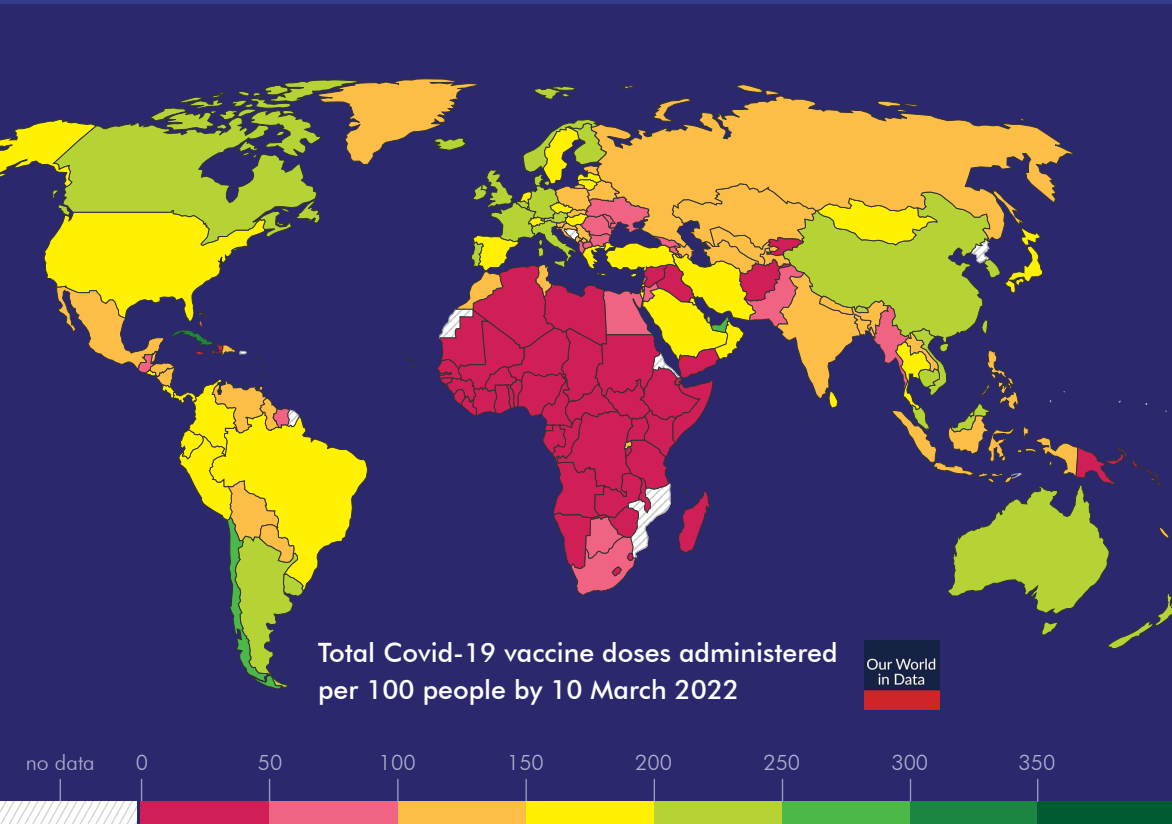


Pandemics and the illumination of “hidden things”

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

Activist Q&A with Leena Menghaney

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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 (ACTA). 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 licensee 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 COVISHIELD 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 licensee 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 ACTA 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 ACTA 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 ACTA 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, ACTA could not push back on those clauses.

Lastly, ACTA 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.

ACTA 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.

ACTA, 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.

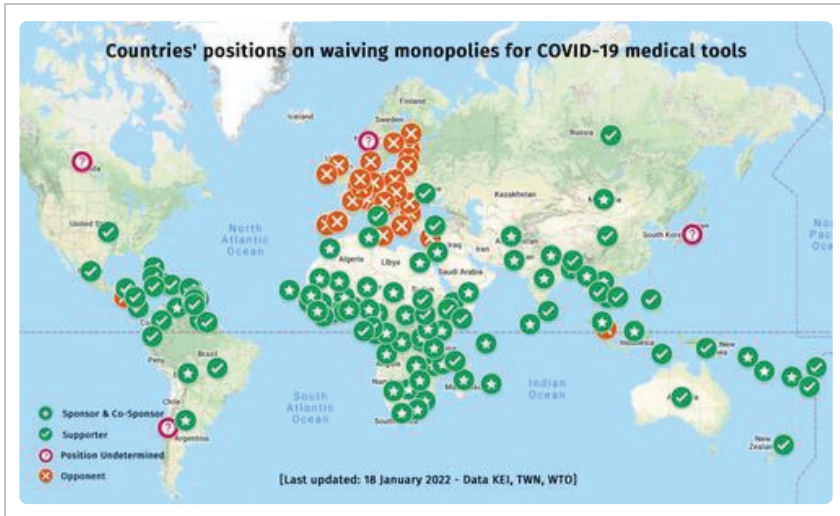


Figure 1: Countries' positions on waiving monopolies for Covid-19 (MSF)

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.



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