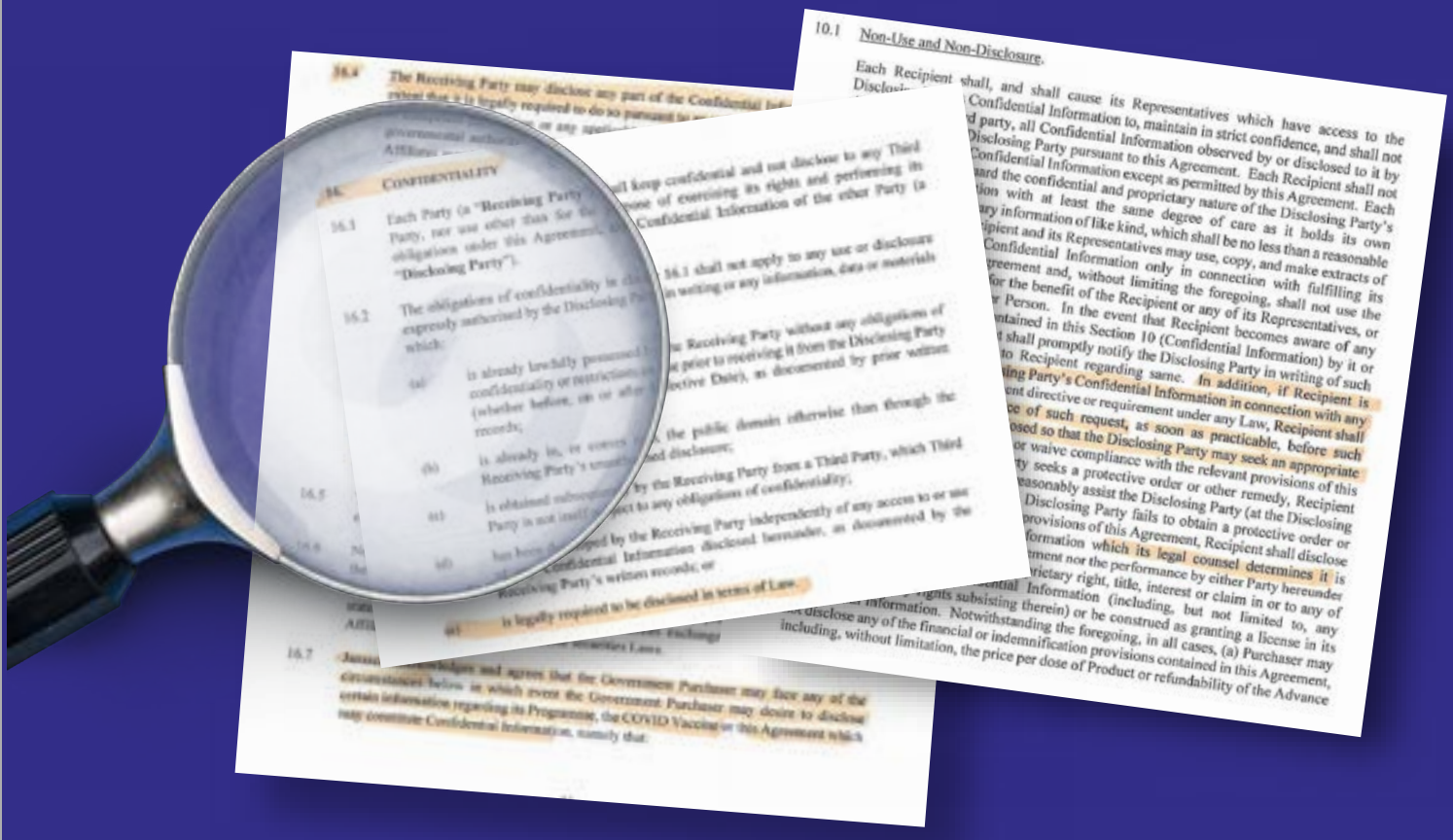
"ONE-SIDED"

THE BIG PHARMA BULLIES:

Secrecy for Vaccine Supplies in a Pandemic



A MULTI-STAKEHOLDER ANALYSIS:

SOUTH AFRICAN COVID-19 VACCINE PROCUREMENT CONTRACTS

HJI and MULTI-STAKEHOLDER GROUP, 5 September 2023

O'NEILL INSTITUTE FOR NATIONAL & GLOBAL HEALTH LAW GEORGETOWN LAW

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Executive Summary

After reviewing and studying the documents making up the four Contracts/Agreements handed over to the Health Justice Initiative (HJI), we found that in all four Contracts/Agreements, the pernicious nature of pharmaceutical bullying and GAVI's heavy-handedness are evident: the terms and conditions are overwhelmingly one-sided and favour multinational corporations. This placed governments in the Global South, and in turn, the people living in these countries, in an unenviable position of having to secure scarce supplies in a global emergency (2020-2022) with unusually hefty demands and conditions, including secrecy, a lack of transparency, and very little leverage against late or no delivery of supplies or inflated prices resulting in gross profiteering. Moreover, SA's sovereignty was bartered for scarce supplies.

This should never happen again. It is unconscionable, imperial, and unethical.

The most egregious example of this, in our review, has been a multinational pharmaceutical company (Johnson & Johnson/ J&J) trading scarce or very delayed supplies for extractionist terms and conditions that undermine national sovereignty. This was mainly to benefit their bottom line or patients in Northern countries first: in Europe, not Africa. The connection between this Agreement and a second, non-state, bilateral agreement between J&J and Aspen (SA company) needs interrogation. All of this requires further investigation.

Equally problematic is another very profitable multinational company, Pfizer, which extracted over the top concessions from SA, shirking its own liability, and worse, demanded that it retains 50% of the "first payment", even upon its own default to register or deliver. Pfizer also included a one-side disclaimer of non-infringement of other right holders' Intellectual Property (IP).

By all reasonable accounts and based on what was agreed to with SA, COVAX overpromised and under delivered for SA supplying even fewer vaccines than what the US Government (USG) donated to SA in the first three quarters of 2021. SA received no price guarantee under the COVAX Agreement: while the all-inclusive weighted average estimated cost per dose was US$ 10.55, SA had the right to reject doses costing more than US$21.10. J&J charged SA US$10 per vaccine dose, while the EU reportedly paid US$8.50, and there are also claims that the non-profit price could have been in the region of US$7.50. It is not clear from the contracts if SA was refunded the balance in price difference.

For the Serum Institute of India (SII), it is also likely that SA overpaid compared to European countries by at least more than two and half times! In the UK and EU, Astra Zeneca charged £2.17 and £2.15, respectively.
The Contracts require SA to seek permission from said companies to divert or donate or sell doses which have already been paid for by the SA public, despite the benefit to other poorer countries or buyers.

In a global pandemic, this is paternalistic and imperialist, harms public health programmatic planning, and deliberately reduces the autonomy of African states.[1]

In particular - J&J, Pfizer, and COVAX, did not commit itself to supply volumes and dates making it increasingly difficult to plan and run a timely and proper vaccination programme.

This Multi Stakeholder Group Analysis sets out why this type of "take it or leave it" contracting signals a dangerous precedent for future pandemic readiness measures and systems, and why this level of bullying, secrecy, and lack of transparency, has no place in any democracy.

Here, we must stress that it is unfortunate that the South African Government spent almost two years resisting disclosure, for the benefit of big pharmaceutical corporations and GAVI/COVAX. Lack of timely public access to these contracts fueled mistrust and limited public accountability action towards these corporates during a global pandemic. It created opportunities for price variations, prevented proper planning, and enabled these multinationals to negotiate on an unequal footing with Government – this defeats the very purpose of signing a supply agreement.

Essentially, the point of a contractual purchase agreement is to have minimum certainty for SA to order and purchase vaccines or medicines. These Agreements and Contracts belie that purpose.

And regrettably, this is not once-off COVID-related modus of operating: At present, even more pharmaceutical corporations are insisting on Non-Disclosure Agreements (NDAs) - with broad confidential information clauses, including and insisting on them more aggressively in supply agreements to suppress the disclosure of pricing and supply terms, particularly in negotiations covering monopoly products such as HIV medicines.

[1] "Beggars" is the term used by President Ramaphosa of South Africa at the New Global Financing Pact Summit in Paris, France when referencing the issue of vaccine nationalism and lack of vaccine supplies, and tech sharing, during COVID: See https://www.news24.com/news24/politics/government/we-are-not-beggars-treat-us-as-equals-ramaphosa-tells-world-leaders-20230624

This deference to and fear of pharmaceutical power, in the middle of a crisis, in a Constitutional democracy, should be of deep concern to the global public health community. It shows how much power was put into the hands of private sector actors and how few options governments had, when acting alone, in the middle of a pandemic.

This is not a problem that can be solved by a single government but requires a regional and global solution and the exercise of state sovereignty. Unless acted upon with clear, legally binding international agreement, we will arrive at the next pandemic with little more to enforce fair terms than platitudes and scathing press statements from the Minister and President in SA and other world leaders in the Global South.

This must be deliberated upon in Pandemic Accord Negotiations and revisions of the International Health Regulations currently underway and at the upcoming United Nations General Assembly (UNGA).

Thankfully, the courts in SA have mitigated and addressed some of the uglier sides to contracting for scarce supplies in the COVID pandemic with this ground-breaking judgement. The SA Minister of Health's decision not to appeal the Judgment must also be applauded.

The HJI case and ***Millar J's Judgment in the Gauteng High Court*** *have opened secret COVID-19 vaccine procurement Agreements and Contracts to foster transparency and accountability in public procurement of health goods. This will hopefully have far-reaching implications, not just for the next set of pandemic procurement negotiations and contracts / agreements here and elsewhere, but also for the substantial amount of procurement due to take place under SA's future National Health Insurance (NHI) system.*

We, therefore, call on governments in the Global South and the Boards, as well as the wealthy Shareholders of these companies and the Geneva-based not-for-profit initiatives, to take the necessary steps to ensure that this type of bullying and extremes of non-disclosure are not repeated in the next pandemic.

We need open procurement processes, not secretive ransom negotiations.
We say, Never Again...!

Introduction

As of 4 June 2023, more than thirty-eight million COVID-19 vaccines doses have been administered in SA. SA has during and after the globally declared COVID-19 pandemic received several millions of vaccine doses by directly buying from pharmaceutical companies, or through the COVAX facility administered by GAVI or by receiving donations. These vaccines have been procured at great cost.

The public has, until now, not known the content of these Agreements / Contracts nor the complete details of the contracting parties, nor the details of unsuccessful or paused negotiations with other entities too. In other parts of the world, civic groups and journalists have also attempted to obtain copies of contracts entered there, and using a variety of means, secured a combination of unredacted /redacted versions through leaked copies or information access requests and legal filings. We hope that this case and Judgment will ensure that a clear precedent is set so that in future pandemics, this information is automatically placed in the public domain and that transparency is prioritised.

Para 2 of the Judgment is clear and unambiguous about the role vaccines play in mitigating a health crisis and in managing a global pandemic:

> In this application, it is not in issue between the parties that Vaccines play a pivotal role in mitigating the consequences of Covid-19, by preventing death and controlling the spread of the virus. They are a central element of the global - and the South African - response to Covid-19, prompting a worldwide effort to immunize billions of people. The Organisation for Economic Co-operation and Development (OECD) has emphasised the importance, to trust in the vaccination programme, of governments demonstrating their ability to procure vaccines and to develop effective and inclusive roll-out plans. It recommends that such plans should be open to public scrutiny and require proactive disclosure of information.

Yet these contracts are a critical part of pandemic policymaking—among the most critical given the importance of vaccines in pandemic response. “Vaccine procurement contracts and APAs provide the perfect opportunity for the state to insist on public interest safeguards to be included as part of the agreement,” which Hawkins and Slade detail to include rights vis-a-vis resale and donation, limits on indemnification, assurances of regulatory compliance, and beyond.[2] Yet, states have struggled to do so on many fronts—including, as detailed below, the SA Government in negotiations with J&J, Pfizer, SII, and the COVAX facility.

[2] Hawkins, N., and A. Slade. "Intellectual property rights and advance purchase agreements in a crisis." *Intellectual Property Quarterly* 1 (2023): 1-32.

The Judgment is significant for current negotiations on a Pandemic Accord too. For example, Article 9 of the Zero Draft of the WHO Pandemic Accord has provisions on the publication/disclosure of prices and contractual terms for public procurement in times of pandemics, in addition to Articles 11,12 and 13. Worryingly, informal discussions are underway to rework all these Articles, to dilute transparency norms[3], among others. [4]

Background

A global context of inequity and bullying

At least 14 million people lost their lives in two years (2020-2021); these are excess deaths associated with the COVID-19 pandemic.[5] Many of these deaths were preventable. The response to the COVID-19 pandemic has been correctly described as a "moral failure" including by the World Health Organization (WHO). In that time, the majority of black and brown people in the Global South struggled to access life-saving vaccines supplies. Many parts of the Global South especially, saw declining public health outcomes, premature death and suffering, and terrible socio-economic devastation.

By early February 2023, within three years, according to Our World in Data,[6] 69.7% of the world population had received at least one dose of a COVID-19 vaccine. 13.32 billion doses have already been administered globally, and 28% of people in low-income countries have

[3]Article 9. Increasing research and development capacities 1. The Parties recognize the need to build and strengthen capacities and institutions for innovative research and development for pandemic-related products, particularly in developing countries, and the need for information sharing through open science approaches for rapid sharing of scientific findings and research results. 2. With a view to promoting greater sharing of knowledge and transparency, each Party, when providing public funding for research and development for pandemic prevention, preparedness, response and recovery of health systems, shall, taking into account the extent of the public funding received: (a) promote the free, public dissemination of the results of publicly and government-funded research for the development of pandemic-related products; (b) endeavour to include terms and conditions on prices of products, allocation, data sharing and transfer of technology, as appropriate, and publication of contract terms; A/INB/4/3 16 (c) ensure that promoters of research for pandemic-related products assume an appropriate level of the associated risk; (d) promote and incentivize technology co-creation and joint venture initiatives; and (e) establish appropriate conditions for publicly funded research and development, including on distributed manufacturing, licensing, technology transfer and pricing policies. 3. Parties shall increase the transparency of information about funding for research and development for pandemic-related products by: (a) disclosing information on public funding for research and development of potential pandemic-related products and provisions to enhance the availability and accessibility of the resulting work, including freely available and publicly accessible publications and public reporting of the relevant patents; (b) making it compulsory for manufacturers that receive public funding for the production of pandemic-related products to disclose prices and contractual terms for public procurement in times of pandemics, taking into account the extent of the public funding received; and (c) encouraging manufacturers that receive other funds, external to the manufacturer, for the production of pandemic-related products to disclose prices and contractual terms for public procurement in times of pandemics.

[4] See https://apps.who.int/gb/inb/ and https://www.who.int/news-room/questions-and-answers/item/pandemic-prevention--preparedness-and-response-accord. Zero Draft: https://apps.who.int/gb/inb/pdf_files/inb5/A_INB5_6-en.pdf

[5] https://www.who.int/news/item/05-05-2022-14.9-million-excess-deaths-were-associated-with-the-covid-19-pandemic-in-2020-and-2021

[6] https://ourworldindata.org/covid-vaccinations Edouard Mathieu, Hannah Ritchie, Lucas Rodés-Guirao, Cameron Appel, Charlie Giattino, Joe Hasell, Bobbie Macdonald, Saloni Dattani, Diana Beltekian, Esteban Ortiz-Ospina and Max Roser (2020) - "Coronavirus Pandemic (COVID-19)". Published online at OurWorldInData.org. Retrieved from: 'https://ourworldindata.org/coronavirus' *[Online Resource]*

received at least one dose. During the COVID pandemic, given this context, HJI tracked vaccine equity, supplies, and access for SA.

For the better part of 2021, we found that SA either had negligible or staggered access (also referred to as a "drip-drip" supply system) for several reasons. Thus, for months, while people were getting vaccinated in the Global North and elsewhere, with even two shots of vaccine doses, people in SA were waiting for vaccine supplies and for the national vaccine programme to properly kick off (save for a few hundred clinical trial participants, a few hundred thousand healthcare workers via a J&J donation/ "study programme" called Sisonke, and oddly and unfairly, if not unethically, through that programme, a handful of sports people and celebrities too).[7]

While SA scientists and researchers led global efforts on genomic surveillance, detecting variants first, well ahead of other countries in the Global North, the SA Government led a proposal on a waiver of IP rules[8] at the World Trade Organization (WTO) with others. SA also supported and took part in at least four clinical trials, contributing to the global generation of knowledge for vaccine approval and use too. People in SA volunteered for trials for Pfizer, J&J, Astra Zeneca and Novavax. But SA was placed in the back queue, the African queue, like apartheid, this time by powerful companies, where ACCESS to the very same vaccines tested on people in SA was delayed or denied.

The same companies also lobbied and, in some cases, invoked subtle threats to block the IP waiver proposal led by SA. POLITICO reported that government officials in Belgium were lobbied by J&J representatives who "asked" them not to support the waiver proposal, in return for retaining their investments and plants in Belgium.[9]

> *"Is that a direct threat? I don't know." The adviser to the Belgian prime minister spoke calmly as they recounted a lobbying phone call from 2021, but the contents of the conversation are extraordinary. The call was from a spokesperson for Janssen, the Belgian-founded pharmaceutical arm of J&J that developed the company's single-shot COVID-19 vaccine. According to the adviser, the spokesperson warned them that if Belgium supported a radical proposal made by India and*

[7] See HJI's Submission on the first Departmental briefing on the national vaccine programme here: https://healthjusticeinitiative.org.za/2021/01/07/vaccine-equity-access-and-allocation/ and https://healthjusticeinitiative.org.za/2021/08/10/hji-petition-calling-for-the-prioritisation-of-all-adults-living-with-a-comorbidity-in-the-vaccine-programme-in-sa/
HJI's amicus intervention in support of the SA Government fora single and equitable allocation plan for South Africa: https://healthjusticeinitiative.org.za/2021/05/12/solidarity-and-afriforum-vs-minister-of-health-and-16-others/
And see: https://healthjusticeinitiative.org.za/2021/03/03/afriforum-solidarity-case-amicus/
https://www.news24.com/news24/bi-archive/sports-stars-will-get-the-final-doses-of-sisonke-jj-vaccine-this-week-2021-5
https://www.medicalbrief.co.za/application-to-compel-public-release-of-expert-covid-advice-and-decisions/
[8] See: https://healthjusticeinitiative.org.za/2021/06/04/frequently-asked-questions-the-trips-waiver-and-the-wto/
[9] https://www.politico.eu/article/covid-vaccine-poor-countries-waiver-killed/

South Africa at the World Trade Organization, then Janssen might rethink its vast billion-dollar research and development investments in Belgium."

Despite this inherent unfairness, recently, approval was given for additional clinical trials for COVID, for Moderna too, even though Moderna for the better part of 2021, according to the *New York Times,* REFUSED to supply any African country, then belatedly entered COVAX due to poor publicity with modest dose contributions, and has since 2020, never once supplied any patient in SA with a vaccine (outside of a clinical trial or sample vaccines). It's unjustified patent-seeking behaviour also threatens to hobble the work of the first WHO-backed mRNA Hub,[10] in Cape Town, SA.[11]

Procuring at a time of vaccine apartheid

The complex issue of vaccine apartheid and nationalism has been extensively set out in HJI's legal papers in this case and by several leading CSOs in multiple other reports, academic journals, health publication, opinion pieces, and media articles and stories,[12] and by the WHO. The same issue has been emphasised on multiple occasions on global platforms by SA's President, Cyril Ramaphosa as well, most recently at the World Leaders' Summit for a New Global Financing Pact.[13]

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[10] https://www.nature.com/immersive/d41586-022-01898-3/index.html and https://www.theguardian.com/global-development/2022/oct/05/covid-vaccine-inequity-south-africa-afrigen-mrna

[11] See Hassan, F, Baker B, COVIDs Silver Lining? The mRNA Hub in South Africa, forthcoming: in: *Health Justice Initiative Pandemics and the illumination of "hidden things" – Lessons from South Africa on the global response to Covid-19*. Edited Volume.

[12] https://www.bmj.com/content/bmj/374/bmj.n2027.full.pdf
See reports from:
www.peoplesvaccine.org
https://speakingofmedicine.plos.org/2022/05/23/vaccine-apartheid-is-racist-and-wrong/;
https://foreignpolicy.com/2021/02/23/dont-let-drug-companies-create-a-system-of-vaccine-apartheid/
https://apnews.com/article/climate-change-united-nations-general-assembly-united-nations-africa-science--11425d2449903ba448a96b2b0f106a70
United Nations Committee on the Elimination of Racial Discrimination's (CERD) 'Statement on the lack of equitable and non-discriminatory access to COVID-19 vaccines' at 106th session on 25 April 2022 ["Deeply concerned that (vaccine administration is) creating a pattern of unequal distribution within and between countries that replicates slavery and colonial-era racial hierarchies; and which further deepens structural inequalities affecting vulnerable groups protected under the Convention; Deeply concerned that the pattern of unequal distribution of lifesaving vaccines and COVID-19 technologies between and within countries manifests as a global system privileging those former colonial powers to the detriment of formerly colonised states and descendants of enslaved groups…".
https://www.cels.org.ar/web/en/2022/05/un-committee-decries-racial-discrimination-in-global-covid-19-vaccine-access-2/
https://www.reuters.com/business/healthcare-pharmaceuticals/world-has-entered-stage-vaccine-apartheid-who-head-2021-05-17/

[13] https://www.youtube.com/watch?v=jG1IC-cdkGY and https://www.news24.com/news24/politics/government/we-are-not-beggars-treat-us-as-equals-ramaphosa-tells-world-leaders-20230624

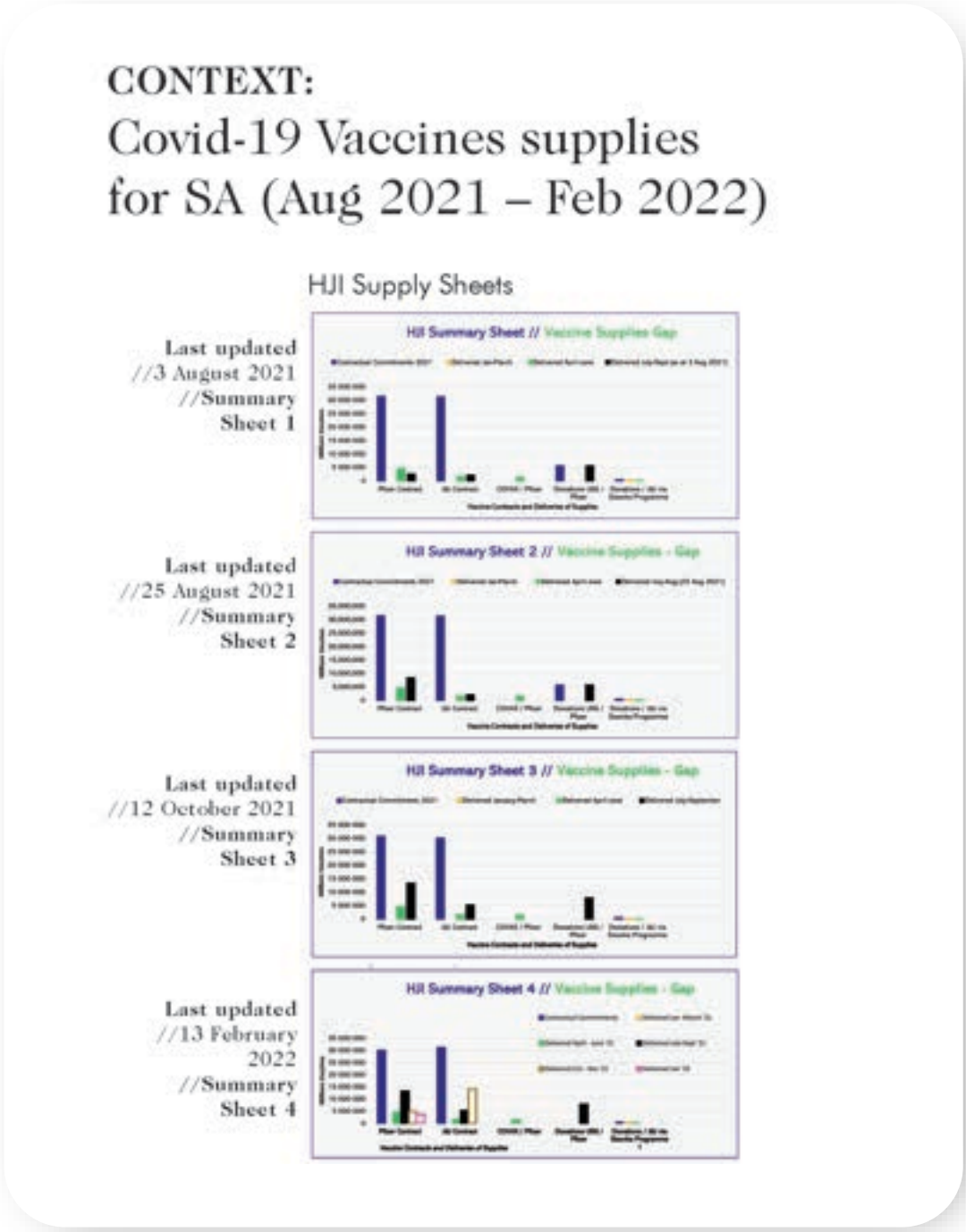
For the period 2021-2022, HJI tracked vaccine supplies for SA:

The HJI *Vaccine Supply Summary Sheets* (Figure 1 below) indicate when SA received vaccine supplies and from whom:

1. The main suppliers of vaccine doses were Pfizer and J&J.
2. COVAX provided a minimal amount in the end, and while the SII initially provided vaccine supplies, first meant for healthcare workers on the frontline, that was paused in SA because, according to the Department, the SA executive arm of Government (the Cabinet) took the decision to pause the roll out of the SII/AZ vaccine for healthcare workers in February 2021 already, based on expert or other advice that it has refused to make public, on the basis of the privilege given by law to Cabinet minutes.[14]
3. The SA Ministerial Advisory Committee's (MAC) scientific advice and expert recommendations (if any) and its or any other conflict of interest disclosures in this regard are not public. The Department has stated under oath that Cabinet (not a scientific expert body), which comprises the President, Deputy President, and all Ministers took the decision to pause the use of the vaccine in SA.

[14] See, Marlise Richter (forthcoming) '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'- in: *Health Justice Initiative Pandemics and the illumination of "hidden things" – Lessons from South Africa on the global response to Covid-19*. Edited Volume.

Figure 1: Extract from: HJI Vaccine Supply Summary Sheets



Globally, the vaccine access situation in January 2021, was as follows:

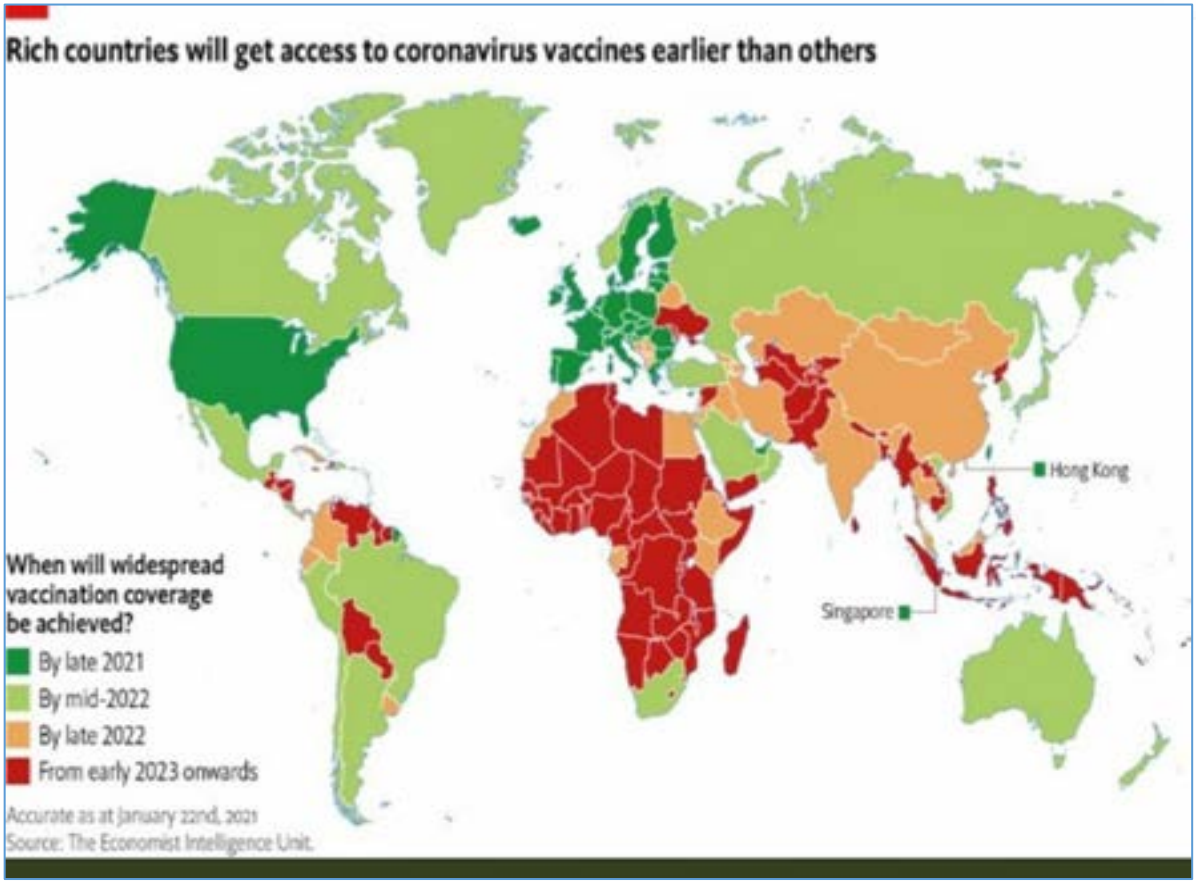


Figure 2: Source: Economist Intelligence Unit

The vaccine supply and over ordering situation in early 2021 was as follows (bi-laterals and COVAX):

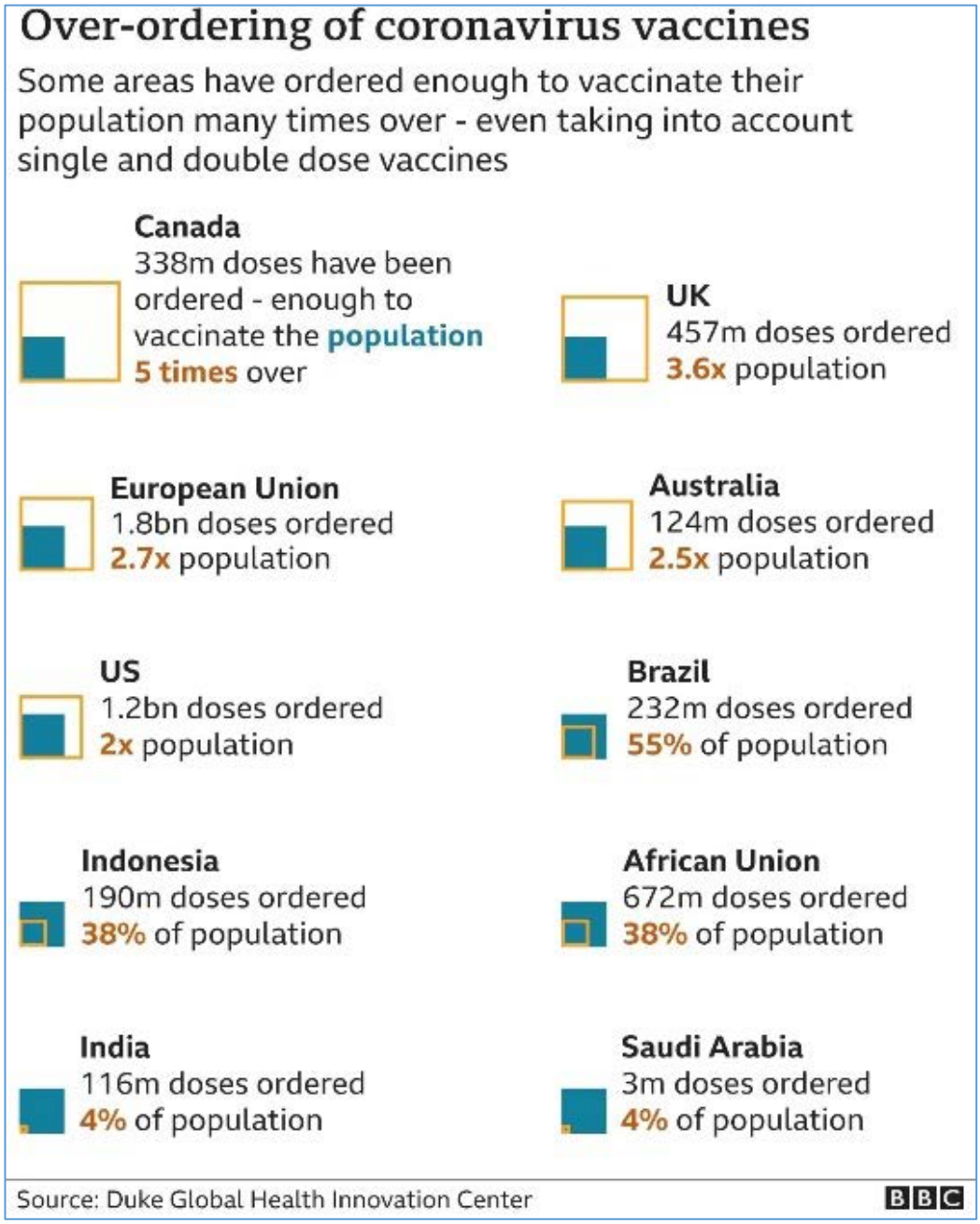


Figure 3: Source: Duke Global Innovation Centre as published in BBC "Covid vaccines: Boris Johnson pledges surplus to poorer countries at G7" 19 February 2021
Available: https://www.bbc.com/news/uk-politics-56117120

How did the HJI case come about?

The SA Government, acting through the National Department of Health (Department) entered into agreements with private manufacturers and/or suppliers for the supply of COVID-19 vaccines.

1. In mid-2021, the HJI requested and then filed access to information requests (using the "Promotion of Access to Information Act" - PAIA – a freedom of information law, in SA) to obtain copies of the Agreements, among other documents, which request, and internal appeal were refused or rejected by the Department. The case details and history, including the basis for HJI's request and its legal standing, are set out in a FAQ by the HJI (updated July 2023) here. HJI also tried to get the contracting parties' details and complete identities, but these requests were also "rebuffed" (see below).
2. As a result, in 2022, the HJI filed legal papers against the SA Minister of Health and the National Department of Health's Information Officer. It was argued on 24 July 2023 in the Pretoria High Court in Gauteng.
3. Shortly thereafter, on Thursday 17 August 2023, the High Court ruled in HJIs favour in its bid to compel the Department to provide access to the COVID vaccine procurement Contracts and other documents. The Court, in a ground-breaking Judgment, ordered (per Millar J) the disclosure of:
    a. Copies of all COVID-19 vaccine procurement contracts, and memoranda of understanding, and agreements (we refer to this as "part 1")
    b. Copies of all COVID-19 vaccine negotiation meeting outcomes and/or minutes, and correspondence (we refer to this as "part 2") within ten **court days of the Judgment** (**being 31 August 2023**).

The Minister of Health did not pursue an application for leave to appeal the judgment:

1. The Department's legal representatives, however, requested an extension until 29 September 2023 for the handover of the "part 1" and "part 2" documents.
2. HJI granted the extension for the "part 2" documents (negotiation meeting outcomes, minutes, and correspondence) but did not grant it for the "part 1" documents (Contracts, MOUs, and Agreements).
3. On **Thursday, 31 August 2023** there was a **handover of documents** from the National Department of Health to HJI's legal representatives purporting to be the "Contracts, MOUs, and Agreements" (part 1) with three companies (Jansen/ J&J, Pfizer, SII, and with one not for profit initiative – GAVI (for COVAX). The documents were not redacted.
4. The HJI awaits the "part 2" documents by **29 September 2023**, which date constitutes the extension period that HJI has agreed to.

5. In response to the Department's momentous handover of the part 1 documents on **1 September 2023**, the HJI has stated:

> *We [HJI] are encouraged that the Minister and the Department of Health will not be appealing this ground-breaking judgment and that it has undertaken to release all meeting minutes, agreements, and contracts relating to its procurement of COVID-19 vaccines. This is an important day for our democracy and for "opening up'' the process of health procurement. It sends a strong signal to powerful pharmaceutical companies and others that in SA, transparency cannot be bartered and is not up for sale - there really is no room for this much secrecy in the health or any other sector.*

6. On receiving the "part 1" documents, the HJI, with Power and Associates (HJI's legal representatives), with a diverse range of academics, lawyers, and researchers from different organisations and universities, immediately worked on verifying what was handed over, and since the evening of 31 August 2023, studied and reviewed the documents, to provide the following **Joint Multi Stakeholder SA Contracts Analysis (preliminary).**
    a. The HJI has chosen this approach because this case is of grave importance, both locally in SA and globally for transparency norms in the domain of vaccines and pharmaceuticals. As such, HJI drew on its partners to assist with the review.
    b. At a time of social media and other forms of disinformation and anti- science messaging, which is anti-evidence, and where anti-vaccine groups are becoming more vocal on social media, we have chosen this path to share proper and accurate information with the public.
    c. Our starting point is that approved vaccines are safe and effective, can save lives, and that if COVID vaccines were more speedily available in the Global South in 2021 especially, and with a greater focus on broad universal and unencumbered technology sharing, immediate suspension of IP rules, and proper attention to public health equity needs, then the devastation on our societies and health sectors in particular during that time, in SA, everywhere in the Global South, and beyond could have been mitigated.

The Gauteng High Court in SA ordered the disclosure of:

1. Copies of all COVID vaccine procurement contracts, and memoranda of understanding, and agreements (we refer to this as "part 1"); and
2. Copies of all COVID-19 vaccine negotiation meeting outcomes and/or minutes, and correspondence (we refer to this as "part 2").

This includes agreements and negotiations with:

1. Janssen Pharmaceuticals/ J&J
2. Aspen Pharmacare
3. Pfizer
4. Serum Institute of India/Cipla
5. Sinovac/Coronavac
6. Any other vaccine manufacturer/licensee
7. The African Union Vaccine Access Task Team
8. "COVAX"
9. The Solidarity Fund.

At the outset it is important to note that this Analysis and Review is only based on four sets of Agreements provided by the State to HJI in terms of the Court Order and hand-delivered to HJI's legal representatives on 31 August 2023. The outstanding documents are due to be delivered by September 2023.

1. There are four contracts, being the four entitities that SA procured and/or received vaccines from, during the COVID pandemic, where payment was made from the national fiscus. Donations from the US Government of Pfizer supplies are not included. The four contracts are for J&J/ Janssen, Pfizer, SII (licensee of AstraZeneca), and COVAX (GAVI) [see "Vaccine Suppliers" Table below with the complete details of the relevant contracting parties].
    a. Within the four contracts, while the following documents are referenced for COVAX/GAVI ("Terms and Conditions"; "Allocation Framework") and for Pfizer ("Indemnification Agreement"), they were not attached and/or included in the handover of 31 August 2023.
    b. If separate NDAs were signed for any or all the parties, those NDAs have not been provided either. **HJI's legal representatives have accordingly requested confirmation of or copies of same.* All four Agreements were legally obtained as part of a Court ordered process. These contracts were thus not "leaked" to the HJI. The Contracts/Agreements, per the Court Order, are not redacted, and are now available for public viewing.[15]

[15] Note: On HJI's website, the versions loaded are as provided to HJI by the Department, save for one aspect: HJI has blacked out the respective parties' representatives' actual individual and personal signatures – where applicable - but their full names and official designations remain, and are visible.

Narrative Analysis of Agreements and Contracts handed over to HJI – Never Again

After reviewing and studying the documents making up the four Contracts/Agreements handed over to the HJI, we found that in all four Contracts/Agreements, the pernicious nature of pharmaceutical bullying and GAVI's heavy-handedness are evident: the terms and conditions are overwhelmingly one-sided and favour multinational corporations. That placed governments in the Global South, and in turn, the people living in these countries, in an unenviable position of having to secure scarce supplies in a global emergency (2020-2022) with unusually hefty demands and conditions, including secrecy, a lack of transparency, and very little leverage against late or no delivery of supplies or inflated prices resulting in gross profiteering. Moreover, SA's sovereignty was bartered for scarce supplies. This should never happen again. It is unconscionable, imperial, and unethical.

The most egregious example of this in our review has been a multinational pharmaceutical company (J&J) trading scarce or very delayed supplies for extractionist terms and conditions that undermine national sovereignty. This was mainly to benefit their bottom line or patients in Northern countries first: in Europe, not Africa. This requires further investigation.

Equally problematic is another very profitable multinational company, Pfizer, which extracted over the top concessions from SA, shirking its own liability, and worse, demanded that it retains 50% of the "first payment"', even upon its own default to register or deliver. Pfizer also included a one-side disclaimer of non-infringement of other right holders' IP.

By all reasonable accounts and based on what was agreed to with SA, COVAX overpromised and under delivered for SA (and elsewhere), supplying even fewer vaccines than what the US Government (USG) donated to SA in the first three quarters of 2021.
South Africa received no price guarantee under the COVAX Agreement: while the all-inclusive weighted average estimated cost per dose was US$ 10.55, SA had the right to reject doses costing more than US$21.10.

J&J charged SA US$10 per vaccine dose, while the EU reportedly paid US$8.50, and there are also claims that the non-profit price could have been in the region of US$7.50. It is not clear from the Contracts if SA was refunded the balance in price difference.

For the SII, it is also likely that SA overpaid compared to European countries by at least more than two and a half times! In the UK and EU, Astra Zeneca charged £2.17 and £2.15, respectively.

The Contracts require SA to seek permission from said companies to divert or donate or sell doses which have already been paid for by the SA public, despite the benefit to other poorer countries or buyers. Frankly, in a global pandemic, this is paternalistic and imperialist, harms public health programmatic planning, and deliberately reduces the autonomy of African states.16 In particular, J&J, Pfizer, and COVAX did not commit itself to supply volumes and dates making it increasingly difficult to plan and run a timely and proper vaccination programme.

This Multi Stakeholder Group Analysis sets out why this type of "take it or leave it "contracting signals a dangerous precedent for future pandemic readiness measures and systems, and why this level of bullying, secrecy, and lack of transparency has no place in any democracy.

It is unfortunate that the SA Government spent almost two years resisting disclosure, for the benefit of big pharmaceutical corporations and GAVI/COVAX. Lack of timely public access to these Contracts created mistrust and limited public accountability action towards these corporates during a global pandemic. It created opportunities for price variations and enabled these multinationals to negotiate on an unequal footing with Government, which defeats the purpose of signing a supply agreement.

The point of a contractual purchase agreement is to have a minimum certainty for SA to order and purchase vaccines or medicines. These Contracts belie that purpose. And regrettably, this is not once-off COVID-related modus of operating: At present, even more pharmaceutical corporations are insisting on Non-Disclosure Agreements (NDAs - with broad confidential information clauses) and including them more aggressively in supply agreements to suppress the disclosure of pricing and supply terms, particularly in negotiations covering monopoly products such as HIV medicines.

[16] ''Beggars'' is the term used by President Ramaphosa of South Africa at the New Global Financing Pact Summit in Paris, France when referencing the issue of vaccine nationalism and lack of vaccine supplies, and tech sharing, during COVID: See https://www.news24.com/news24/politics/government/we-are-not-beggars-treat-us-as-equals-ramaphosa-tells-world-leaders-20230624

This deference to and fear of pharmaceutical power, in the middle of a crisis, in a Constitutional democracy should be of deep concern to the global public health community. It shows how much power was put into the hands of private sector actors and how few options governments had, when acting alone, in the middle of a pandemic. This is not a problem that can be solved by a single government but requires a regional and global solution and the exercise of state sovereignty.

Unless acted upon with clear, legally binding international agreement, we will arrive at the next pandemic with little more to enforce fair terms than platitudes and scathing press statements from the Minister and President in SA and other world leaders in the Global South. This must be deliberated upon in Pandemic Accord Negotiations and revisions of the International Health Regulations currently underway and at the upcoming United Nations General Assembly (UNGA).

Thankfully, the courts in SA have mitigated and addressed some of the uglier sides to contracting in the COVID pandemic, with this ground-breaking judgement. The SA Minister of Health's decision not to appeal the Judgment must also be applauded. The HJI case and Millar J's Judgment in the Gauteng High Court have opened secret COVID-19 vaccine procurement contracts to foster transparency and accountability in public procurement of health goods.

This will hopefully have far-reaching implications not just for the next set of pandemic procurement negotiations and contracts / agreements here and elsewhere, but also for the substantial amount of procurement due to take place under SA's future National Health Insurance (NHI) system.

We, therefore, call on governments in the Global South and the Boards, as well as the wealthy Shareholders of these companies and the Geneva- based not-for-profit initiatives to take the necessary steps to ensure that this type of bullying and extremes of non-disclosure are not repeated in the next pandemic. We need open procurement processes, not secretive ransom negotiations.

We have to say, Never Again...!

The public paid

In each of these Contracts, and with each entity, the SA public PAID for supplies via the National Department of Health and National Treasury per pricing conditions that are at times set out in the Agreements. It did so at a time when reports about corruption in health procurement emerged too.[17] The SA public, through the national fiscus, has also underwritten an unprecedented and one-sided Compensation Scheme - providing full indemnification to at least J&J, Pfizer, and Serum.

The procurement, and the mechanisms required of SA by these companies, to ensure often late or scarce vaccine supplies, involves considerable public money. [18]

Why bullying is anti-democratic

Below we set out why this type of "the bully rules" one-sided contracting ***signals a dangerous precedent for future pandemic readiness measures and systems***, and why this level of secrecy, lack of transprency, has no place in a democracy, and not just for SA.

We should also note that it is unfortunate that the SA Government spent almost two years resisting disclosure, for the main benefit of big pharmaceutical corporations and GAVI (for no good cause based on our review of the COVAX contract- see below), which we believe, unhelpfully, enabled a lack of corporate and general transparency in this time, especially.

This deference to and fear of pharmaceutical power, in the middle of a crisis, in a Constitutional democracy, has to be better regulated and managed at a global level, in the next pandemic, with more than just platitudes and scathing press statements from the Minister and President in SA.

[17] https://www.dailymaverick.co.za/article/2023-02-26-lest-we-forget-digital-vibes-two-years-on-zweli-mkhize-co-still-free-probe-ongoing/ and https://www.dailymaverick.co.za/article/2021-09-06-babita-deokarans-colleague-speaks-out-looting-networks-rife-at-gauteng-department-of-health/

[18] https://pmg.org.za/page/Vaccine%20trials,%20procurement%20&%20roll-out%20programme;%20with%20Minister%20&%20Deputy%20Minister

The parties

The legal entities, that is, the parties to the Contracts, were until the Court ordered disclosure this past week, also kept a secret. This feature of the litigation by HJI was one of the most surprising:

A. In preparing the application to Court to compel disclosure in 2022, after HJI's access to information requests were refused, the HJI requested the service / legal address and full and complete details of the contracting parties. But as Millar J in his Judgment noted, the HJI efforts were "rebuffed" in this regard (Para 23) by the Department.[19]

a. That information was also witheld by offices making up the relevant entities, both corporate and charitable: In particular, a Pfizer representative replied to the HJI's legal representatives stating "...that information too is confidential..."! (the contracting parties details).

The "purchaser" in all four Contracts was the Government of the Republic of SA –

acting through the National Department of Health of SA ("NDOH") –

Director General and as follows:

- Dr AB Xuma Building, 1112 Voortrekker Rd, Pretoria Townlands 351-JR, Pretoria, 0187; and
- Civitas Building, Comer Andries Sehume and Struben Streets, Pretoria 0001

[19] "[23] In the present instance section 47(1) of PAIA11 imposed upon the NDOH, the obligation to *"take all reasonable steps to inform a third party to whom or which the record relates of the request. "* It is not in issue in the present matter that this was done by the NDOH. Extensions of time were agreed between HJI and the respondents for this very purpose. Furthermore, HJI went further and sought to independently ascertain the identity of the third parties but was rebuffed."

The vaccine suppliers: Table 1

Common Name/s	Legal Name and Address	Local Office/ Representative	Price per dose	Agreed upon volumes	Legal Jusridiction for Contract/ Disputes between the Parties
Johnson & Johnson / J&J / Janssen	JANSSEN PHARMACEUTICA NV Incorporated in Belgium, with company number 0403834160. Registered office 30 Turnhoutseweg, B-2340 Beerse	None included	US $ 10 (one shot regimen at first) Non-refundable "Unsure of balance in difference in price will be or has been refunded to SA. EU reportedly paid $8.50. NFP price reportedly $7.50	30 000 000, at least	Laws of England and Wales -without regard to any conflicts of law principles The Parties specifically disclaimed the UN Convention on Contracts for the International Sale of Goods (CISG) The UK have not signed the CISG, and the J&J contract stipulated the UK as having jurisdiction
Pfizer	Pfizer Inc A corporation organized and existing under the laws of Delaware, with offices at 235 East 42nd Street, New York, New York 10017, USA	PFIZER LABORATORIES (Pty) (Ltd) 85 Bute Lane, Sandton, South Africa	US $ 10 (two shot regimen at first, then booster shots-3rd) Non-refundable in the main	30 000 000, at least	Laws of the State of New York, USA -without regard to conflict of Law principles other than Section 5-1401 of the New York General Obligations Law, except that any dispute regarding the arbitrability or the scope and application of this Section shall be governed by the Federal Arbitration Act of the United States.
Serum Insitute of India / SII	1. SERUM INSTITUTE OF INDIA PRIVATE LIMITED, CIN NO. U80903PN1984PTC032945 A company incorporated under the laws of India 212/2, Off Soli Poonawalla Road, Hadapsar, Pune - 411 028, Maharashtra, India 2. SERUM LIFE SCIENCES LIMITED A company duly incorporated, situated in England and Wales, formerly known as Covicure Holdings Limited. 12 New Fetter Lane, London, United Kingdom, EC4A 1JP	None included	US $ 5.35	1.5 million	Laws of India -without giving effect to the conflicts of law's provisions thereof. Courts of Pune, Maharashtra, in India, shall have exclusive jurisdiction over any disputes.
COVAX/ GAVI	THE GAVI ALLIANCE Non-profit foundation registered in the canton of Geneva (registry number CH-660-1699006-1) Chemin du Pommier 40, 1218 Le Grand-Saconnex, Switzerland	None	Uncertain But: "All-Inclusive Weighted Average Estimated Cost per dose - US $ 10.55" SA 'permitted to reject doses costing more than the Maximum Adjusted Cost Per Dose of US $ 21.10. The down payment: The *Solidarity Fund* paid 19.2 million US $ (ZAR283million) '- "15% of the total cost for 10% of the population"	12 000 000	GOVERNING LAW: None per se, interpretation independent of any national law. An Arbitration Tribunal (see below) may refer to English law, if there is ambiguity in interpretation DISPUTE RESOLUTION: Arbitration shall be conducted in accordance with the then-current rules of the United Nations Commission of International Trade Law (UNCITRAL). Arbitration proceedings in Geneva, conducted in English.

Table 1: Analysis of key features of the Contracts/Agreements provided to the HJI by the SA Government on 31 August 2023. *Note: Documents not in the possession of the HJI, including any NDA's (if separate) and Annexures have since been requested from the Department through HJI's legal representatives, on Monday 4 September 2023*

Table 2:
Specific aspects and clauses searched for and analysed in each of the four Contracts

Any Amendments to the original Agreement
Any Annexures to the Agreement
1. Breach clause
2. Confidentiality clause / Opening of Agreement if a Court orders disclosure
3. Donation clause
4. Export restrictions clause – affecting the SA government's ability to stop supplies *leaving* SA
5. Guaranteed delivery date/s / Timeline for deliveries
6. Late delivery clause (penalties)
7. Indemnification clause (civil/criminal liability)
8. Indemnification Fund provisioning/rules (funding, design)
9. IP or TRIPS WAIVER reference
10. Regulatory alignment and duties / SAHPRA or other
11. mRNA Hub in SA
12. NDA Attachment or NDA clause / Confidential Disclosure Agreement
13. Price and Volumes
14. Returns or refunds / Down payment and rules
15. Supply terms / priority
16. Surety provision (sovereign assets)
17. Termination clause

The Contracts and Agreements

We found the following for and in each Contract/Agreement:

Johnson & Johnson

The Receiving Party may disclose any part of the Confidential Information solely to the extent that it is legally required to do so pursuant to an order of a court or arbitral tribunal of competent jurisdiction or any applicable Law or, in the case of Janssen, a competent governmental authority, or the rules of any securities exchange to which Janssen or its Affiliates may be subject or under applicable securities Laws; provided that and subject to clause 16.6 the Receiving Party shall (a) unless prohibited by Law, promptly notify the Disclosing Party prior to making such disclosure and limit such disclosure and, if permitted, provide the Disclosing Party with an opportunity to intervene to protect its Confidential Information, including an opportunity to make representations to the relevant court, arbitral tribunal, or governmental authority (as applicable) objecting to disclosure, and (b) use reasonable efforts to obtain assurances that confidential treatment will be accorded to the Confidential Information to be disclosed pursuant to this clause 16.4. Without prejudice to the generality of the foregoing, the Government Purchaser acknowledges and agrees that Janssen's Confidential Information (a) constitutes commercial, financial, scientific and/or technical information supplied to the Government Purchaser in confidence, and (b) is competitively sensitive and proprietary information of Janssen that, if disclosed or otherwise made available to the public, would result in significant competitive prejudice and undue loss to Janssen and its Affiliates. Accordingly, Janssen reserves and relies upon all of its rights under any applicable freedom of information Laws, and the Government Purchaser shall assist Janssen in protecting Janssen's Confidential Information and take all other reasonable steps to prevent disclosure of any such Confidential Information under such applicable Laws.

(a) the Government Purchaser believes transparency as regards the Programme is important to garner public trust and confidence in and support for the Programme; so as to encourage maximum public uptake of the COVID-19 vaccines, or

(b) during the course of the Programme, the Government Purchaser considers it possible that emergency situations may arise which necessitates expeditious disclosure of Confidential Information in order to protect public safety; or

16.8 Accordingly, if the Government Purchaser believes that any of the circumstances envisioned in clause 16.7 exist, (i) the Government Purchaser shall provide notice of such circumstances to Janssen which describes the circumstances, the Government Purchaser's desired disclosures and an identification of the portion of such disclosure which constitutes Janssen's Confidential Information; and (ii) Janssen and the Government Purchaser shall generally co-operate with one another in good faith with respect reaching a mutually agreeable approach to such disclosure. As part of such cooperation, the Parties will discuss, among other things:

(a) the value of disclosure of Janssen Confidential Information toward resolution of the circumstances in clause 16.7;

(b) the commercial, regulatory, scientific, strategic or other value of the Janssen Confidential Information to Janssen, and, the extent to which, if disclosed or otherwise made available to the public, would result in significant competitive prejudice and undue loss to Janssen and its Affiliates;

(c) the extent to which similar information of other vaccine manufacturers has been disclosed (or has not been disclosed) by the Government Purchaser;

(d) the extent to which similar information has been disclosed (or has not been disclosed) by Janssen in other countries; and

(e) redaction, partial or selective disclosure (whether as to content or audience) or other mechanisms by which appropriate disclosure may considered to be made while providing reasonable assurances that confidential treatment will be accorded to the Confidential Information.

Context – while SA waited, Europe was first the line

1. J&J is a company with offices in among others, SA, Belgium, and the US . It is not elected in SA to serve on any arm of Government nor is it a political party. It should have no sway on executive policy making in any country.
2. In late 2020 and early 2021, it announced and then finalised an Agreement with *Aspen Pharmaceuticals* (a company in SA, Eastern Cape). [20] This was via a voluntary *fill and finish license* (ironically heralded at the time as an Africa "first" vaccine, and with much fanfare) when COVAX was unable to deliver supplies to the Global South with speed and in large volumes, for multiple reasons.
3. **J&J in its Agreement with the SA Government, we can now confirm, did insert an indefensible export ban requirement:**
    a. J&J demanded in its bilateral Agreement with the SA Government that the SA Government was not allowed to impose ANY export restrictions for ANY of its supplies, even if filled and finished **IN** SA, mainly for the benefit of J&J in a second, separate and private, undisclosed licensing arrangement and Agreement with Aspen[21] (vaccines filled and finished at Gqeberha (Eastern Cape).
    b. A *New York Times* August 2021 investigation exposed this unethical diversion, and export-free reign by J&J[22] - and stated:

> *Many Western countries have kept domestically manufactured doses for themselves. That wasn't possible in SA because of an unusual stipulation in the contract the Government signed this year with J&J. The confidential contract, reviewed by The Times,* ***required SA to waive its right to impose export restrictions on vaccine doses****. Popo Maja, a spokesman for the SA Health Ministry, said the Government was not happy with the requirements in the contract but lacked the leverage to refuse them. "The Government was not given any choice," he said in a statement.* ***"Sign contract or no vaccine."*** [emphasis added]

    c. The *New York Times* story led to a reported, and yet undertaking (unenforceable) by J&J to pause / halt the export of vaccines filled and

[20] https://www.reuters.com/business/healthcare-pharmaceuticals/safricas-aspen-signs-deal-package-sell-jj-covid-vaccine-2022-03-08/ and https://www.fiercepharma.com/pharma/johnson-johnson-locks-vaccine-licensing-deal-aspen-teeing-africas-first-local-covid-19-shot and https://www.reuters.com/business/healthcare-pharmaceuticals/safricas-aspen-signs-non-binding-agreement-with-jj-covid-vaccine-license-2021-11-30/

[21] https://www.reuters.com/business/healthcare-pharmaceuticals/safricas-aspen-signs-deal-package-sell-jj-covid-vaccine-2022-03-08/ and https://www.fiercepharma.com/pharma/johnson-johnson-locks-vaccine-licensing-deal-aspen-teeing-africas-first-local-covid-19-shotand https://www.reuters.com/business/healthcare-pharmaceuticals/safricas-aspen-signs-non-binding-agreement-with-jj-covid-vaccine-license-2021-11-30/

[22] At the same time, in the US, EU and India, export bans restricted the number of supplies that could leave a country, through executive member state action- measures that companies could not contract away)

finished in SA to Europe, in 2021, to allegedly favour Africa. But this was too little too late (by this time SA was rolling out a two dose Pfizer regimen, and demand for J&J also dropped due to other factors).

d. The *New York Times* estimates that, when it mattered most (timing), **at least 32 million doses were exported** / sent to Europe in early 2021, by Aspen from the Eastern Cape, on J&J's instructions, while SA and the rest of Africa waited for promised orders of vaccines. At the time, only 2% of people in Africa had even received one dose of a vaccine.[23]

I. This occurred while SA faced a devastating wave of infections, with inadequalte supplies for its national vaccine programme, in Q 1 and Q 2 of 2021 (effectively delaying the programme). ***This is a perfect example of bullying and requires Parliamentary and other forms of investigation***.

II. In addition, in 2023, we could find no evidence that the problematic condition was legally amended in the Agreement itself (if at all). No counter signed amendments to the main Agreement were shared.

e. We note that in **July 2021**, in a Parliamentary submission to the SA Parliament – J&J, with no hint of irony, stated the following about the principle of transparency in the Constitution in relation to health products' procurement:

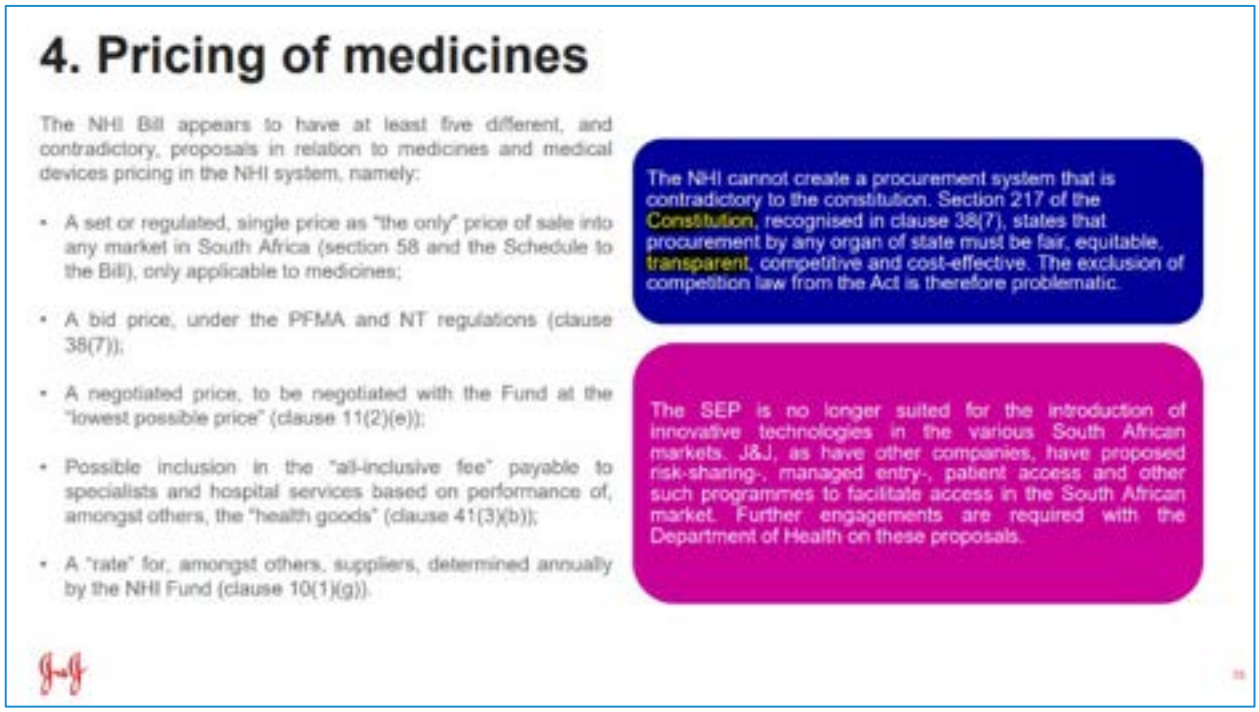


Figure 4: J&J presentation to the Portfolio Committee on Health, SA Parliament - on the National Health Insurance Bill (NHI) on 20 July 2021[24] (highlight added).

[23] NYT said: "Germany in April received shots produced by Aspen, a spokesman for Germany's health ministry said. In June and July, Spain received more than 800,000 doses, according to the country's health ministry."
https://www.nytimes.com/2021/08/16/business/johnson-johnson-vaccine-africa-exported-europe.html

[24] J&J submission to Presentation to the Portfolio Committee on Health, SA Parliament on the National Health Insurance Bill (No: 11 of 2019) on 20 July 2021, available https://pmg.org.za/committee-meeting/33306/

Analysis of the Agreement handed over to the HJI:

Findings: J&J

a. PRICE: We believe that SA may have overpaid and are uncertain if SA was refunded by J&J, in line with the Agreement.
    a. J&J charged SA US $10 per dose, while the EU reportedly paid US $8.50 and other sources say the non-profit price was US $7.50 (note US price = $10). Even with local licensing arrangements.[25]
    b. Para 3.1 states that the price per dose is US $ 10 dollars. It also has a statement relevant to international diversion, indicating that SA "acknowledges" that the price is set "in reliance" of the Agreement that the vaccines will be used solely in their territory.
    c. Para 3.4 states that the price does not include "all costs, duties, fees or other compensation in relation to the allocation, maintenance, distribution, storage, transport, administration and management of the Vaccine Volume following Delivery, and, for clarity, of VAT and other taxes."
    d. Janssen has the discretion to revise the price downward if the price in SA "is higher than the global price for the Vaccine Dose calculated in accordance with its Global Not-for-Profit Framework."
        i. At the time of the agreement the Global Not-for-Profit Framework was still being developed, according to 3.2, and the objective sought with this framework according to 3.2 was "to strengthen its commitment to making its initial production allocation of the Vaccine Candidate in 2021 available on a not-for-profit basis."
        ii. If the price was revised downward and SA had already paid the price, Janssen committed to in Para 3.2 to "refund the difference between the Price and the Adjusted Price to the Government Purchaser for such Vaccine Volume as soon as reasonably practicable". We do not know if this happened.
        iii. Nevertheless, Para 3.3 states that the Global Not-for-Profit Framework would remain confidential and that Jassen was under no obligation to

[25] See: https://guardian.ng/news/single-dose-jj-covid-19-vaccine-costs-nigeria-7-50-per-dose-says-afreximbank/ and https://healthpolicy-watch.news/african-union-special-envoy-slams-covax-as-covid-deaths-spike-on-the-continent-urges-donors-to-pay-up-on-vaccine-pledges/ https://www.theguardian.com/world/2020/dec/18/belgian-minister-accidentally-tweets-eus-covid-vaccine-price-list and https://www.biopharmadive.com/news/johnson-johnson-vaccine-not-for-profit-price/608477/#:~:text=J%26J%20has%20sold%20its%20vaccine,transition%20toward%20for%2Dprofit%20saleshttps://www.axios.com/2021/10/19/johnson-johnson-q3-covid-vaccine-sales and https://www.biopharmadive.com/news/johnson-johnson-vaccine-not-for-profit price/608477/#:~:text=J%26J%20has%20sold%20its%20vaccine,transition%20toward%20for%2Dprofit%20sales https://www.biopharmadive.com/news/johnson-johnson-vaccine-not-for-profit-price/608477/#:~:text=J%26J%20has%20sold%20its%20vaccine,transition%20toward%20for%2Dprofit%20sales https://www.axios.com/2021/10/19/johnson-johnson-q3-covid-vaccine-sales

disclose the framework to SA. It states that SA has no right "to assess, audit, analyse, question, or otherwise have access to or evaluate, the Global Not-for-Profit Framework". So while in theory the price could be reduced, in accordance with the Global Not-for-Profit Framework, both Agreements provided do state that "that the price payable for any Further Vaccine Volume or for COVID Vaccine that is for use other than for the Purpose, may be higher than the Price, and that the Global Not-For-Profit Framework is expected to apply only to Janssen's initial production of the Vaccine Candidate in 2021 ... after which Janssen expects to transition to a commercial pricing framework for the COVID Vaccine" [emphasis added] indicating that it would abandon discounts for low and middle-income countries over time.[26]

iv. The J&J "Global Not-for-Profit Framework" is unsurprisingly not available online and we are unable to locate any compelling evidence that the price was subsequently adjusted downwards for SA.[27] Also, in October 2022, DEVEX article highlighted that despite J&J's considerable delay in delivering vaccines, SA will have to still pay, donate or destroy these vaccines for various reasons – this same article notes that "as of April 2021, SA paid US$ 10 per dose for the J&J vaccine... and that ... this is US$ 2.50 more per dose than the prices paid by UNICEF for the jab".

v. Para 9.5 states that "Janssen is selling the Vaccine Volume to the Government Purchaser at the Price solely for use for the Purpose". Purpose is defined in page 7 as the use of the vaccine "in the Territory (and only in the Territory) to vaccinate individuals in the Territory against SARS-CoV-2/COVID-19, prior to its applicable Vaccine Expiry

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[26] https://commission.europa.eu/system/files/2021-05/jj_apa_202005071550.pdf and https://www.estudiosanticorrupcion.org/wp-content/uploads/2022/11/ACUERDO-JANSSEN_compressed.pdf

[27] See here J&J statement on making the vaccine available "on a not-for-profit basis for emergency pandemic use: https://www.janssen.com/southafrica/johnson-johnson-single-dose-covid-19-vaccine-granted-registration-south-african-health-products.

See also https://www.jnj.com/johnson-johnson-announces-landmark-agreement-to-enable-its-covid-19-vaccine-to-be-manufactured-and-made-available-by-an-african-company-for-people-living-in-africa where J&J states: "In 2021, Johnson & Johnson provided its vaccine globally at a not-for-profit price, and through its advance purchase agreements and country donations, shipped approximately 70% of its global vaccine supply to LMICs. The Company remains committed to ensuring its vaccine is accessible to people around the world and continues to advocate that governments with available doses follow the example of the U.S., European Union and others and immediately ramp up dose sharing, particularly through the COVAX Facility."

See: https://www.csreurope.org/newsbundle-articles/johnson-johnson-publishes-its-2021-health-for-humanity-report - where J&J also claimed that "To drive global health equity, J&J provided its COVID-19 vaccine globally at a not-for-profit price and shipped 180 million doses of its single-shot COVID-19 vaccine to the African Union, COVAX, and South Africa through advanced purchase agreements and country donations". In a July 2021 Reuters article it was also reported that "J&J estimated its vaccine price at $5 per dose in the first half of the year and said it would likely be as much as $8 by year end. The healthcare conglomerate, which promised it would not make a profit on the vaccine during the pandemic, said the fluctuating price reflected the net costs of the vaccine and production volumes. The $8 price is a bit lower than previous indications. South Africa has said it is paying $10 per dose for both the J&J and the two-shot Pfizer/BioNTech (PFE.N), vaccines. AstraZeneca Plc (AZN.L) is charging $3 per shot for its two-dose vaccine."

Date". Territory is defined in page 8 as "the Republic of SA, including all of its provinces and territories". Together, these clauses mean that SA is required to distribute the vaccines solely in their territory.

b. Para 9.6 opens the door to the possibility of **re-selling, donating, or distributing** the vaccines outside of SA, but only with the "prior written approval of Janssen". Janssen's written consent "shall not be unreasonably withheld or delayed". One of the factors Jassen is required to consider when deciding whether to approve onward distribution is "the possibility for the vaccine doses to be used in markets other than SA where such doses may have a higher efficacy".

c. **Indemnification (liability):** J&J secured extensive indemnification "rights" covering a broad range of civil and criminal claims—a breathtaking level of indemnification by most standards. The SA Government essentially takes on unlimited liability while J&J takes on none even if their manufacturing or testing are faulty, except in a case where willful misconduct can be proven.
    a. Para 17.1. This includes claims based on damages arising from "the design, research, development, testing, manufacture, labelling, packaging, sale, procurement, delivery, deployment, distribution, storage, administration, effects and/or use of the COVID Vaccine".
    b. Para 17.2 states that indemnification "rights" will not be available if the losses "result directly from the Adjudicated Willful Misconduct or Adjudicated Failure to comply with cGMP of such Indemnified Persons".
    c. **Article 17.4 states that the SA Government's indemnification obligation is "not subject to a financial limitation or maximum" no matter how many claims are brought.**
        i. Here SA had to establish a "no fault compensation system" following the minimum requirements described in detail in Exhibit B, at pages 37-38 of the agreement - aligning with comments made by the Minister of Health at the time to Parliament (see above).

d. **Returns or refunds:** Para's 8.6, 10.3, and 18.5 have provisions on refunds. Under Para 8.6, the Government of SA is only entitled to a refund or replacement of "non-conforming vaccines". Determination of non-confirming vaccines is governed by the provisions of Exhibit C in the Agreement.

e. **Down payment:** Under Para 10.1, SA is required to make a down payment of **US $ 27.5 million** within five business days *after the date in which the US FDA has issued an emergency use authorization for the J&J vaccine candidate*.
    a. Para 10.3 states that the US$27.5 million down-payment is <u>not</u> refundable by J&J to SA, "in any circumstances", including if the vaccine does not receive full regulatory approval, or if the development or manufacturing of the vaccine is "unsuccessful".

b. However, SA can bring a contractual claim for a refund of the down payment under Para 22.10 in the event of willful default by J&J.
c. SA also has rights for refunds under Para 18.5 if it terminates the agreement after determining that the J&J vaccine "is not safe and/or efficacious in vaccinating individuals in the Territory".

f. **Medicine Regulatory alignment:** J&J estimated Regulatory Approval to be granted or issued on or prior to **1 May 2021**.
   a. And the Agreement states that: "...the Government Purchaser acknowledges that if Regulatory Approval is not granted or issued by the Expected Approval Date, Janssen shall be entitled to adjust such schedule and quantities as Availability (and subsequent Delivery) will likely be delayed".
   b. Exhibit A further states that "is dependent on Regulatory Approval as well as on the local quality release of Vaccine Volume by local competent authorities".

g. **Donations/Onward Sale** (this is relevant when a Government wishes to ensure it does not stockpile close to expiry vaccines or if ''demand is low'' for that vaccine, as happened with J&J vaccines — per the Department's presentation to Parliament in late 2022):
   a. Para 9.6 creates the possibility of re-selling, donating, or distributing the vaccines outside of SA but only with the "prior written approval of Janssen". Janssen's written consent "shall not be unreasonably withheld or delayed".
   b. One of the factors Jassen is required to consider when deciding whether to approve onward distribution is "the possibility for the Vaccine Doses to be used in markets other than SA where such doses may have a higher efficacy". [Para Section 9.5 provides that "Janssen is selling the Vaccine Volume to the Government Purchaser at the Price solely for use for the Purpose". Purpose is defined in page 7 as the use of the vaccine "in the Territory (and only in the Territory) to vaccinate individuals in the Territory against SARS-CoV-2/COVID-19, prior to its applicable Vaccine Expiry Date". Territory is defined in page 8 as "the Republic of SA, including all of its provinces and territories". Together, these clauses mean that SA is required to distribute the vaccines solely in its territory.]

h. While J&J may terminate the Agreement if SA fails to pay the down payment or price balance (10.5) there are NO guaranteed delivery dates.
   a. Under Para 8.2, SA recognised that "the Tentative Availability Schedule is a **best-case scenario** and assumes the Vaccine Volume will be either created by improvements in Janssen's supply capacity or be sourced with the cooperation of other customers for the COVID Vaccine, and as such **no assurances can be given by Janssen that such improvements will happen or that other customers will give up their doses**". **This is a remarkably prejudicial provision for SA.**

i. Para 8.2 also states that J&J cannot be "held responsible" if the vaccine doses are not delivered in accordance with the tentative schedule. There are no non-delivery penalty provisions that deal with J&J's own diversion of available supplies to customers in Europe or the USA!

b. SA can **terminate** the agreement if regulatory approval is discontinued, withdrawn, or becomes invalid according to Para 18.1. Either party can terminate if the other party incurs in material breach and does not curate within ninety days according to 18.3.

c. J&J can also determine under additional circumstances provided in 18.4, which are: a) abandoning the development programme; failure to obtain regulatory approval; and if the implementation of the agreement becomes impossible (where J&J is acting reasonably).

i. **Confidentiality clause:** Definition of "confidential information" covers "all information, data, documents and materials," including "know-how." Para 16.1 provides the general confidentiality provision and Para 16.5 states that the general confidentiality obligation **survives for ten years** following the expiration or termination of the Agreement. This can be interpreted to include information on manufacturing know-how disclosed by Janssen to SA that may be relevant to promote the efforts of the mRNA technology transfer hub or other hubs.

j. As per a hand up of this specific clause to Millar J, on the day of the hearing, there is room for the SA Government to disclose the Agreement - if a Court orders disclosure (highlighted, as received in the handover of documents on 31 August 2023).

10.1 Non-Use and Non-Disclosure.

Each Recipient shall, and shall cause its Representatives which have access to the Disclosing Party's Confidential Information to, maintain in strict confidence, and shall not disclose to any third party, all Confidential Information observed by or disclosed to it by or on behalf of the Disclosing Party pursuant to this Agreement. Each Recipient shall not use or disclose such Confidential Information except as permitted by this Agreement. Each Recipient shall safeguard the confidential and proprietary nature of the Disclosing Party's Confidential Information with at least the same degree of care as it holds its own confidential or proprietary information of like kind, which shall be no less than a reasonable degree of care. The Recipient and its Representatives may use, copy, and make extracts of the Disclosing Party's Confidential Information only in connection with fulfilling its obligations under this Agreement and, without limiting the foregoing, shall not use the Confidential Information for the benefit of the Recipient or any of its Representatives, or for the benefit of any other Person. In the event that Recipient becomes aware of any breach of the obligations contained in this Section 10 (Confidential Information) by it or its Representatives, Recipient shall promptly notify the Disclosing Party in writing of such breach and all facts known to Recipient regarding same. In addition, if Recipient is required to disclose the Disclosing Party's Confidential Information in connection with any court order, statute or Government directive or requirement under any Law, Recipient shall give the Disclosing Party notice of such request, as soon as practicable, before such Confidential Information is disclosed so that the Disclosing Party may seek an appropriate protective order or other remedy, or waive compliance with the relevant provisions of this Agreement. If the Disclosing Party seeks a protective order or other remedy, Recipient shall promptly cooperate with and reasonably assist the Disclosing Party (at the Disclosing Party's cost) in such efforts. If the Disclosing Party fails to obtain a protective order or waives compliance with the relevant provisions of this Agreement, Recipient shall disclose only that portion of Confidential Information which its legal counsel determines it is required to disclose. Neither this Agreement nor the performance by either Party hereunder shall transfer to the Recipient any proprietary right, title, interest or claim in or to any of the Disclosing Party's Confidential Information (including, but not limited to, any Intellectual Property rights subsisting therein) or be construed as granting a license in its Confidential Information. Notwithstanding the foregoing, in all cases, (a) Purchaser may not disclose any of the financial or indemnification provisions contained in this Agreement, including, without limitation, the price per dose of Product or refundability of the Advance

Analysis of the Agreement handed over to HJI

Notes and cautions: Pfizer

A [seemingly] separate Indemnification Agreement (see here Para 2.1) was not attached in the handover, and it has since been requested by HJI's legal representatives. These documents might provide more information on additional indemnification requirements of the SA Government.

Context: Pfizer

1. In July 2021 Pfizer / BioNTech announced a licensing deal for "fill and finish" with a company in SA commonly called Biovac, for at first, at least about 20 million vaccine doses, for purposes of the African Union[28] with volumes growing to about 100 million vaccine doses "annually" and by 2022. Subsequently, when multiple COVID variants emerged, Omicron - Pfizer and BioNTech adapted and pivoted to a bivalent vaccine (Original and Omicron BA.4/BA.5 strains) in the US and elsewhere[29]. To date, BIOVAC is yet to provide a single dose of vaccine in terms of that licensing arrangement in the African market, also because it is awaiting regulatory approval.
2. In early 2022, it was also announced that BioNTech will send, by ship, vaccine factory kits (made from shipping containers, then to be assembled) to Africa—in Rwanda—to "secure mRNA vaccine production on the continent", in line with a public pledge it made in 2021 (fill and finish). Activists have previously referred to this as "colonial-CON-tainers".[30]
3. While it was reported that in the case of SA, Pfizer backed down on demands for sovereign assets to be offered as surety for payment, the indemnification and no-fault compensation fund requirement was not dropped and had to be given effect to. Elsewhere in Latin America for example, in Argentina and Brazil, the requirement was not dropped, as reported extensively by the Bureau for Investigative Journalism (BIJ) in early 2021.
    a. The BIJ revealed that: "Pfizer has been accused of "bullying" Latin American governments in COVID vaccine negotiations and has asked certain countries to put up sovereign assets, such as embassy buildings and military bases, as a

[28] Pfizer Inc. (NYSE: PFE) and BioNTech SE (Nasdaq: BNTX) today announced the signing of a letter of intent with The Biovac Institute (Pty) Ltd, known as "Biovac," a Cape Town-based, South African biopharmaceutical company, to manufacture the Pfizer-BioNTech COVID-19 Vaccine for distribution within the African Union. https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-announce-collaboration-biovac

[29] On April 18, 2023, the Food and Drug Administration amended the emergency use authorization (EUA) of Pfizer-BioNTech COVID-19 Vaccine, Bivalent to simplify the vaccination schedule for most individuals. This action includes authorizing the current bivalent vaccine (Original and Omicron BA.4/BA.5 strains) to be used for all doses administered to individuals 6 months of age and older. The monovalent Pfizer-BioNTech COVID-19 Vaccine is no longer authorized for use in the United States. https://www.fda.gov/vaccines-blood-biologics/coronavirus-covid-19-cber-regulated-biologics/pfizer-biontech-covid-19-vaccines

[30] https://www.reuters.com/business/healthcare-pharmaceuticals/biontech-ship-mrna-vaccine-factory-kits-africa-2022-02-16/

guarantee against the cost of any future legal cases... In the case of one country, demands made by the pharmaceutical giant led to a three-month delay in a vaccine deal being agreed. For Argentina and Brazil, no national deals were agreed at all. Any hold-up in countries receiving vaccines means more people contracting COVID-19 and potentially dying". [31]

b. While Pfizer initially demanded the sole and exclusive right to determine the nature of the guarantee against indemnification claims in SA, it backed down[32] from that demand, because of negative publicity. Note: It did not do so in Latin America.

c. But that early 2021 Pfizer haggling and dispute with the SA Government (who the latter to their credit lambasted Pfizer publicly for its heavy-handed imperial negotiation tactics) played a part in considerably DELAYING supplies arriving in SA in 2021, in turn, delaying the commencement of the country's mass national vaccination programme (at the time only healthcare workers had received a vaccine, from a J&J "donation" / study programme), while more variants were emerging, and while the country was in repeat lockdowns with rising death tolls from COVID.

d. At the time, the then Health Minister famously stated: *"As government we have found ourselves in a precarious position of having to choose between saving our citizens lives and risking putting the country's assets into private companies' hands''. [33]*

4. By mid-2021, Pfizer commenced with its vaccine deliveries for SA (see HJI Vaccine supply sheets, referenced above).
5. The UK/EU Pfizer contracts[34] it should be noted, like the SA Agreement, also reify Pfizer's sole ownership over IP.

Findings: Pfizer

1. As reported extensively, in 2021 and 2022, the Agreement confirms that Pfizer did indeed insist on Global South countries such as SA, first establishing an Indemnification and Compensation Fund, in exchange for supplies, and this was, a non-negotiable precondition.

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[31] Madlen Davies , Rosa Furneaux , Iván Ruiz , Jill Langlois "'Held to ransom': Pfizer demands governments gamble with state assets to secure vaccine deal" IBJ 23 Feb 2021 Available: https://www.thebureauinvestigates.com/stories/2021-02-23/held-to-ransom-pfizer-demands-governments-gamble-with-state-assets-to-secure-vaccine-deal

[32] https://www.bloomberg.com/news/articles/2021-04-19/pfizer-backed-down-from-demand-that-posed-risk-to-south-africa#xj4y7vzkg
https://www.news24.com/fin24/companies/pfizer-backed-down-from-demand-that-posed-risk-to-south-africa-20210419

[33] https://www.parliament.gov.za/press-releases/media-statement-decision-temporarily-halt-johnson-johnson-vaccine-rollout-taken-precautionary-measure

[34] UK Contract: https://www.contractsfinder.service.gov.uk/notice/f6adf3ca-59a4-4976-95e6-27a62a2a4c6e and Slade and Hawkins ref the EU Contract here: https://ec.europa.eu/info/sites/default/files/redacted_advance_purchase_agreement_biontech-pfizer_0.pdf

2. The Vaccine Injury Scheme / Fund, a first of its kind established in and for SA, was established with unprecedented approval and speed by SA lawmakers in 2021 and with heavily truncated public submission timelines (whilst other key laws designed to address pharma price and patent bullying are yet to be tabled, not having been prioritised for introduction during the pandemic either...). For more information, see the HJI's *Submission on the Vaccine Injury Scheme Fund in South Africa*.[35]
3. None of the public interest flexibilities on IP and related issues identified in a recent study by *Slade and Hawkins*, including access to test data, march-in rights in the event of abandonment, localised manufacturing, or dose redistribution, which are contained in **some** UK/EU Agreements, are present or included in the SA Agreement/Contract.[36]
4. The **language is also extreme** compared to richer countries' Agreements and in the company's favour (hence one-sided).
    a. For example, the prospect of donation or resale of doses is framed as an issue of "diversion" in the SA Agreement (para. 4.6). This is problematic, because every country wishes to avoid having a stockpile of close to expiry vaccines and would prefer it being used by a third country, rather than destroyed.
    b. Similarly, while Pfizer committed in its contract with the UK Government to supply goods made from Pfizer sites *in* Europe, the SA Agreement (para. 4.2(c)) grants Pfizer complete and total discretion over where its vaccines are made, for SA. In other words, no subsequent prefrence was added via an Amednment, for Biovac's supply, despite the license granted to it by Pfizer/BioNTech (see above).

Specific aspects and provisions of the SA Agreement that are a concern: Pfizer

5. As we understand the Agreement, in the event Pfizer fails to deliver doses, SA could go seek 50% of the "advance payment" back from Pfizer.

[35] https://healthjusticeinitiative.org.za/2021/04/19/hji-submission-proposed-vaccine-injury-scheme/

[36] Intellectual Property Rights and Advance Purchase Agreements in a Crisis, Alison Slade, and Naomi Hawkins Intellectual Property Rights and Advance Purchase Agreements in a Crisis *(2023) Intellectual Property Quarterly 1-32.* Slade and Hawkins investigated the nature and scope of the IP and IP related contractual clauses included in the APAs concluded by the UK government and EU Commission. The study (for purposes of this analysis) looked *at* eleven publicly accessible advanced purchase agreements which were signed in 2020, i.e. prior to an approved vaccine being available, five concluded by the UK government and six by the EU Commission including also: EU & AstraZeneca (27 August 2020) – unredacted; UK & AstraZeneca (28 August 2020) – redacted; UK & Pfizer/BioNTech (12 October 2020) – redacted; EU & Janssen (21 October 2020) – redacted; EU & Pfizer/BioNTech (11 November 2020) – redacted.
https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4360150

a. The advance payment was US$ 40 million, so the SA Government would — in the event of breach — only be entitled to seek US$ 20 million, which amounts to 10% of the total cost to be paid under the contract.

6. The Agreement does not give SA any rights to export or donate any number of supplies (even if SA has excess supplies), without Pfizer's consent. This is also framed as an issue of ''diversion''.
    a. Further, although the agreement suggests that the SA Government could "resell, export, transfer, donate or otherwise distribute" vaccines in the event that Pfizer provides "prior written consent", there is no stipulation that Pfizer cannot "unreasonably withhold or delay" its consent—an important caveat that is present in the J&J contract as well as Agreements between companies and high-income countries.
7. The Agreement states that the "price'' already considers the indemnification and liability clauses, implying that the price would have been much higher if those clauses were watered down in some way.
8. The Agreement includes an overly broad confidentiality clause that survives beyond the Agreement for a period of ten years unless the information in question is a trade secret (in which case the confidentiality obligation continues until the information is no longer a trade secret).
9. It is clear from the language in Para 10.1, that the Agreement prevents disclosure of provisions in the Agreement surrounding indemnification, pricing, and refundability. If a Court orders disclosure, Pfizer is to be "notified" so they can seek a protective order if they so choose.
10. The Agreement contemplates an "Interim Delivery Schedule" only, which is subject to change depending on when market authorisation for the vaccine is obtained. And, in any event, Pfizer is not liable for late deliveries per the contract.
11. There is no Non-Disclosure Agreement (NDA) attached, apart from the confidentiality provisions already in the Agreement, it is thus unclear whether there is a separate NDA, which HJI has sought clarification on.
12. Pfizer retains "sole ownership" of any/all IP. Yet, ironically, Pfizer does not — by virtue of the Agreement — "make any representations regarding non-infringement and/or the need to obtain an IP license'' for itself. The Agreement, as mentioned above, reifies Pfizer's sole ownership over IP.
13. There appears to be an attempt to prevent any sort of localised testing of the vaccine. Unless Pfizer engages in "willful misconduct", the SA Government is responsible for all costs of any *recall or market withdrawal* per Para 4.7. Normally, the company would bear the financial burden of such a recall or withdrawal.
14. Para 2.4 (h) of the Agreement states that if authorisation is received by 30 September 2021, but by 31 March 2022 Pfizer is unable to manufacture or deliver any Contracted Doses for technical or other reasons from any Facilities, Pfizer will have no obligation

to deliver against the Interim Delivery Schedule, Adjusted Delivery Schedule, or a Purchase Order. This is very vague and broad language.

a. The point of a contractual purchase agreement is to have a minimum certainty for SA to order and purchase the vaccine. Especially given that SA had to agree to far-reaching and egregious conditions, including indemnification in the broadest possible sense. If the purchaser's orders comply with the Agreement and Pfizer does not face any force majeure event, Pfizer should be obligated to deliver. In a nutshell, if we read the above and Para 2.5 there is no supply certainty.

Analysis of the Agreement handed over to HJI

Notes and cautions on COVAX / GAVI

The Term & Conditions and Allocation Framework referenced in the COVAX / GAVI Agreement were not attached in the handover, and it has since been requested by HJI's legal representatives. These documents might provide more information on actual prices, allocation, and delivery of vaccines, GAVI's mark-up, and other adjustments, as well as the global country priority framework GAVI used during the pandemic.

In the absence of such details, if they in fact were agreed to and either redacted or agreed to separately, it is difficult to fully assess the mutual undertakings of GAVI and SA.
There is no confidentiality clause in the COVAX – GAVI Agreement that was handed to HJI, hence the above documents are relevant for our assessment.

Context

1. By Q 3 2022, it is estimated that GAVI (a not-for-profit foundation in Geneva) only delivered about 1.3 million Pfizer vaccines to SA, no one has publicly explained what agreement or concessions were struck between GAVI and SA on the remainder of the committed doses, and balance of the down payment, close to quarter of a billion rand, even after the initial pressure for a "down payment" (which was first paid by the Solidarity Fund, as confirmed by the SA Government in December 2020 here:

> The National Department of Health and the Solidarity Fund are pleased to announce that the down payment of $19.2 million (amounted to R283m at the exchange rate at time of payment) has been made to GAVI (the Vaccine Alliance) to secure South Africa's entry into the COVAX facility. The payment was made in line with the Fund's previous allocation of funds and commitment to support Government's efforts to accelerate the roll-out of vaccines in South Africa....COVAX has confirmed South Africa's entry into the facility. The down payment represents 15% of the total cost of securing access to vaccines for 10% (roughly 6 million) of the population. The country's membership in the COVAX facility ensures that South Africa receives its equitable share of the vaccine once it becomes available. [emphasis added]

2. COVAX has also since its inception been heavily criticised by several organisations and commentators for failing to ensure equity, allowing richer countries to use it to bypass equity promises, and for underdelivering at a time when the Global South countries, who were promised by COVAX that they would be prioritised if they opted in to the self-created and self-designed voluntary mechanism, were desperate for supplies.[37]

Findings: COVAX / GAVI

1. The COVAX/SA Commitment Agreement (Committed Purchase Agreement) of COVAX approved COVID-19 vaccines is decidedly one-sided in favour of GAVI—with no committed delivery date, volume, or price but significant commitments required on the part of the SA Government.
2. COVAX overpromised and underdelivered for SA, supplying even fewer vaccines than what the USG donated to SA in the first three quarters of 2021. This could be because the USG donation and Pfizer's own commitments in bi-lateral agreements with the SA Government resulted in sufficient supplies by late 2021—early 2022, or for other reasons, but COVAX in the end only sent a paltry 1.3 million doses of vaccines Pfizer to SA in 2021 versus a committed Agreement for substantially more (12 million) at a time when SA really needed sufficiently greater supplies.
3. We note that there is no explicit confidentiality clause, though it may be included in the Terms and Conditions, yet not handed over. Alternatively, there may have been a separate NDA. Considering this, we are unsure why the Department resisted the disclosure of THIS Agreement.
    - On the face of it, there was no obligation to GAVI to do so. As such, GAVI too could have also proactively disclosed the contract, and all its other Agreements in other jurisdictions too, and at the very least, respond to HJI's 2022 request to provide confirmation of its legal service details.

SA's "promises": COVAX / GAVI

1. On its side, SA committed to purchasing vaccine doses from approved, specified manufacturers selected by GAVI according to an Allocation Framework, which has not been disclosed in the documents handed over. Thus, it is not clear how doses secured by GAVI would be allocated between SA and other COVAX participants.

[37] https://msfaccess.org/covax-broken-promise-world; https://www.theguardian.com/global-development/2021/jun/24/rich-countries-deliberately-keeping-covid-vaccines-from-africa-says-envoy; https://www.dailymaverick.co.za/article/2020-12-06-the-great-covid-19-vaccine-heist/; https://www.washingtonpost.com/world/2022/03/22/covax-problems-coronavirus-vaccines-next-pandemic/; https://www.theguardian.com/world/2021/jan/29/canada-and-uk-among-countries-with-most-vaccine-doses-ordered-per-person; https://www.theguardian.com/world/2021/nov/26/rich-countries-could-have-prevented-new-covid-variant-say-experts; https://www.theguardian.com/global-development/2022/jul/21/covid-vaccine-figures-lay-bare-global-inequality-as-global-target-missed

2. SA committed to purchasing twelve million doses, sufficient to vaccinate 10.12% of its population, a percentage less than the 20% COVAX self-determined target. SA did, however, retain the right to seek and pay for additional allocations.
3. SA received no guarantees with respect to the actual number of doses that it might receive, nor when those doses might be delivered. Thus, it remained liable to pay for its committed volume even if it was forced to enter bilateral deals, as it did, because of late deliveries from GAVI. We are unaware at present what penalty SA paid, if any, pursuant to this provision or how this issue was resolved.
4. SA promised to pay for all available allocated doses, even those it did not want or use, and promised to pay Gavi for all undelivered doses subject only to GAVIs duty to take reasonable steps to "mitigate" (which might require it to try to arrange sales to other participants). If SA elects to purchase additional quantities, it remains liable to pay for all such quantities.
5. SA received no price guarantee under the Agreement, though it does retain the right to reject doses costing more than US$ 21.10.
6. GAVI discloses an average price of doses, which is meaningless, but then specifies that it can unilaterally set an actual purchase price based on the actual procurement price from the specified manufacturer, any actual access/speed premium, and any financing/risk mitigation and [Gavi] operating costs.
7. The premiums paid by GAVI are undefined in the Agreement, as a percentage or otherwise, and there is no provision for reporting or verification of said amounts. An additional cost element relates to any taxes or duties that must be paid by GAVI or the specified manufacturer with respect to the purchases. The actual price paid will be adjusted with a deduction for any down payment or other [advance] additional payment made by SA. Payment is due when the doses "become available", the meaning of which is unspecified but does not mean "upon delivery".
8. Payments to specified manufacturers shall be confirmed with a commitment satisfaction certificate countersigned by the supplier.
9. SA provides a truly remarkable (for a public health organisation) indemnification pledge to GAVI for any costs, loss, or liability it might experience because of SA's payment or delay in payment, procurement, financing condition, or tax gross up [payment]. As stated previously, Gavi does have a duty to mitigate its losses.
10. In addition, SA must use all reasonable endeavours to procure a guarantee or other form of credit to ensure its financial guarantee amount (the total US$ 126 600 000 it has promised to pay if the Agreement is fulfilled). In the absence of securing such financing guarantee by 15 December 2020, GAVI retained the right to terminate the Agreement.
11. SA promised to obtain regulatory approval for vaccines from selected manufacturers but does not require that selected manufacturers apply for and receive conditional or full regulatory approval from SA. Instead to satisfy GAVI, selected manufacturers only need WHO prequalification or, exceptionally, approval from a stringent regulatory authority.

12. SA further guarantees that its procurement of vaccine doses from GAVI and its specified manufacturers will comply with all applicable laws and international treaties to which SA is a party. This could make SA that guarantor that no IP rights or treaty provisions with respect to such rights have been violated in the countries of manufacture, transshipment, or purchase/use [SA].

GAVI's promises (for COVAX):

1. GAVI promises to allocate doses pursuant to (undisclosed) ''Terms and Conditions'' and an "Allocation Framework".
2. GAVI undertakes to take all reasonable steps to mitigate taxes related liabilities and any costs, losses, or liabilities resulting from SA default of its contractual obligations.
3. GAVI aspires to procure two billion doses of safe and efficacious vaccines by the end of 2021, but makes no enforceable promise to do so, and in our view, failed miserably in that regard.

Key ambiguity: COVAX / GAVI

The Agreement has a maximum commitment [payment amount] but also a promise to procure 12million doses. Since the actual price is not specified, a question arises of whether SA must procure twelve million doses even if the cost thereof exceeds the average vaccine price upon which the twelve million dose purchase was calculated.

The best way to resolve this ambiguity is to conclude that SA is committed to purchase either the entire twelve million doses if the total cost is less than the committed US$126 600 000 **or** to buy as many doses as that sum will pay for.

Specific provisions that are a concern: COVAX / GAVI

1. Volumes: 12 million (see above):
    a. There is a set number of ''Total Participant Doses'' but its impact is uncertain because of Para 2.1 which says that SA's undertakings to pay "shall not, at any time in aggregate, exceed the Committed Amount, which is set at US $126 600 000. This sum would buy 12 million doses at the average estimated cost, but not if the cost per dose increased.
    b. The ambiguity is whether there is an upper limit on quantities or an upper limit on overall cost.
    c. There is no guaranteed delivery date, nor any specified penalties for non-delivery. In general, delivery will be pursuant to [missing] Terms and Conditions and the [missing] Allocation Framework. There is no mention of priority frameworks/other; and the sole reference on supply term obligations reference the undisclosed "Terms and Conditions" and "Allocation Framework".

d. The Preamble in this Agreement, at *para. F,* states that the "lack of funding or readiness by a participant or set of participants (countries) would not delay the distribution of vaccines to other Participants (other countries) in alignment with the Allocation Framework". This emphasises why adequate financing for Global South countries and proper resourcing for pandemic responses, is critical.

2. There are no provisions about returns or refunds for any reason, substandard batches or otherwise.
3. Para 4.3 deals with the "Failure to procure Participant Doses": If Participants in the programme such as SA do not purchase its Participant Doses (or part thereof) for any reason or exchange its Participant Doses on the COVAX Exchange, then SA must notify GAVI immediately and will be obliged to pay GAVI the cost of its Remaining Participant Doses (an amount equal to the product of the Adjusted Cost Per Dose and the Remaining Participant Doses—see above).
4. COST: The price per vial is unclear.[38]
    e. As explained in the summary above, there is an All-Inclusive Weighted Average Estimated Cost per dose of US$ 10.55. But the average means nothing with respect to doses actually allocated to SA. Though SA is permitted to reject doses costing more than the Maximum Adjusted Cost Per Dose (US$ 21.10).
        i. The actual amount payable per dose is the "Adjusted Cost Per Dose", which included the "Actual Procurement Price", the actual access/speed premium, financing/risk mitigation, and operating costs [of Gavi] (an unspecified amount with no requirement of verifiable reporting), and a deduction based on Participant Down Payment Discount, and the Participant Additional Payment Discount (if any).
        ii. There is also an adjustment for taxes paid (Para. 7: Tax Gross Up and Indemnities).
    f. Payment must be made with the Procurement Period, which is basically when the doses become available (when availability occurs is undefine, which is a limitation).

[38] *Definitions and Interpretations 1.1(b):* "Committed Amount" means US$ 126 600 000. Down Payment" means US$ 19 200 00. "Financial Guarantee Amount" means US$ 107 400 000. "All-Inclusive Weighted Average Estimated Cost Per Dose" means US$ 10.55 "Maximum Adjusted Cost Per Dose" means US$ 21.10 "Actual Procurement Price" means the actual procurement price per dose of an Approved Vaccine at the time of purchase thereof from the Specified Manufacturer (GAVI acts as the middleman effectively) "as notified by the Specified Manufacturer to GAVI prior to the procurement of an Approved Vaccine by the Participant, which notification shall constitute conclusive evidence of the Actual Procurement Price "Participant Down Payment Discount" means US$ 1.60.

5. SA had to provide unrestricted indemnification to GAVI with respect to all clauses of the Agreement, though GAVI has a duty to take reasonable steps to mitigate circumstances giving rise to indemnification.
    g. This duty to mitigate could be interpreted to include a duty to sell any Remaining Participant Doses and to deduct the proceeds from the amount owed by SA.
    h. In understanding the indemnification commitment, it is important to take account of Para 4.3, which obligated SA to pay in full for all Remaining Participant Doses that it does not buy as agreed.
    i. There is a separate Tax Indemnification Agreement that could add to the ultimate cost of the Agreement (not reviewed here).
6. Although there is no "indemnification fund" requirement, there is a requirement in Para 5 that SA undertake to "procure a guarantee or other form of credit support" in a form satisfactory to GAVI for the Financial Guarantee Amount, which shall be "payable irrevocably and unconditionally upon demand to GAVI".
    j. GAVI has a right to terminate the Agreement for substantial breach and further, has strong indemnity protections in addition to this provision requiring financial guarantees (Para. 5).
        i. Para. 11(a) provides that GAVI may terminate the Agreement if SA is in breach of Para 2; fails to satisfy the Financing Condition; or commits a material breach of any other provisions of the Agreement and fails to remedy said breach within fifteen business days of GAVI's written notice of breach (or longer at GAVI's sole discretion).
7. There is no express condition limiting resale or donation of GAVI supplies.
8. Para. 8(c)(iv) requires a guarantee from SA that any vaccine doses procured will not "infringe any existing applicable law, rule, regulation, judgment, order or decree applicable to it or any international treaty convention or agreement ...".
    k. This could be interpreted as a guarantee that no intellectual property laws have been violated either by the authorised manufacturer in the place of manufacture and export, or in SA.

22. Miscellaneous

22.1 Confidentiality.

Confidential Information shall mean any and all proprietary information, whether oral, written or electronic, irrespective of its form owned, possessed or controlled or passed on by Serum, before or after execution of this Agreement, to the DOH including without limitation to technical or scientific or clinical trial data, standard operating procedures, quality management systems, unpublished records, know-how, formulas, product specifications, quality control process, clinical trials, flow charts, operating policies and procedures, transactions, data and information, manuals, patterns, patents, trademarks, copyrights and other intellectual property related matters, designs, sequences, drawings, commercial, manufacturing, information relating to costs, strategic plans, processes, techniques, technologies, ideas, improvements, studies, products and any other information disclosed in relation to this Agreement. Notwithstanding the foregoing, any Confidential Information disclosed during a tour, site visit of the Serum's laboratories, manufacturing plants or other facilities shall automatically be deemed as Confidential Information for purposes of this Agreement.

Any Confidential Information disclosed by Serum shall be strictly confidential and shall not be used, shared with or disclosed to, directly or indirectly, with any third party by DOH. The absence of any marking or legend indicating that any particular information disclosed by Serum is to be treated as confidential shall not limit or diminish the obligation of DOH to treat such information as Confidential Information. Serum reserves all rights to any remedies, whether under the law, or at equity to remedy any unauthorized use or disclosure by DOH.

The Serum Institute of India (SII

Analysis of the Agreement handed over to HJI

Context: Why an Agreement with the Serum Institute of India (SII) and not AstraZeneca

1. During 2020, the Jenner Institute at the University of Oxford with UK Government support, developed a COViD-19 vaccine. Oxford promised the world a no-profit people's vaccine, in a pandemic. That did not materialise because Oxford eventually entered into an exclusive agreement with AstraZeneca (AZ), to market and commercialise the vaccine, for a royalty payment.[39] Oxford "gave the pharmaceutical giant sole rights and no guarantee of low prices—with the less-publicised potential for Oxford to eventually make millions from the deal and win plenty of prestige".[40] In turn, when the world needed greater sharing of technology, and billions more doses of vaccines speedily, AZ exercising unfettered control (like J&J and Pfizer), in a pandemic, decided it would only sub-license a handful of companies that affected smoother supply chains only.

   The SII was included in these licenses and was meant to manufacture the vaccine, primarily to supply countries in the Global South and COVAX in the main. This decision has come to haunt the global response to the pandemic because subsequent developments in India affected SII's ability to deliver prompt supplies of vaccines to COVAX or other bilateral agreements in early 2021 especially.
2. The UK Government signed an Agreement with AZ, which we believe guaranteed the UK "priority customer status'' for third party supply too, whereas SA and other Global South countries, mainly had to enter into an Agreements with SII, a sub-licensee whose market—determined by AZ—was meant to be "the Global South'', unless the UK needed supplies first!
   a. The main Agreement between AZ and SII is available in the UK, but in a heavily redacted form.
   b. Medicine access activists and other groups in the UK and India have long argued that even with this dispensation (licensing arrangement, with a market carve out) that the UK Government insisted on and secured priority customer status —meaning if at any point the UK needed vaccine supplies, AZ could divert supplies from its own pool (leaving other customer waiting) or divert supplies made by SII, to the UK, even if Global South customers had paid and were waiting for doses.
   c. This is also one of the factors that led to the massive dispute between the EU and AZ early in the pandemic, which also explains why the EU decided to sue

[39] See https://www.wsj.com/articles/oxford-developed-covid-vaccine-then-scholars-clashed-over-money-11603300412 and see also: https://kffhealthnews.org/news/rather-than-give-away-its-covid-vaccine-oxford-makes-a-deal-with-drugmaker/

[40] https://www.politico.com/news/2022/09/14/global-covid-pandemic-response-bill-gates-partners-00053969

AZ and disclose that Contract or Agreement, but not others yet also redacted.[41]

d. What we do know is that the UK did receive 5 million doses of from SII,[42] but a second delivery of 5 million doses was disrupted by India's export ban in or about May 2021. Even with just the first 5 million doses, the UK was the third biggest recipient at the time of Indian-made AZ/Oxford vaccines. So, SII (like Aspen in SA with J&J, see above) had a license, but no meaningful autonomy or control over the geographical allocation of scarce supplies nor the differential and unfair pricing system used for rich and poor country purchasers. So, despite granting Global South-based companies licenses, these licensees did not call the shots in material respects.

3. AZ and SII plans for prompt, affordable, and global deliveries were then hampered by two developments, affecting deliveries for SA, COVAX, India, and other countries, including the EU and UK:
    a. In Q 2 2021, the Modi Government in India (like the US and EU)—after AZ had announced its licensing arrangement with SII who had started mass manufacturing for Global South countries—imposed an EXPORT BAN on all vaccine supplies produced in India for COVID-19 to first vaccinate all Indian nationals.[43]
    b. After President Ramaphosa called PM Modi to ask for a once off exemption from the export ban for just the first tranche of deliveries meant for healthcare workers in SA in February 2021 (1.5 million doses), the beta variant was identified in SA, which had a further impact on the timely use of this vaccine in SA, resulting in its eventual non-use.
    c. It is common cause that the SII delivered supplies (1.5 million doses) in terms of that Agreement, were paid for by the SA Government (i.o.w., the public), and then, per media reports at the time, because of the decision referred to above to not use it at all, was either donated or sold to a third country (Jamaica, AU).
    d. To date, we have no knowledge if the SA Government was reimbursed for that diversion; or if AZ/ SII was required to pre-approve that diversion; and/or whether the National Treasury recovered the down payment paid to SII or any other costs associated with the sale/donation. The Department has previously stated to the HJI that the National Treasury has those details, not them.
    e. Considering the pre-payment conditions in the agreement, this is important.

Brazil and Japan. https://www.fiercepharma.com/manufacturing/astrazeneca-to-supply-millions-covid-19-shot-to-brazilian-government-swamped-by-new and https://ec.europa.eu/commission/presscorner/detail/en/ip_

[41] https://edition.cnn.com/2021/01/30/europe/uk-eu-astrazeneca-vaccine-nationalism-gbr-intl/index.html; https://www.bbc.com/news/56483766'https://www.bbc.com/news/world-europe-55852698

[42] Serum Institute Seeks Centre's Nod To Send 50 Lakh Covishield Doses To the UK thewire.in

[43] https://edition.cnn.com/2021/05/25/asia/covax-india-serum-institute-intl-hnk-dst/index.html

i. According to the DDG in the Department, the Astra-Zeneca vaccines were sold to the AU: He said on oath: "The NDoH is not in possession of the sale agreement between the AU and the Government. This information falls within the province is the National Treasury. Thus, the NDoH is unable to provide this information requested" [Answering Affidavit, *HJI v Minister of Health and Others* (Case No 19343/2022)].[44]

f. When SA finally received the first tranche of SII vaccines, through a special concession brokered by President Ramaphosa (with Modi, due to the India export ban, no one outside of India could receive supplies) it also ironically emerged through media reports that SA may have been asked to pay more than double what the EU was paying for the same vaccine.[45] *The Guardian* at the time reported that:

> *South Africa will have to buy doses of Oxford-AstraZeneca's COVID-19 vaccine* ***at a price nearly 2.5 times higher than most European countries****, the country's health ministry has said. The African continent's worst virus-hit country has ordered at least 1.5m shots of the vaccine from the Serum Institute of India (SII), expected in January and February. A senior health official on Thursday told AFP those doses would cost US$5.25 (€4.32) each – nearly two and a half times the amount paid by most European countries. European Union members will pay US$2.16 (€1.78) for AstraZeneca's shots, according to information [mistakenly] leaked by a Belgian minister on Twitter.*[46]

Findings: SII

The SII Agreement outlines the vaccine purchase terms between SII and the SA Government. This includes indemnification arrangements, payment and delivery terms, termination clauses, responsibilities for vaccine storage and handling, **confidentiality agreements**, and a delivery schedule for vaccine doses in SA. Price: The SA Government was to pay in advance a sum of US $ 8 025 000 for 1.5 million doses. (See above, paying two and a half times more than the EU). SII indemnified the Department (SA Government) for vaccine proven gross negligence or proven willful misconduct, while the SA Government indemnified SII for actions related to the vaccine, including its administration and breaches of representation. Vaccine

[44] Affidavit available here: https://healthjusticeinitiative.org.za/wp-content/uploads/2022/04/19323-22-MAC-Answering-Affidavit-2.pdf
[45] https://www.theguardian.com/world/2021/jan/22/south-africa-paying-more-than-double-eu-price-for-oxford-astrazeneca-vaccine
[46] https://www.theguardian.com/world/2021/jan/22/south-africa-paying-more-than-double-eu-price-for-oxford-astrazeneca-vaccine
https://www.theweek.co.uk/951750/what-do-covid-vaccines-cost-who-pays-what?amp

doses had to be delivered in two tranches as specified in an Annexure to the Agreement. The Agreement could be terminated for "material breach, liquidation, or reasonable grounds". But it is silent on what happens when a new variant emerges—which is what happened in SA.

Specific provisions for that are a concern: SII

1. Volumes 1.5 million, with a price of US$ 5.35 according to which includes freight and insurance.
    a. There is no donation provision per se in the Agreement. Para 9.3.5 states that "title" of the supplied vaccines "shall pass on to the DOH upon delivery to DOH…" With "title" over vaccines, SA may have retained rights to decide where they are commercially distributed or donated.
    b. There is also no specific onward sale restriction in any of the sections. This is probably the basis upon which SA was entitled to sell on the 1.5 million doses (at an unknown price), to the "AU" (see above) after it decided to no longer use the vaccine in early 2021.
2. But, given that India and SA led the TRIPS Waiver proposal from 2020, an Indian company, SII, ironically entered into an Agreement with SA that potentially has long-lasting implications for TRIPS waivers and several other IP policy options, including compulsory licensing. See here Para 9.3.4:
    a. Under 9.3.4, SA committed to "not take any action that may adversely affect or impair the rights, title and interest of SII in or to any of its property and IP rights" in their vaccine.
    b. The phrase "any action" is overly broad and can be interpreted to include political support for IP TRIPS waivers and other international measures. "Any action" can also be interpreted as including the grant of compulsory licenses at the national level. "Any action" may even include refusals to grant applications that fail to meet patentability criteria or the enactment of laws that would facilitate refusal of unmerited patent applications.
    c. Although Para 9.3.4 does not explicitly mention the SA mRNA Hub (it was not established at that time), it can also be interpreted to limit legal maneuvering space to implement reverse engineering and technology transfer measures that would affect ChAdOx1 viral vector platforms. This provision could potentially be asserted against efforts to expand the existing hub or launch a new hub specifically for viral vector platforms in SA.
    d. Given that Para 9.3.4 broadly refers to action that may "affect" and "impair" IP, it can be interpreted to prohibit measures that are not directly targeted to ChAdOx1 technologies but may "impair" them. The threshold for SII to enforce this can be interpreted to be exceptionally low, since they might only need to show that the measures in dispute "may" affect their IP.
3. Under 7.6, SA must seek the prior written consent of SII before recalling the vaccine

from the market. SII cannot "unreasonably" withhold that consent, but the exact threshold for this standard is subject to interpretation. Provisions 7.5 and 7.6 both create adverse incentives for vaccine recalls, giving the manufacturer power over the regulator. SA did pause the use of the SII vaccine, see above.

4. Indemnification clause: The Agreement contains a robust but general indemnity clause:

   Serum shall indemnify South Africa losses from and against "proven gross negligence or proven willful misconduct of the Serum with regards to the manufacture of the said Vaccine according to the GMP standards," according to clause 10. South Africa shall indemnify Serum from and against gross negligence or willful misconduct of DOH with regard to the handling, storage, distribution, and administering of the vaccine in South Africa. Losses against breach of representation, warranty, or obligation in the agreement; losses relating to use or administration of the vaccine allocated to its jurisdiction—irrespective where the vaccine is administered, claim jurisdiction, if defect is from distribution, administration, clinical testing, investigation, manufacture, labelling, formulation, packaging, donation, dispensing, prescribing, or licensing.

5. Returns or refunds: Para 2.5 states that if, "subject to receipt of regulatory approval," SII fails to supply in full the 1.5 million doses "by the end of February 2021" it had to return the advanced payment it received for the quantity of doses that it failed to supply following notice from SA. If SII fails to obtain regulatory approval, SII was required to return the advanced payment. This is different to the Agreements with J&J and Pfizer.

6. Confidentiality clause: [extract from Agreement, as received from the State]
   a. Para 22.1 requires SA to keep "confidential information" (as defined in the agreement) confidential. SII has the right to seek remedies under the law against "any unauthorised use or disclosure" by SA.
      i. The Agreement does not appear to have a broad exception to Confidentiality when ordered by Court, as other agreements tend to have.
      ii. Yet, the term "unauthorised use or disclosure" in 22.1 may be interpreted as stating that SII does not have remedy against disclosures that have been authorised, including by a court order. The confidentiality provision is quite broad. It includes, for instance, "clinical trial data," "know-how", "formulas", "patents", "manufacturing", "information relating to costs", "ideas", "improvements", "intellectual property", "sequences", among other items ().''
      iii. Importantly, Para 22.1 was drafted to survive the termination or expiration of the agreement (survival of confidentiality clauses is a typical practice in commercial agreements).

Useful links and references:

The HJI Legal Case:

https://healthjusticeinitiative.org.za/pandemic-transparency/ - which contains:

1. HJI Legal Papers: Health Justice Initiative v The Minister of Health and Information Officer, National Department of Health
2. Case No: 10009/22, Gauteng High Court, Judgment
3. Contracts Handed Over by Department of Health in South Africa (Four Contracts, with certain Annexures)
4. Multi Stakeholder Group Analysis [***this document***]

Vaccine equity related:

https://healthjusticeinitiative.org.za/2022/02/22/hji-summary-sheets-vaccine-supplies/ and https://healthjusticeinitiative.org.za/vaccine-equity/

Reports and key articles on similar contracting for other jurisdictions:

- 17 August 2023, MSF refuses to sign ViiV's last-minute NDA for access to most-effective HIV prevention drug. MSF Access Campaign, Press Release
- May 2023, Transparencia en la financiación y distribución de recursos para la vacunación de la COVID-19 en Colombia / Transparency in the financing and distribution of resources for COVID-19 vaccination in Colombia Médicos del Mundo Francia – Colombia, Centro de pensamiento, medicamentos, información y poder de la Universidad Nacional de Colombia, Oxfam Colombia, Vacunas Para La Gente Latinoamerca, Colombia / Medecins du Monde France – Colombia; Center for Thought, Medicine, Information, and Power at the National University of Colombia; Oxfam Colombia, PVA LAC
- 6 December 2022, Intellectual Property Rights and Advance Purchase Agreements in a Crisis. https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4360150 Intellectual Property Quarterly 1-32 (2023), Alison Slade, University of Leicester, Naomi Hawkins, University of Sheffield School of Law.
- 29 November 2022, Official delivery of copies of COVID 19 contracts Anticorruption Institute / National Disaster Risk Management Unit (UNGRD), Colombia
- 19 October 2021, Pfizer's Power Public Citizen, USA
- 16 August 2021, 'Covid Vaccines Produced in Africa Are Being Exported to Europe. Johnson & Johnson is sending shots from South Africa to other parts of the world. African countries are waiting for most of the doses they've ordered'. NEW YORK TIMES (NYT), https://www.nytimes.com/2021/08/16/business/johnson-johnson-vaccine-africa-exported-europe.html

- 2 August 2021, Colombia: ICJ publishes briefing paper advocating for transparency in COVID-19 vaccine contracts International Commission of Jurists (ICJ)
- 11 May 2021, Summary of Colombian Ruling on the Public Release of Covid-19 Vaccine Contracts https://www.estudiosanticorrupcion.org/covid-19/ International Institute of Anticorruption Studies (Instituto Internacional de Estudios Anticorrupción), Colombia
- May 2021/December 2022, Transparency International, *For Whose Benefit 1 and 2 (updated)* https://ti-health.org/wp-content/uploads/2021/05/For-Whose-Benefit-Transparency-International.pdf and updated version: https://ti-health.org/content/secret-contracts-preventing-vaccine-inequity/
- 23 February 2021, Held to ransom': Pfizer demands governments gamble with state assets to secure vaccine deal The Bureau of Investigative Journalism (BIJ)
- 29 January 2021, Covid: EU-AstraZeneca disputed vaccine contract made public BBC News
- 29 January 2021, Vaccines: contract between European Commission and AstraZeneca now published European Commission (EC) Press Release

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Secrecy for Vaccine Supplies in a Pandemic

DOWNLOAD:

MULTI-STAKEHOLDER ANALYSIS AND THE SOUTH AFRICAN COVID-19 VACCINE PROCUREMENT CONTRACTS HANDED TO HJI, HERE:

https://healthjusticeinitiative.org.za/pandemic-transparency/

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