as the Phase 3 trials were powered to deliver a prespecified number of endpoints in terms of laboratory-confirmed infections, the available safety data were limited. The ICMRA and WHO listed the many ways in which this evidence gap could be addressed by regulators, health systems and manufacturers (ICMRA/WHO, 2022). These included:

- reviewing and analysing adverse events reported by healthcare professionals and consumers;
- actively sharing emergent information, among regulators and researchers;
- requiring manufacturers to continue safety surveillance from their ongoing clinical trials; and
- requiring manufacturers to develop and implement risk management plans, in some cases with additional post-authorisation safety studies.

Such requirements could be included as conditions to registration or appended to section 21 approval.

In SA, there has traditionally been a degree of separation between the monitoring of adverse events following immunisation and adverse events associated with the use of other medicines. Although the routine, passive surveillance pharmacovigilance systems did not specifically exclude reporting on vaccine safety, the Expanded Programme on Immunisation gathered reports on adverse events, which were then considered by the National Immunisation Safety Expert Committee (NISEC).

NISEC is specifically enjoined to assess causality, using a standardised method. SAHPRA's pharmacovigilance unit staff contribute to the NISEC process. Although the national Covid-19 vaccination programme was not initially entrusted to the usual advisory structure (the National Advisory Group on Immunisation), NISEC was assigned the task of assessing Covid-19 adverse events following immunisation for causality (NDH, 2021).

Communication about vaccine safety issues was, nonetheless, managed by SAHPRA. A dedicated micro-site which gathered together all Covid-19 adverse events following immunisation materials in an easily accessible format was created (SAHPRA, 2022b). Apart from definitions and explanations of the terms used, the site provided links to various ways in which adverse events following immunisation could be reported. Data on the number of Covid-19 vaccine doses administered were linked with a dedicated Covid-19 NDH website. Graphic representations of aggregated data on the adverse events following immunisation reported were provided, as shown in Figure 2.

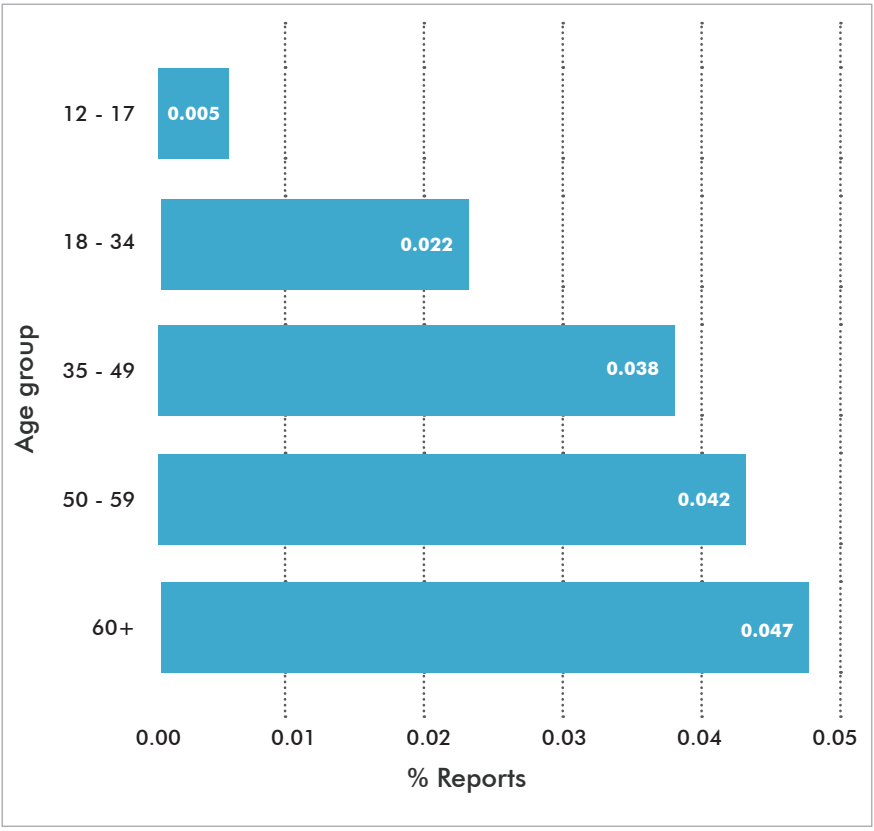


Figure 2: Total number of adverse events following immunisation reports by age group as a percentage of total vaccinations as of 7 March 2023, reproduced from SAHPRA's dedicated website.

By 31 October 2022, a total of 7,009 reports had been received and about 37 million Covid-19 doses had been administered. Data were presented separately for the two vaccines used in the national programme, Pfizer-BioNTech's Comirnaty and Janssen's Covid-19 vaccines, and the 10 most frequently reported adverse events following immunisation were summarised (see Figure 3).

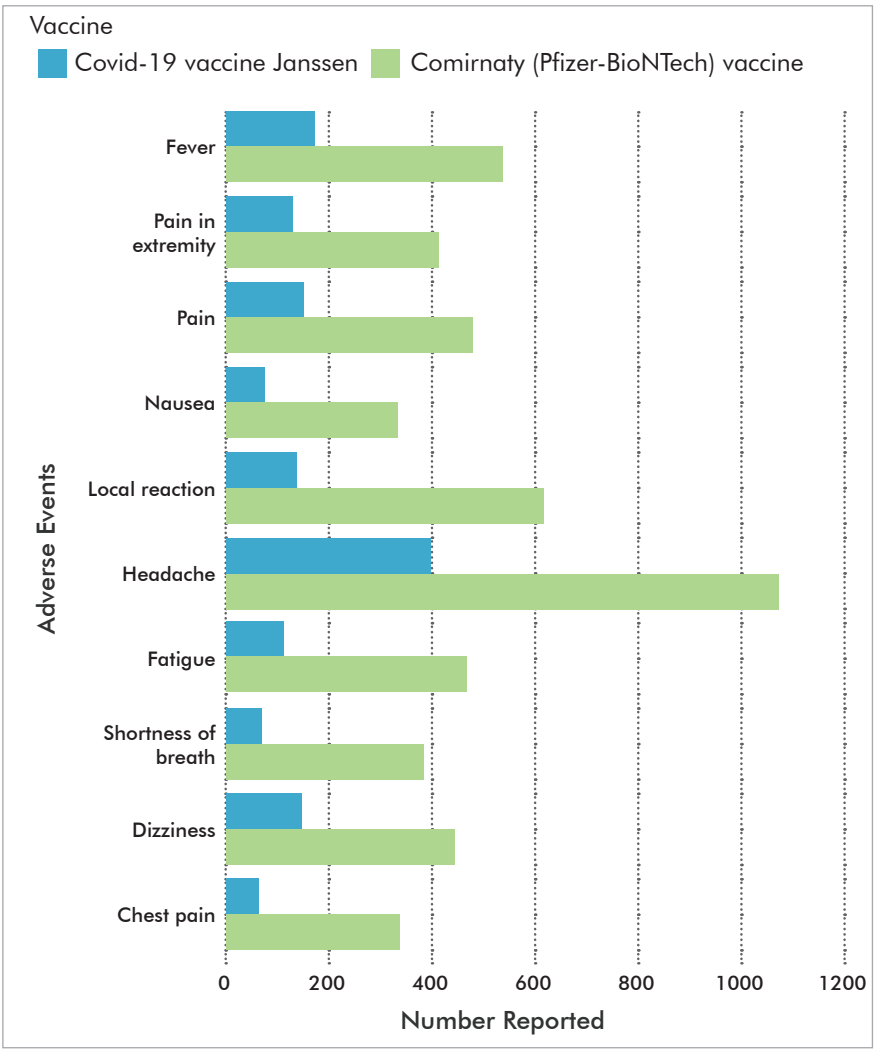


Figure 3: The 10 most frequent adverse events following immunisation reported by vaccine type as of 7 March 2023, reproduced from SAHPRA's reporting website.

Separately, a brief summary of serious adverse events following immunisation was provided, as well as the outcome of causality assessments conducted by NISEC. SAHPRA defines serious adverse events following immunisation, including those that are life-threatening, requiring hospitalisation or prolonging an existing hospitalisation, causing a congenital anomaly or birth defect, and/or that result in death.

By 31 October 2022, SAHPRA and NISEC had received 217 reports of deaths of people who had received Covid-19 vaccines. Of these, 194 had been investigated and causality had been assessed and 38 were under investigation. The outcomes were:

- 30 cases were unclassifiable, as the available information was inadequate;
- 162 cases were assessed as coincidental; and
- 2 cases were causally linked to the use of the vaccine.

The SAHPRA micro-site also provided a description of the causality assessment process.

In addition, SAHPRA issued brief media statements on the two fatal cases of the rare Guillain-Barré Syndrome, in which the immune system attacks a person's nerves, that were reported and causally linked to administration of the Janssen vaccine (SAHPRA, 2022c; SAHPRA, 2022d).

Early in the process, a webinar on vaccine safety was arranged in March 2022, which was addressed by the NISEC chairperson, the chairperson of SAHPRA's pharmacovigilance advisory committee and SAHPRA's pharmacovigilance manager.

In her seminal 2020 book, *Stuck*, American anthropologist and the founding director of the Vaccine Confidence Project, Heidi Larson, notes that "vaccination, from its start, has always walked a tense line between personal choice and public health, between autonomy and cooperation, and those waving the libertarian flag find a welcoming home in broader movements against government control" (Larson, 2020: 22).

"Vaccination campaigns and trials in different corners of the world have been stalled or suspended because individuals and groups feel as if they were not consulted and their views not respected," she

continues. "Immunisation has become a profound test of our ability to cooperate."

Although SAHPRA has expanded access to safety data in an unprecedented way, the extent to which the general public or public interest groups have been engaged, in a meaningful manner, is less evident. Communications have been largely driven by the regulator and health authorities, and ultimately in a unidirectional fashion.

SA's "secrecy clause" and regulatory transparency

In May 2021, the ICMRA and WHO issued a joint statement calling for maximum transparency and data integrity in relation to Covid-19 medicines and vaccines (ICMRA/WHO, 2021). The statement was directed at the pharmaceutical industry: "ICMRA and WHO call on the pharmaceutical industry to provide wide access to clinical data for all new medicines and vaccines (whether full or conditional approval, under emergency use, or rejected)."

However, the statement also included this line: "Regulators are opening their decisions to public scrutiny demonstrating confidence in their work." It was claimed that "the first benefit is public trust".

Despite still labouring under the restrictions of an outdated "secrecy clause" in SA law, SAHPRA did communicate more openly than usual about which applications for registration of Covid-19 vaccines had been received and how the rolling reviews were progressing (Vawda and Gray, 2017; SAHPRA, 2021).

The "secrecy clause" is contained within section 34 of SA's Medicines and Related Substances Act and has been interpreted as prohibiting the sharing of almost all information about deliberations and decisions taken by the SAHPRA — other than the final registration of medicines and vaccines. Advisory committee meetings are closed, their documents marked as confidential, and the advice they offer to the SAHPRA staff is not disclosed.

Meanwhile, other regulators are committed to increasing transparency in relation to their regulatory decisions. Still, unlike more mature regulators — notably the European Medicines Agency and the Australian Therapeutic Goods Administration — SAHPRA does not yet publish public assessment reports, so does not detail

the reasoning behind its regulatory decisions in a publicly accessible format.

The Covid-19 vaccine experience meanwhile has demonstrated SAHPRA's ability to increase transparency, despite the "secrecy clause".

Of note, SAHPRA communicated in detail about its concerns with the safety of the Gamaleya Sputnik V vaccine and the reasons for refusing its section 21 approval. It has also shared more information about Covid-19 serious adverse events following immunisations than it had ever done before for other vaccines or for medicines in general. The data are accessible; however, they are not shared proactively with the public and in ways that are more easily understandable. SAHPRA communications are not exclusively aimed at health professionals, but neither are they deliberately crafted for a lay audience.

At the time of writing, it was unclear whether SAHPRA will be asked to approve adapted or bivalent vaccines, which are specifically aimed at protecting against variants with immune escape mutations. Although such vaccines are now being deployed in high-income settings, no applications for their registration have yet been received as of January 2023, and no indication has been offered by the government that they are considered necessary.

Covid-19 spurred new, more agile regulation and transparency, but will they live on?

Covid-19 vaccines have been a truly critical component of the global response, enabling the development of hybrid immunity which has protected millions of people and enabled a lessening of restrictions. Public health and social measures such as mask-wearing in specific contexts remain important, and ongoing booster vaccination may prove to be necessary.

A commentary in early 2023 in The Lancet proposed that Covid-19 vaccines could exert a positive influence on global disease prevention, by drawing attention to the need for greater use of available adult vaccines (Agus, 2023). There is already some

evidence — from both global and local regulatory practice — that the need for agility, transparency and improved public engagement in relation to Covid-19 vaccines has shaken up entrenched assumptions and processes. SAHPRA has shown that it can interpret its existing statute and mandate in ways that enable flexibility and transparency. The challenge remains to entrench those new ways of working, to resist the effects of entropy and habit. The trend towards greater harmonisation, reliance and co-operative regulatory practice augurs well for the nascent African Medicines Agency, which looks to increase harmonisation and to which SA is seemingly committed.

Andy Gray is a Senior Lecturer in the Division of Pharmacology, Discipline of Pharmaceutical Sciences, University of KwaZulu-Natal. The Discipline is designated as a WHO Collaborating Centre on Pharmaceutical Policy and Evidence-Based Practice. He is also an Honorary Senior Scientist: Consultant Pharmacist for the Centre for the AIDS Programme of Research in SA (CAPRISA) and a Visiting Fellow in the Faculty of Pharmacy, Rhodes University, Makhanda (Grahamstown).

References

Agus DB, Nguyen A, Sall AA and Bell J (2023). Covid-19 and other adult vaccines can drive global disease prevention. *Lancet* 401(10370): 8-9.

Fauci A (2022). The story behind Covid-19 vaccines. *Science* 372(6538): 109.

Gilbert PB, Donis RO, Koup RA, Fong Y, Plotkin SA and Follmann D (2022). A Covid-19 milestone attained - a correlate of protection for vaccines. *New English Journal of Medicine* 387: 2203-2206.

Graham BS (2020). Rapid Covid-19 vaccine development: Finding the fastest pathway to vaccine availability includes the avoidance of safety pitfalls. Science 368(6494): 945-946.

Gray A and Vawda YA (2018). Health legislation and policy. *South African Health Review* 2018(1): 1-11.

International Coalition of Medicines Regulatory Authorities (2020). International regulators align positions on phase 3 Covid-19 vaccine trials. Available at https://icmra.info/drupal/en/news/22june2020_2 (accessed 9 January 2023).

International Coalition of Medicines Regulatory Authorities/World Health Organization (2020). WHO-ICMRA joint statement on the need for improved global regulatory alignment on Covid-19 medicines and vaccines. 6 November 2020. Available at https://www.who.int/news/item/06-11-2020-who-icmra-joint-statement-on-the-need-for-improved-global-regulatory-alignment-on-covid-19-medicines-and-vaccines (accessed 9 January 2023).

International Coalition of Medicines Regulatory Authorities/World Health Organization (2021). Joint Statement on transparency and data integrity - International Coalition of Medicines Regulatory Authorities (ICMRA) and the World Health Organization (WHO). 7 May 2021. Available at https://www.icmra.info/drupal/en/covid-19/joint_statement_on_transparency_and_data_integrity (accessed 9 January 2023).

Larson HJ (2020). Stuck: How vaccine rumors start—and why they don't go away. Oxford University Press, New York.

International Coalition of Medicines Regulatory Authorities/World Health Organization (2022). Statement for healthcare professionals: How Covid-19 vaccines are regulated for safety and effectiveness. 17 May 2022. Available at https://www.icmra.info/drupal/covid-19/icmra_who_vaccines_confidence_statement_for_hcps_2 (accessed 9 January 2023).

Mathieu E, Ritchie H, Rodés-Guirao L, Appel C, Giattino C, Hasell J, Macdonald B, Dattani S, Beltekian D, Ortiz-Ospina, E, Roser Max (2023). Coronavirus Pandemic (Covid-19). Published online at OurWorldInData.org. Available at https://ourworldindata.org/coronavirus (accessed 3 March 2023)

Minister of Health (2017). General regulations issued in terms of the Medicines and Related Substances Act, 1965. Available at https://www.sahpra.org.za/wp-content/uploads/2022/07/General-Regulations-Medicines-and-Related-Substances-Act-25-Aug-2017-Gazetted.pdf (accessed 9 January 2023).

National Department of Health (2021). What is the National Immunisation Safety Expert Committee (NISEC)? 21 December 2021. Available at https://vaccination.sacoronavirus.co.za/support/solutions/articles/101000359858-what-is-the-national-immunisation-safety-expert-committee-nisec- (accessed 9 January 2023).

Republic of South Africa (1965). Medicines and Related Substances Act (Act 101 of 1965), as amended. Available at https://www.sahpra.org.za/wp-content/uploads/2019/09/Medicines-and-Related-Substances-Act_101-of-1965_Act_GG-40869_2017-05-26.pdf (accessed 9 January 2023).

South African Health Products Regulatory Authority (2021). SAHPRA update on vaccine approvals. 21 June 2021. Available at https://www.sahpra.org.za/wp-content/uploads/2021/06/MEDIA-RELEASE-Vaccine-status-V6_21.06.2021-Update.pdf (accessed 9 January 2023).

South African Health Products Regulatory Authority (2021a). Update On The SAHPRA Review Of The Sputnik V Vaccine. 18 October 2021. Available at https://www.sahpra.org.za/wp-content/uploads/2021/10/MEDIA-RELEASE-Sputnik-Vaccine_18Oct-2021.pdf (accessed 9 January 2023).

South African Health Products Regulatory Authority (2022). Annual Report 2021/22. Available at https://www.sahpra.org.za/document/annual-report-2021-2022/ (accessed 9 January 2023).

South African Health Products Regulatory Authority (2022a). Availability of medicines for use in a Public Health Emergency (PHE) (SAHPGL-PEM-01). 1 June 2022. Available at https://www.sahpra.org.za/document/availability-of-medicines-for-use-in-a-public-health-emergency-phe/ (accessed 9 January 2023).

South African Health Products Regulatory Authority (2022b). Adverse events following immunisation (AEFI) for Covid-19 vaccines. Available at https://aefi-reporting.sahpra.org.za/index.html (accessed 9 January 2023).

South African Health Products Regulatory Authority (2022c). Update On Covid-19 Vaccine Janssen – Guillain-Barré Syndrome. 4 August 2022. Available at https://www.sahpra.org.za/wp-content/uploads/2022/08/Media_Release_Covid-19_Vaccine_Janssen_Public_Update_GBS_Causality_04August2022.pdf (accessed 9 January 2023).

South African Health Products Regulatory Authority (2022d). Covid-19 Vaccine Janssen update – Second fatal case of Guillain-Barré Syndrome. 12 September 2022. Available at https://www.sahpra.org.za/wp-content/uploads/2022/09/Media_Release_Covid-19_Vaccine_Janssen_Public_Update_GBS_Causality_12-September-2022.pdf (accessed 9 January 2023).

Vawda YA and Gray A (2017). Transparency in medicines regulatory affairs - reclaiming missed opportunities. *South African Journal of Bioethics and Law* 10(2): 70-74.

World Health Organization (2022). Status of Covid-19 Vaccines within WHO EUL/PQ evaluation process. 8 November 2022. Available at https://extranet.who.int/pqweb/sites/default/files/documents/Status_COVID_VAX_08November2022.pdf (accessed 9 January 2023).

Covid-19 vaccines explained

The Covid-19 pandemic saw the first use of an mRNA vaccine outside of clinical trials. Still, mRNA technology had been years in the making, benefiting from intensive efforts to develop vaccines for HIV, Hepatitis B and respiratory syncytial virus (RSV), for example. Here are the four major types of Covid-19 vaccines.

1. **Whole virus vaccines:** Use either weakened (also called attenuated) or dead viruses that cannot reproduce. These kinds of viruses would not make a person sick, but they do jump-start the body's immune response to provide future protection against a disease. These are the earliest forms of vaccines.

   Some attenuated vaccines may not be recommended for some people with underlying health issues such as HIV or who are on cancer treatment because even a weak virus may cause some illness in people with already compromised immune systems.

2. **Subunit, recombinant, polysaccharide, and conjugate vaccines**: Rely on pieces from viruses, like bits of protein, to trigger an immune response. Often, this is done with the help of adjuvants — substances used to super-charge vaccines and help them work better. Sometimes, these adjuvanted vaccines can cause more swelling or redness in your arm after a jab, or flu-like symptoms than immunisations without this super boost, but these symptoms pass quickly.

   These vaccines can be used on almost everyone who needs them, including people with weakened immune systems and long-term health problems. However, since vaccines contain only a small fragment of the antigen, people usually have to take more than one dose to develop memory cells that last for a long period.

3. **Nucleic acid vaccines:** Use pieces of a virus' genetic material — either DNA or messenger RNA (mRNA) — to give our cells the recipe to produce proteins that look like virus components, but are not. These look-alikes trick our immune system into thinking it is under attack and mounting a defence, leaving it ready to respond when our body meets the real baddies.

   DNA vaccines are largely confined to animal use, but more companies are looking to explore these in humans.

   In the case of mRNA Covid-19 vaccines, these vaccines give a person's cells instructions for how to make the spike protein found on the surface of SARS-CoV-2. After vaccination, cells begin making spike protein pieces and displaying them on cell surfaces, prompting the body to create antibodies. Once these vaccines have passed along these instructions to a cell, the mRNA breaks down and disappears. Still, the antigen-like proteins your cells churn out are enough to prompt an immune response.

   Because mRNA vaccines are in some ways faster to make than traditional vaccines, African countries began to invest in this kind of vaccine development and production during the Covid-19 pandemic.

4. Viral vector vaccines: Use one of several harmless and common viruses like delivery trucks, carrying into cells a genetic code to produce proteins that look like virus components but are not, prompting an immune response.

How are vaccines developed safely?

Before any vaccine reaches a local health centre, it goes through years of testing and re-testing to make sure it works to protect you (also called efficacy), and whether it is safe to use. Then, vaccines must be approved for use by national regulators, bodies of local scientists, and other experts. Many countries also require the WHO to approve vaccines before they roll them out locally, especially if they rely on donors like the vaccine alliance, GAVI or UNICEF to buy them.

Once vaccines are introduced publicly, the work does not stop there. Scientists also conduct further studies to determine how well a vaccine works in the real world, outside of controlled clinical studies. Here, they look at how well it reduces the rates of disease in broader communities once it is introduced.

How do clinical trials work?

Vaccine trials begin in laboratories, where scientists often spend years testing out early versions against diseases without any humans involved. If these tests show promise, vaccines may next be tested in animals like mice, rabbits or monkeys. Each of these steps can involve many different studies as scientists double-check results.

If experimental vaccines are safe and show promise after all these steps, only then do researchers begin to test them in humans as part of clinical trials.

Before any clinical trial can proceed, scientists must submit an ethics proposal to an independent ethics review board. As part of this, researchers must show that studies have been designed to minimise risks to potential participants and that they have put in place every reasonable measure to protect participants from harm. Scientists must show that they have done this before ethics review bodies give their approvals to allow studies to go ahead.

Ethics proposals must also explain why the trial is important and how aspects such as randomisation and participant recruitment will be conducted ethically. Importantly, the review must show that the potential benefit of a clinical trial balances out the risks to participants.

Ethics committees monitor clinical trials after they start and until they finish. Scientists also provide ethics committees with regular reports on safety and side effects, for instance, that allow committees to protect participants' rights and safety.

Clinical trial steps: A ladder of evidence

Clinical trials happen in a series of steps, or phases, to test for safety and how well they work to protect people from infection in a controlled setting — what scientists call "efficacy."

Efficacy is the degree to which a vaccine prevents disease, and possibly also transmission, under ideal and controlled circumstances — comparing a vaccinated group with a placebo group.

Effectiveness, meanwhile, refers to how well a vaccine performs in the real world.

Most vaccine trials regardless of the phase should be designed as randomised controlled clinical trials.

What are randomised controlled clinical trials? In clinical trials, participants are often randomly assigned to different groups, or arms, of a study. When this happens, trials are known as randomised clinical trials, and they are the gold standard in clinical trial research.

Trial participants are randomised to either receive an experimental vaccine or a dummy vaccine, also known as a placebo. When this happens, it means that any characteristic — like a chronic illness — that could potentially influence the study's outcome is randomly and equally distributed among these two groups.

Comparing results from the two groups suggests whether

changes in the test group result from the vaccine or occur by chance. In many trials, no one actively in the trial — not even the research team — knows who gets the vaccine or the placebo. This reduces the chances of treating people differently depending on the study group they are in. When participants, their family members, and staff are all "blind" to the treatment while the study is underway, the study is called a "double-blind, placebo-controlled" clinical trial.

The phases of vaccine clinical trial testing

Phase I: The vaccine is tested among a very small number of healthy people who are at a low risk for the relevant disease. For their protection, people who want to fall pregnant are excluded from studies like these because scientists still are not sure at this stage whether a vaccine might cause complications in pregnant people.

Scientists are not yet looking to test how well the vaccine works to fend off infection. Instead, they are making sure that the vaccine is safe to use**.** Plus, they find out more about how it works in the body.

Phase II: If phase I trials show a vaccine is safe, it moves on to phase II. Here, scientists continue to evaluate an experimental vaccine's safety and whether it works. In particular, scientists will be looking at whether or not the vaccine kick-starts the body into producing what are called "memory cells" as part of the immune system. Also known as B-cells and T-cells, memory cells work against specific germs — and they are relatively long-lived so they "remember" how to fight their enemies for a long time.

In Phase IIa trials, an experimental vaccine is tried among hundreds of people at a natural risk of the disease because they live in areas of the world where the relevant disease is prevalent. Additionally, researchers are also looking to test how many doses a vaccine will need to be effective.

Sometimes Phase II research can also include "proof of

concept" trials. These studies are meant to determine if the vaccine being tested *might* work. Proof of concept studies can be conducted among several hundred to thousands of people, depending on how prevalent the disease is. It is not designed to tell if a particular vaccine works; instead, it helps scientists figure out if they should move forward with testing in bigger groups of people.

Phase III: If a vaccine's safety and potential signs of efficacy have been satisfactory in Phase II studies, it progresses to Phase III trials. Usually conducted among 10,000 or more people, these studies tell us whether an experimental vaccine works. This trial phase also gathers additional information on rare side effects, as the number of people included is in the thousands.

Phase IIIb: This kind of study can occur after a vaccine is considered to be safe and elicits an immune system response, but before it has been registered for use in a country by a national regulator. The goal of Phase IIIb studies is usually to provide additional data to guide the policymaking and launch of a vaccine in a country.

Phase IV: Phase IV studies are done when a drug or vaccine has already been proven safe and effective and approved for use. These studies may track side effects over decades.

Phase IV research can also involve what is called implementation studies. In this instance, they can be used to learn more about how to best use these new tools in real life. Why? Because countries have different healthcare systems and face different levels of disease.

Collecting data on vaccines in the real world can help policymakers decide, for example, whether they can afford to introduce a vaccine or how it should be given (for example, in schools or at clinics).

How long does it take to develop a vaccine?

On average, it can take at least a decade to develop a new vaccine, from the time it is first discovered until it has passed clinical trials and is available to the public.

Many vaccines will never pass all three initial phases of clinical trials.

Still, scientists were able to produce initial Covid-19 vaccines in less than a year — how? Many Covid-19 vaccines relied on long-used, traditional approaches to immunisation. Even mRNA vaccines — which had not been used outside of clinical trials until Covid-19 — had been in the works for at least a decade.

And the world threw everything it had towards developing Covid-19 vaccines.

Scientists and the people who work to oversee trials knew the world was facing an emergency. Countries invested large amounts of public, taxpayer money in finding vaccines to help deal with the crisis. Scientists who were working on other diseases — like HIV, TB or cancer — also shifted to try to discover a Covid-19 vaccine.

They worked together to allow some of these phases of research to run at the same time, but only after vaccines had been shown to be safe. They also put in longer hours to review clinical trial applications faster.

This section has been adapted from Lopez Gonzalez, Laura. Vaccines: A guide for African activists from science to access. African Alliance, 2021. (In publication)

CONTEXT:
Analysis: How well did SAHPRA do?

Originally published:

Catherine Tomlinson "Analysis: How well did SAHPRA do in 2022?" *Spotlight* 13th December 2022

Following the emergence of Covid-19 and the regular mention of the SAHPRA in the news – mostly in relation to what health products have or have not been registered for use against Covid-19 – more people are now familiar with SAHPRA as a national regulatory institution. Yet understanding SAHPRA's exact role and its importance remains tricky, given the expansive scope of products that the institution is responsible for regulating, as well as the broad array of activities that it must carry out to fulfill this role. Professor Helen Rees, chairperson of SAHPRA's board, has found her own way of trying to explain what the regulator does and why it is important. "Whenever I am asked to give the elevator speech about the importance of a health products regulatory authority, the easiest pitch is to ask people if they trust the medicines they buy from a pharmacy or the antibiotic they give to their sick child," says Rees. "If the answers are yes, then the important role of [SAHPRA] is quickly understood."

The processes for ensuring that the medicines used in South Africa are safe and effective are by no means simple. Rather, they involve a complex array of intersecting steps and processes.

To fulfill its mandate for medicines regulation, which is outlined in the Medicines and Related Substances Act, SAHPRA must review safety, efficacy, and quality data for new and generic medicines prior to their market introduction to determine whether they are safe for use in the country and for what conditions. The regulator must determine whether the facilities in which medicines are manufactured and handled are up to scratch and are

consistently able to produce safe medicines that meet quality standards. SAHPRA must also decide whether a medicine can be made available over the counter, or if its use requires a prescription. And once a medicine is on the market, SAHPRA must facilitate and monitor reporting of adverse events. In addition to regulating the use of approved medicines, SAHPRA must take steps to prevent the import and use of unauthorised medicines in the country through, for example, working with the police to seize and destroy unauthorised products.

SAHPRA's mandate appears even more dizzying when one considers that medicines are only one of the many types of products that the institution is responsible for regulating.

In addition to medicines, SAHPRA must ensure the safety and efficacy of biological products (including vaccines), medical devices (which range from medical implants to diagnostics to face masks), cannabis grown and sold for medical use, complementary medicines, and radiation-emitting devices.

SAHPRA's processes and capacity for regulating different types of health products are at different stages of development, with medical device regulation, for example, being introduced in a phased manner, while the scope of complementary medicines that SAHPRA must regulate remains under consideration following a court ruling that an earlier definition of complementary medicines was overly broad.

SAHPRA was established in February 2018 to replace the MCC, which had been in operation since 1967. Since then, the still relatively young institution has made impressive progress in fulfilling its mandate in several areas, though it continues to face challenges in others.

WHO recognition

The most exciting development at SAHPRA in 2022 was the achievement of a maturity level 3 ranking for vaccines regulation from the WHO. The WHO uses a ranking system ranging from one (the lowest) to four (the highest) to rank the maturity and effectiveness of health products regulatory organisations in meeting their mandates to ensure that health products are safe and effective. Following an initial 2021 and subsequent 2022 assessment of SAHPRA by the WHO, the regulator announced in October 2022 that it had received WHO maturity level 3 (ML3) ranking for vaccine regulation and maturity level 4 (ML4) status for vaccine lot release.

Only five health product regulatory authorities on the African continent have received a maturity level 3 designation from the WHO. South Africa and Egypt have received this designation for vaccines regulation, while Ghana, Tanzania, and Nigeria have achieved this status for medicine regulation.

Only South Africa has received a maturity level 4 ranking for lot release, which involves evaluating batches of vaccines before they are released for use in the country. All batches of vaccines used in South Africa must be evaluated at the national control laboratory in Bloemfontein prior to their use.

Achievement of these WHO rankings for vaccine regulation and lot release provides strong reassurance that vaccines used in South Africa are appropriately evaluated, safe, and effective. It also provides a boost for the country's nascent vaccine manufacturing sector.

"If you consider what this means at a global level, is that we are among the best [at vaccine regulation] across the world," says SAHPRA CEO Boitumelo Semete-Makokotlela. "Any vaccines that are manufactured in South Africa, that would have a SAHPRA authorisation [and are] released by our control lab, can therefore stand scrutiny when they're considered for the quality, safety, and efficacy. So, these vaccines can be made available across the world."

Clearing the inherited backlog

Another important development at SAHPRA announced earlier this month was the clearance of the regulatory backlog inherited from the MCC. When SAHPRA took over from the MCC it inherited around 16 000 regulatory applications dating all the way back to 1992.

SAHPRA developed a plan and raised funding for a dedicated budget and staff to clear the inherited backlog. The backlog clearance project was launched in August 2019 and on 2 December 2022, SAHPRA announcedthat the backlog had been fully cleared.

Dr Nicholas Crisp, Deputy DG for National Health Insurance at the Department of Health called clearance of the backlog "a milestone for SAHPRA", while Stavros Nicolaou, chairperson of the Pharmaceutical Task Group (PTG) said that the PTG "welcomes this development and congratulates the SAHPRA Board and management in achieving the significant clearing of the registration backlog that has historically hampered the MCC".

Reducing decision times

SAHPRA has explained that the regulator has introduced new strategies and approaches both to clear the backlog of applications inherited from the MCC and to speed decision-making on new applications made to SAHPRA. These strategies include introducing 'reliance pathways' that allow SAHPRA to use evaluatory materials and decisions from other regulatory authorities in its own decision-making processes.

"We enter into agreements for information sharing [with other regulators] and we cooperate in making regulatory decisions," explains Kuda Kapfumvuti, senior manager of Health Products Authorisation at SAHPRA. He says this allows SAHPRA to "rely on prior decisions that have been taken by well-resourced and mature regulators… [and] focus our efforts only on issues that are specific to circumstances in the country."

In addition to developing the relevant guidelines and entering agreements to enable SAHPRA to draw on the efforts of other regulators, SAHPRA has also introduced rolling reviews to allow the regulator to review data as it becomes available (as done for Covid-19 vaccines) and piloted engagement meetings with applicants prior to reviewing applications to reduce the need for back and forth during the application process.

SAHPRA has pinpointed incomplete applications that require back-and-forth engagement with applicants, and delays in receiving unredacted information from other regulators as key culprits behind delays in regulatory decisions.

Processing new applications

According to data supplied by SAHPRA on request from Spotlight, in its first four years of operations (February 2018 to February 2022), SAHPRA received 173 applications for registration of new chemical entities (NCEs), 79 applications for registration of new biological entities (NBEs), and 2 428 applications for registration of generic products. (Note: SAHPRA clarified that these numbers are similar to, though not exactly the same as, figures reported for the 2021/22 financial year in its most recent annual report, as the figures reported in a financial year include applications received in the reporting year, as well as pending applications from previous financial years).

A total of 55% (95) of the 173 applications for registration of NCEs have been registered, according

to SAHPRA. Only one of the 173 regulatory applications received for NCEs since February 2018 has been pending a regulatory decision for longer than 590 working days – SAHPRA's targeted decision-making time for NCE registration applications.

Of the 79 applications for registration of NBEs (including vaccines) received, 59% (47) have been registered. Turnaround time for regulatory applications for Covid-19 vaccines has been particularly impressive. "SAHPRA reduced the time taken to register Covid-19 vaccines to less than three months, where the required standard of data is available."

Of the 2 428 applications received for registration of generic products, 25% (608) have been registered. 51% (1 236) of the applications for registration of generic products received since February 2018 have been pending a regulatory decision for longer than 250 working days –SAHPRA's targeted turnaround time for registration of generic products.

These data show that while the new regulator has been able to keep pace with applications received for NCEs, a concerning new backlog of generic medicine applications has already developed. This backlog may delay market entry for certain generic medicines, thereby contributing to reduced competition and higher prices.

Funding shortfalls

The regulator has repeatedly highlighted funding shortages as a key challenge to fulfilling its mandate. Semete-Makokotlela told Members of Parliament in October 2022 that "while we were able to achieve what we have, it's been a very challenging period for us from a financial perspective… we are in a country with a very tight fiscus and whilst that is the case, I think it is important that the regulator is adequately capacitated."

SAHPRA has seen its allocation from Treasury decline in recent years. SAHPRA's funding from Treasury fell from R183 million in the 2019/20 financial year to R146 million in 2021/22. SAHPRA has been able to offset some of these losses by generating more fee income. Fee-generated income rose from R54 million in the 2019/20 financial year to R181 million in 2021/22.

In October, SAHPRA's CFO, Regardt Gouws, told Parliamentarians that the 2021/22 financial year marked the first year that SAHPRA's income raised through fees exceeded

government grants. This year, SAHPRA also received its first unqualified audit – reflecting the regulator's strengthened financial management and reporting systems.

While the increase in fee revenue is a step in the right direction to ensuring that the regulator is properly financed, adequate government financing remains critical to ensuring that the regulator can carry out its mandate without undue influence from fee-paying companies.

Staff shortages

Funding shortfalls at the regulator have contributed to staffing shortages. SAHPRA told MPs in Parliament in October that more staff are needed for digitisation, quality management, regulatory inspections, and pharmacovigilance.

"The MHRA [Medical and Healthcare Products Regulatory Agency] in the UK, the size of the team they have in the area of pharmacovigilance, is about 60 individuals. At SAHPRA, we only have five individuals in this area, and we know that the reports that we receive in terms of numbers are quite comparable. So, we are severely understaffed in this area," said Semete-Makokotlela.

According to SAHPRA's 2021/22 annual report, only 265 out of 375 positions at SAHPRA are filled. Gouws explained to Parliament that 95 positions at SAHPRA remain unfunded and that filling these positions would require an additional R67 million in annual funding.

In response to questions from Spotlight, SAHPRA indicated that progress has been made since the October presentation to Parliament and that only 25 positions now remain unfunded.

SAHPRA indicated that funding has been secured to fill previously unfunded positions through fee-generated income, from the Global Fund (via the Department of Health), and through securing approval from National Treasury to run on a budget deficit based on prior accumulated revenue surpluses.

SAHPRA also told Spotlight that funding has been secured from Germany's development agency (GiZ GmBH) and the UK Department of International Trade to support its planned digitisation efforts and that additional funding proposals for these efforts were going out.

Withstanding political pressure

A key function of any health products regulator is to maintain its independence

and ensure that its decisions are evidence- and science-based and made purely in the public interest. In its first few years, SAHPRA's leadership team has experienced a crash course in how to handle political pressure with the regulator facing intense pressure, protests, and even legal challenges related to the regulation of health products for Covid-19, as well as the introduction of regulatory processes for complementary medicines.

SAHPRA appears to be faring well in ensuring that its decision-making processes remain independent and are not influenced by outside interests or pressure. Where needed, they have defended their decisions in court. Yet, public trust in its regulatory decision-making processes and outcomes may have eroded given the ongoing demand for ivermectin and vaccine reluctance in the country, which is at odds with Covid-19 communications and recommendations from SAHPRA.

What is next?

SAHPRA has made significant strides toward strengthening its capacity and fulfilling its mandate over the past year. In 2022, SAHPRA received its first unqualified audit, cleared the backlog of regulatory applications inherited from the MCC, and received strong validation of its effectiveness in regulating vaccines from the WHO.

Further, over the past few years, the regulator has been agile in its response to Covid-19 – developing new processes to regulate relevant products and reducing decision-making times.

Yet, much remains to be done by the regulator to address areas for which regulatory systems must still be developed and strengthened, including complementary products and medical devices and addressing its organisational weaknesses (that is, lacking digital systems and skills).

SAHPRA has also become more transparent and improved its communications in recent years, most notably with a searchable database of registered products, but here too there remains some way to go, especially on the reasoning and evidence behind regulatory decisions.

SAHPRA has highlighted plans to further strengthen the organisation's capacity over the next year by focusing on digitisation and recruiting more staff. SAHPRA has also said that a process is underway to review the Medicines and Related Substances Act to assess whether legislative reform is needed to address ambiguities and align the Act with the current context and needs.

Negotiating Pandemic Preparedness, Response and Recovery in a hierarchical global system

Lauren Paremoer

The Covid-19 pandemic has exposed the life-and-death consequences of the hierarchies that characterise the contemporary multilateral system, prompting what has been seen by many as a need for a new international pandemic treaty. In December 2021, the WHO's main governing body, the World Health Assembly (WHA), established an intergovernmental negotiating body to draft and negotiate a new treaty to strengthen pandemic prevention, preparedness and response. The WHO's intergovernmental negotiating body presented a preliminary conceptual draft of the treaty in December 2022 at the intergovernmental negotiating body's (INB) third meeting (INB3). Known as the Conceptual Zero Draft, the version provided the first steps towards an eventual initial draft of the treaty.

To be effective, any new international agreement promoting pandemic preparedness, response, and recovery (PPRR) must institutionalise measures to overcome these hierarchies. This chapter focuses on December 2022 discussions surrounding the Conceptual Zero Draft of the new pandemic treaty undertaken at the

INB3 (WHO, 2022). Specifically, this chapter unpacks developing countries' comments that provide insights into the forms of international cooperation they consider essential for building a fair and equitable PPRR framework. These include:

1. greater reliance on legally binding mechanisms to ensure co-ordinated cooperation for PPRR;
2. guaranteeing the WHO's role as the lead co-ordinating body in international health emergencies;
3. building research and development, production and regulatory capacities for pandemic response products in low and middle-income countries;
4. increasing states' power to regulate the practices of pharmaceutical corporations during pandemics; and
5. promoting functional people and worker-centred public health systems.

Lessons from previous pandemics

The Covid-19 pandemic highlighted long-standing shortcomings of existing PPRR measures. During the early years of the HIV pandemic, for example, equal access to antiretroviral treatment was made impossible by the high prices of patented antiretrovirals and the lack of generic alternatives. This was a direct consequence of the TRIPS Agreement of 1995. As discussed before, the TRIPS Agreement grants inventors intellectual property rights over their innovations for a period of 20 years. During this period, they have exclusive control over who may manufacture their new technologies, which markets they should be sold in, and at what price. TRIPS has been justified on the grounds that it promotes innovation because it allows inventors to recover their research and development costs. However, a growing body of literature suggests that it has done little to promote innovation, technology transfer, and access to new medicines in developing countries (Thambisetty et al., 2021).

Another lesson from previous pandemics was that developed states tended to prioritise national health security at the expense

of international cooperation. The response to the 2014 West African Ebola outbreak largely in Liberia, Guinea, and Sierra Leone demonstrated that international solidarity only became a political priority to high-income countries when the outbreak directly threatened their populations through imported cases of the virus (DuBois et al., 2015). The outbreak also indicated that developed countries' governments and non-governmental organisations (NGOs) tended to dominate pandemic response decision-making processes, with national government representatives and even the WHO being marginalised within these processes.

This dynamic is repeating itself in the context of the Covid-19 pandemic. Developed countries have been guilty of vaccine nationalism, hoarding more Covid-19 vaccines for their populations than they could ever use (Dyer, 2020). The voices of developed countries' NGOs and philanthropic foundations have dominated multi-stakeholder initiatives such as COVAX, a global initiative that aimed (and ultimately failed) to provide more equitable access to Covid-19 vaccines and, in particular, guarantee the poorest countries access to enough immunisations to vaccinate the most vulnerable.

Even though developing countries' governments and the WHO are subject to oversight — and the WHO is mandated to take a leadership role in co-ordinating international health governance — they were marginalised within multi-stakeholder initiatives such as COVAX that were meant to respond to the pandemic (Gleckman, 2022). In doing so, developed countries have neglected their obligations under Article 44 of the International Health Regulations (IHR). This chapter calls on countries to collaborate on technical cooperation and logistical support during outbreaks declared by the WHO to be Public Health Emergency of International Concern (PHEIC), and to support legal proposals and regulations to address these outbreaks at home and abroad. These regulations were amended in 2005, after the 2002 outbreak of the severe acute respiratory syndrome (SARS) demonstrated the international community's failure to engage in co-ordinated international cooperation in response to the outbreak. Despite this, countries did no better on this count during the Ebola outbreak roughly a decade later.

Both the HIV and Ebola outbreaks showed the importance of

health systems strengthening as a baseline condition for launching effective PPRR interventions. Unfortunately, subsequent efforts to obtain this goal have led to reforms that introduce new distortions and sources of vulnerability into developing countries' health systems that undermined their Covid-19 responses. For example, after the 2002 SARS outbreak, the WHO proposed universal health coverage as an approach to strengthening health systems and promoting "individual health security" (WHO, 2007). For the WHO, "[f]inancial protection is at the core" of universal health coverage (WHO, no date).

In other words, the WHO's approach to universal health coverage focuses on ensuring individuals and households are protected against financial catastrophe when they have to pay for health services. The WHO is, however, agnostic about whether those services are provided by the public or private sector, as long as they are free or affordable at the point of care (Sanders et al., 2019). As a result, the shift to universal health coverage has not reversed the commercialisation and privatisation of healthcare services, which have contributed to the deterioration of the public health sector in developing states (WHO, 2007).

Finally, the HIV pandemic led to the employment of community health workers as a mechanism to strengthen developing countries' health systems, particularly their abilities to deliver routine care to marginalised populations. During the Ebola outbreak of 2014, community health workers were crucial in convincing communities to follow prevention and treatment protocols (Ballard et al., 2022).

And, during the Covid-19 pandemic, community health workers were charged with supporting Covid-19 prevention education, contract tracing, and vaccine uptake efforts in many developing states (Ballard et al., 2022). The incorporation of community health workers has strengthened developing countries' ability to deliver health services. Sadly, this has come at the expense of creating an exploited workforce — mostly consisting of women and ethnic or racial minorities — who experience low and irregular pay, poor job security, dangerous working conditions, and a lack of support and respect by more elite health workers. In the next section I discuss how some of these long-standing lessons on PPRR were revisited

during the INB3 in December 2022 through proposals by developing countries aimed at ensuring any new pandemic treaty explicitly addresses these issues and through legally binding measures.

Covid-19 and what pandemic preparedness means now

Rethinking the idea of an emergency

What does PPRR mean when conceptualised from the perspective of people forced to "maintain life and a degree of self-respect" in "the underbelly of economies that cannot, or will not, provide reasonably for the population" (Chabal, 2009: 128) PPRR discussions at the global level tend to frame the experiences of disaster, crisis and risk associated with pandemics as extraordinary events. This is understandable: outbreaks of rare or new diseases like Covid-19, SARS, and Ebola have catastrophic consequences in terms of loss of life, long-term disability, and economic hardship for households and national economies. Additionally, the early phases of these pandemics were characterised by a lack of specialised tests and treatments, thereby heightening their sense of exceptionality. However, it is also true that these emergencies occur alongside the overlapping "slow catastrophes" of "grinding poverty, food insecurity and hunger, everyday violence and climate shocks" (Robins, 2020). Similarly, pandemics occur alongside pre-existing economic inequality, social oppression and ecological destruction (Andrews, 2021). These crises are understood as "neither spectacular nor instantaneous, but rather incremental and accretive" (Nixon in Shepherd, 2019: 2). Their negative effects are most acutely felt by marginalised social groups such as impoverished people, racial minorities, migrants, and women (Paremoer et al., 2021).

These slow catastrophes have been driven by the increased privatisation and commercialisation of basic services over the past three decades, which have been associated with poorer health outcomes in developing and developed states (Viva Salud, 2019). A fuller conception of PPRR involves taking these slow catastrophes and their causal drivers seriously to ensure that dismantling them forms part of PPRR efforts. Finding ways to rebuild public institutions that protect and promote social rights, including the

right to health, should be a foundational feature of any new PPRR instrument. Without this, seemingly straightforward, common-sense advice about how to survive pandemics like Covid-19 becomes wildly impractical for impoverished individuals in both developed and developing states.

For example, common-sense advice like going to a hospital when a Covid-19 infection causes difficulty in breathing is near-impossible in countries where decades of under-investment in public hospitals leave people without free transport to medical facilities, and where facilities do not have the infrastructure and budgets to provide sufficient beds and oxygen. Where vaccines were available and provided for free, uptake is undermined by the everyday manifestations of slow catastrophes such as fear of authorities amongst marginalised communities such as racial minorities and migrants (Njoku et al., 2021), lack of required documentation to register for vaccination or to be residing in a particular country (Matlin et al., 2022), and workers' inability to take leave (Matahari Global Solutions, 2022).

How do these everyday struggles relate to the global governance measures being developed in the name of "better" PPRR for future pandemics? Interventions by WHO Member States during INB3 serve as reference points for how "health systems strengthening" might be translated into concrete policies that do the work required to address slow catastrophes.

For example, financing provisions in the Conceptual Zero Draft of the new pandemic treaty includes calls for strengthening domestic financing for PPRR as well as making funds rapidly available for countries, in part through new or established international mechanisms, for instance.

Uganda astutely observed that these provisions are incomplete without references to debt relief (Intervention by Uganda, 2022).

> We propose that measures to initiate debt relief mechanisms to developing countries with active disease outbreaks [for] purposes of epidemic response [be included]. Number two: measures to restrict payment of existing

> national debt for a time bound period for developing countries with active epidemic events. Number three: measures to ensure that commercial banks have mechanisms to relieve or restructure their debt payments for citizens in time-bound periods in the event of an epidemic or pandemic …

Uganda's intervention clearly acknowledges the strain debt servicing requirements have placed on health budgets during "normal" years, and the reality that the Covid-19 pandemic has forced developing countries to take on additional debts in order to keep their populations alive (Dentico et al., 2022). Similarly, Bangladesh highlighted that "fiscal space for developing countries would be important to increase domestic financing" for health systems (Intervention by Bangladesh, 2022). "Fiscal space" is a term used by the International Monetary Fund (IMF) to refer to the amount of money a government can spend on a specific policy priority like healthcare, without undermining the stability of the entire economy. The term is also repeated in WHO publications.

In referring to it during discussions of the pandemic treaty's Conceptual Zero Draft, Bangladesh effectively pushed back against the austerity measures, that is, budget cuts on social spending, that many developing states are being forced to adopt by the IMF in the name of speeding up their economic recovery from the pandemic.

In sections of the Draft dedicated to "health systems strengthening", it suggests measures such as improving disease surveillance, increasing access to related technology and safeguarding other essential healthcare services during outbreaks.

The Africa group, Colombia and Nigeria all cautioned against conflating health systems strengthening with measures narrowly focused on PPRR like surveillance and related data dissemination systems, with Nigeria pointing out that developing countries would need external financial support to achieve health systems strengthening. Mozambique warned against adopting vertical approaches to health systems strengthening that "in the long run … induce weak coordination … hampering the capability of

health systems to respond to health challenges, and also drives to duplication of efforts and resource ineffectiveness" (Intervention by Mozambique, 2022). Member States pointed to the importance of employing enough health workers and providing them with good quality wages and conditions of employment. Addressing the maldistribution of health workers globally, Botswana requested that the 2010 WHO Global Code of Practice on the International Recruitment of Health Personnel be explicitly captured in the pandemic treaty's Conceptual Zero Draft (Intervention by Botswana, 2022). This would represent a modest first step towards exposing the benefits that high-income country health systems reap from employing health workers trained with public funds in low and middle-income countries. This practice by high-income countries exacerbates shortages of personnel in these states, thus making them less capable of developing the PPRR capabilities.

Building medical manufacturing capabilities in low and middle-income countries

During the Covid-19 pandemic, developed countries benefited from their status as pharmaceutical manufacturing mRNA Hubs. These governments could shape the research and development, and manufacturing scale-up efforts of corporations like Pfizer and Moderna through massive public subsidies (Rizvi, 2022). This helped to ensure that these countries would be the first in line to receive vaccines for their populations. The lack of pharmaceutical manufacturing capabilities in many developing states meant this type of policy intervention was not available to them. In response to this kind of vaccine nationalism, the best some low and middle-income countries could do was offer to participate in clinical trials as one way of obtaining early access to vaccines for some of their populations. However, participation in vaccine trials did not secure developing countries access to broader benefits like preferential pricing, timely procurement deals or technology transfer. In fact, developing countries' manufacturers that had the capability to produce viral vector Covid-19 vaccines were prevented from doing so as companies who held the intellectual property rights to these vaccines refused to issue timely voluntary licences to developing

countries' producers. The Serum Institute of India was one of the very few developing countries' producers that early on received a voluntary licence to produce just one Covid-19 vaccine.

In the case of mRNA vaccines, developing countries' producers had to contend with spurious arguments that this technology was too complex for them to produce, despite research by MSF identifying more than 100 companies in Africa, Asia and Latin America whose existing facilities could have been retrofitted to manufacture mRNA vaccines within a matter of months following a "full and transparent transfer of vaccine know-how". The success of the WHO's mRNA Technology Transfer Hub in producing its own mRNA Covid-19 vaccine within seven months of its establishment suggests that a co-ordinated international effort to promote technology transfer could, by now, have contributed to expanding mRNA vaccine manufacturing capabilities in developing countries (Maxmen, 2022). In light of this, it is understandable that many developing countries are insisting that concrete and legally binding measures to support technology transfer be included in any new pandemic instrument. Many developing countries' interventions at INB3 showed support for provisions in the pandemic treaty's Conceptual Zero Draft that could alter the balance of power between pharmaceutical companies and states. These include proposals to ensure corporations assume part of the liability associated with bringing pandemic response products to the market while they are still in the research phase, sharing information about the results of publicly and government-funded research and development efforts, sharing regulatory dossiers, and compelling companies to disclose the prices and contractual terms of public procurement contracts (WHO, 2022: 16-18). These measures would significantly increase ease of access to information required by developing countries to build their local manufacturing capacities, and to assess whether corporations are charging extortionate prices for pandemic response products.

The INB3 negotiations also offer an opportunity to negotiate legally binding mechanisms that limit the TRIPS agreement's relevance during pandemics. The Conceptual Draft Zero includes four different proposed formulations of its paragraph 38 aimed

at "recognising" the ways in which TRIPS impedes technology transfer and building new manufacturing capabilities for pandemic response products.

The first three of these proposed versions all argue that intellectual property rights are "important for the development of new medical products" while recognising concerns about their negative impact on medicines prices and equitable access. They are not expressly coupled with an acknowledgement that these effects of the TRIPS regime violate the rights to health and to enjoy the benefits of scientific progress and its applications, as codified in the ICESCR (ICESCR, 1967). Most countries in the world are signatories to the covenant and have a legal obligation to protect and promote these rights. The fourth and final proposed formulation of paragraph 38 in the draft is the only one that explicitly recognises "concerns that intellectual property on life-saving medical technologies continue to pose [a] threat and barriers to the full realisation of the right to health and to scientific progress for all" (WHO, 2022). Article 7 of the Conceptual Draft Zero, which discusses, "promoting sustainable and equitably distributed production and transfer of technology and know-how" is also drafted in a manner that remains ambivalent about whether countries should institutionalise voluntary or legally binding multilateral mechanisms "that promote and provide relevant transfer of technology and know-how in a manner consistent with international legal frameworks, to potential manufacturers in developing countries/all regions to increase and strengthen regional and global manufacturing capacity".

Despite the failure of voluntary measures during the Covid-19 pandemic and previous pandemics (Paremoer, 2022), many high-income countries have used the INB3 to emphasise their support for voluntary international co-ordination and cooperation during health emergencies. The US for example "reiterate[d] that any references to technology transfer in the document must be clear that such transfer should always be voluntary and occur on mutually agreed terms consistent with past WHO agreed language" (Intervention by the United States, 2022). The EU echoed the US's position, saying:

> [I]ssues related to technology diffusion and transfer as well as manufacturing capacities will be important to improve PPR… At the same time, we think that technology transfer should be conducted on a voluntary basis. We also believe the World Trade Organization and World Intellectual Property Organization are the most appropriate for a for international rule making on intellectual property rights. In the framework of the INB we remain open to discuss how the cooperation between WHO, World Trade Organization and World Intellectual Property Organization can be strengthened when it comes to health-related matters.
>
> (Intervention by the EU, 2022).

Framing the relationship between the WHO, WTO and World Intellectual Property Organization (WIPO) as one amenable to cooperation — as this intervention does — obscures the fact that WHO's mandate to promote the realisation of the highest attainable standard of health for all is diametrically opposed with WTO's and WIPO's mandates to protect property rights and for-profit markets. As Bangladesh highlighted during INB3, in the "case of cross cutting issues involving the WTO, WIPO or other institutions" any new pandemic instrument "needs to clarify whose institutions and provisions would be triggered during [a Public Health Emergency of International Concern] and pandemic, otherwise we shall see people dying while we are at negotiations" (Intervention by Bangladesh, 2022).

That said, the Covid-19 pandemic suggests that unless the WHO is explicitly mandated to take a leading role in co-ordinating access to pandemic response products — including by offering support for the production of generic versions of patented products — other institutions will step into this space. If the WTO does so, it is likely to prioritise the defending conservative interpretations of the

TRIPS Agreement rather than suspending these rules to promote equitable access to life-saving medical technologies, as the WTO did in response to the failed TRIPS waiver request that would have temporarily waived some intellectual property protections on Covid-19 tools that countries needed to implement pandemic response programmes.

Fair and equitable benefit sharing

Developing countries have strongly resisted the idea that any new pandemic instrument should legitimate PPRR efforts organised around nebulous notions of voluntary cooperation or "sharing" information in the interest of securing rapid access to pandemic response products. The controversy generated by the Conceptual Zero Draft's demand for "early, safe, transparent and rapid sharing of samples and genetic sequence data of pathogens, as well as the fair and equitable sharing of benefits arising therefrom" (WHO, 2022) provides a good example of this. This debate revolves around whether countries that share samples of pathogens or their genetic sequences should be entitled to demand that they be given fair and equitable access to any benefits (for example, vaccines or treatments) that recipients derive from this. An international treaty known as the 2010 Nagoya Protocol of the Convention on Biodiversity sets out a legally binding framework to govern access and benefits sharing and many developing states are calling for these principles to be applied to pathogens and their genomic sequencing data.

For example, during the INB3's discussion of the draft in December 2022, Namibia called for "guard[ing] against final outcomes… where access to pathogens and genetic sequencing data is prioritised without a clear and comprehensive benefit sharing mechanism" (Intervention by Namibia, 2022). The country went further, arguing that it did not want the relevant article in the draft "to be interpreted as an aspiration on access and benefit sharing to be achieved in the distant future".

Following this, Namibia supported Indonesia's call for an annex on access and benefit sharing to be added to the instrument.

Several countries, including Egypt and Botswana explicitly called for access and benefit sharing to be treated in a manner consistent with the Nagoya Protocol of the Convention on Biodiversity. For instance, Botswana proposed that "access and benefit sharing should be a legally binding multilateral mechanism negotiated as part of the instrument". Kenya joined the chorus, saying: "We take this opportunity to underscore that sovereign rights, prior informed consent and benefit sharing are established principles that cannot be undermined in the text" (Intervention by Kenya, 2022).

Bangladesh argued that benefit sharing should not be reduced to accessing final products, for example, but should be conceived of in more robust terms (Intervention by Bangladesh, 2022). Bangladesh stated that "under [the] aegis of access and benefit sharing mechanisms it would be important to create a space for WHO to receive technology and know-how with a right to use them in designated manufacturing facilities during a [Public Health Emergency of International Concern] and pandemics". The South Asian country similarly argued for greater benefit sharing around genetic sequencing information:

> In the whole process of sharing research and use of [genetic sequencing information] we would ask for the source entities the right to access information, research and its commercial use. It would be important to facilitate participation of the professionals of the source countries in research and manufacturing processes as a part of training and capacity building.

The Russian Federation pointed out the importance of defining and contextualising terms such as "benefits" or "research ecosystems", and to whom they were addressed, for instance (Intervention by the Russian Federation, 2022). However, unlike the aforementioned interventions, the Russian Federation insisted that "the requirements under a centralised system should be voluntary and not legally binding".

Developed countries with large pharmaceutical sectors shared this aversion to legal provisions that would make access to pathogens and their genetic sequencing information dependent on benefit sharing. Their interventions echo the position of the industry association, the International Federation of Pharmaceutical Manufacturers and Associations (Cueni, 2021) that legally mandated benefit sharing would amount to a form of "pathogen protectionism" that would impede access to medical countermeasures for PPRR. Switzerland, for example, argued that the "sharing of pathogens has to be a priority; this allows us to develop very quickly medical products that helps during outbreaks… we should find [access and benefit sharing] solutions that are not tied to each other, otherwise we would slow down access" (Intervention by Switzerland, 2022). However, as the Covid-19 pandemic has shown, the speedy and efficient development of pandemic response measures means little when those products are unavailable due to limited supplies or are unaffordable because of excessive pricing.

Rethinking the social organisation of care

The "social organisation of care" refers to how "care needs are met by the interaction between households, the state, the market and community organisations" (Rodríguez Enríquez and Farga, 2021). The INB process to develop a pandemic treaty must reflect on how to institutionalise PPRR interventions that depend less on the people — largely women and girls — who provide free care work within their households during health emergencies, effectively subsidising the state. This free labour is an important source of the "resilience" that health systems exhibited during the Covid-19 pandemic. The persistent silence about the unequal and gendered organisation of social care work in PPRR discussions suggests that this extractivist orientation to women's care labour is seen as unproblematic. This has the unfortunate effect of normalising the gendered division of care work, including during pandemics that expose caregivers to heightened risks of infection and death. Unless this is addressed, women offering both professionalised medical care and invisible, unpaid care within households will be forced to act as the "shock absorbers" (Fakier and Cock, 2009) of

health emergencies, particularly in developing states, and at great cost to their economic security and health.

During the Covid-19 pandemic, governments across the world experimented with temporary measures aimed at increasing households' access to publicly provided or subsidised care services. These included public facilities where people with Covid-19 could isolate, food distribution schemes, temporary cash transfers to vulnerable groups, universal basic income measures, and anti-eviction measures (Rodríguez Enríquez and Farga, 2021). A "whole of government and whole of society" approach to PPRR includes converting these temporary measures into permanent institutions in order to "break the cycle of 'panic and neglect'" associated with health emergencies (WHO, 2022,). However, without ensuring that the "communities" referred to in the Conceptual Zero Draft have the basic resources they need to live well, the principles of "gender equality" and "full engagement by communities" endorsed by the Conceptual Zero Draft are likely to be symbolic at best.

For example, the Conceptual Zero Draft's call to mobilise "social capital in communities for mutual support, especially to persons in vulnerable situations" (Art.15(2)(c)) may seem innocuous. In practice this is a tough ask: In the absence of public welfare measures, impoverished communities have long been forced to rely on mutual aid practices to manage the slow catastrophes of daily life outlined above. This is a coping mechanism, aimed at "deriv[ing] maximal outcomes from a minimal set of elements" (Simone, 2004). Asking communities to double down on such coping mechanisms by mobilising whatever "spare" social capital they have during health emergencies runs the risk of developing a framework that prioritises what governments and transnational corporations need to survive pandemics over the needs of communities.

As Rodríguez Enríquez and Farga point out:

> [o]ne of the lessons from this period is that, contrary to the dominant narrative, governments can actively implement public policies and allocate budgetary resources. In other words, the recovery of the essential role of the State in attending to the care

> needs of the population and exercising a leadership role in the social organisation of care seems to be possible when there is political will (Rodríguez Enríquez and Farga, 2021).

Additionally, without concerted efforts to build the resource base and political power of communities as part of pandemic preparedness, communities will not be able to effectively participate in national decision-making processes or co-ordinating mechanisms that involve vastly more powerful actors from government and the private sector (WHO, 2022). The same will be true at the global level. The Conceptual Zero Draft includes a proposal that the governing body of a new pandemic treaty could include non-state actors, including the private sector, in decision-making processes. This risks giving representatives of commercial interests the power to influence how future PPRR efforts are governed, despite the lack of solidarity these entities have shown during the Covid-19 pandemic.

Conclusion

In this chapter I have spotlighted the contributions made by developing WHO Member States during December 2022 INB3 discussions over the Conceptual Zero Draft of a proposed pandemic treaty that are aimed at creating a fairer and more equitable PPRR regime. These nations' contributions are informed by their own domestic experiences with managing PPRR. For developing states, these experiences have clearly been defined by their treatment as second-class citizens of the global community. It is for this reason that the term "vaccine apartheid" has been so apt to characterise the racialised inequalities that have defined unequal access to Covid-19 technologies. In contrast, developed countries' interventions at INB3 convey the confidence of countries expecting to retain their position of dominance in controlling the terms on which access to information, financial resources, and medical infrastructures is governed between and during pandemics.

As health activists, we are often critical of the lack of leadership

our governments in the Global South display in global governance processes. They have been criticised for paying lip service to the Alma Ata agenda of "health for all" but ultimately failing to propose bold alternatives that advance this agenda in practical terms. Additionally, their participation in WHO processes has been described as largely symbolic, given WHO's declining authority and fiscal autonomy *vis-à-vis* donors, super public-private partnerships and powerful countries within the international system (Storeng et al., 2021). This has contributed to reducing WHO's authority as the lead agency in global governance for health. The Covid-19 pandemic unfortunately revealed the lethal consequences of these hierarchies in the global political economy.

Nevertheless, I would like to end on a hopeful note by arguing that the interventions by low and middle-income countries at INB3 offer a ray of hope that the ongoing discussions about PPRR will serve as an entry point for institutionalising systemic reforms that could destabilise these trends. The discussion above shows that the Covid-19 pandemic did not necessarily present the world with new lessons about how the hierarchies that characterise the global system hamper international cooperation during times of crisis. What is new, perhaps, is the opportunity the pandemic has offered to move from a model of voluntary cooperation to one specifying concrete and legally binding measures that prevent more powerful states from ignoring the principle of common but differentiated responsibilities and commit them to reforms that expand and deepen developing states' capabilities to promote the health of their populations.

Dr Lauren Paremoer is a member of People's Health Movement SA and the representative of the Democratising Global Health Governance Programme on the Global Steering Council of People's Health Movement. She is a member of the University of Cape Town Political Studies Department.

References

Andrews D. (2021). Towards building feminist economies of life. *Feminist Africa* 2(1):126-133

Ballard M, Johnson A, Mwanza I, Ngwira H, Schechter J, Odera M, Mbewe DN, Moenga R, Muyingo P, Jalloh R and Wabwire J (2022). Community health workers in pandemics: Evidence and investment implications. Global Health: Science and Practice 10(2).

Chabal P (2009). *Africa: the politics of suffering and smiling*. Bloomsbury Publishing.

Cueni T (2022). It's time to put an end to pathogen protectionism. SwissInfo**.** Available at https://www.ifpma.org/global-health-matters/its-time-to-put-an-end-to-pathogen-protectionism/(accessed 5 January 2023).

Dentico N, Aye B, and Meurs M (2022). Financial justice for pandemic prevention, preparedness and response: G2H2 Report. Available at https://g2h2.org/wp-content/uploads/2022/11/G2H2-Report-2022.pdf (accessed 5 January 2023).

Doctors Without Borders / Médecins Sans Frontières (2021). Pharmaceutical manufacturers across Asia, Africa and Latin America with the technical requirements and quality standards to manufacture mRNA vaccines. Available at https://msfaccess.org/pharmaceutical-firms-across-asia-africa-and-latin-america-potential-manufacture-mrna-vaccines.(accessed 5 January 2023).

DuBois M, Wake C, Sturridge S, and Bennett C (2015). *The Ebola response in West Africa: Exposing the politics and culture of international aid.* Overseas Development Institute Humanitarian Poverty Group Working Paper. *Available at* https://cdn.odi.org/media/documents/9903.pdf (accessed 5 January 2023)

Dyer O (2020). Covid-19: Many poor countries will see almost no vaccine next year, aid groups warn. *BMJ* 371.

Fakier K and Cock J (2009). A gendered analysis of the crisis of social reproduction in contemporary South Africa. *International Feminist Journal of Politics* 11(3):353-371

Gleckman H (2022). *The three Covid crises and multistakeholderism: Impacts on multistakeholderism.* Amsterdam: Friends of the Earth and Transnational Institute. Available at https://www.tni.org/files/publication-downloads/three-covid-crises-7-18-2022-web.pdf (accessed 5 January 2023)

Intervention by the Africa Group, INB3, Day 2, Session 1 (2022). Livestream recording time stamp 1:29:08.Available at https://apps.who.int/gb/inb/e/e_inb-3.html (accessed 1 January 2023).

Intervention by Bangladesh, INB3, Day 2 Session 2 (2022). Livestream recording time stamp 14:05:00. Available at https://apps.who.int/gb/inb/e/e_inb-3.html (accessed 1 January 2023).

Intervention by Botswana, INB3, Day 2, Session 1 (2022). Livestream recording time stamp 2:06:11. Available at https://apps.who.int/gb/inb/e/e_inb-3.html (accessed 1 January 2023).
Intervention by the European Union, INB 3, Day 2, Session 1 (2022). Livestream recording time stamp 2:38:50. Available at https://apps.who.int/gb/inb/e/e_inb-3.html (accessed 1 January 2023)
Intervention by Kenya, INB 3, Day 2 Session 1 (2022). Livestream recording time stamp 2:11:12. Available at https://apps.who.int/gb/inb/e/e_inb-3.html (accessed 1 January 2023).
Intervention by Mozambique, INB3, Day 2, Session 2 (2022) Livestream recording time stamp 4:25:00. Available at https://apps.who.int/gb/inb/e/e_inb-3.html (accessed 1 January 2023).
Intervention by Switzerland, INB3, Day 2, Session 2 (2022). Livestream recording time stamp 11.00:00. Available at https://apps.who.int/gb/inb/e/e_inb-3.html (accessed 1 January 2023).
Intervention by the Russian Federation, INB3, Day 2, Session 1 (2022). Livestream recording time stamp 2:23:29. Available at https://apps.who.int/gb/inb/e/e_inb-3.html (accessed 1 January 2023).
Intervention by Uganda, INB3, Day 2, Session 2 (2022). Livestream recording time stamp 1:28:47. Available at https://apps.who.int/gb/inb/e/e_inb-3.html (accessed 1 January 2023)
Intervention by the United States of America, INB3 Day 2, Session 1 (2022). Livestream recording time stamp 2:04: 11. Available at https://apps.who.int/gb/inb/e/e_inb-3.html (accessed 1 January 2023)
Matahari Global Solutions (2022). Mapping access gaps in COVID-19: Results from 14 countries and territories. Available at https://itpcglobal.org/wp-content/uploads/2022/08/Mapping-Access-Gaps-in-COVID-19.pdf (accessed 5 January 2023).
Matlin S A, Smith AC, Merone J, LeVoy M, Shah J, Vanbiervliet F, Vandentorren S, Vearey J and Saso L (2022). The challenge of reaching undocumented migrants with Covid-19 vaccination. I*nternational Journal of Environmental Research and Public Health* 19(16):9973.
Maxmen A (2022). South African scientists copy Moderna's Covid vaccine. *Nature*. Available at https://www.nature.com/articles/d41586-022-00293-2 *(*accessed 5 January 2023*)*
Njoku A, Joseph M and Felix R (2021). Changing the narrative: structural barriers and racial and ethnic inequities in Covid-19 vaccination. *International Journal of Environmental Research and Public Health* 18(18):9904.
Paremoer L, Nandi S, Serag H and Baum F (2021). Covid-19 pandemic and the social determinants of health. *BMJ*, 372.

Paremoer L (2022). Berlin Declaration: Key claims and critiques. People's vaccine. Available: https://peoplesvaccine.org/wp-content/uploads/2022/11/Berlin-Declaration_2022.pdf (accessed 5 January 2023)

Rizvi Z (2022). Sharing the NIH-Moderna Vaccine Recipe. *Public Citizen*. Available at https://www.citizen.org/wp-content/uploads/Sharing-the-Vaccine-Recipe-Aug-10.pdf (accessed 5 January 2023)

Robins S (2020). Beyond the emergency: "Slow catastrophes" after Covid-19. *Daily Maverick*. Available at https://www.dailymaverick.co.za/article/2020-04-20-beyond-the-emergency-slow-catastrophes-after-covid-19/ (accessed 30 December 2023)

Rodríguez Enríquez C and Farga C (2022). The social organisation of care: a global snapshot of the main challenges and potential alternatives for a feminist trade union agenda. Available at https://pop-umbrella.s3.amazonaws.com/uploads/18ad4bcb-c002-4f85-b93c-4dbe751bae11_EN_SOOC_2021_Page.pdf (accessed 5 January 2023)

Sanders D, Nandi S, Labonté R, Vance C and Van Damme W (2019). From primary health care to universal health coverage—one step forward and two steps back. *The Lancet* 394(10199):619-621.

Shepherd N (2019). Making sense of "day zero": slow catastrophes, Anthropocene futures, and the story of Cape Town's water crisis. *Water* 11(9):1744.

Simone A (2004). People as infrastructure: Intersecting fragments in Johannesburg. *Public Culture* 16(3):407-429.

Storeng KT, de Bengy Puyvallée A and Stein F (2021). COVAX and the rise of the "super public private partnership" for global health. *Global Public Health*1-17.

Thambisetty S, McMahon A, McDonagh L, Kang HY and Dutfield G (2021). The TRIPS Intellectual Property Waiver Proposal: creating the right incentives in patent law and politics to end the Covid-19 pandemic. LSE Legal Studies Working Papers. Available at https://eprints.lse.ac.uk/112227/ (accessed 5 January 2023)

United Nations (1967). International covenant on economic, social and cultural rights. Available at https://www.ohchr.org/en/instruments-mechanisms/instruments/international-covenant-economic-social-and-cultural-rights (accessed 5 January 2023)

World Health Organization (no date). SDG 3.8.2 Catastrophic health spending (and related indicators). Available at https://www.who.int/data/gho/data/themes/topics/financial-protection (accessed 5 January 2023)

World Health Organization (2007). The World Health Report 2007: A safer future — global public health security in the 21st century. Geneva: World Health Organization. Available at https://www.who.int/publications/i/item/9789241563444 (accessed 5 January 2023)

World Health Organisation (2022). Conceptual zero draft for the consideration of the Intergovernmental Negotiating Body at its third meeting (A/INB/3/3), 25 November 2022. Available at https://apps.who.int/gb/inb/pdf_files/inb3/A_INB3_3-en.pdf (accessed 5 January 2023)

Why access to information and expert advice given to government is important in a pandemic. A case study of the Covid-19 Ministerial Advisory Committees in SA's pandemic response – transparency matters

Marlise Richter

Introduction

The Covid-19 pandemic catalysed worldwide fear, anxiety and panic. In fact, the WHO found that there was an increase of more than 25% in depressive and anxiety disorders worldwide in 2021 alone (WHO, 2022). The lack of knowledge about the new pathogenic coronavirus, its rapid spread, the morbidity and mortality it leaves in its wake — and the repressive public health measures enacted in several countries to curtail the spread of the pandemic — instilled immense public distress.

Amidst this anxiety, many people looked to their governments to provide strong leadership with evidence-based and carefully co-ordinated programmes to ameliorate the pandemic's impact and to keep people safe. A prerequisite for the success of a government policy or programme is people's trust in government action and confidence that government decisions are based on evidence and fact and taken in good faith. This trust, in turn, is dependent on

transparent decision-making and government accountability, which underlie the social contract between government and citizens.

On this, Singh writes:

> Transparency is an element of procedural fairness and is a key condition for accountable decision-making and the promotion of public trust. Evidence and assumptions used by authorities in making decisions, the manner in which those decisions are being made, and by whom, are crucial to building trust and maintaining confidence in policy makers. Accordingly, all relevant information about a pandemic and its decision-making processes ought to be communicated or made accessible to the public to uphold its trust. (2020: 439)

Characteristics of an open, transparent and evidence-based pandemic response would include the following:

1. Government decision-making is informed by the latest evidence on the pandemic;
2. Experts in a variety of fields, disciplines and experiences — including civil society — would provide knowledgeable inputs to government decision-makers, and base their guidance on the country's particular context and needs;
3. All expert advice considered and the names of experts consulted by government are placed in the public domain in a timeous manner;
4. Experts consulted should state any conflict of interests they may have, and these disclosures should be published;
5. Where government policy-making diverges from the expert advice given, clear rationales need to be provided for why the advice was not followed;
6. Governments should communicate their decisions to the public — and the evidence that these were based on — in a timely, accessible and appropriate manner; and
7. Experts should be able to interact freely with the media and public forums to provide public education and information related to their expertise.

Undoubtedly, decision-making affecting millions of lives during a crisis is immensely complex. Schippers and Rus point out the following challenges with crisis decision-making on a country-level:

> Essentially, policymakers have to react to a threat, of which the extent is unknown, and they are making decisions under time constraints in the midst of immense uncertainty. The stakes are high, the issues involved are complex and require the careful balancing of several interests, including (mental) health, the economy, and human rights. These circumstances render policymakers' decision-making processes vulnerable to errors and biases in the processing of information, thereby increasing the chances of faulty decision-making processes with poor outcomes. (Schippers & Rus, 2021).

Against this background, officials may be tempted to restrict public access to information on decision-making forums, the material and advice with which they are provided, and the rationales for their decisions to limit public criticism during a pandemic. Such an approach fosters secrecy, it avoids accountability and is likely to erode public trust, increase suspicion of government actions and could catalyse resistance to implementation of national policies. Conversely, some decision-makers may not be deliberately secretive about internal processes, but inadvertently deprioritise proper communication and transparency in the midst of the urgency of the crisis.

In open societies, government decision-making should always be transparent; and during pandemic times, the transparency imperative is even more pronounced. Dheepa and Koch (2020: 26) posit that:

> Especially trade-offs [implicit in government policy-making in a pandemic] need to be made more explicit to justify far-reaching measures depriving populations of basic freedoms, with the aim of giving people good reason to adhere to them. In an environment which easily fosters fake news and protest marches against Covid-19 restrictions, a high level of transparency can form the basis of a communication strategy which addresses what those trade-offs means for people's daily lives.

In view of this, how did multiple governments heed this call during the height of the Covid-19 pandemic?

Existing research is not encouraging. A rapid analysis research project by Rajan and colleagues (2020) assessed expert Covid-19 advisory bodies or taskforces in 24 countries early on in the pandemic. It found that a number of countries did not publish the official membership of the experts appointed to these bodies, while there was also limited transparency on the sources of advice that decision-makers consulted. Regrettably, this study was not replicated later on in the pandemic to assess whether decision-makers had changed their practices in line with greater transparency and accountability, and indeed whether such, more transparent strategy had a positive impact on policy implementation and adherence.

Research into this area is still evolving.

The UK's response: Case study of SAGE

The UK's approach to the issues of expert advice, information-sharing and communication on pandemic management is relevant here.

The Scientific Advisory Group for Emergencies (SAGE) is a British government body of experts that have been advising the government on urgent public health threats since the late 2000s. The relationship between the UK government and SAGE advisors is governed by a comprehensive SAGE-specific policy. It

provides that SAGE experts are "responsible for co-ordinating and peer reviewing, as far as possible, scientific and technical advice to inform decision-making" (UK Cabinet Office, 2012:2).

Early on in the Covid-19 pandemic, several UK researchers emphasised the need for transparency and the sharing of information to strengthen international responses to the pandemic, and called for the publication of all data and assumptions informing all epidemiological models used in pandemic management (Barton et al., 2020). Scientists there appealed to the UK government in March 2020 already to "urgently and openly share the scientific evidence, data, and models it [was] using to inform current decision-making related to Covid-19 public health interventions within the next 72 [hours] and then at regular intervals thereafter" (Alwan et al., 2020: 1036). In April 2020, Landler and Castle (2020) wrote that SAGE:

> …operates as a virtual black box. Its list of members is secret, its meetings are closed, its recommendations are private and the minutes of its deliberations are published much later, if at all. Yet officials invoke SAGE's name endlessly without ever explaining how it comes up with its advice — or even who these scientists are.

There were also concerns expressed by members of SAGE about the presence of political strategists who are not scientists but who attended SAGE meetings (Lawrence et al., 2020). An online survey conducted with more than 9,000 participants in April 2020 in the UK, found that only half (52.1%) of respondents felt that the UK government was making good decisions and that "generalised mistrust, concerns about the transparent use and communication of evidence and insights into decision-making processes [of the UK government on pandemic matters] can affect perceptions of the government's pandemic response" at that time (Enrina et al., 2021).

In response to this criticism and public pressure, the UK

government published the names of SAGE members (UK government, 2020a) and the minutes of the meetings of SAGE (UK government, 2020b) in May 2020, while a list of SAGE members' interests was released in December 2020 (UK government, 2020c).

Challenging this initial lack of transparency in the SAGE group, an alternative group — called Independent SAGE or "Indie_SAGE" — was formed in early May 2020 by a group of independent scientists. On 4 May 2020, it held its first meeting which was, pointedly, live streamed. This was the same day that the UK government finally released its own list of SAGE members, which the head of Indie _SAGE, Sir David King, noted was no coincidence (Baker, 2020). Indie_SAGE hosted weekly online briefings with the latest pandemic developments and research, during which the public could ask questions, and it curated an engaging and educational social media presence.

Following this public pressure in the UK, it would seem that the UK government started to pay particular attention to pandemic transparency and more thoughtful communication. The official SAGE website is now richer with more information and is regularly updated (UK government, undated); and at the time of writing this chapter in April 2023, the last update entry on that website was 23 December 2022. The website now contains meeting minutes, the terms of reference of SAGE members, a list of members' interests (clearly stating on what dates updates were uploaded to the website), research reports, key statistics and information, modelling data sets, and educational material on understanding evidence. The website also includes a useful FAQ section, an explainer video about what the UK SAGE is and even directions on how to make an official Freedom of Information request, if needed.

Regrettably some lasting damage to public trust is evident: an assessment of SAGE by the UK House of Commons in 2021 found that the initial withholding of information by SAGE created a sense of suspicion of the UK government that lingered despite subsequent information sharing and communication. This suspicion served to undercut policy implementation (House of Commons, 2021).

While SAGE initially operated behind closed doors, it relatively quickly adapted its practices in line with public demands and

democratic values on transparency, accountability and accessibility. It serves as a useful example of how expert taskforces and governments could evolve to operate responsively and transparently, while serving an important public education function.

Let us now turn to the expert advice that informed, or should have informed, the SA government's pandemic response and how much access the public had to it.

The SA response: the Ministerial Advisory Committees

The Ministerial Advisory Committees (MACs)

The SA government committed early on in the pandemic that its response will be based on "science and evidence". The president remarked repeatedly that policy was "guided by the advice from scientists" (Ramaphosa, 2020a) and "based on empirical evidence, scientific and economic data and international best practice" (Ramaphosa, 2020b). In his 2022 State of the National Address, President Ramaphosa described the response in the following way: "Our [the South African government's] approach has been informed throughout by the best available scientific evidence, and we have stood out both for the quality of our scientists and for their involvement in every step of our response" (Ramaphosa, 2022).

On 30 March 2022, the SA Minister of Health, drawing on the National Health Act, appointed a Covid-19 Ministerial Advisory Committee, or "the C-19 MAC." The C-19 MAC originally had 51 members and included specialists in epidemiology, virology, vaccinology, microbiology, and infectious diseases — many of them internationally renowned. The C-19 MAC Terms of Reference have never been part of the material made available to the public on the SA Department of Health's (NDH) website or the department's special Covid-19 portal, www.Sacoronavirus.co.za. It (five pages) appears only on the health journalism website Bhekisisa (2022).

The MAC Terms of Reference notes that members need sign a confidentiality agreement.

In July 2020, the formation of a Social Behavioural Change MAC, the "SBC MAC" was announced, while a MAC on "vaccine development" (the "V-MAC") was constituted by September

2020. When announcing the V-MAC, the NDH noted that it had "reconfigured" the C-19 MAC (Department of Health, 2020) and a significant number of MAC members were released from the committee. Many people expressed concerns about the fact that the more outspoken MAC members who had questioned government pandemic decision-making (about lock down rules) were removed in this reconfiguration and that this potentially served as an implicit warning to remaining MAC members— and indeed other researchers and scientists — to not publicly criticise government policy and decisions. (Rose, 2020) (Singh et al., 2020).

Advising the Minister of Health

The Terms of Reference for the C-19 MAC shared by *Bhekisisa* make it clear that the committee serves in an advisory capacity to government and "is not responsible for the delivery or co-ordination of services related to the Covid-19 response" (No terms of reference have been published for the other two MACs). The NDH serves as secretariat for the MACs and is the custodian of the MAC advisories, and also determines whether any such advice will be made public or not.

Similar to other countries, there was pressure on the SA government to publish the expert advice it received as well as the epidemiological models that guided its far-reaching decisions on the country's initial Covid-19 lockdown rules. A media house, *News24*, launched two Promotion of Access to Information applications to obtain this information in May 2020 (Cowen et al., 2020). The then-Minister of Health stated in July 2020 that the MAC advisories would not be publicly released (Cowen et al., 2020).

Pressure and advocacy for greater access to information continued to build and at the end of August 2020, the Minister then announced a surprising turn-around: the NDH would from thereon publish the MAC advisories (SA government, 2020). Several MAC advisories were then uploaded on the governments SA Coronavirus online portal - https://sacoronavirus.co.za/.

Regrettably, uploading delays persisted. Lockdown and other far-reaching policy decisions were announced by the SA government

without disclosure of the expert advice underpinning it (if at all). In some cases, the advice or recommendations provided would be published weeks or months later.

An HJI analysis in 2021 of the time delays between advisories submission to the Minister of Health and subsequent publishing is telling. HJI found then that on average, it took 68 days for C-19 MAC advisories to be published and 111 days for V-MAC advisories to be shared during the period August 2020 to August 2021 (Nokhepheyi et al., 2021). During this period, 120 MAC and V-MAC advisories were published in total. Not a single SBC MAC advisory was publicly released (assuming they did make recommendations) (and there was a joint MAC on "strategies to address Covid-19 vaccine hesitancy" published in April 2021 that included all three MACs). Minutes of MAC meetings and all MAC members' material or financial interests were not shared publicly.

In March 2021, the HJI wrote to the MAC secretariat at the NDH expressing concerns about the lack of advisories being made public. This was at a time of rapid developments regarding Covid-19 vaccines, and people in SA eagerly awaiting news of being able to access vaccines to protect themselves. For example, in early 2021, the SA government announced that it had secured one million doses of the AstraZeneca/ University of Oxford vaccine called COVISHIELD for healthcare workers, but by February 2021 it halted the programme because of concerns that it would "not be effective" for Covid-19 variants circulating in SA at that time. This was despite the same vaccine being rolled out elsewhere and highly regarded experts in SA calling for its continued use. The expert advice provided to pause the roll-out, any competing interests involved, and the processes for such a weighty decision should have been in the public domain — particularly as this programme required substantial amounts of public funds and halting it, also risked the lives of many healthcare workers (earmarked to receive those vaccines first).

Similarly, early indications from public briefings and statements from the President and the Minister of Health, and the V-MAC recommendations were that SA would prioritise particularly vulnerable groups including people living with comorbidities, in the vaccine roll-out. In yet another u-turn, the SA government and the

NDH did not prioritise this group in the first vaccine roll out and opted for a strict age cohort framework instead of one informed by vulnerability without an adequate explanation. This meant that a 30-year-old who is immunocompromised and at increased risk of getting sick from Covid-19 would have to wait for that age group to "open up".

The HJI followed up on these matters frequently by corresponding with the NDH and asking for more information. When requests from the HJI were ignored, the organisation submitted a formal request for information under the Promotion of Access to Information Act (PAIA) of 2000 on 20 July 2021 (and on 23 July 2021 and 19 July 2021 on other matters related to making pandemic information public). Within a few days of filing the requests, 26 advisories were uploaded (Nokhepheyi et al., 2021).

The HJI's request for information to the NDH on the MAC advisories included the following aspects:

A. A list of the names of all local and international expert advisors to the national NDH on Covid-19, irrespective of whether they also serve on a/any MAC for Covid-19;
B. Copies of all C-19 MAC and V-MAC Advisories and other expert advice, that are currently not in the public domain;
C. Copies of all memoranda and advisories that relate to options and recommendations for vaccinating all people with comorbidities;
D. Copies of all written advice and recommendations related to the vaccine selection and priority group eligibility criteria for SA from December 2020 onwards;
E. A copy of the risk and priority group framework and timeline or similar, and the timeline, that the NDH was using for vaccinations and to make vaccine allocation and eligibility decisions, including submissions to the department by any other department or entity on these issues;
F. Copies of all C-19 MAC and V-MAC advisories on the use or non-use in SA of the AstraZeneca/ COVISHIELD vaccine including any recommendation by the national medicine

regulator, the South African Health Product Regulatory Authority or other experts setting out the basis for pausing this vaccine; and

G. Copy of the contract and details of the sale of the AstraZeneca vaccine.

The NDH did not respond to the formal PAIA requests nor the subsequent internal appeals lodged by HJI under PAIA. The HJI eventually had no choice but to serve legal papers on the Minister of Health, the information officer of the NDH and the Minister of Co-operative Governance and Traditional Affairs in April 2022 to compel disclosure. The HJI asked the court to direct the government to provide the information and to ensure that all subsequent MAC advisories would be placed in the public domain within 72 hours of receipt by the Minister (*HJI v Minister of Health et al.*, 2022).

The Deputy Director-General (DG) of health's answering affidavit was filed in July 2022 (*HJI v Minister of Health et al.*, 2022). He claimed that much of the information was already in the public domain, that some information did not fall under the ambit of the NDH and resided with National Treasury, and that some information was "protected by mandatory non-disclosure in terms of PAIA" that some decisions on pandemic responses were "made by Cabinet, thus the minutes of Cabinet are protected from disclosure, in terms of PAIA. The NDH is not at liberty to divulge this information to the applicant" (para 30).

This attitude and legal defence by the NDH is relevant not just for this pandemic, but also for potential advisory and benefit selection structures being proposed under the National Health Insurance scheme. The HJI has in its analysis of provisions of the National Health Insurance Bill found that a range of concerns related to transparency and in particular whether and how the deliberations of the various Advisory and Technical Committees would be made available (HJI, 2022).

The HJI Request to the NDH	Response from the NDH (selected paragraphs)	HJI outstanding issues
A.) A list of the names of all local and international expert advisors on Covid-19, irrespective of whether they also serve on a/any MAC for Covid-19.	"The applicant [HJI] is aware of the names of all the ministerial advisory committee Covid-19. The attention of the Court is drawn to p.62 of the founding affidavit. This is a list of the names of the Ministerial Advisory Committee for Covid-19 ("MAC"). Para 22	The answering affidavit does not address the composition of the V-MAC. Because of the unreliable uploading of information on the website portal, it is not clear whether the list of the members of the three MAC released in 2020 was up-to-date. To ascertain this, the HJI wrote to the Department in November 2021 to request the updated composition of the C-19 MAC and V-MAC for a Briefing Paper. The HJI was informed that "the request [need] be submitted through the Office of the Minister of Health."
B.) Copies of all C-19 MAC and V-MAC Advisories and other expert advice that are currently not in the public domain.	"The copies of the MAC and V-MAC advisories are matters of public knowledge. These advisories are in the public domain. They are accessible in the NDH's website" para 23 "The applicant should perhaps indicate a specific advisory that it would like to access which cannot be found on the website. The NDH will make the advisory available" para 24	It is unclear how the public would know whether a specific MAC advisory exists in order to request it from the department, if MAC meeting minutes are not published and that MAC members have to sign confidentiality clauses. Advisories were sporadically uploaded to the website — oftentimes months after submission to the minister — with no indication whether all the advisories submitted to the Minister were in fact in the public domain. Legal action had to be taken to ascertain this.
C.) Copies of all memoranda and advisories that relate to options and recommendations for vaccinating all people with comorbidities.	"The advisories include the advisory relating to the recommendations for vaccinating people with comorbidities" para 24	See below

The HJI Request to the NDH	Response from the NDH (selected paragraphs)	HJI outstanding issues
D.) Copies of all written advice and recommendations related to the vaccine selection and priority group eligibility criteria for SA from December 2020 onwards.	"The NDH's view is that the record [on vaccine selection and priority group eligibility] contains advice, opinion, report, or recommendation obtained or prepared, or on account of a consultation, discussion for the purposes of assisting to formulate a policy or take a decision in the exercise of power or performance of duty conferred or imposed by law. **The NDH has considered the request and decided that in line with section 44(1) of PAIA the information requested could not be made available to the applicant."** Para 25	S.44 provides for the possibility for information officers to refuse a request for information if it hampers the operation of a public body. Information that could be refused in this instance includes records pertaining to the formulation of policies or recommendations. However, an override exists to above if the record is in the interest of the public. The HJI believes that information pertaining to the selection of life-saving vaccines and the considerations informing eligibility would unequivocally be in the public interest.

The HJI Request to the NDH	Response from the NDH (selected paragraphs)	HJI outstanding issues
E.) A copy of the risk and priority group framework and timeline or similar, and the timeline, that the NDH was using for vaccinations and to make vaccine allocation and eligibility decisions.	"Our understanding of the virus and the best manner of dealing with it changed constantly during 2020, and continues to do so, as the result of additional scientific studies and investigations become available. In this context no government can have fixed or required strategies for distributors of vaccines. Instead, what is required is a constantly evolving vaccine strategy that takes account of the latest scientific developments." Para 26 Due to the diversity of the strategy, the NDH also adopted a flexible approach to deal with vaccinations. A framework for rational Covid-19 vaccine allocation in SA and prioritisation of fair allocation of Covid -19 vaccines, identification of risk groups and the supporting documents are available on the website." Para 27	Certainly, a fast-changing environment in a new and devastating pandemic requires a flexible government approach. Yet, detailed rationales for not prioritising particularly vulnerable groups at first, such as people who are immunocompromised or those with comorbidities for vaccination should be published particularly if they diverge from international guidelines issued by the WHO and run counter to the expert advice provided to the government. The V-MAC for example recommended the "prioritisation of people with existing vulnerabilities" in several advisories, while initial public statements by President Ramaphosa and the Minister of Health supported their prioritisation Yet, the initial vaccine roll-out did not provide for preferential vaccination for these groups - it opted for a strict age cohort model - but where sports stars and we believe certain government officials received vaccines ahead of their age cohort.

The HJI Request to the NDH	Response from the NDH (selected paragraphs)	HJI outstanding issues
F.) Copies of all C-19 MAC and V-MAC advisories on the use or non-use in SA of the AstraZeneca/ COVISHIELD vaccine including any recommendation by the South African Health Product Regulatory Authority or other experts setting out the basis for pausing the use of this vaccine.	"The information relating to the use and the non-use of the AstraZeneca/ COVISHIELD vaccine is available on the website. This is part of the advisories made as a recommendation to the government. This information includes the advice indicating that AstraZeneca/Covishield vaccine had an efficacy of 22% as against the 501Y. V2 variant." Para 29 "The decision to pause the use of the AstraZeneca in SA was based on the recommendation of the V-MAC and the MAC and other experts. However, the decision was made by Cabinet, thus the minutes of Cabinet are protected from disclosure, in terms of PAIA. The NDH is not at liberty to divulge this information to the applicant." Para 30	A 7 February 2021 V-MAC advisory (of only two pages long) noted that there was "insufficient data to assess the efficacy of any of the vaccines with regard to protection against serious infection and hospitalisation with the 501Y.v2 variant". It also noted that a high-level meeting would take place on 8 February 2021 to "develop a considered advisory on the way forward". No minutes of this meeting have been published (if indeed it took place). It is probable that a far-reaching decision to pause the first vaccines that SA could access in a global crisis would include more discussion and advice than the two- page document of 7 February 2021 currently in the public domain. It is also odd that Cabinet would make this decision, as barring the Minister of Health, none of them are experts on vaccines and vaccinology.
G.) Copy of the contract and details of the sale of the AstraZeneca vaccine	"The Astra-Zeneca vaccines were sold to the African Union. The NDH is not in possession of the sale agreement between the African Union and the government. This information falls within the province is the national treasury. Thus, the NDH is unable to provide this information requested." Para 31	The HJI believes that all contracts related to procurement and selling of vaccines should be in the public domain. It is pursuing legal action asking the courts to instruct government to publish all its vaccine agreements — including those related to the AstraZeneca vaccine.

Table 3: Summary of the HJI PAIA request, the SA NDH responses and the HJI's remarks on the NDH's response

Conclusion

From March 2020 to January 2023, during the Covid-19 pandemic, the MAC advisory bodies submitted a total of 162 advisories to the Minister of Health (Richter et al., forthcoming).

Scientific experts provided an important service to guide and advise the government on the implementation of a vigorous and evidence-based pandemic strategy. During the height of the crisis, government decision-making had to happen under immense pressure while ameliorating public anxiety at the same time. It is laudable that the SA government publicly committed to be led by the "best evidence", and that some aspects of the pandemic were approached with urgency, thoughtfulness and efficiency. But, that was not the case throughout the crisis.

Regrettably, the first few months of SA's Covid-19 pandemic response were shrouded in non-sharing of information and even secrecy. Following, public, civil society and journalists questioning and advocacy, the NDH eventually committed to placing some of the expert advice in the public domain, but not all, despite legal challenges to do so. Disappointingly, making information available was not always executed in a timely or systematic manner — nor do we believe — that all essential information that should have been in the public domain has been provided. Without MAC members confirming on record which of the advisories were not published, we can only ask questions.

It is unfortunate that a civil society organisation had to take legal action to compel the NDH to respond to requests for access to information — a right that is guaranteed by SA's Constitution. A period of 16 months had passed between the HJI first engagement with the Department on the MAC advisories and the MAC composition, and the department's written engagement with our requests.

In all of this, the information sought by HJI was neither controversial nor unreasonable and went to the core of transparent pandemic decision-making. This information should automatically and almost immediately have been placed in the public domain — as demonstrated by the UK SAGE and Indie_SAGE models and experiences (see above). Alternatively, the NDH should have

responded to the PAIA requests in a timely manner and provided the information and its response immediately. Having to take legal action against a health department (and others) during a public health crisis, to foster public trust, is an unenviable task even if it is in the public interest. Arguing the case further and in particular what the scope of public interest exceptions should be in a pandemic and even after, would have taken many more years and would be costly. Of concern for NHI implementation, from this experience, is the approach of the Minister's legal team – that he decides what should be in the public domain in respect of expert advice given to the department.

Pandemic readiness requires robust, proactive lines of communication and information-sharing between government and the public. The Covid-19 experience shows the NDH where systemic weaknesses lie and thus poses a key opportunity to remedy these — working collaboratively with civil society — and to put the necessary processes in place for the next pandemic. It is also incumbent on experts and scientists who may be called upon to serve on such structures to not agree to strict confidentiality requirements and to insist that all of their advice be promptly and publicly published. There is ultimately no place for secrecy in a pandemic — it undermines trust in decision making and in science.

Dr Marlise Richter is a senior researcher at the Health Justice Initiative, and an associate researcher at the African Centre for Migration and Society, University of the Witwatersrand and the School of Public Health and Family Medicine, University of Cape Town. She serves on the steering committee of the coalition Collective Voices for Health Access.

References:

Alwan NA, et al. (2020). Evidence informing the UK's Covid-19 public health response must be transparent. *The Lancet* 395(10229): 1036-1037.

Baker H (2020). Independent SAGE and their continued quest for transparency. Centre for Research in the Arts, Social Sciences and Humanities Blog. Available at https://www.crassh.cam.ac.uk/blog/independent-sage-and-their-continued-quest-for-transparency/ (accessed 18 Jan 2023).

Barton CM, Alberti M, Ames D, et al. (2020). Call for transparency of Covid-19 models. *Science* 368(6490):482-483.

Bhekisisa (2020). Who's new on SA's Covid-19 Ministerial Advisory Committee? Available at _https://bhekisisa.org/resources/general-resource/2020-05-22-what-south-africas-covid-19-ministerial-advisory-committee-did-and-didnt-advise-on/ (accessed 19 Jan 2023).

Cowan K, Karrim A, and Hunter Q (2020). "Mkhize doubles down on keeping advice secret as scientists push for transparency." [online] *News24*, 19 July 2020. Available at https://www.news24.com/news24/SouthAfrica/Investigations/mkhize-doubles-down-on-keeping-advice-secret-as-scientists-push-for-transparency-20200719 (accessed 2 December 2021).

Department of Health (2020). Media statement: Update on Covid-19 (14th September 2020). SA Corona Virus Online Portal. Available at https://sacoronavirus.co.za/2020/09/14/update-on-covid-19-14th-september-2020/ (accessed 26 November 2021).

Enria L, Waterlow N, Rogers NT, et al. (2021). Trust and transparency in times of crisis: Results from an online survey during the first wave (April 2020) of the Covid-19 epidemic in the UK. *PLoS ONE* 16(2)

Health Justice Initiative (2022). South Africa's National Health Insurance Bill and the future of medicine selection, pricing and procurement – Some critical questions for affordable patient access. National Health Insurance Series: Issue Paper 1, October.

HJI v Minister of Health and others. Case no 19343/2022. Available at https://healthjusticeinitiative.org.za/pandemic-transparency/

House of Commons (2021). Coronavirus: lessons learned to date. Sixth report of the health and social care committee and third report of the science and technology committee of session 2021–22, 21 September 2021. Available at https://committees.parliament.uk/publications/7496/documents/78687/default/ (accessed 14 December 2021).

Landler M and Castle S (2020). The secretive group guiding the U.K. on Coronavirus. *New York Times*. Available at https://www.nytimes.com/2020/04/23/world/europe/uk-coronavirus-sage-secret.html (accessed 18 Jan 2023).

Lawrence F, Carrell S and Pegg D (2020). Attendees of Sage meetings worried by presence of Cummings. *The Guardian*. Available at https://www.theguardian.com/world/2020/apr/26/attendees-of-sage-coronavirus-meetings-worried-by-presence-of-dominic-cummings (accessed 18 Jan 2023)

Richter M, Nokhepheyi Y and Hassan F (forthcoming). Tracking the South African "MAC" advisories. When expert advice and secrecy collide in a pandemic: Assessing government transparency in public health decision making and vaccine prioritisation and selection. Update of HJI Briefing Paper update. Cape Town: Health Justice Initiative (HJI)

Richter M, Nokhepheyi Y and Hassan F (2021). Tracking the South African 'MAC' Advisories when expert advice and secrecy collide in a pandemic: Assessing government transparency in public health decision making and vaccine prioritisation and selection. August 2020 – August 2021. *HJI* Briefing Paper no 1. Cape Town: Health Justice Initiative (HJI)

Rajan D and Koch K (2020). The health democracy deficit and Covid-19. *Eurohealth* 26 (3): 26-28.

Rajan D, Koch K, Rohrer K, et al. (2020). Governance of the Covid-19 response: A call for more inclusive and transparent decision-making *BMJ Global Health* 5.

Ramaphosa C (2022). State of the Nation Address 2022. Available at https://www.stateofthenation.gov.za/assets/downloads/SONA-2022-SPEECH.pdf (accessed 8 Feb 2023).

Ramaphosa C (2020a). SA's response to Coronavirus Covid-19 pandemic [online]. Available at https://www.gov.za/speeches/president-cyril-ramaphosa-south-africas-response-coronavirus-covid-19-pandemic-23-apr-2020 (accessed 14 December 2021).

Ramaphosa C (2020b). From the Desk of the President [online]. Available at 4 May 2020. Available at https://www.thepresidency.gov.za/from-the-desk-of-the-president/desk-president%2C-monday%2C-4-may-2020 (accessed 14 December 2021).

Rose R (2020). "Hear no evil: Mkhize axes the critics from his experts panel." *Business LIVE*. Available at https://www.businesslive.co.za/fm/opinion/editors-note/2020-09-30-rob-rose-hear-no-evil-mkhize-axes-the-critics-from-his-experts-panel/ (accessed 26 November 2021).

South African government (2020). Health on availability of Coronavirus Covid-19 MAC advisories being accessible to public. South African Government. Available at https://www.gov.za/speeches/health-availability-coronavirus-covid-19-mac-advisories-being-accessible-public-27-aug-2020 (accessed 26 November 2021).

Schippers MC and Rus D.C (2021). Optimizing decision-making processes in times of Covid-19: Using reflexivity to counteract information-processing failures. *Frontiers in Psycholology*.12.

Singh J A (2020). How SA's Ministerial Advisory Committee on Covid-19 can be optimised. *South African Medical Journal* 110(6)

UK Cabinet Office (2012). Enhanced SAGE Guidance - A strategic framework for the Scientific Advisory Group for Emergencies (SAGE). Available at https://www.gov.uk/government/publications/scientific-advisory-group-for-emergencies-sage (accessed 17 Jan 2023)

United Kingdom government (2020a). Transparency data: List of participants of SAGE and related sub-groups. Government Office for Life Sciences. Available at https://www.gov.uk/government/publications/scientific-advisory-group-for-emergencies-sage-coronavirus-covid-19-response-membership/list-of-participants-of-sage-and-related-sub-groups (accessed: 18 Jan 2023).

United Kingdom government (2020b). Government publishes SAGE minutes. Available at https://www.gov.uk/government/news/government-publishes-sage-minutes (accessed 18 Jan 2023).

United Kingdom government (2020c). Covid-19: "SAGE register of participants' interests." Available at https://www.gov.uk/government/publications/covid-19-sage-register-of-participants-interests (accessed 18 Jan 2023).

United Kingdom government (undated). Scientific Advisory Group for Emergencies. Available at https://www.gov.uk/government/organisations/scientific-advisory-group-for-emergencies (accessed 18 Jan 2023).

World Health Organization (2022). Mental Health and Covid-19: Early evidence of the pandemic's impact. WHO Scientific brief, 2 March 2022

People's Vaccine Alliance Open letter:

March 2023

THE PEOPLE'S VACCINE

THREE YEARS INTO PANDEMIC, 200 WORLD LEADERS SAY "NEVER AGAIN" TO THE "SCAR" OF VACCINE INEQUALITY

More than 200 current and former world leaders, Nobel laureates, civil society organisations, faith leaders, and health experts have united to call on governments to "never again" allow "profiteering and nationalism" to come before the needs of humanity in a pandemic, in a letter coordinated by the PVA to mark three years since the WHO first characterised Covid-19 as a pandemic.

President José Manuel Ramos-Horta of Timor-Leste, recipient of the 1996 Nobel Peace Prize, has signed the letter, alongside the former leaders of more than 40 countries, including Joyce Banda, former President of Malawi; José Luis Rodríguez Zapatero, former Prime Minister of Spain; Fernando Henrique Cardoso, former President of Brazil; and Viktor and Kateryna Yushchenko, former President and First Lady of Ukraine.

They join Graça Machel, former First Lady of SA and Mozambique; Nobel laureates like Joseph E. Stiglitz and Sir Richard Roberts; faith leaders including the Archbishop of Cape Town and the Bishop of Salford, and former heads of institutions including the United Nations, World Bank, the UN General Assembly, the UN Framework Convention on Climate Change, the OECD, UNICEF, and the International Labour Organization.

The leaders put forward a scathing analysis of the world's pandemic response. Covid-19 countermeasures were developed and delivered with enormous public funding, signatories say. Therefore, they are "the people's vaccines, the people's tests, and the people's treatments". But instead of distributing Covid-19 vaccines, tests, and treatments based on need, pharmaceutical companies sold doses first to the "richest countries with the deepest pockets".

This inequity led to one preventable death every 24 seconds in the first year of the Covid-19 vaccine rollout alone, according to analysis from the PVA based on a study published in Nature. It is "a scar on the world's conscience" that those lives were not saved, signatories say.

Signatories call on world leaders to pledge that "Never again will the lives of people in wealthy countries be prioritised over the lives of people in the Global South. Never again will publicly funded science be locked behind private monopolies. Never again will a company's desire to make extraordinary profits come before the needs of humanity."

They call on governments to embed "equity and human rights in pandemic preparedness and response" by treating publicly funded medical innovations as "global common goods… used to maximise the public benefit, not private profits", and by embedding these principles in the Pandemic Accord that is currently under negotiation at the WHO.

This requires an automatic mechanism in any pandemic to remove the intellectual property barriers that prevent the sharing

of scientific knowledge and technology, the signatories say. To address these barriers in the ongoing pandemic, they call on governments to act at the WTO to ease patents on Covid-19 tests and treatments.

Governments should support and invest in public research, development, and manufacturing capacity, particularly in the Global South, the leaders say. They call on governments to provide "political, financial, and technical support" for the WHO's mRNA Technology Transfer Hub project, which is sharing mRNA technology with producers in 15 low and middle-income countries.

The letter will be sent to all governments via their representatives in Geneva.

His Excellency José Ramos-Horta, President of the Democratic Republic of Timor-Leste, said:

"In the Covid-19 pandemic, those of us in low and middle-income countries were pushed to the back of the line for vaccines and denied access to the benefits of new technologies. Three years on, we must say 'never again' to this injustice that has undermined the safety of people in every country. Steps that we take today can hasten global access to vaccines, medicines, and tests in the next pandemic, with regional hubs researching, developing, and manufacturing medical products for everyone, everywhere."

Helen Clark, former Prime Minister of New Zealand, co-chair of the Independent Panel for Pandemic Preparedness and Response, and Member of Club de Madrid, said:

"Publicly funded science contributed a lot to the phenomenal success of Covid-19 vaccines. Yet, that public investment did not lead to vaccines being treated as global common goods. Rather, nationalism and profiteering around vaccines resulted in a catastrophic moral and public health failure which denied equitable access to all. We need to fix the glaring gaps in pandemic preparedness and response today, so that people in all countries can be protected when a pandemic threat emerges."

Ban Ki-Moon, Eighth Secretary-General of the United Nations and Honorary Member of Club de Madrid, said:

"The great tragedy of the Covid-19 pandemic has been the failure of multilateralism and the absence of solidarity between the Global North and Global South. These past three years should act as a warning for future pandemics. We need a return to genuine cooperation between nations in our preparation and response to global threats. That requires a Pandemic Accord rooted in equity and human rights, which places the needs of humanity above the commercial interests of a handful of companies."

Winnie Byanyima, Executive Director of UNAIDS and co-chair of the People's Vaccine Alliance, said:

"In the AIDS pandemic, pharmaceutical monopolies have resulted in an appalling number of unnecessary deaths– and it has been the same story with Covid-19. It was only the production of inexpensive generics in developing countries that made the first generation of HIV medicines available and affordable to people in the South. But governments still have not learned that lesson. Unless they break the monopolies that prevent people from accessing medical products, humanity will sleepwalk unprepared into the next pandemic."

The full letter and list of signatories is available here: http://bit.ly/3yregbL

People's Vaccine activists are staging memorials and demonstrations across the world to mark three years since the WHO first characterised COVID-19 as a pandemic in Democratic Republic of the Congo, India, Indonesia, Malawi, Nepal, Niger, Nigeria, Palestine, Philippines, Qatar, Rwanda, Senegal, Sierra Leone, the United Kingdom, Zambia, and across the United States – in La Puente California, Citrus Springs Florida, Boston Massachusetts and Alice and Houston Texas. More information and pictures will be updated here: https://peoplesvaccine.org/take-action/never-again-covid-monopolies/

An estimated 1.3 million fewer people would have died if COVID-19 vaccines were distributed equitably in 2021, according to a study published in Nature (Moore et al, 2022). This is equivalent to one preventable death every 24 seconds: https://www.nature.com/articles/s41591-022-02064-y

Pharmaceutical companies have made profits of $90 billion from Covid-19 vaccines, according to research from SOMO: https://www.somo.nl/big-pharma-raked-in-usd-90-billion-in-profits-with-covid-19-vaccines/

Governments have put an extraordinary amount of public funding into Covid-19 vaccines. The US government has invested $31.9 billion in mRNA, including hundreds of millions of dollars over the thirty years preceding the COVID-19 pandemic, according to research published in the British Medical Journal (BMJ).

Governments have provided billions of dollars of funding for Covid-19 tests and therapeutics: https://www.policycuresresearch.org/covid-19-r-d-tracker/

The mRNA Technology Transfer Hub is backed by the WHO and MPP. It will share mRNA technology with manufacturers in 15 low and middle-income countries: https://medicinespatentpool.org/news-publications-post/who-and-mpp-announce-names-of-15-manufactures-to-receive-training-from-mrna-technology-transfer-hub

SECTION E:

THE PROMISE OF THE mRNA HUB

Reflections from the mRNA Hub in SA: Successes, challenges, lessons and future opportunities

Petro Terblanche
Morena Makhoana

Never before has a disease outbreak underscored the gross inequity in access to vaccines than the Covid-19 pandemic. It confirmed, as many chapters in this collection show, once again, that low and middle-income countries are highly vulnerable to inequitable access to new immunisations and other health technologies, in part because manufacturing capacity remains concentrated in a small number of high-income countries.

A more globally distributed manufacturing capacity for vaccines and other health technologies would reduce the gap in making future vaccines timeously and equitably available and accelerate the collective effort to control outbreaks.

"A key moment for increasing vaccine capacity"

By mid-July 2021, high-income countries had administered more

than one billion doses of Covid-19 vaccines. Low and middle-income countries, in contrast, had given out almost 600 million despite being home to more than 75% of the world's population (Mathieu, 2021).

In the midst of this startling inequality came the 21 June 2021 WHO statement announcing the creation of an "mRNA Hub". It would be dedicated to making mRNA vaccine manufacturing technology available to low and middle-income countries to enable them to, one day, produce immunisations and build future pandemic preparedness (WHO, 2021).

"Today's announcement is a great step forward for SA, and for the world," WHO DG, Tedros Adhanom Ghebreyesus, said of the launch shortly after (UN News 2021). "I hope this will be a key moment for increasing production capacity in Africa for Covid-19 vaccines, but also for future vaccines."

Partners would provide training and funding to support production, quality control, production regulation and — where needed — assist with necessary licences. The mRNA Hub, meanwhile, would develop mRNA technology as a public good, sharing it with local producers from around the world to enable them to make affordable, locally produced mRNA vaccines in the future.

Afrigen Biologics and Vaccines (Afrigen), in SA, was selected by the WHO to host the mRNA Hub and establish mRNA vaccine production. The South African Medical Research Council (SAMRC) would provide the research and the partly state-owned bio-pharmaceutical company, Biovac, would become the first "spoke" — a recipient of the technology that would eventually join others from low and middle-income countries.

That the WHO selected Afrigen Biologics and Vaccines, a small, start-up biotech company in the Southern tip of Africa to house the mRNA Hub, raised eyebrows.

Many must have wondered: Could a small, unknown African biotech firm deliver on the goals of such an ambitious programme?

However, the addition of Biovac — one of Africa's foremost vaccine suppliers — to the consortium reduced that scepticism. Biovac's addition would fast-track market access for the mRNA

Hub's home-grown mRNA Covid-19 vaccine, following a technology transfer from Afrigen.

Although decades in the making, mRNA vaccine technology had become especially alluring for low and middle-income countries during Covid-19 and ahead of the mRNA Hub's creation. This is, in part, because established producers had been able to use modular solutions or repurpose existing plants relatively quickly to scale up mRNA Covid-19 vaccine production in a matter of months. Today, many experts also believe the technology holds promise beyond Covid-19 and could, one day, unlock vaccines aimed at HIV and TB, for instance. For reasons such as these, expanding mRNA technology in Africa had been a feature of discussion at the African Union aimed at increasing local production as part of pandemic preparedness from as early as 2021.

But for the mRNA Hub, only one question remained unanswered.

Where would the mRNA vaccine technology come from?

This question became the single biggest driver of implementation and partnership strategies. It also fuelled a determination to succeed.

Early successes: Incremental steps, phenomenal support

No existing Covid-19 mRNA vaccine producer was willing to partner with the mRNA Hub to share its technology.

In the absence of an established mRNA vaccine partner, its ultimate success would clearly lie in small scientific and technological steps coupled with unparalleled funding and technical support from the WHO, civil society organisations, the United Nations, governments and the MPP. The MPP is a United Nations-backed organisation working to increase access to life-saving medicines. As part of its innovative model, MPP negotiates licensing agreements with patent holders to allow broader, more affordable versions of medicines to be produced for low and middle-income countries.

The first technological milestone came within three months of the mRNA Hub's inception, when scientists at the University of the Witwatersrand and Afrigen successfully produced a mRNA vaccine

candidate at lab scale. In laboratory testing, the immunisation elicited high levels of immune response and demonstrated an ability to neutralise SARS-CoV-2 comparable with relevant international benchmarks. It also demonstrated a good tolerance and safety profile in early studies.

Although there was a misconception that SA's first, home-grown mRNA vaccine was a "copy" of existing mRNA Covid-19 vaccines, this is untrue. Instead, SA scientists combined scant information from patent applications with years of their own research in the field of mRNA — some of which was dedicated to, one day, producing treatments for neglected, tropical diseases affecting the continent.

Subsequently, the Afrigen team demonstrated its ability to scale up laboratory processes and has supplied material for further preclinical studies of the mRNA Hub's first mRNA vaccine. At the time of writing, the SAMRC was expected to begin early human clinical trials of the vaccine by mid-2023.

The candidate vaccine's name is AfriVac 2121, in honour of the date the mRNA Hub was announced by the WHO.

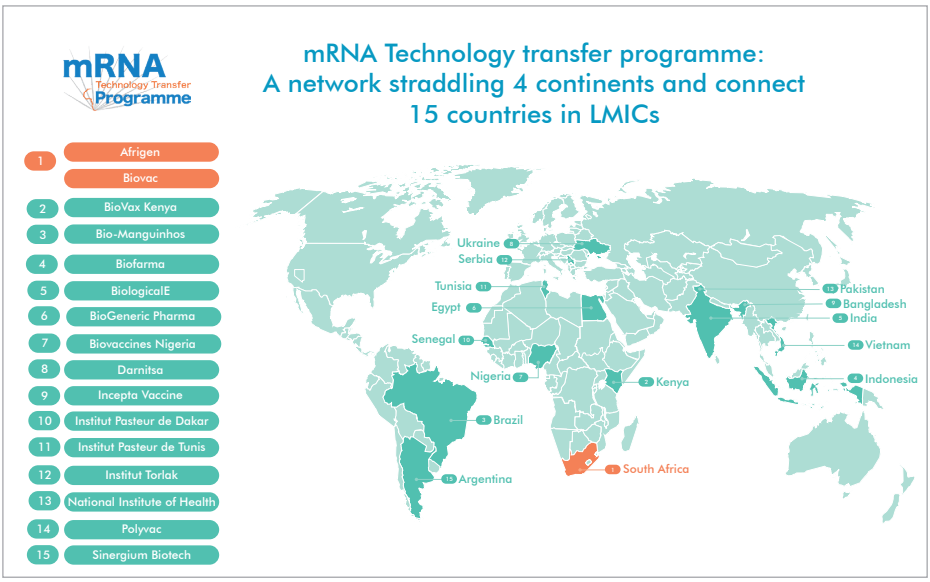


Figure 4: The 15 local producers selected as initial spokes for the Hub. Together these producers span four continents.

In parallel with the Hub's mRNA technology platform development and soon after the first laboratory-scale product was developed, Afrigen started transferring knowledge to the 15 low and middle-income country "spokes" that form the mRNA Hub's initial network (see Figure 4).

By the end of 2022, Afrigen had trained nine out of 15 spokes in introductory mRNA vaccine production. Biovac integrated well with the programme and is assisting with the development of quality control assays and support to ensure Afrigen processes meet stringent regulatory standards. Biovac will be taking Afrigen's good manufacturing practice production process, currently used for laboratory testing, and developing it for commercial use.

Conscious of the challenge to ensure the sustainability of the programme, the mRNA Hub engaged early with partners to address three challenges:

1. Operating in a complex intellectual property landscape;
2. Ensuring mRNA vaccines produced by the mRNA Hub would be fit-for-purpose: heat-stable and without the need for ultra-cold storage, for example, not available in existing, lowand middle-income country supply chains; and
3. Achieving production cost efficiencies to ensure affordability of next generation vaccines.

These goals led the mRNA Hub to collaborate with the US's NIH, mRNA production specialists Quantoom Biosciences, and mRNA immunotherapies experts eTheRNA. Many more strategic partnerships are expected in 2023.

Complex and ever-evolving intellectual property issues remain a challenge to manage and will require partnerships — and policy changes — in the near future.

Early challenges yield unexpected opportunities

It is evident that the mRNA Hub's challenges and successes have been intertwined.

For example, in the absence of a willing technology transfer partner, the mRNA Hub was forced to innovate, expanding its own

knowledge base. This resulted in the creation of an mRNA vaccine development platform (not just a product) that now carries the opportunity for vaccine innovation, multi-product production capabilities and new technology partnerships.

As more low and middle-income countries receive this platform technology, it will create a network of new vaccine producers that will contribute to vaccine production and innovation, complementing rather than disrupting existing global supply.

Still, the absence of a product-specific technology transfer partner did result in significant challenges in quality and regulatory systems that had to be developed in-house and from scratch. The time needed to develop these systems delayed original timelines for a turnkey technology transfer project. However, it allowed for significant capacity building and learning as well as the design of a facility and systems that lend themselves to different economies of scale. mRNA Hub-created systems that can accommodate a wide range of production volumes provide an opportunity to de-risk investment in multiple, smaller production units. We believe the mRNA Hub will show that even at smaller scales, mRNA vaccine production can be done with sustainable operating costs, which is important as countries ramp up production or perhaps choose to keep lower levels of manufacturing at the ready as part of pandemic preparedness units.

For decades, many vaccine producers in low and middle-income countries have been relegated to the final "fill and finish" steps of vaccine production — simply filling vials and finishing vaccines received from established producers. This has meant that emerging firms have been overly reliant on producers in high-income countries for vaccines.

As mentioned above, the mRNA Hub programme has already created and capacitated a network of vaccine producers. Some spokes are established vaccine producers and their participation in the mRNA Hub has enabled them to diversify existing production platforms to include mRNA. This has allowed some producers to — for the first time — establish drug product manufacturing capabilities to go beyond fill and finish.

Others, of course, will establish wholly new manufacturing capabilities to produce and supply mRNA vaccines.

Ultimately, the impact of this programme will reach far beyond the Covid-19 pandemic.

The collective knowledge and innovation capacity of the mRNA Hub and its spokes will usher in a new era of mRNA vaccines designed, developed and produced in low and middle-income countries and relevant for their burden of diseases. In this way, the programme could radically begin to shift the vaccine landscape, fostering greater equity and capacity in previously vulnerable and disadvantaged regions of the world.

We must build the complete vaccine production ecosystems that empower low and middle-income countries to address local needs effectively.

In 2021, the African Centres for Disease Control and Prevention launched the Partnerships for African Vaccine Manufacturing (PAVM) as part of a larger strategy to build a continental approach and capacity for vaccine production. This approach is the way forward and needs to be implemented effectively. The mRNA Hub and partners will strive to support the continent's ambition to self-supply 60% of its essential vaccines by 2040 by providing access to mRNA vaccine production technology alongside training and support.

This will be done through providing access to mRNA vaccine production technology, developing a portfolio of mRNA vaccines, training and building capacity to ensure that vaccine innovation platforms, integrated with GMP facilities for production of clinical material, are available to support supply and security.

Covid-19's most important lesson is that countries and regions that cannot locally produce significant volumes of vaccines and other health products have no guarantee of timely access to the tools they need to respond to epidemics or pandemics. This lesson need not be re-learned.

Professor Petro Terblanche is the chief executive officer of Afrigen Biologics and Vaccines, a professor at SA's North West University and an extra-ordinary Professor at the University of Pretoria in the School of Health Systems and Public Health. Previously, she served as the executive director for technology and innovation at the South African Medical Research Council as well as the Food, Biological and Chemical Technologies Division of SA's Council of Scientific and Industrial Research and the president of the Global Alliance for TB Drug Discovery and Development's stakeholder association, among others.

Dr Morena Makhoana is the chief executive officer of Biovac. Previously, he served as the company's medical affairs director and then deputy chief executive officer. He serves on several committees within the vaccine industry and as a board member of other healthcare and non-healthcare companies.

References

African Centres for the Disease Control and Prevention. (2021). Partnerships for African vaccine manufacturing "from aspiration to action" Concept Note. December 2021. Available at https://africacdc.org/wp-content/uploads/2021/11/ENGLISH_PAVM_Public-Stakeholder-Engagement_Concept-note_Final-version.pdf [accessed 15 Mar. 2023].

Mathieu, E., Ritchie, H., Ortiz-Ospina, E. et al. (2021). A global database of Covid-19 vaccinations. Natural Human Behaviour.

World Health Organization (2021). WHO supporting South African consortium to establish first Covid mRNA vaccine technology transfer hub. [online] WHO.int. Available at https://www.who.int/news/item/21-06-2021-who-supporting-south-african-consortium-to-establish-first-covid-mrna-vaccine-technology-transfer-hub [accessed 10 Mar. 2023].

UN News. (2021). Covid-19: First mRNA vaccine tech transfer hub a "great step forward". [online] Available at https://news.un.org/en/story/2021/06/1094402 [accessed 14 Mar. 2023].

Covid-19's silver lining? The WHO mRNA Technology Transfer Programme for the Global South Overcoming IP Barriers is central to the South-South Innovation and Access Goals of the WHO mRNA Technology Transfer Programme

Brook K. Baker
Fatima Hassan

Background

Despite early warnings, (Kashyap, 2020) (Hassan, 2021) intellectual property protectionism and vaccine nationalism defined the Covid-19 pandemic response (Hassan et al., 2021) resulting in vaccine apartheid. As early as December 2020, activists warned that nine out of 10 people in poor countries were set to miss out on Covid-19 vaccinations. Indeed, as late as April 2023, nearly three-fourths of people in high-income countries were vaccinated whereas only 59% of people in lower- and middle-income countries

had received a first dose (Mathieu, 2023). Vaccination rates in low-income countries were dramatically lower.

Exclusive market control and gross nationalism resulted in more than 18 months of artificially-restricted supplies of essential Covid-19 vaccines and other health technologies, needlessly high prices, breath-taking pandemic profiteering (Allen, 2022) and grossly inequitable global distribution (PVA, 2021).

Existing intellectual property laws and global intellectual property rules (WTO Agreement on TRIPS, 1994) permit companies and vaccine innovators to use patents, data protection, trade secrets, and other intellectual property protections / barriers to exclude competition and to prevent alternative, qualified vaccine manufacturers from offering additional supplies, lower prices, and more equitable distribution (Baker, 2021a) (Hassan, 2020).

Not satisfied with existing prices already many multiples over estimated costs of production, (Public Citizen, 2021) (Kis, 2020) in 2023 Pfizer and Moderna are expected to raise vaccine prices four-fold to US$110-$130 per dose for private sector sales in the US as public sector purchases dwindle (Silverman, 2023).

As discussed in earlier chapters here, early on in the pandemic, certain rich country governments, especially the US, invested billions to accelerate and de-risk Covid-19 vaccine research and development, clinical trials, and expanded manufacturing capacity (Global Health Centre, 2021) (Baker & Koons, 2020) (Lalani, 2023). Although these countries could have insisted on technology transfer, fair pricing, and equitable distribution requirements on their public investments, they neglected to do so and instead attached only one condition: Subsidised vaccine manufacturers preferentially supply initial stockpiles of Covid-19 vaccines to them. Other rich countries also hoarded vaccine supplies early in the pandemic via advance purchase agreements. This meant that many people in low and middle-income countries simply waited for Covid-19 vaccines throughout 2021 and beyond. Many low and middle-income countries did not have timely access to a first shot, and while they waited countries such as the US and Europe administered second and in some cases, booster shots to their populations (Johnson et al., 2021) (Mathieu, 2023).

Vaccine innovators expanded their production capacity to a limited extent through partnerships and contract manufacturing agreements (Baker, 2021b) but this was still insufficient to meet global need. Meanwhile, major vaccine producers largely boycotted or undermined voluntary technology sharing/transfer initiatives, including the WHO's Covid-19 Technology Access Pool (C-TAP), the MPP, and the Access to Covid-19 Tools Accelerator (ACT-A), which were meant to increase access to Covid-19 tools such as tests, medicines and vaccines. As a consequence, these firms denied technology transfer requests from multiple qualified producers (Dalberg, 2021).

Paradoxically, the same pharmaceutical representatives that originally scoffed at the idea of allowing voluntary licences to independent vaccine producers later touted industry's alleged commitment to "voluntary measures" in their Berlin Declaration (International Federation of Pharmaceutical Manufacturers & Associations, 2022).

Still, one early response in October 2020 to address the need for meaningful and timely technology transfer was the proposal by the governments of India and SA at the WTO to adopt a temporary waiver of multiple intellectual property rights, such as patents, trade secrets/confidential information, copyright, and industrial design on Covid-19-related medical technologies for the duration of the pandemic. The proposition became commonly known as the "TRIPS Covid-19 waiver" proposal. This proposal was preceded by an important submission by the SA government in July 2020 warning of the dangers of hoarding knowledge and the need to relax international intellectual property rules during the pandemic (Hassan, 2022) (Vawda et al., 2022a) (Vawda et al., 2022b) (Hassan et al., 2022) (HJI, 2022) (Yu, 2023) (Public Citizen, 2022) (SA Government, 2020) (Balasubramaniam, 2020) (Proposal by the African Group et al., 2001) (MSF, 2017).

Pharmaceutical companies and front-runner vaccine manufacturers lambasted the TRIPS Covid-19 waiver proposal and actively lobbied US and European governments to block it (Fang, 2023). Ultimately, developed countries — led by Germany, Switzerland, the UK and the EU — prevented any decision on the

waiver proposal for approximately 20 months, and were enabled to do so by the WTO secretariat. The US initially opposed the waiver but then announced limited support for a vaccine-only approach in May 2021 (Office of the US Trade Representative, 2021).

The WTO membership finally acceded to a highly watered down and ineffectual version of the original proposal, known as the "TRIPS Covid decision" in June 2022, that mainly focused on overcoming a limitation affecting exports to developing countries by means of compulsory licences on patents but does nothing more substantial (WTO, 2022).

The SA government has tried to put a positive spin on the woefully insufficient and defective TRIPS Covid-19 decision. Still, the decision does virtually nothing to expand Covid-19 vaccine access now, though proponents at the WTO continue to try to extend the decision to the more promising areas of access such as diagnostics and therapeutics. Unfortunately, the six-month time period within which to decide on whether to include the latter had been postponed indefinitely at the time of writing (Patnaik, 2022). Simultaneously, the US Trade Representative requested a 10-month study by the US International Trade Commission on whether the US should also support the extension of the decision to include therapeutics and diagnostics too.

Another response — the pandemic's potential "silver lining" and the subject of this and another companion article in this Compendium — is the establishment of the WHO mRNA Technology Transfer Programme with its "mRNA Hub" in SA and at least 15 country "Spokes", or local manufacturers in Global South countries (now called "partners"). The Programme (Hub and Spokes) as of January 2023 is shown in Figure 5. (Note: The Programme was initially established on a Hub and Spoke model but is now referred to as a partnership; we will use the original terms only for convenience.)

The mRNA Hub — regarded as a "radical plan" to reduce dependency by the South on the North (Maxmen, 2022) — was established by the WHO in May of 2021 after a year-long unsuccessful effort to convince Moderna, Pfizer/BioNTech, and other pharmaceutical companies to share knowledge and vaccine

technologies in the middle of a devastating global pandemic. It is one of the most important and innovative approaches to reduce dependency on Global North countries that have fuelled gross inequity in global pandemic responses.

Crucially, it has to succeed for the people of Africa, Latin America and the broader Global South to realise the advantages of open science research, and the fruits of scientific progress and its applications. Not surprisingly, companies such as Moderna have not explicitly committed to cooperating with the mRNA Hub. Instead, Moderna's CEO, Stéphane Bancel, in an interview with the *Financial Times* in 2021 likened the Hub's work to a "fake luxury handbag" (Smyth et al., 2022).

In addition to setting up the Hub and selecting Spoke partners, the Hub has also begun training of the workforce from several Spoke countries (Brennan, 2022).

mRNA Technology Transfer Hub Programme ("Hub and Spokes")

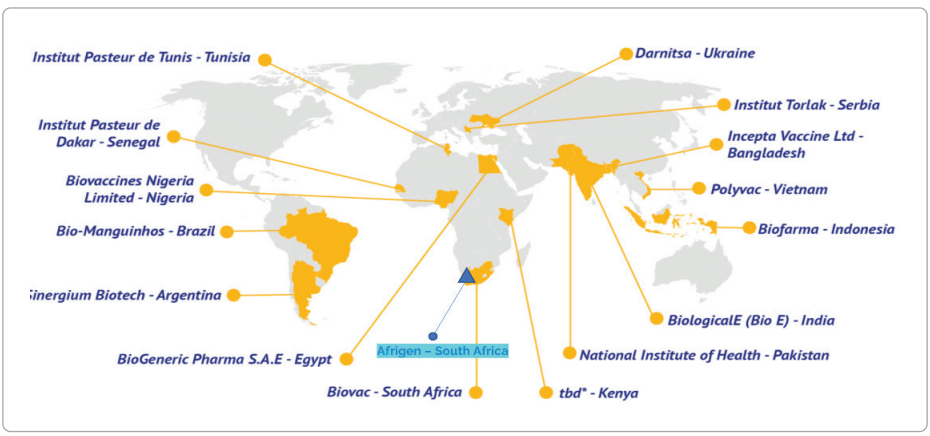


Figure 5: The WHO's mRNA Technology Transfer Programme is based at its "Hub" in Cape Town, SA but is set to engage in technology transfer with a broad network of other local producers in the Global South or "Spokes" to produce mRNA vaccines.

It should be noted that intellectual property rights still guard Covid-19 mRNA vaccines and many of their components, and their (intellectual property) breadth and duration threaten efforts to develop independent mRNA manufacturing capacity (Li et al., 2022). A database established by the MPP— a Geneva based organisation that facilitates voluntary licences — shows a complex web of patenting by several entities. This includes component and finished product rights holders with many patents in SA, other Spoke countries, and countries that could potentially import future vaccines made by the mRNA Hub and its Spokes (MPP Pool, 2022a). But despite Moderna's intransigence, and at times arrogance, the Hub still has grand ambitions for both innovation and access.

On the innovation front, the mRNA Hub and its Spokes have contractually committed to pursuing improved mRNA vaccines and therapeutics, optimising manufacturing, and adapting mRNA to address unmet health needs, particularly with respect to infectious and other diseases that disproportionately affect their countries, including HIV, TB, malaria, and neglected diseases. The Hub and Spokes have also agreed to share back all such relevant innovations with each other, creating a virtuous circle of reciprocal and wide sharing of the benefits of scientific progress and its applications.

The sharing will not only include patentable inventions but also information and data, and complex, commercial-scale manufacturing know-how. In terms of enhancing equitable access, it is expected that the Hub and Spokes will not only serve their domestic populations with earlier, expanded and more certain sources of supply, but that they will also supply regional and global markets on fair and equitable terms. Unlike the mRNA Hub in SA, certain country Spokes or partners that are led by companies that are 100% state owned (for example, Brazil) are not required to also ensure commercial and for-profit success (they are set up as not for profit). Fiocruz, the lead Brazilian partner, is not only a highly capable R&D and technology transfer centre for Latin America (PAHO, 2021), it is also developing a new self-amplifying RNA (saRNA) technology and is fully committed to sharing its technology with partner organisations and other countries (Aizenman, 2022).

Ultimately, the SA and Brazilian partners could help to

diversify and democratise biopharmaceutical manufacturing in all regions of the world and potentially enable more affordable, reliable, and equitable access to mRNA and saRNA vaccines and therapeutics for this and other pandemics. The Programme could revolutionise the way diseases affecting the poor and vulnerable are researched, especially in the fields of HIV, TB, the deadly childhood illness, Haemophilus influenzae type b and perhaps even cancer.

Preliminary comments about the SA mRNA Hub

Governance

The governance framework of the Programme is slightly unclear, raising questions on the part of civil society recently. The names of the SA mRNA Hub's steering committee were eventually shared in late 2022 by the MPP after civil society raised concerns about the lack of information sharing around key details related to the Programme's general and SA -specific "governance". As of July 2022, the mRNA Hub's steering committee — now and since formally called the Scientific and Technical Review Committee — consisted of:

1. Marie-Paule Kieny - Chair of the Governance Board of the MPP and Chairperson of the Committee
2. Mmboneni Muofhe - Deputy DG at SA Department of Science and Innovation
3. Michel de Wilde - Independent vaccine research and development expert
4. Nicaise Ndembi - Senior Science Advisor at the Africa Centres for Disease Control and Prevention
5. Marion Gruber - Vice President Public Health and Regulatory Science AIDS at the International AIDS Vaccine Initiative
6. Nadia Tornieporth - Professor of Clinical Research and Pharmacovigilance at the Hannover University of Applied Sciences and Arts in Hannover, Germany

According to the MPP , the Committee acts "as the advisory body" for the Programme, on areas such as:

- project directions, including the technology(ies) to pursue the design of the preclinical and clinical evaluation plans as needed for technologies to be developed;
- the regulatory pathway for technologies;
- allocation of flexible funds, and approval of disbursements of funds by the MPP consistent with terms provided in relevant funding agreements; and
- other issues of critical importance to the successful accomplishment of the goals of the mRNA Programme.

It is unclear whether each Spoke country (or other country partners to the Programme) also has a similar steering committee and who serves on those. Similarly opaque is what relationship these bodies, if they exist, have with the mRNA Hub in SA and the above Committee. In other words: Does this Committee make decisions for all the Spoke or partner countries too? If not, who does?

In respect of SA, and the Hub that is based in Cape Town:

- Only one person representing the SA government from the Department of Science and Innovation, is on the Programme's Scientific and Technical Review Committee. The Programme is effectively run by the MPP and WHO and its main "steering" committee is chaired by a person who is not from the Global South.
- The SA Presidency and the country's Ministries of Health, Trade, Industry and Competition have no formal representation. In addition, the Department of Science and innovation's practical and political coordination with the Department Trade, Industry and Competition is unclear.

We are unaware of the details of how the remaining Spoke countries are included in decision-making of the Programme.

So far, there is no elected civil society representation on the Committee. In September 2022, the MPP indicated that a process to select a civil society representative was being developed (Communicated by MPP at 2nd Civil Society Forum: MRNA Technology Transfer Hub Programme, September 2022), but it has not yet been publicised or implemented. Moreover, it is unclear how one permanent civil society representative will fulfil the mandate of representing civil society across approximately 15 diverse countries.

Meanwhile, the "model" mRNA Technology Transfer Spoke Agreement Template and Agreements are now available online (MPP, 2022a). In January 2023, the MPP's General Counsel reported that 10 Agreements have already been signed and it summarised the Spoke licences as follows: (MPP, 2022a) (note: Brazil has not yet signed this agreement in part because of its competing saRNA technology platform)

1. Freedom to Operate: The MPP and WHO will not guarantee freedom to operate at country level but will provide an intellectual property landscape analysis detailed at country level. The confirmation of actual status and scope of patents / claims filed and/or granted in the country in each Spoke's responsibility.

2. MPP grant of licence to Spoke:

    - The MPP grants to each Spoke a non-exclusive licence to technology transfer packages to develop and commercialise "products" based on the technology.
    - The MPP agrees to grant to each Spoke non-exclusive rights to data/inventions developed by other Spokes and any other sublicensable rights it obtains through other mRNA Hub agreements (for example, through South African Medical Research Council grantees).

The patent wars: Risks and mitigation

Moderna's obstructionist and misleading conduct

The SA mRNA Hub, and the Spokes and their host countries cannot rely on the goodwill and misleading promises of Moderna to moderate its mRNA IP empire. In a largely cynical offer with illusory benefits, Moderna had promised not to enforce its patents on the Covid-19 mRNA vaccine in low and middle-income countries for the duration of the pandemic (Moderna, 2020). Moderna has subsequently updated its commitment to "equitable access" and publicly affirmed "that its intellectual property will not create a barrier to Covid-19 vaccine distribution ... by Afrigen Biologics", although subsequent statements have cast doubt on this declaration (Roelf & Steenhuysen, 2022). A non-enforcement pledge on Covid-19 vaccine patents, even if enforceable and non-revocable, will not create a freedom to operate with respect to non-Covid-19 vaccines.

Emphasising the importance it places on its patent rights, Moderna recently sued Pfizer and BioNTech (Moderna, 2022) in the US for patent infringement, showing Moderna's willingness to defend its patents and seek royalties/ financial compensation. Pfizer has responded by countersuing (Brittain, 2022). In addition, to the best of our knowledge, these cases are alongside at least seven other legal cases involving intellectual property claims on the mRNA technology and Moderna, the US government and other US-based biopharmaceutical companies.

Throughout the pandemic, Moderna has steadfastly refused to share underlying, trade-secret protected know-how that is essential to commercially scale production of the vaccine. It does so despite multiple requests from the mRNA Hub, medicine access activists and even the US government (Meyer, 2022) (Malpani & Maitland, 2021) (Baumgaertner, 2021), which had financed most of Moderna's research and development expenses, via the US National Institutes of Health. This funding included the costs of clinical trials and investments in expanded manufacturing capacity.

Moderna and the biopharmaceutical industry, more broadly, have justified their refusal to share technology developed with public support and with public scientists on spurious grounds, claiming

alternately — and inconsistently — that technology transfer was "too hard". The pharmaceutical industry made these claims even as it transferred technology to favoured contract manufacturing partners. Similarly, it argued that it was "too busy" to conduct technology transfers and that there were "no qualified alternative producers" although researchers identified 120 potential manufacturers (MSF, 2021).

It also claimed without any basis that other producers could not manufacture "quality vaccines" and would "waste and disrupt component supplies and supply chains". In addition, despite initial decisions to supply only high-income countries almost exclusively, (Robbins, 2021) Moderna, Pfizer and industry trade groups began to vociferously claim that global supplies were "sufficient" and that there was "no need for additional capacity", despite very delayed and sporadic access to mRNA vaccines in low and middle-income countries (Johnson et al., 2021).

Moderna also revealed its true intentions in calls with investors — basically arguing that the mRNA technology platform was the foundation of its plan to maintain "monopoly control" over future applications of mRNA technology to develop vaccines and treatments for other conditions, including "gold-mine" cancer medicines.

Although this discussion has focused on Moderna, this is equally applicable with respect to Pfizer and BioNTech.

Moderna's refusal to license or share its technical knowledge and manufacturing know-how with the SA mRNA Hub and others has necessitated a much longer timeline for the SA mRNA Hub to independently develop its own technical and manufacturing know-how, which it plans to share on an incremental basis with its partners, thereby accelerating their capacity to bring identical mRNA products to the market.

Steps needed to extend freedom to operate and to create viable export/import markets

The SA Hub is currently working with the initial freedom to operate to research, develop, and register a clone of Moderna's mRNA Covid-19 vaccine under SA's so-called Bolar or early working

exception to patent protections. This exception contained in section 69A(1) of the Patents Act allows SA scientists to work with and on the patented product to produce quantities for clinical trials, to continue to work to independently develop commercial scale manufacturing processes and know-how to satisfy Good Manufacturing Practices requirements, and thereafter to file for regulatory approval in SA and other countries.

Still, the SA mRNA Hub's ability to actually research and market non-Covid-19 vaccines or future therapeutics may be highly constrained by existing intellectual property protections.

Even the ability of the SA mRNA Hub to sell a new or improved heat-stable Covid-19 vaccine might be constrained if Moderna does not formalise its verbal offer not to enforce its patents. Likewise, the mRNA Hub's work would be jeopardised if Moderna revokes the same pledge although we would argue that it can no longer unilaterally withdraw this offer given its public statements (Contreras, 2022) including submissions made in its legal papers in its recent claim against Pfizer in the US courts (*Moderna v Pfizer Inc, BioNTech, 2022*). In paragraph 23 of Moderna's Complaint for Patent Infringement, the company references the WHO's COVAX initiative that sought to guarantee access particularly to the world's poorest 92 countries, writing:

> Critically, however, and to further its belief that intellectual property should never be a barrier to access, as part of this announcement, Moderna committed to never enforce its patents for any Covid-19 vaccine used in the 92 low and middle-income countries in the GAVI COVAX Advance Market Commitment ("AMC"). **This includes any product manufactured outside the AMC-92 countries, such as the WHO's project in SA, with respect to Covid-19 vaccines destined for and used in the AMC-92 countries.** Although they have continued to use Moderna's intellectual property, Pfizer and BioNTech have not reached out to Moderna to discuss a license….. (Emphasis added).

Not only will the mRNA Hub in SA potentially be constrained, but other countries might be limited as well by their own domestic patent laws and Moderna's global patent landscape. We say this because Moderna has filed and is expected to continue to file mRNA-related patent applications in multiple low and middle-income countries, especially those with manufacturing capacity. Admittedly, it has not filed its basic mRNA Covid-19 vaccine patent in all the countries that are part of the Programme, nor has its broader underlying mRNA technology patent application been widely filed or granted in countries, although this broader patent has regrettably already been granted in SA (without patent examination). (As a bit of good news, the saRNA vaccine technology being developed by Fiocruz might "work around" Moderna's patents and thus have more freedom to operate.)

Nonetheless, Moderna has already indicated intentions to research and develop mRNA vaccines for multiple other conditions, including cancer, cardiovascular and respiratory infectious diseases (Tong, 2022) — as have other mRNA vaccine originators. It is inconceivable that Moderna will not seek extensive patent protection for those new products.

Moderna is also initiating plans to develop its own regional manufacturing capacity that might "compete" with the Programme. Moderna has already entered into "sweetheart" deals in several countries — including Kenya — whereby it has promised governments that if they co-invest in the facility, Moderna will in turn preferentially supply the host country (Moderna, 2023). And here, of course, Moderna will continue to control the quantity and price of what it produces.

On the other hand, whilst aware of the full extent of Moderna's conduct and actions, the SA government has regrettably not shared its plan to protect the mRNA Hub in SA through legislative and executive action, which the Constitution of SA — we argue — would permit and indeed require. The SA government's inaction comes despite health justice and activist groups requesting that it intervenes.

This absence of clear planning could be the net result of the SA government — from the Presidency to key government ministries

and departments — not being central in the design and decision-making of the Programme itself. Alternatively, and even worse, the SA government may not have the political will to stand up to Moderna and other right holders or to the rich countries that support them nor the funders of the Programme (ironically, most of the European funders to the Programme blocked SA's request for the TRIPS waiver - see above). SA officials may also be deterred by the potential backlash as embodied by trade threats that have materialised in the past with respect to efforts to increase access to life-saving medicines (Fisher & Rigamonti, 2005).

This is a worrying and immediate risk because recently, the MPP stated that while it designed and set up the mRNA Hub and Spokes (the Programme) in multiple countries: the "MPP and WHO will not guarantee FTO (freedom to operate) at country level but will provide an IP landscape analysis detailed at country level. The confirmation of actual status and scope of patents/claims filed and/or granted in the country *is each Spoke's 'responsibility*'" *(*emphasis added) (MPP, 2023).

This means that the SA government — here the Department of Trade, Industry and Competition — is in receipt of such an intellectual property landscape (discussed above and below) and knows full well the risks for the mRNA Hub from an intellectual property point of view. Still, to date, the department has been unable to or been unwilling to take any executive action against Moderna and others to actually protect the mRNA Hub's work.

We ask: Is it simply awaiting the forbearance and benevolence of Moderna?

During December 2022 the HJI requested the Minister of Department of Trade, Industry and Competition in SA to provide any details about how it plans to protect the mRNA Hub (executive action). The Ministry provided a vague and non-committal response.

This clarification of individual country responsibility ultimately to assure freedom to operate (to override patent barriers) means that if countries where the Partners are located are unable — or are unwilling — to take the necessary steps to safeguard the freedom to operate, then the promise of the model may be compromised with resulting negative impacts on mRNA vaccine supply, price, and

availability.

Under these circumstances, government action will be required in each place as follows:

- Each country with blocking patents will need to muster the political will to issue compulsory or government use licences on pending or granted component, process, and product patents to ensure freedom to operate.
- Host countries might also need to issue compulsory licences that permit export of finished mRNA products to other countries.
- Governments, including SA, must promptly amend their patent laws to allow mandatory or presumptive compulsory licences on key biopharmaceutical products, processes, and manufacturing components. Such reform should not be limited to mRNA products only, though those products may be key to global health in the future.
- In order to guarantee freedom to export/import and to expand markets so as to achieve economies of scale, importing countries facing patent barriers might also need to grant compulsory licences to mRNA Hub and Spoke producers.
- Because countries often face intense pressure from high-income countries and Big Pharma when they act unilaterally, it would be preferable for SA, with the partner countries and other low and middle-income countries to issue compulsory licences on a co-ordinated basis in order to aggregate a viable market for the Programme.

A key question for the Programme being "successful" is: Who ultimately will control the intellectual property and will countries be willing to adopt and use compulsory and government use licences and limited exceptions on patents, data protections, and trade secrets? Will innovations be declared global public goods and be shared beyond the mRNA Hub's formal Spoke partners, and who will make decisions about technology sharing beyond the mRNA Hub and Spokes?

These decisions are complicated by the fact that not all the Spokes

nor the SA mRNA Hub have 100% state-owned partners — they largely have commercial partners. For SA for example: Local firms and Hub partners Afrigen and Biovac are not 100% state-owned although publicly funded universities and a statutory research body, the South African Medical Research Council, are also involved in the product research phase. It should be noted that while the list of Hub and Spoke partners is publicly available, the respective percentage of state ownership for each entity in the Hub and in Spoke countries, if applicable, is not yet known (MPP, 2022b).

The mRNA Hub's technology transfer / sharing licences

At present, the now public mRNA Technology Transfer Spoke Agreement Template only has one firm access-performance requirement for the Spokes, although it does impose quality assurance and regulatory requirements. Pursuant to paragraph 4.5, in the event of a public health emergency of international concern, mRNA Hubs are obligated to supply 10% of their output to the WHO or public sector agencies at cost-of-manufacture plus 20%. However, there are no direct requirements concerning fair pricing for the remaining 90% of production and no requirement to distribute equitably to other countries.

There will be distributed manufacturing and perhaps an expectation of more affordable pricing and equitable distribution, but there are no contract terms to that effect. Instead, in the case of SA, Afrigen with others have focused on trying to achieve market entry and sustainability by having diversified product lines beyond mRNA vaccines and therapeutics, and by entering into advance agreements with governments and entities such as GAVI and UNICEF to guarantee that the mRNA Hub and its Spokes will become preferred suppliers (GAVI, 2022). These efforts to ensure commercial sustainability make sense for profit-dependent private enterprises — and maybe for industrial policy, but deference to the logic of private markets also risks compromising some of the potential access goals of the mRNA Hub to help ensure adequate supplies, affordable prices, and equitable distribution.

Specific steps needed in SA

The WTO TRIPS decision has not been domesticated in SA nor has the fully drafted Amended Patents Act (enacting many of the long-promised TRIPS-flexibility patent law reforms) been tabled in the Parliament of SA as promised by the Minister of Trade, Industry and Competition, Ebrahim Patel, who is in charge of this portfolio. These long-awaited patent law reforms in SA could have benefited the mRNA Hub if adopted sooner but nevertheless, still could — if passed in the near future. If these reforms are undertaken, they would:

- help avoid future unwarranted patents being granted (by requiring patent examination pursuant to stringent eligibility and disclosure requirements and pre- and post-grant opposition procedures); and
- expand the grounds and simplify processes for the issuance of compulsory and government-use licences.

This is important because in 2021 several broad patents on mRNA technology platforms were granted to Moderna by SA's Companies and Intellectual Property Commission without any substantive patent examination and without any opportunity for pre-grant opposition, including to the best of our knowledge: ZA 201403783 B, ZA 201303161 B, ZA 201403666 B (div of ZA 2013/03161), ZA 201402547 B. These patents were not examined for compliance with SA's patentability criteria, and organisations and groups acting in the public interest were precluded from opposing the patents before they were granted, as is the case with all patent applications currently. Similar patents have been rejected in other countries or withdrawn by Moderna's representatives there.

In addition to domesticating the WTO TRIPS decision and amending the Patent Act, the SA government will need to take concrete steps to file for compulsory licences as needed to overcome present and future patent barriers to existing and emerging mRNA vaccines and therapeutics. Showing a determination to act may provoke reluctant acquiescence by Moderna and others, but if not, actual compulsory licences must be pursued.

Conclusion

The mRNA Hub's decision to develop its own commercial manufacturing and quality control know-how overcomes the trade-secret/know-how barriers. Still, the mRNA Hub, its Spokes, and the countries they will seek to supply will continue to face patent barriers that must also be overcome. SA and other low and middle-income manufacturing countries and importers must consider co-ordinated compulsory licensing campaigns to create sustainable markets for mRNA vaccines and medicines — especially for conditions other than Covid-19.

Moderna and other transnational biopharmaceutical companies in the mRNA space are expected to patent new uses of mRNA vaccines and therapeutics broadly and to resist voluntary licensing. In light of this, SA and other low and middle-income countries will have to resort to so-called involuntary measures to create the freedom to operate for manufacture and for export/import. The long-delayed SA patent law reform would go a long way to clear the path for needed compulsory licences in SA, but Spoke countries may also need similar reform. It is important to emphasise, however, patent barriers in import market countries will also need to be overcome to aggregate viable and sustainable markets for new mRNA vaccine manufacturers.

The SA government and especially the Department of Trade, Industry and Competition, Department of Science and Technology, the Presidency, the mRNA Hub and its partners — particularly the WHO and MPP — cannot continue to act as if intellectual property barriers are not real. When the mRNA Hub was conceptualised and set up in SA — in assessing the patent and legal landscape — they should have anticipated that they also need to prepare for overcoming these real intellectual property barriers even as they advanced this exemplary experiment in South-South collaboration to make mRNA vaccines and therapeutics global public goods. Political, legislative, and executive inaction now will contribute to challenges down the road and potentially undermine the mRNA Hub's work. It is a huge risk for the SA government not to act promptly when for over two years the President of SA especially, on behalf of Africa, advocated for the lifting of intellectual property

rules in the Covid-19 pandemic and championed vaccine equity calling for more and especially South- South cooperation (Fabricius, 2022).

The pandemic has clearly shown that the "benevolence" of Big Pharma is a misnomer, and that the potentially unenforceable pledges or charity of Moderna or any other pharmaceutical company is a ruse that cannot be relied upon. It behoves the Global South to act now, and act decisively, starting with the SA government and the multiple partners to the mRNA Hub based in SA. It is certain that vibrant civil society campaigns can and should be undertaken to convince governments hosting the mRNA Technology Transfer Programme to engage in domestic and co-ordinated action to ensure its success.

Professor Brook K Baker is a professor of law at Northeastern University and an honorary research fellow at the University of KwaZulu Natal in Durban, SA. Baker is also a senior policy analyst for Health GAP (Global Access Project) and has consulted on intellectual property for organisations such as the African Union, the WHO, and countries such as SA, Uganda and Venezuela.

Fatima Hassan is a human rights lawyer and social justice activist and the founder / director of the Health Justice Initiative. She has dedicated her professional life to defending and promoting human rights in SA, especially in the field of HIV/AIDS where she worked for the AIDS Law Project and also acted for the Treatment Action Campaign in many of its legal cases. She is an Honorary Research Associate at the University of Cape Town School of Public Health & Family Medicine; she serves on the Board of Global Witness, is the Recipient of the Calgary Peace Prize in 2022 and is a 2023 Echoing Green Fellow.

References

Aizenman N (2022). These Brazilian besties are inventing an mRNA vaccine as a gift to the world. Nat't Public Radio. Available at https://www.npr.org/sections/goatsandsoda/2022/07/13/1111137152/these-brazilian-besties-are-inventing-an-mrna-vaccine-as-a-gift-to-the-world.

Allen A (2022). How pfizer won the pandemic, reaping outsize profit and influence. *Kaiser Health News*. Available at https://kffhealthnews.org/news/article/pfizer-pandemic-vaccine-market-paxlovid-outsize-profit-influence/.

Baker B K (2021a). Hamstringing the health technology response to Covid-19 – The burdens of exclusivity and policy solutions. *Northeastern University Law Review*. Available at https://static1.squarespace.com/static/56a67d1e05caa777b1877b09/t/609ade33e29e626e829ce7d1/1620762163987/Volume+13_Issue+2_Baker.pdf.

Baker B K (2021b). Policy brief: Third-way proposals from Big Pharma and the WTO are the same-old way – commercial control of supply, price, and distribution. People's vaccine campaign. Available at https://app.box.com/s/4rux5flb05pzc7fubs8qaeeffw0ykwe2; and see http://infojustice.org/wp-content/uploads/2021/05/Baker-April-2021.pdf.

Baker S and Koons C (2020). Inside Operation Warp Speed's $18 Billion sprint for a vaccine. *Bloomberg*. Available at https://www.bloomberg.com/news/features/2020-10-29/inside-operation-warp-speed-s-18-billion-sprint-for-a-vaccine.

Balasubramaniam T (2020). WTO TRIPS Council: India and South Africa submit draft decision text on a waiver from certain provisions of the TRIPS Agreement for the prevention, containment and treatment of Covid-19. Knowledge Ecology International. Available at https://www.keionline.org/34061.

Baumgaertner E (2021). Pfizer-BioNTech, Moderna refused to join WHO's C-TAP for vaccines. Now the India surge is causing crisis. *Los Angeles Times*. Available at https://www.latimes.com/world-nation/story/2021-04-30/vaccine-companies-and-the-u-s-government-snubbed-who-initiative-to-scale-up-global-manufacturing.

Brennan Z (2022). mRNA for all: WHO establishes biomanufacturing training hub in Korea. *Endpoints News*. Available at https://endpts.com/mrna-for-all-who-establishes-biomanufacturing-training-hub-in-korea/.

Brittain B (2022). Pfizer, BioNTech countersue Moderna over Covid-19 vaccine patents. *Reuters*. Available at https://www.reuters.com/legal/pfizer-biontech-countersue-moderna-over-covid-19-vaccine-patents-2022-12-05/.

Contreras J (2022). No take-backs: Moderna's attempt to renege on its vaccine patent pledge. Bill of Health. Available at https://blog.petrieflom.law.harvard.edu/2022/08/29/no-take-backs-modernas-attempt-to-renege-on-its-vaccine-patent-pledge/.
Cross R (2022) Moderna reaped more than $12 billion in profits from COVID vaccine sales last year. *The Boston Globe*. Available at https://www.bostonglobe.com/2022/02/24/business/moderna-reaped-more-than-12-billion-profits-covid-vaccine-sales-last-year/.
Council for Trade-Related Aspects of Intellectual Property Rights. Available at https://www.wto.org/english/tratop_e/trips_e/mindecdraft_w312_e.htm.
Dalberg (2021). ACT-Accelerator Strategic Review: An independent report prepared by Dalberg. Available at https://www.who.int/docs/default-source/coronaviruse/act-accelerator/act-a_strategic_review_report_8oct2021_final.pdf?sfvrsn=152da120_1&download=true.
Fabricius P (2022). Ramaphosa warns G7 leaders of new aim for patent waiver on Covid therapeutics and diagnostics. *Daily Maverick*. Available at https://www.dailymaverick.co.za/article/2022-06-29-ramaphosa-warns-g7-leaders-of-new-aim-for-covid-patent-waiver/
Fang L (2023). Covid-19 drugmakers pressured twitter to censor activists pushing for generic vaccine. *The Intercept*. Available at https://theintercept.com/2023/01/16/twitter-covid-vaccine-pharma/.
Fisher W W and Rigamonti C (2005). The South Africa AIDS controversy: A case study in patent law and policy. Harvard Law School. Available at https://dash.harvard.edu/bitstream/handle/1/37373367/South%20Africa.pdf?sequence=1
GAVI the Vaccine Alliance (2022). White Paper: A new era of vaccine manufacturing in Africa. Available at https://www.gavi.org/sites/default/files/covid/covax/new-era-vaccine-manufacturing-in-africa-wp.pdf.
Global Health Centre (2021). Covid-19 Vaccine R&D investments. Knowledge portal on innovation and access to medicines. Available at https://www.knowledgeportalia.org/covid-19-vaccine-r-d-funding.
Hassan F (2020). The great Covid-19 vaccine heist. *Daily Maverick*. Available at https://www.dailymaverick.co.za/article/2020-12-06-the-great-covid-19-vaccine-heist/.
Hassan F (2021). Drug companies and rich countries are creating a system of accine apartheid. *Foreign Policy*. Available at https://foreignpolicy.com/2021/02/23/dont-let-drug-companies-create-a-system-of-vaccine-apartheid/.
Hassan F, Yamey G and Abbasi K (2021). Profiteering from vaccine inequity: a crime against humanity? *BMJ* 374.
Hassan F (2022) A new and weak WTO deal on TRIPS is not fit for purpose. Think global health. Council on Foreign Relations. Available

at https://www.thinkglobalhealth.org/article/new-and-weak-wto-deal-trips-not-fit-purpose#:~:text=South%20Africa%2C%20India%2C%20and%20other,once%20again%20contest%20this%20notion.%22.
Hassan F, Vawda Y and London L (2022). The leaked WTO Covid patent waiver text promises a very bad deal. *Al Jazeera*. Available at https://www.aljazeera.com/opinions/2022/4/8/the-leaked-wto-covid-patent-waiver-text-promises-a-very-bad-deal.
Health Justice Initiative (2022). Explainer: The June 2022 WTO TRIPS "deal" that tried to save reputations, not lives! Available at https://healthjusticeinitiative.org.za/2022/06/30/the-wto-deal-explainer/.
Human Rights Watch (2020). Campaigners warn that 9 out of 10 people in poor countries are set to miss out on Covid-19 vaccine next year. Available at https://www.amnesty.org/en/latest/press-release/2020/12/campaigners-warn-that-9-out-of-10-people-in-poor-countries-are-set-to-miss-out-on-covid-19-vaccine-next-year/.
International Federation of Pharmaceutical Manufacturers and Associations (2022). Berlin Declaration: Biopharmaceutical Industry Vision for Equitable Access in Pandemics. Available at https://ifpma.org/wp-content/uploads/2023/01/i2023_IFPMA_Berlin-Declaration_Biopharmaceutical-industry-vision-for-equitable-access-in-pandemics-1.pdf.
Johnson T, Moultrie T, Gonsalves G and Hassan F (2021). An inconvenient truth: The real reason why Africa is not getting vaccinated. *News24*. Available at https://www.news24.com/news24/opinions/analysis/analysis-an-inconvenient-truth-the-real-reason-why-africa-is-not-getting-vaccinated-20211012.
Kashyap A (2020). Whoever finds the vaccine must share it. Human Rights Watch. Available at https://www.hrw.org/report/2020/10/29/whoever-finds-vaccine-must-share-it/strengthening-human-rights-and-transparency.
Kis Z, Kontoravdi C, Shattock R and Shah N (2020). Resources, production scales and time required for producing RNA vaccines for the global pandemic demand. *Vaccines* 9(1): 3.
Lalani H S, Nagar S, Sarpatwari A, Barenie R E, Avorn J, Rome B N and Kesselheim A S (2023). US public investment in development of mRNA covid-19 vaccines: Retrospective cohort study. *BMJ* 380.
Li M, RenJ, Si X, SunZ, Wang P, Zhang X, et al. (2022). The global mRNA vaccine patent landscape. *Human Vaccines and Immunotherapeutics* 18(6): 2095837.
Malpani R and Maitland A (2021). Dose of reality: How rich countries and their corporations are breaking their vaccine promises. People's Vaccine Alliance. Available at https://webassets.oxfamamerica.org/media/documents/A_Dose_of_Reality-Briefing_Note_kOW1yUs.pdf.

Mathieu E, Ritchie H, Ortiz-Ospina E, et al. (2023) A global database of Covid-19 vaccinations. *NatureHuman Behaviour* 5: 947-953.

Maxmen A (2022). Unseating big pharma: The radical plan for vaccine equity. *Nature* 226-233.

Meyer D (2022). Moderna wouldn't share its vaccine technology, so South Africa and the WHO made a Covid jab based on it anyway. Fortune. Available at https://fortune.com/2022/02/04/south-africa-afrigen-moderna-covid-vaccine-mrna-who-hotez-corbevax/.

Medicines Patent Pool (2022a). mRNA Vaccine Technology Transfer Agreement. Available at https://medicinespatentpool.org/uploads/2022/10/Technology-Transfer-Agreement-Template.pdf.

Medicines Patent Pool. (2023). How to build a health commons approach to pandemic preparedness and response. [PowerPoint Slides]. DNDi webinar (16 January 2023).

Medicines Patent Pool (2022b). WHO and MPP announce names of 15 manufacturers to receive training from mRNA technology transfer hub. Available at https://medicinespatentpool.org/news-publications-post/who-and-mpp-announce-names-of-15-manufactures-to-receive-training-from-mrna-technology-transfer-hub.

Médecins Sans Frontières (2017). A fair shot for vaccine affordability: Understanding and addressing the effects of patents on access to newer vaccines. Available at https://msfaccess.org/fair-shot-vaccine-affordability.

Médecins Sans Frontières (2021). Pharmaceutical firms across Asia, Africa and Latin America with potential to manufacture mRNA vaccines. Available at https://msfaccess.org/pharmaceutical-firms-across-asia-africa-and-latin-america-potential-manufacture-mrna-vaccines.

Moderna (2020). Statement by Moderna on intellectual property matters during the COVID-19 Pandemic. Available at https://investors.modernatx.com/Statements--Perspectives/Statements--Perspectives-Details/2020/Statement-by-Moderna-on-Intellectual-Property-Matters-during-the-COVID-19-Pandemic/default.aspx.

Moderna (2022). Moderna sues Pfizer and BioNTech for infringing patents central to Moderna's Innovative mRNA Technology Platform. Available at 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.

Moderna (2023). Moderna finalizes agreement with the Government of the Republic of Kenya to establish an mRNA manufacturing facility. Available at https://investors.modernatx.com/news/news-details/2023/Moderna-Finalizes-Agreement-with-the-Government-of-the-Republic-of-Kenya-to-Establish-an-mRNA-Manufacturing-Facility/default.aspx.

ModernaTx, Inc and Moderna US, Inc v Pfizer Inc, BioNTech SE, BioNTech Manufacturing GMBH and BioNTech US Inc. (US District Court for the District of Massachusetts 2022). Available at https://htv-prod-media.s3.amazonaws.com/files/01-main-1661517480.pdf.

Office of the United States Trade Representative (2021). Statement from Ambassador Katherine Tai on the Covid-19 TRIPS Waiver. Available at https://ustr.gov/about-us/policy-offices/press-office/press-releases/2021/may/statement-ambassador-katherine-tai-covid-19-trips-waiver.

Patnaik P (2022). High drama, but no outcome at the WTO: TRIPS extension decision for Covid-19 tests and treatments. Geneva Health Files. Available at https://genevahealthfiles.substack.com/p/high-drama-but-no-outcome-at-the.

People's Vaccine Alliance (2021). Covid vaccines create 9 new billionaires with combined wealth greater than cost of vaccinating world's poorest countries. Available at https://www.oxfam.org/en/press-releases/covid-vaccines-create-9-new-billionaires-combined-wealth-greater-cost-vaccinating

Pan American Health Organization (PAHO) (2021): PAHO selects centers in Argentina, Brazil to develop COVID-19 mRNA vaccines. Available at: https://www.paho.org/en/news/21-9-2021-paho-selects-centers-argentina-brazil-develop-covid-19-mrna-vaccines.

Public Citizen (2021). $25 Billion to vaccinate the world. Available at https://www.citizen.org/article/25-billion-to-vaccinate-the-world/#:~:text=The%20United%20States%20can%20help,income%20countries%20in%20one%20year.

Public Citizen (2022). CSO statements in response to shameful result on intellectual property and COVID at 12th WTO ministerial. Available at https://www.citizen.org/news/cso-statements-in-response-to-shameful-result-on-intellectual-property-and-covid-at-12th-wto-ministerial/.

Roelf W and Steenhuysen J (2022). Moderna patent application raises fears for Africa COVID vaccine hub. *Reuters*. Available at https://www.reuters.com/business/healthcare-pharmaceuticals/moderna-patent-application-raises-fears-africa-covid-vaccine-hub-2022-02-17/.

Robbins R (2021). Moderna, racing for profits, keeps COVID vaccine out of reach of poor. *New York Times*. Available at https://www.nytimes.com/2021/10/09/business/moderna-covid-vaccine.html.

Silverman E (2023). Moderna plans to follow in Pfizer's footsteps, charge up to $130 for COVID-19 vaccine in U.S. *STAT*. Available at https://www.statnews.com/topic/vaccines/page/3/.

Smyth J, Cotterill J and Donato P M (2022). Will "open-source" vaccines narrow the inequality gap exposed by COVID? *Financial Times*. Available at https://www.ft.com/content/61e1d51e-b415-4161-b157-032e5207ab7f.

South African Government (2020). South Africa's submission on IP and the public interest – beyond access to medicines and medical technologies towards a more holistic approach to TRIPS flexibilities. Knowledge Ecology International. Available at https://www.keionline.org/33551.

Tong A (2022). The urgency is increasing: Moderna spotlights vaccine, orphan drug programs, as it plots growth beyond Covid. *Endpoints News*. Available at https://endpts.com/the-urgency-is-increasing-moderna-spotlights-vaccine-orphan-drug-programs-as-it-plots-growth-beyond-covid/.

Vawda Y, Hassan F. and Johnson T (2022a). New WTO deal is a slap in the face for poorer countries. *News24*. Available at https://www.news24.com/fin24/opinion/opinion-new-wto-deal-is-a-slap-in-the-face-for-poorer-countries-20220618.

Vawda Y, Hassan F and Johnson T (2022b). Say no to rich nations and WTO bullying in Geneva – why South Africa should stand up and not be silenced. *Daily Maverick*. https://www.dailymaverick.co.za/article/2022-06-15-south-africa-must-say-no-to-rich-nations-and-wto-bullying-in-geneva/8.

World Trade Organization (2001). Proposal by the African Group, et al.Draft Ministerial Declaration. IP/C/W/312, WT/GC/W/450.

Council for Trade-Related Aspects of Intellectual Property Rights. Available at https://www.wto.org/english/tratop_e/trips_e/mindecdraft_w312_e.htm.

World Trade Organization (2022). Draft Ministerial Decision on the TRIPS Agreement WT/MIN(22)/W/15/Rev.2. Available at https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/WT/MIN22/W15R2.pdf&Open=True.

Yu P (2023). The Covid-19 TRIPS Waiver and the WTO Ministerial Decision in IPR in Times of Crisis: Lessons Learned from the Covid-19 Pandemic. (Jens Schovsbo ed., Edward Elgar Publ'g forthcoming 2023). Available at https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4150090.

CONTEXT:
It is time for ambitious, transformational change to the epidemic countermeasures ecosystem”

Originally published:
Torreele *et al The Lancet* 13th March 2023

It is time for ambitious, transformational change to the epidemic countermeasures ecosystem

Published Online
March 13, 2023
https://doi.org/10.1016/
S0140-6736(23)00526-3

We are living in an era of unrivalled convergence of epidemic and other health threats, exacerbated by the climate and biodiversity crises. The hazards of emerging and re-emerging infectious diseases spread from animals to humans increase the risk of future pandemics.[1] Increasing concerns about cases of avian influenza A (H5N1) infections in people, birds, and mammals are another grave warning.[2,3] To protect people and reduce the risk of pandemics, health threats must be rapidly contained with appropriate health countermeasures where and when they occur.[4] Now is the time for an ambitious, transformative approach to epidemic and pandemic health technologies. A transformative approach requires a fundamental change in why, how, where, and by whom these technologies are developed and produced, and about who has access to this knowledge and know-how.

The existing approach to research and development (R&D), manufacturing, and access to and delivery of essential epidemic countermeasures is deeply inequitable, especially for people in low-income and middle-income countries (LMICs), and for vulnerable populations worldwide. For example, the Geneva-based Access to COVID-19 Tools Accelerator (ACT-A) platform, largely dependent on existing market-based mechanisms, could not provide timely or equitable access to essential countermeasures.[5] A transformed epidemic countermeasures ecosystem is urgently needed that is rooted in equity at every step, regional resilience, and knowledge and technology sharing. It must foster R&D, manufacturing, availability, and procurement and delivery of appropriate, essential health countermeasures in a timely and equitable way for everyone's benefit, based on a common goods approach.[4]

In the wake of the COVID-19 pandemic, norms, architecture, governance, and financing must be redefined with public, private, academic, and civic partners collaborating towards achieving the collective goal of epidemic control. All stakeholders need to seize upcoming opportunities to advance this agenda, including in the follow-up to the February, 2023 South Africa-hosted meeting on building consensus for an equitable and sustainable medical countermeasures platform for the next pandemic; the WHO consultation on “Developing a new platform for equitable access to medical countermeasures in pandemics”;[6] the Intergovernmental Negotiating Body's (INB) efforts to adopt a global pandemic instrument with equity as a core principle;[7] the G7 and G20 meetings later this year; and the UN General Assembly's high-level meeting on pandemic prevention, preparedness and response on Sept 20, 2023, at which a political declaration is expected to be adopted.[8]

***Panel* 1: Core principles that must be included in an equitable, effective, and sustainable transformed pandemic countermeasures ecosystem**

Human rights
People's right to health, including to health countermeasures, and dignity must underpin a transformed ecosystem

Guaranteed equitable protection
In times of health crises, no persons living in low-income and middle-income countries or anywhere else should be dependent on charity to gain access to essential countermeasures

National and regional resilience
This includes leadership in and access to research and development to address priority health issues

A common goods approach
Health technologies for pandemic preparedness and response should be considered common goods, not private commodities

Inclusive governance and decision making
No decisions should be made about low-income and middle-income countries without the involvement of their governments, scientists, researchers, parliamentarians, and civil society groups in the decision-making process

Equity
Equity must be built in from start to finish, or end-to-end, in meaningful ways, from the laboratory, to clinical testing, manufacturing, access, delivery, and impact on people's health

Access and freedom to operate
To avert or manage crises, researchers everywhere must have access to, and freedom to operate on, the crucial knowledge and health technologies to develop solutions to address the health threats facing their regions without undue intellectual property restrictions

Sustainable financing designed for health impact
Structure public–public and public–private partnerships and finance towards achieving public health goals using pre-negotiated contracts and conditions that prioritise people's health and the public interest

Accountability for investment and impact
Through the establishment of independent, transparent, impartial, and regular evaluation mechanisms at each level

***Panel* 2: Urgent priorities and actions for a transformed pandemic countermeasures ecosystem**

An end-to-end ecosystem that delivers equitable research, development, manufacturing, and access to epidemic countermeasures, grounded in a common goods approach that responds to local needs, with equity built in from research to access

- Create, invest in, and protect coordinated, sustained, and networked regional research and development and manufacturing hubs, with freedom to operate without undue intellectual property restrictions, which build and sustain capacity and self-reliance in low-income and middle-income countries
- Link well funded regional research and development hubs to independent clinical trial networks conducting public-health focused trials and to manufacturing capacity
- Establish transparently governed and adequately financed pre-negotiated agreements and partnerships, involving the public and private sectors, academic institutions, and civil society, including conditionalities that guarantee a focus on public health outcomes
- Plan and invest from the outset in systems that ensure access and delivery to people in need

Inclusive and networked governance with decentralised decision making to address health needs optimally when and where they occur, shifting the centre of gravity to regions and countries

- At the national level, engage key stakeholders and ensure funding, investment, regulation, and legislation that fosters and protects the freedom to research and manufacture epidemic countermeasures
- At the regional and subregional levels, engage key stakeholders to set priorities and oversee development and implementation of regional action and investment plans
- At the global level, establish a multisectoral Global Health Threats Council
- Strengthen and finance WHO in its mandate and comparative advantage

A globally and regionally pre-negotiated financing system

- Pre-negotiated conditional co-funding arrangements between global, regional, and national levels should be prioritised to transform the current top-down model
- Countries must establish their own mechanisms for increasingly self-financed pandemic preparedness and service delivery, and can raise additional financing through, for example, progressive taxation and addressing corruption
- International and regional financial institutions must have an instrumental role in financing and be designed to ensure technology sharing and equitable access. The Pandemic Fund must be made fit-for-purpose, including by having a sustainable financing strategy based on a global public investment model, and must fund research and development for the common good as part of pandemic preparedness

We believe that LMIC representatives, civil society and community organisations, the scientific research and public health communities, and humanitarian groups must be meaningfully involved in all these discussions and processes.

Core principles must be included in a transformed pandemic countermeasures ecosystem (panel 1) and we underline three urgent priorities that require transformative change to achieve an equitable ecosystem for pandemic countermeasures (panel 2).

First, countries must design and implement a sustainable end-to-end ecosystem to contain outbreaks and pandemic threats where and when they occur, grounded in a common goods approach, knowledge and technology sharing, and collective ownership. Such an ecosystem must make outbreak tools, including diagnostics, treatments, and vaccines, equitably available where needed from the earliest possible opportunity. Creating, investing in, and protecting coordinated, sustained, and networked regional R&D and manufacturing hubs will be fundamental for this transformed ecosystem. These hubs must build and expand LMIC capacity and self-reliance and ensure that epidemic countermeasures are developed and delivered as common goods and in response to local needs. The hubs must therefore be operated and staffed by a local, skilled workforce who have the guaranteed freedom to operate around technology platforms for vaccines, treatments, and diagnostics in response to epidemics, including with regard to intellectual property rights and technological know-how, and be financed adequately so that these can be rapidly adapted to emerging health threats.

The WHO-initiated mRNA vaccine technology transfer hub based in South Africa, partnering with manufacturers in at least 15 LMICs, is one example[9] that could be replicated and extended to other technologies and countries. Manufacturing capacity needs to be linked to R&D capability to respond to local health needs, with the freedom to operate for epidemic preparedness and response and with dedicated regional and global health security financing. Well funded regional R&D hubs must link to independent clinical trial networks and must pursue research priorities for epidemic countermeasures adapted to respond to local needs and health-system contexts. Collective intelligence, knowledge sharing, and, as needed, technology transfer among hubs must be a guiding principle throughout.

The second priority is for inclusive and networked governance with decentralised decision making to address health needs where and when they occur. To this end, the centre of gravity, agency, and locus of control must shift to regions and countries in a harmonised, co-funded, resource-shared, and co-created approach that respects the principle of subsidiarity, including allowing freedom to operate at the appropriate level.

At the national level, governments must adopt a whole-of-government approach to design an enabling policy environment for collaborations between public,

private, academic, and civil society sectors. This includes research funding, health-industrial policy with access to investment capital, a conducive health regulatory environment, and legislation that promotes collective intelligence and technology sharing, and protects the freedom to research and operate for epidemic countermeasures. Greater use of the existing flexibilities around intellectual property that reside in international trade rules is also needed to protect public health. Given that regions self-organise in different ways, appropriate regional and subregional governance and decision making are required. Governance should engage key stakeholders, including governments, regional banks, regional public health authorities, and civil society; set priorities for regional and subregional contexts; and oversee development and implementation of regional action plans.

At the global level, given the multisectoral, whole-of-government approach required, a Global Health Threats Council, as recommended by the Independent Panel for Pandemic Preparedness and Response[10] and by several other high-level bodies, is essential to combat health threats and to advocate for a cohesive system that enables prompt and equitable responses to health emergencies, fosters inter-regional collaboration, and advocates for and monitors system financing. We underscore the central role of WHO and call on its member states to support its mandate fully and finance its core budget. WHO should focus on its comparative advantage through providing normative, policy, and technical guidance; supporting countries and collaborating with regional platforms and institutions to build technical capacity for pandemic preparedness and response, including the development and manufacturing of countermeasures; and strengthening technical capacity for resilient and equitable health systems.

Third, a transformed ecosystem requires a globally and regionally pre-positioned, pre-negotiated financing system. Countries must invest in their own systems for increasingly self-financed pandemic preparedness, response, and service delivery. Additional domestic financing can be raised, including through progressive taxation, leveraging resources of other sectors, and addressing corruption and money laundering. This approach is fundamental to ending the dependency of LMICs on charity models of aid, which have served them poorly throughout the COVID-19 pandemic and that perpetuate inequities and coloniality. Globally and regionally, despite the damaging effects of the COVID-19 pandemic on health systems, development progress, and economies, only a small fraction of the funds required have been committed, including to The Pandemic Fund.[11]

As an essential component of preparedness, networked R&D and manufacturing must be fully included in financing. This approach will make it possible to break away from the legacy system whereby manufacturers capture monopoly rights and unfettered profits that derive from publicly funded R&D; instead contracts need to be designed with binding commitments towards knowledge and technology sharing, pricing, and equitable access.[12]

International and regional financial institutions and the new Africa Epidemics Fund[13] must have an instrumental role in financing. The proposed Bridgetown Initiative for the reform of global financial architecture has the potential to unleash substantial funding for development financing, including for pandemic prevention and preparedness.[14] Such initiatives must be encouraged, particularly given that climate change increases the risk of zoonotic spillover and of pandemic threats.[1]

Next, before The Pandemic Fund's ways of working become entrenched, it must be made fit-for-purpose, including by having a sustainable financing strategy based on a global public investment model where each country contributes according to its means and allocations are made based on need. The Pandemic Fund should expand its focus and funding to supporting investments in R&D as a core part of preparedness. We propose that the Pandemic Fund prioritise investments in: national, regional, and subregional platforms for R&D that are linked to manufacturing and supply chains dedicated to equity with unrestricted sharing of knowledge and intellectual property; and national, regional, and subregional institutions and capabilities for disease surveillance, outbreak detection, and effective response to epidemics before they can spread and become pandemics. The Pandemic Fund should also broaden the number of implementing entities and give priority to those that are regionally based, or in proximity to the health needs they seek to address, particularly in LMICs. Solutions must also be agreed to leverage up to the US$100 billion required[10] for rapid response should a pandemic threat materialise. Additionally, there could

www.thelancet.com Published online March 13, 2023 https://doi.org/10.1016/S0140-6736(23)00526-3

be a role for the International Finance Corporation of the World Bank in financing the development of manufacturing capacity.

Market-based systems cannot deliver essential epidemic countermeasures in a timely, fair, equitable, and sustainable manner. Now is the time for ambition and transformative change to protect people everywhere. If not now, when?

ETor is a consultant to WHO doing a case study on the mRNA technology transfer hub for the WHO Council on the Economics of Health for All. CM has been a consultant for WHO. OA reports consulting fees from WHO, the World Bank, and Pharos (for participation in the firm's evaluation of the Global Fund's COVID-19 Response Mechanism) and speaker's fees from Pfizer. RB is currently under contract with the WHO Regional Office for Europe to help facilitate strategy discussions of its senior leadership team. MK is an independent Board Member of Exevir Bio (a biotechnology company designing therapeutic monoclonal antibodies to SARS-CoV-2). JK reports he was a consultant for SK Bioscience (a bioscience firm that specialises in vaccine development and manufacture); consulting fees from Moderna; and he is an unpaid member of the Scientific Advisory Board of Everest (a biopharmaceutical company focused on developing and commercialising pharmaceutical products that address unmet medical needs for patients in Asian markets). ETod reports the Pandemic Action Network (PAN) has received grants from several charitable foundations, as well as from Johnson & Johnson Global Public Health and from Merck, and that PAN's conflict of interest policy makes it clear that the PAN's policy, advocacy, and campaign work is developed independently; she reports support to take part in an ACT-A-related panel at the World Health Summit in Berlin in 2022. None of these roles relate to the content of this Comment. JK, KR, PT, and MdSF's work is focused on vaccine research and development. PT is the CEO of Afrigen Biologics, a Cape Town based company hosting the WHO mRNA Vaccine Technology Development and Transfer hub. HK conducts research on political origins of health inequity, and serves as the Executive Director at the RIGHT Foundation. HC and EJS were Co-Chairs of the Independent Panel for Pandemic Preparedness and Response (IPPPR). MK and JL were members of the IPPPR. CM and HL-Q are former Secretariat members of the IPPPR. All the other authors declare no competing interests. Work that led to the convening at the Bellagio Centre held February 14–16, 2023, was funded through a grant from Open Society Foundations (OSF). OSF had no role in determining the content of the convening and had no editorial input into this Comment. This Comment builds on recommendations of the IPPPR and on ideas presented in a previous *Lancet* Comment,[4] enriched through three webinars held in January and early February, 2023, and a meeting titled "Advancing a new approach to pandemic tools as common goods" at The Rockefeller Foundation Bellagio Centre, Italy, on Feb 14–16, 2023. The Rockefeller Foundation Bellagio Centre covered international transport for many participants. The Rockefeller Foundation had no input into the meeting agenda, contents, or outcomes.

*Els Torreele, *Christine McNab, Olusoji Adeyi, Roxana Bonnell, Mandeep Dhaliwal, Fatima Hassan, Michel Kazatchkine, Hani Kim, Jerome Kim, Helena Legido-Quigley, Joanne Liu, Sania Nishtar, Kiat Ruxrungtham, Petro Terblanche, Eloise Todd, Marcos da Silva Freire, Germán Velásquez, Ellen Johnson Sirleaf, Helen Clark*

christinemcnab@gmail.com

Institute for Innovation and Public Purpose, University College London, London, UK (ETor); Independent Consultant, Geneva, Switzerland (ETor); Independent Consultant, Toronto, ON, Canada (CM); Resilient Health Systems, Washington, DC, USA (OA); Independent Consultant, Mountain Brook, AL, USA (RB); United Nations Development Programme, New York, NY, USA (MD); Health Justice Initiative, Cape Town, South Africa (FH); School of Public Health and Family Medicine, University of Cape Town, Cape Town, South Africa (FH); Global Health Centre, The Graduate Institute for International Affairs and Development, Geneva, Switzerland (MK); RIGHT Foundation, Seoul, South Korea (HK); International Vaccine Institute, Seoul, South Korea (JK); College of Natural Sciences, Seoul National University, Seoul, South Korea (JK); Saw Swee Hock School of Public Health, National University of Singapore and National University Health System, Singapore (HL-Q); School of Population and Global Health and Pandemics and Health Emergencies Readiness Lab, McGill University, Montréal, QC, Canada (JL); Senate of Pakistan, Islamabad, Pakistan (SN); Chula School of Global Health and Chula Vaccine Research Center, Faculty of Medicine, Chulalongkorn University, Bangkok, Thailand (KR); Afrigen Biologics, Cape Town, South Africa (PT); North West University, Cape Town, South Africa (PT); Pandemic Action Network, Brussels, Belgium (ETod); Departamento de Desenvolvimento Tecnológico (Bio-Manguinhos), Fundação Oswaldo Cruz (Fiocruz), Rio de Janeiro, Brazil (MdSF); The South Centre, Vernier, Switzerland (GV); Ellen Johnson Sirleaf Presidential Centre for Women and Development, Montserrado, Monrovia, Liberia (EJS); The Helen Clark Foundation, Auckland, New Zealand (HC)

1 Carlson CJ, Albery GF, Merow C, et al. Climate change increases cross-species viral transmission risk. *Nature* 2022; **607**: 555–62.

2 Davis N. WHO says avian flu cases in humans "worrying" after girl's death in Cambodia. The Guardian. Feb 24, 2023. https://www.theguardian.com/world/2023/feb/24/who-says-h5n1-avian-flu-cases-in-humans-worrying-after-girls-death (accessed March 10, 2023).

3 Abbasi J. Bird flu has begun to spread in mammals—here's what's important to know. *JAMA* 2023; **329**: 619–21.

4 Torreele E, Kazatchkine M, Liu J, et al. Stopping epidemics when and where they occur. *Lancet* 2023; **401**: 324–28.

5 Open Consultants. Open Consultants External Evaluation of the Access to COVID-19 Tools Accelerator (ACT-A). Berlin: WHO, 2023.

6 WHO. Developing a new platform for equitable access to medical countermeasures in pandemics: design & consultation process. 2023. https://www.who.int/news-room/articles-detail/who-design-and-consultation-process-on-a-new-medical-countermeasures-platform-for-pandemics (accessed March 6, 2023).

7 WHO. Intergovernmental Negotiating Body. "The World Together": the Intergovernmental Negotiating Body to draft and negotiate a WHO convention, agreement or other international instrument on pandemic prevention, preparedness and response. 2023. https://inb.who.int/ (accessed March 6, 2023).

8 UN General Assembly. Resolution adopted by the General Assembly on 24 February 2023. Scope, modalities, format and organization of the high-level meeting on pandemic prevention, preparedness and response. https://documents-dds-ny.un.org/doc/UNDOC/GEN/N23/062/05/PDF/N2306205.pdf?OpenElement (accessed March 9, 2023).

9 Medicines Patent Pool. Brochure on the mRNA Technology Transfer Hub Programme. 2023. https://medicinespatentpool.org/news-publications-post/brochure-on-the-mrna-technology-transfer-hub-programme (accessed March 6, 2023).

10 Sirleaf EJ, Clark H. Report of the Independent Panel for Pandemic Preparedness and Response: making COVID-19 the last pandemic. *Lancet* 2021; **398**: 101–03.

11 The World Bank. The Pandemic Fund. 2023. https://fiftrustee.worldbank.org/en/about/unit/dfi/fiftrustee/fund-detail/pppr#1 (accessed March 6, 2023).

12 Roy V. Financing COVID-19 mRNA vaccines. *BMJ* 2023; **380**: p413.

13 Jerving S. South African President to lead fundraising for new AU epidemics fund. Devex. March 2, 2023. https://www.devex.com/news/south-african-president-to-lead-fundraising-for-new-au-epidemics-fund-105056 (accessed March 9, 2023).

14 Ministry of Foreign Affairs, Government of Barbados. The Bridgetown Initiative. 2022. https://www.foreign.gov.bb/the-2022-barbados-agenda/ (accessed March 6, 2023).

www.thelancet.com **Published online March 13, 2023 https://doi.org/10.1016/S0140-6736(23)00526-3**

Afterword: Can global health abandon saviourism for justice?

Madhukar Pai

Any autopsy of how the world dealt with the Covid-19 pandemic must examine the structural inequities and power asymmetries that are deeply rooted in all of global development and global health (Abimbola, 2021). Global health and development are current versions of old, colonial systems, and hence deeply rooted in white supremacy and white saviourism (Binagwaho, 2022) (Khan, 2021) (Khan, 2023). Anti-Blackness and de-prioritisation of Black, Brown and Indigenous lives is an inescapable consequence.

As we described in a recent article by Kyobutungi and colleagues (Kyobutungi, 2023), the Covid-19 pandemic is a striking recent example of anti-Blackness and racism that is inherent in global health and development. No continent is less vaccinated and boosted than the African continent. While wealthy nations cleaned up the shelves, hoarded vaccines, and trashed millions of expired vaccines, the African region was left last in the line. Covid-19 vaccine hoarding might have cost more than a million lives in 2021 alone (Ledford, 2022).

Despite the efforts of activists — including many of the authors of this Compendium — rich countries, heavily lobbied by Big Pharma, delayed and blocked the TRIPS waiver that could have significantly expanded vaccine manufacturing in the Global South. More than

two years after vaccination began in wealthy nations, barely one in four people in the African region are vaccinated with two doses of any Covid-19 vaccine (Pandem-ic, 2023a). The African region has also had the lowest Covid-19 testing rate, and access to antiviral medications such as Paxlovid is practically non-existent. It is almost as if an entire continent simply did not matter.

As AIDS activists have repeatedly pointed out, this pattern of discrimination is not new. More than 30 years ago, when ARVs became available, they were too expensive to roll out in the African region. As late as 2001, some experts maintained that ARV treatment in Sub-Saharan Africa was impossible. It took incredible activism, legal action, and community effort before they started becoming available, by which time millions of Africans had died.

When the Ebola outbreak hit West Africa during 2014 — 2016, it killed more than 11,000 people. While an overwhelming majority of the mostly white American and European healthcare workers who contracted Ebola survived because of good supportive clinical care, the infection killed two-thirds of West Africans with Ebola. Even intravenous hydration was seen as being too challenging in Africa. Investments in research and development dramatically increased only after white people fell sick with Ebola; in fact, investment for new product development increased more than 900-fold after that (Fitchett, 2016).

Africa is the only continent where mpox has been endemic for decades. And yet, when the global outbreak occurred, the West was prioritised for vaccine rollouts. A giant share of the mpox vaccines is still held by some of the richest nations in the world, while the African region has been once again left behind (Kozlov, 2022).

When the same patterns echo across diseases and across decades, racism and anti-Blackness are the real explanations. From HIV to Covid-19, the de-prioritisation of Black and Brown lives by the rest of the world continues to have devastating consequences.

With Covid-19, data clearly show that low and middle-income countries have borne the brunt of the Covid-19 pandemic, with the highest excess deaths. In fact, developing countries' excess death rates are much higher than the relatively younger demographic profiles of these countries would suggest (Pandem-ic, 2023b). Early

in the pandemic, a myth emerged that rich nations had suffered the most Covid-19 deaths and morbidity. This myth was then used to make the argument that low and middle-income countries did not need equal access to vaccines and tools. Three years later, we now know that the truth was just the opposite.

Global health is all about power and privilege

Historically, and even today, every aspect of global health is dominated by rich nations in the Global North. Decisions about the health of people in low and middle-income countries are made in countries far away. Unsurprisingly, initiatives such as COVAX were found to have "insufficient inclusion and meaningful engagement" of low and middle-income countries (Yamey, 2022). In her article in this Compendium, Fifa Rahman states "ACT-A's failure to integrate Global South expertise in shaping its agenda and approaches ultimately cost it time and money that the world — and in particular its South — could not afford."

Data show that two-thirds of global health agencies are headquartered in just three countries: Switzerland, the UK and the US (Global Health 50/50, 2020). More than 80% of CEOs and board chairs of global health organisations are nationals of high-income countries. Leadership across the global health sector is mainly in the hands of older men from high-income countries. A typical CEO of a global health agency is three-times more likely to be a male, four-times more likely to be from a high-income country, and 13-times more likely to have been educated in a high-income country. A survey of more than 2,000 board seats of global health organisations shows that less than 3% of these seats are held by nationals of low-income countries (Global Health 50/50, 2022).

Vast amounts of global health funding are granted to the same Global North organisations, even when the research or programmatic work is meant to be done in low and middle-income countries (Erondu, 2021). African researchers are often neither first nor senior authors on publications, even when the research is entirely done in Africa (Hedt-Gauthier et al., 2019). A survey of 615 journal editorial boards showed that none of the editors-in-chief and

only 27 editors in total were women based in low-income countries (Dada, 2022). When it comes to participation in international conferences and meetings, African delegates often struggle with unjust visa barriers (Pai, 2022).

Without intention and effort, everything in global health defaults to the same, predictable settings, as shown in Figure 6.

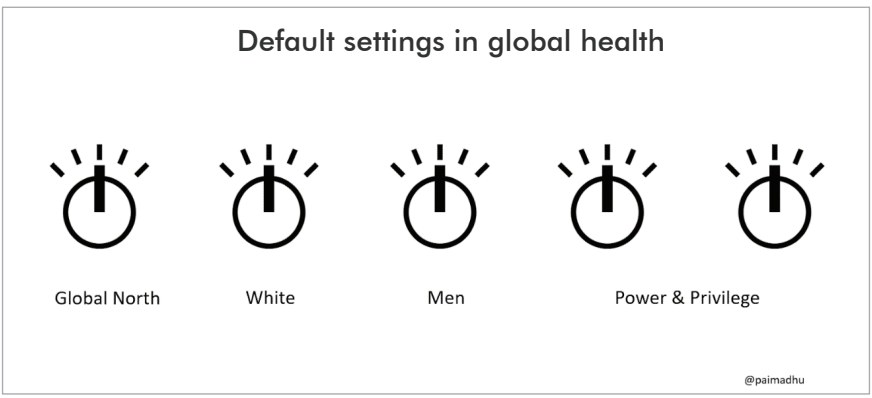


Figure 6: Research shows that the "default settings" for many positions of power within global health agency boards and journals continue to be white, male, and drawn from the Global North, reflecting broader dynamics of power and privilege within global health.

Global health is firmly centred on those with power and privilege, and focused on their generosity and saviourism (for example,. "vaccine donations"). Teju Cole called it the "White Savior Industrial Complex" (Cole, 2012). "White saviorism is simultaneously a state of mind and a concrete unequal power structure between the Global North and the Global South," wrote Themrise Khan and colleagues in their recent book, *White Saviorism in Global Development* (Khan et al., 2023).

> "White saviorism not only strips the agency of racialised people but also falsely implies that white agents need to save them from their positions as victims. While it ends up alleviating poverty on the margins, it undermines the struggles of Global South

> people to emancipate themselves from economic, social, and political oppression, and often reinforces the capitalist-heteropatriarchal system,"
> Khan and colleagues

This saviourism or charity model is archaic, unfair, and unfit for purpose, as we have witnessed during the past three years. In a global crisis, we saw that rich nations chose to hoard millions of vaccines and let them expire, rather than donate in a timely manner and save lives. We also saw rich nations actively block the TRIPS waiver proposal and delay decision-making for almost two years.

Relying on the generosity of rich countries or Big Pharma is a futile, even dangerous option.

What is the way forward?

It is clear that any future pandemic or crisis will result in the same inequities and outcomes as what we have seen with HIV, Ebola, mpox, and Covid-19. If anything, the growing momentum towards far-right, populist and autocratic leaders makes it even more likely that nationalism will trump global solidarity (Kavanagh & Singh, 2023).

The very architecture of global health and development is designed to favour those who benefit from the default settings. The entire global health security and pandemic preparedness agenda is tightly controlled by high-income nations and organisations based in the Global North. Keeping rich nations "safe" is more important than justice or equity for low and middle-income countries. As Lauren Paremoer states in her article, "developed states prioritise national health security at the expense of international cooperation."

For any meaningful change to happen, we need to challenge the dominant ways of centering global health on people and countries with the most power and privilege. It is time for people in low and middle-income countries, especially Africans, to claim the seat they have historically been denied at the global health decision-making

table (Gitahi, 2022). It is time to abandon the charity, saviourism model of global health, and demand a model rooted in justice, equity, human rights, and self-determination, as highlighted in Figure 7.

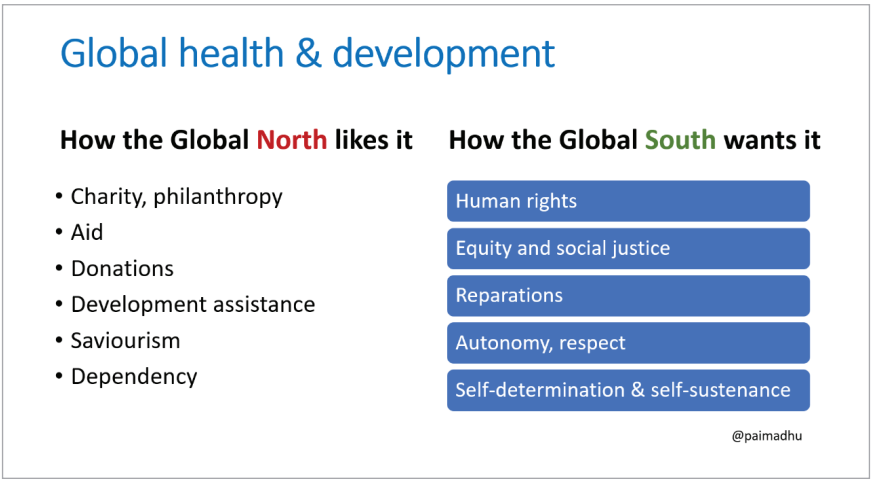


Figure 7: Global health and development

Like the fight for climate justice, this will require a people's movement, and genuine South-South solidarity among low and middle-income country actors. In her interview in this Compendium, Leena Menghaney spoke about a silver lining — that the Covid-19 pandemic made access to medicines a mainstream issue. She believes many younger activists are now engaged in this struggle and that this bodes well for the future. Tinashe Njani, in his interview, spoke about how the People's Health Movement mobilised communities in SA to support the cause of TRIPS intellectual property waiver.

African and Global South nations must work together in solidarity to realise the agenda of self-determination and self-reliance. As John Nkengasong, former head of the Africa Centres for Disease Control and Prevention, said, "Never ever should we have had to keep counting on externalities to take care of our own security needs. A key pathway for collective global security is an Africa that is self-sufficient" (Akinwotu, 2022). Nkengasong is the current Global AIDS Coordinator for the US President's Emergency Plan for AIDS Relief.

Many others have echoed these sentiments.

In their chapter in this Compendium, Petro Terblanche and Morena Makhoana write, "Covid-19's most important lesson is that countries and regions that cannot locally produce significant volumes of vaccines and other health products have no guarantee of timely access to the tools they need to respond epidemics nor pandemics."

Indeed, Africa's vision for the future, as embodied by the Call to Action: Africa's New Public Health Order, was recently endorsed by African heads of state. The document actively tackles health challenges and plans for the future, shaped by local leadership and regional solutions (Africa Centres for Disease Control and Prevention, 2022). To create a new public health order, Africa will need to strengthen public health institutions and its health workforce; expand local manufacturing of products; increase domestic resources for health; and build respectful, action-oriented, and sustainable partnerships that promote country ownership and African health priorities.

This is why the mRNA Hub in SA is an important test case. As Brook Baker and Fatima Hassan point out in their chapter, the establishment of the WHO mRNA Vaccine Technology Transfer Hub with at least 15 country mRNA Hubs / Spokes is one of the biggest silver linings of the pandemic, and its success is critical.

But it is not in the interests of Big Pharma or rich nations for low and middle-income countries to become self-reliant. Instead, they would prefer to maintain the charity model of global health, as it helps them retain and wield immense power. To fight back, we need to better understand the role the pharmaceutical industry played in creating and sustaining vaccine apartheid and the intellectual property system. Nick Dearden's chapter in this Compendium is all about that.

Nobel Laureate Professor Joseph Stiglitz recently wrote:

> Given the selfishness of rich nations that's been exposed, the only way we can be assured that low and middle-income countries will be protected, the only way that we can make the world safe, given the selfishness, is to have the

> research and production capacity for making vaccines and other pharmaceutical products distributed throughout the world. Having this production and research capacity distributed throughout the world will enable a quicker and better response to the next pandemic (Stiglitz, 2022).

In conclusion, this Compendium has brought together a diverse set of voices, primarily from the Global South, to not only document the failures of the Covid-19 pandemic but also offer invaluable lessons that we need to take away and put to good use. To me, the biggest lesson is that global health is doomed to repeatedly fail on equity unless it shifts from ***charity to justice.***

Professor Madhukar Pai, MD, PhD, FCAHS is a Canada Research Chair in Epidemiology & Global Health at McGill University, Montreal. He is the Associate Director of the McGill International TB Centre. He is Editor-In-Chief of PLOS Global Public Health.

References

Abimbola S, Asthana S, Montenegro C, Guinto RR, Jumbam DT, Louskieter L, et al. (2021). Addressing power asymmetries in global health: Imperatives in the wake of the Covid-19 pandemic. *PLoS Medicine* 18(4): e1003604.

Africa Centres for Disease Control and Prevention (2022). Call to action: Africa's new public health order. Available at https://africacdc.org/news-item/call-to-action-africas-new-public-health-order/ (accessed 9 Jan 2023).

Akinwotu E (2022). Africa must be self-sufficient: John Nkengasong on learning the deadly lessons of pandemics. *The Guardian*. Available at https://www.theguardian.com/global-development/2022/mar/28/john-nkengasong-africa-cdc-covid-pandemic-interview (accessed 9 Jan 2023).

Binagwaho A., Ngarambe B. and Mathewos K (2022). Eliminating the white supremacy mindset from global health education. *Annals of Global Health* 88(1).

Call To Action: Africa's New Public Health Order – Africa CDC. (2022, September 28). Africa CDC. Available at https://africacdc.org/news-item/call-to-action-africas-new-public-health-order/.

Cole T. (2012). The white-savior industrial complex. *The Atlantic*. Available at https://www.theatlantic.com/international/archive/2012/03/the-white-savior-industrial-complex/254843/ (accessed 4 April 2023).

Dada S, van Daalen K R, Barrios-Ruiz A, Wu K T, Desjardins A, Bryce-Alberti M, et al. (2022). Challenging the "old boys club" in academia: Gender and geographic representation in editorial boards of journals publishing in environmental sciences and public health. *PLOS Global Public Health* 2(6): e0000541.

Erondu N A, AnieboI, Kyobutungi C, Midega J, Okiro E, and Okumu F (2021). Open letter to international funders of science and development in Africa. *Nature Medicine* 27(5) 742-744.

Fitchett J R, Lichtman A, Soyode D T, Low A, de Onis J V, Head, et al. (2016). Ebola research funding: A systematic analysis, 1997–2015. *Journal of Global Health* 6(2).

Gitahi G (2022). Opinion: Africa, it's time to take charge of our health agenda. *Devex*. Available at https://www.devex.com/news/opinion-africa-it-s-time-to-take-charge-of-our-health-agenda-103800 (accessed 4 April 2023).

Global Health 50/50 (2020). The Global Health 50/50 Report 2020: Power, privilege and priorities. Available at https://globalhealth5050.org/2020report/ (accessed 13 March 2021).

Global Health 50/50 (2022). The Global Health 50/50 Report 2022: Boards for all? https://globalhealth5050.org/2022-Report/ (accessed 9 Jan 2023).

Hedt-Gauthier B L, Jeufack H M, Neufeld N H, Alem A, Sauer S, Odhiambo J, et al. (2019). Stuck in the middle: a systematic review of authorship in collaborative health research in Africa, 2014–2016. The BMJ Global Health 4(5): e001853.

Kavanagh M M and Singh R (2023). Vaccine politics: Law and inequality in the pandemic response to Covid-19. Global Policy.

Khan T (2021). Racism doesn't just exist within aid. It's the structure the sector is built on. *The Guardian.*

Khan T (2023, April 10). White saviorism in international development: Theories, practices and lived experiences. DarajaPress. Available at https://darajapress.com/publication/the-white-savior-complex-in-international-development-theory-practice-and-lived-experiences.

Khan T, Dixon K and Sonderjee M (2023). White saviorism in international development. Daraja Press.

Kozlov M (2022). Monkeypox in Africa: The science the world ignored. *Nature* 607(7917): 17-18.

Kyobutungi C, Gitahi G, Wangari M C, Siema P, Gitau E, Sipalla, et al. (2023). From vaccine to visa apartheid, how anti-Blackness persists in global health. *PLOS Global Public Health* 3(2): e0001663.

Ledford H (2022). Covid vaccine hoarding might have cost more than a million lives. *Nature* (Lond.).
Pai M (2022). Passport and visa privileges in global health. *Forbes*. Available at https://www.forbes.com/sites/madhukarpai/2022/06/06/passport-and-visa-privileges-in-global-health/?sh=44ef28e74272 (accessed 9 Jan 2023).
Pandem-ic (2023a). The unfinished business of Covid-19 vaccination. Available at https://pandem-ic.com/the-unfinished-business-of-covid-19-vaccination/ (accessed 9 Jan 2023).
Pandem-ic (2023b). The demographics of excess mortality. https://pandem-ic.com/the-demographics-of-excess-mortality/ (accessed 9 Jan 2023).
Stiglitz J E (2022). Vaccinating the world against Covid-19 is a no-brainer. *PLOS Global Public Health* 2(5): e0000427.
Yamey G, Garcia P, Hassan F, Mao W, McDade K K, Pai M, et al. (2022). It is not too late to achieve global covid-19 vaccine equity. *BMJ* 376.

5 May 2023

"It is therefore with great hope that I declare Covid-19 over as a global health emergency.

However, that does not mean Covid-19 is over as a global health threat.

Last week, Covid-19 claimed a life every three minutes – and that's just the deaths we know about.

As we speak, thousands of people around the world are fighting for their lives in intensive care units.

And millions more continue to live with the debilitating effects of post-Covid-19 condition.

This virus is here to stay. It is still killing, and it's still changing. The risk remains of new variants emerging that cause new surges in cases and deaths."

Tedros Adhanom Ghebreyesus
WHO DG

Index

If you found this Compendium useful, please consider making a donation towards our work. See https://healthjusticeinitiative.org.za/donate/