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RESOLUTION 7: DECEMBER 2021

We, the undersigned directors of HEALTH JUSTICE INITIATIVE (HJI) NPC, with registration number K2020779556, hereby authorise:

1. Fatima Hassan in her capacity as Director of the HJI and
2. Dr Marlise Richter in her capacity as Senior Researcher

-to initiate legal proceedings, depose to affidavits and take all steps necessary in the proceedings in the name of the HJI in matters concerning the disclosure of information held by government, state and multi-lateral or other bodies, research institutions, regulators and applicable third parties including vaccine manufacturers, related to the COVID-19 pandemic and the roll out of South Africa's vaccine programme.

Signed at Cape Town, South Africa on this the 10th day of January 2021.



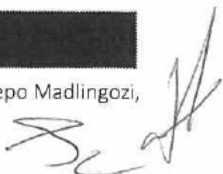
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Enhancing public trust in COVID-19 vaccination: The role of governments

10 May 2021

While the rapid development of vaccines against COVID-19 is an extraordinary achievement, successfully vaccinating the global population presents many challenges, from production to distribution, deployment, and importantly, acceptance. Trust in the vaccines is vital, and is critically dependant on the ability of governments to communicate the benefits of vaccination, and to deliver the vaccines safely and effectively. This brief addresses the role of governments in promoting confidence in the effectiveness and safety through effective communication, as well as trust in their ability to procure and distribute them efficiently and equitably. While only a small minority of the population holds strong anti-vaccination views, hesitancy about COVID-19 vaccination is evident in many countries. Recognising that vaccination campaigns of the magnitude needed are unprecedented, government actions to garner trust will be essential to their success, and to the emergence of more resilient societies after the crisis.

Key messages

While the development of COVID-19 vaccines has been an extraordinary success, vaccinating most of the global population is an enormous challenge, one for which gaining – and maintaining – **public trust in COVID-19 vaccines and vaccination will be as essential as the effectiveness of the vaccines themselves**. Moreover, the experience with COVID-19 will likely shape confidence in other vaccines making it even more important to build confidence at this time.

Trust in vaccination, and in the ability of governments to communicate, and to successfully deliver a vaccination programme, is critically dependent on:

- the extent to which the government can instil and maintain public **confidence in the effectiveness and safety of the vaccines**;
- the competence and reliability of the institutions that deliver them;
- the **principles and processes that guide government decisions and actions** in vaccine procurement, distribution, prioritisation, and administration;
- the **capacity and effectiveness of regulatory agencies** in handling issues and communicating consistently as events arise, while retaining public confidence in their review processes; and
- the effectiveness of the **public engagement and communications** that accompany these.

Given the speed at which COVID-19 vaccine development has taken place it is important for governments to emphasise that **no developmental or regulatory corners were cut in the process**, as:

- development was facilitated by extensive prior research, unprecedented levels of international collaboration among researchers, and massive public investment in R&D and manufacturing capacity; and
- approval processes were accelerated, in part through procedures that allow the acceptance of more preliminary evidence in circumstances of public emergency; and with COVID-19 products accorded the highest priority by regulators.

Successful vaccination campaigns also require governments to partner and support community organisations to conduct **extensive and well-managed community engagement**. A thorough understanding is needed of different populations' specific concerns, prior experiences both with vaccination and the health system in general, religious and/or political affiliations, and socio-economic status. It is also important to ensure that government actions are **open to public scrutiny**, and that **public institutions engage with the population**, by:

- Proactively **releasing timely information** on vaccination strategies, modalities and accomplishments in disaggregated, user-friendly and open source formats;
- **Enhancing transparent and coherent public communication** to address misinformation and the "infodemic"; and
- **Engaging the public** when developing vaccination strategies, and in the form and content of key communications.

Finally, fairness is a hallmark of human behaviour that underpins social cohesion and trust. Governments must therefore **manage public expectations** and explain why it is fair that particular population groups within a country are prioritised for vaccination.




Introduction

“The most important ingredient in all vaccines is trust.”

Barry Bloom, Harvard T.H. Chan School of Public Health

There is broad agreement within the global scientific community that the most effective way to defeat the COVID-19 pandemic is through the mass vaccination of populations around the world. The development of vaccines for COVID-19 has been a powerful demonstration of how substantial public funding, intense focus, and unprecedented levels of scientific collaboration can help spur innovation to address global public needs in a very short time. However, the approval and rollout of vaccines does not herald the immediate end of the health crisis, as attaining herd immunity will require the vaccination of a very substantial proportion of population, and is therefore a major challenge (OECD, 2021^[1]). To succeed in the global effort to immunise billions of people as rapidly as possible, governments need to give priority to addressing issues of trust – trust both in vaccines, and in the institutions responsible for the vaccination endeavour. They need to promote confidence among the public in the effectiveness and safety of the vaccines, as well as in the capacity of governments to manage the logistical challenges competently.

Despite an initial “rally around the flag” effect seen early in the pandemic, many countries are observing increasing levels of distrust in government capacity to handle the crisis and implement coherent policies (OECD, forthcoming^[1]). This has resulted in declining compliance with public health-related rules, and increasing scepticism about long-term economic recovery. More broadly, the pandemic has triggered widespread disinformation that has undermined both understanding and acceptance of science and public policy (de Figueredo et al., 2020^[2]), and this extends to the issue of vaccine acceptance. Despite widespread recognition that COVID-19 is a critical issue to people all around the globe, many remain unwilling to be vaccinated. However, in February 2021, an average of 76% of the population across 11 OECD countries indicated willingness to be vaccinated, an increase from only 66% in December 2020 (Ipsos, 2021^[3]). However, recent data from seven OECD countries showed that a quarter of the population in France, Germany and the United States may refuse COVID-19 vaccination, and an even higher proportion among younger population cohorts. More than 50% of French 25- to 34-year-olds, and one-third of Dutch 25- to 34-year-olds, said they would probably or definitely not get vaccinated (Kantar, 2021^[4]).

Not surprisingly, trust in the safety of vaccines has also been seriously tested by recent reports of rare, but serious, adverse events with a probable causal link to the Oxford/AstraZeneca vaccine. Both the safety signal, and the different responses of regulators around the world, are likely to have undermined public confidence. That said, there is also evidence to suggest that as more people are vaccinated, more will be inclined to accept vaccination. While this may to some degree indicate a gradual dissipation of initial fears about the safety of novel vaccines (recent events notwithstanding), it may also reflect that being vaccinated gradually becomes normative, and is increasingly accepted as the path out of restriction and confinement (Bish et al., 2011^[5]).

Trust in vaccines must also be complemented by trust in the institutions responsible for vaccination. Lack of acceptance of vaccination may derive from previous failures of health systems and public institutions to serve certain population groups effectively and engender their trust. In general, trust in institutions is critical for the effective functioning of society and acceptance of public policy, and particularly so during a crisis. Trust is defined as one’s belief that another person or institution will act in accordance with one’s expectations of positive behaviour by others (OECD, 2017^[6]), and institutional trust is recognised as a key measure of government performance (OECD, 2019^[7]). The OECD has developed a Trust Framework as



a guide for governments in developing specific policy actions to strengthen public trust, built around the five dimensions of government mandates that research shows largely explain people's trust (see Box 1).

Overall, the success of vaccination campaigns will largely be influenced by the extent to which people trust the effectiveness and safety of the vaccines, the competence and reliability of the institutions that deliver them, and the principles that guide government decisions and actions. Drawing on the OECD Trust Framework, this paper identifies some policy priorities for countries to strengthen public trust as they rollout COVID-19 vaccines, and provides examples of good practices that countries have implemented and can enhance people's confidence in vaccination campaigns. The following section discusses the relevance of government competence in building trust in vaccines, with the subsequent sections discussing integrity, openness and fairness in this context.

Box 1. The OECD Trust Framework

The OECD Trust Framework identifies five main policy dimensions that drive people's trust in government institutions: responsiveness, reliability, integrity, openness and fairness. These five dimensions correspond to government mandates such as providing public services, protecting citizens, using power and resources ethically, etc. The empirical relevance of this framework has been tested in eight OECD countries and evidence shows that both government competence and values are strong predictors of public trust (Murtin et al., 2018^[9]; OECD/KDI, 2018^[10]; OECD, forthcoming^[2]).

Trust Component	Government Mandate	Concern affecting trust	Policy Dimension
Competence The ability of governments to deliver to citizens the services they need, at the standard they expect	Provide public services	Access to public services, regardless of socio-economic status; Quality and timeliness of public services; Respect for public service provision, including responsiveness to citizens' feedback;	Responsiveness
	Anticipate change, protect citizens	Anticipation and adequate assessment of evolving citizen's needs and challenges; Consistent and predictable behaviour; Effective management of social, economic and political uncertainty;	Reliability
Values The drivers and principles that inform and guide government action	Use power and public resources ethically	High standards of behaviour; Commitment against corruption, Accountability;	Integrity
	Inform, consult and listen to citizens	Ability to know and understand what government is doing, Engagement opportunities that lead to tangible results;	Openness
	Improve socio-economic conditions for all	Pursuit of socio economic progress for society at large, Consistent treatment of citizens and businesses (vs. fear of capture);	Fairness

Source: OECD (2017^[8]), Trust and Public Policy: How Better Governance Can Help Rebuild Public Trust, <https://doi.org/10.1787/9789264268920-en>



Competence

Provision of quality goods and services is a key indicator of government competence

An important indicator of government competence is responsiveness to people's needs, as demonstrated by the provision of high quality goods and services required by the population. The development of several effective COVID-19 vaccines in less than a year is an impressive demonstration of the ability of public authorities to stimulate scientific R&D efforts in the direction of the greater good, and an exemplar of the benefits of international co-operation between public and private stakeholders.

However, in order to promote public trust in these products, it is essential that governments demonstrate that no quality or safety standards were compromised for the sake of speedy development and approval processes. As with other medical goods, COVID-19 vaccines have been, and are continuing to be developed, evaluated and approved in accordance with existing regulatory guidelines and legal requirements (EMA, 2020^[10]). They are initially tested in the laboratory (in pre-clinical studies), and then in clinical trials involving human volunteers.¹ These trials are intended to confirm how the vaccines work and importantly, elucidate their safety and protective efficacy. In more usual circumstances, developing new vaccines can be a lengthy process, with the different phases of development undertaken sequentially. In the case of COVID-19, a number of factors contributed to significant acceleration of both the development of vaccines, and of the chances of successful candidates (see Box 2). Regulatory evaluation and authorisation processes were also accelerated, in part through rolling review of data as they became available, and through the use of emergency procedures that enable the acceptance of more preliminary evidence in circumstances of significant unmet need or public emergency.

Box 2. How it was possible to develop and approve COVID-19 vaccines so rapidly

A number of factors contributed to the speed with which successful COVID-19 vaccine candidates were able to be developed and tested. These include:

- SARS-CoV-2 is genetically close to various other coronaviruses that have been the subject of previous investigation in the past decade, so vaccine R&D did not start from a zero base, even for the newer technological platforms (e.g. mRNA and non-replicating viral vectors);
- Development was facilitated by extensive knowledge gained with previous vaccines, coupled with unprecedented levels of engagement and collaboration among researchers internationally;
- A large number of vaccine candidates have been, and are continuing to be developed and tested in parallel, using a variety of different platforms, increasing the chances that one or more would prove successful;
- Some vaccine candidates (and two of the products already authorised) rely on a novel messenger ribonucleic acid (mRNA) platform, which allows them to be developed, modified and manufactured more rapidly than vaccines using traditional platforms;
- Governments invested heavily both in R&D and in manufacturing capacity, the latter to enable the production of large quantities of vaccine before the results of the phase III trials were available, and in many cases potentially absorbing the full financial risks of R&D failure;

¹ Pre-registration clinical trials of medicines and vaccines usually occur in 3 sequential phases: phase I trials usually assess safety and tolerability in a small group of less than 100 adults; phase II trials test safety, dosage and method of delivery in a larger group, usually of several hundred people; and, phase III trials aim to establish safety and efficacy usually in a large group of several hundred to several thousand people.



- The scale and severity of COVID-19 underscored the urgency of vaccine development. This drove intensive investment and faster development processes, via for example running trials in parallel that in other circumstances would be conducted sequentially and by combining trial phases I and II, to assess safety and immune responses;
- The combination of the high prevalence of COVID-19 in many locations and rapid clinical trial recruitment accelerated the demonstration of efficacy in preventing symptomatic infection.

Besides the use of emergency procedures, other factors that helped to accelerate the process of approval included:

- National regulatory agencies engaging with COVID-19 vaccine developers, and supporting the research and development effort indirectly, in some cases by providing early scientific advice on the most appropriate study designs for generating robust data;
- Regulatory review being expedited via a process known as “rolling review”, whereby developers submit tranches of data incrementally as they become available rather than waiting to assemble a complete dossier before submission;

COVID-19 products being accorded the highest priority by regulators, with additional resources applied to enable rapid, intensive review of dossiers.

Ongoing surveillance for the potential emergence of adverse effects is also essential to support public trust, using well-developed pharmacovigilance systems to track problems or adverse reactions not detected in the clinical trials. With the rollout of COVID-19 vaccines, stringent regulatory authorities (e.g. FDA, EMA)² are expanding their vaccine monitoring procedures and publishing regular safety updates.³ As the recent controversies about the safety of the Oxford/AstraZeneca vaccine highlight, authorities face a number of complex challenges in communicating about the safety and effectiveness of vaccines, and promoting and preserving public trust in the vaccines as they are rolled out, particularly in a context of health emergencies (see Box 3).

However, while the handling of these issues presents an opportunity to highlight to the public that pharmacovigilance systems work, it is important to ensure that communication regarding potential safety signals are handled with both transparency and care. Communication needs to be balanced and contextualised, to clearly convey what is and is not known, and to avoid reinforcing hesitant people’s cognitive biases, and it should ideally be informed by the expertise of behavioural scientists and risk communication experts. In particular, confirmation bias (i.e. the tendency to select information that

² The concept of a stringent regulatory authority was developed by the WHO Secretariat and the Global Fund to Fight AIDS, Tuberculosis and Malaria to guide medicine procurement decisions, and is now widely recognised by the international regulatory and procurement community as a regulatory authority that is:

- a member of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), being the European Commission, the US Food and Drug Administration and the Ministry of Health, Labour and Welfare of Japan also represented by the Pharmaceuticals and Medical Devices Agency; or
- an ICH observer, being the European Free Trade Association, as represented by Swissmedic, and Health Canada; or
- a regulatory authority associated with an ICH member through a legally-binding, mutual recognition agreement, including Australia, Iceland, Liechtenstein and Norway.³

See: WHO Expert Committee on Specifications for Pharmaceutical Preparations Fifty-first report (Technical Report Series, No. 1003, 2017)

³ <https://www.ema.europa.eu/en/news/first-COVID-19-vaccine-safety-update-published>.



reinforces people's beliefs) and negativity bias (i.e. the tendency of negative feelings and information to have a greater effect on people than positive or neutral ones) should be carefully addressed. For example, a study of parents' attitudes while searching information online about vaccines showed that people tend to select belief-consistent information and tend to rate this information as more credible, useful and convincing (Meppelinka et al., 2019^[11]).

Box 3. Maintaining trust when adverse events occur

In early March 2021, cases began to emerge of serious and even fatal thromboembolic events after vaccination with the Oxford/AstraZeneca vaccine. The detection of these adverse events pointed to the strength of pharmacovigilance mechanisms in rapidly identifying a potential safety signal, and prompted precautionary suspension of the use of the vaccine by 12 EU countries and Thailand pending regulatory review to confirm or exclude the existence of a causal link and if necessary, re-evaluate the benefit-risk profile. On 18 March the EMA recommended the resumption of vaccination with the vaccine, as in its view a causal link with these adverse events had not been established. Despite this, the suspension remained in place in several countries, while others recommenced or continued vaccination with the product albeit with age restrictions reflecting the preponderance of adverse event reports being in people under the age of 50. Subsequently, on 7 April the EMA announced that it had concluded that there was a possible causal link, but that the overall risk/benefit balance remained positive. When a similar pattern of adverse events began to emerge in the United States in relation to the Johnson and Johnson (Janssen) COVID-19 vaccine, on 13 April the US FDA also temporarily paused use of the vaccine pending investigation by the FDA and the US Centers for Disease Control & Prevention (CDC). Subsequently, on 23 April the FDA and CDC recommended the resumption of the use of the vaccine, confirming that the risk-benefit balance remained favourable.

While these temporary suspensions may be seen as appropriate applications of the precautionary principle, they also prompted concern regarding the risks of slowing down vaccination during the pandemic, as well as the potential effects on overall confidence in the safety of COVID-19 vaccination. Similar precautionary measures by regulators are not uncommon in the presence of significant potential safety signals, but are not usually undertaken in circumstances of such widespread public attention, and within populations already partly sceptical about the benefits and risks of the intervention. While temporary suspension of the use of the vaccine reflects that potential safety issues were being thoroughly investigated by regulators, it may also have the effect of prompting or augmenting the doubts among certain population groups that have, for example, led significant quantities to remain unused in France and Germany. That said, failure to take such precautionary measures in the face of emerging reports of rare, but in some cases, fatal adverse events, could have resulted in a similar – or potentially even greater – diminution in credibility and trust.

Further, despite subsequent confirmation by the EMA that the risk-benefit balance remains overwhelmingly in favour of the continued use of the Oxford/AstraZeneca vaccine, two jurisdictions opted to discontinue use of the vaccine. Several others elected to limit its use to particular, but varying, age groups, and this lack of consistency may contribute to ongoing confusion and doubt among the public. While regulatory decisions are routinely made at national level, they rarely pertain to products that are disseminated globally on this scale, or subject to such intense public scrutiny. Currently, information about these various decisions is being widely disseminated in the international media, and while the extent to which these have been influenced by the availability of alternative products is unclear, the uncertainty suggested by the different approaches could further undermine confidence in the product, and in vaccination more broadly.

This points to the value of greater co-ordination among regulators and health authorities that make vaccination policies, and for exceptional care and consistency in messaging around these issues. It is



also important to try to improve general levels of science literacy, and to find ways of communicating concepts of risk and benefit in ways that are more easily understood, in order to create a broader appreciation of the risks and benefits of COVID-19 vaccines relative to the risks posed by COVID-19 itself.

Sources: <https://www.dw.com/en/covid-astrazeneca-vaccine-remains-unpopular-in-germany/a-56630827>,
<https://www.euractiv.com/section/coronavirus/news/unused-stocks-of-astrazeneca-vaccine-pile-up-in-france-germany/>,
<https://forianstigler.medium.com/rare-vaccination-side-effects-should-we-care-da91e3953ad1>,
<https://www.ema.europa.eu/en/news/astrazenecas-COVID-19-vaccine-ema-finds-possible-link-very-rare-cases-unusual-blood-clots-low-blood> <https://www.politico.eu/article/trust-oxford-astrazeneca-coronavirus-vaccine-wanes-europe-survey/>.

Effective and inclusive vaccine policies foster trust in government competence

While it is clear that the development of COVID-19 vaccines has been a remarkable success story, much still needs to be done to engender trust in the vaccination programmes that deliver them. In addition to ensuring the effectiveness of the vaccine and the integrity of the development, evaluation and monitoring processes, governments must also demonstrate their capacity to procure vaccine supplies, and to design and deliver effective and inclusive vaccination campaigns.

To ensure timely delivery, governments need to establish policies and infrastructure for distributing, storing and administering vaccines across their jurisdictions. A recent report to the European Economic Area (EEA) indicated that most EEA countries intended to utilise existing vaccination infrastructure, while only a few had plans to procure additional equipment to ensure the correct storage of vaccines (ECDC, 2020^[12]). However, in many jurisdictions current infrastructure and supplies may not be adequate to ensure a swift vaccination campaign, particularly when considering the particular transport and storage requirements of certain vaccines (e.g. very strict cold-chain maintenance). In fact, there is already evidence that some countries are struggling to maintain their planned timetables.

Co-ordination, involvement in decision-making, alignment of actions, and transfer of resources across levels of government together contribute to effective and inclusive vaccine policy. For example, Spain designed a national vaccination strategy steered by the Inter-territorial Council of the National Health System (ICNHS), a collegiate body in which the Minister of Health participates together with the health advisors of the autonomous communities and cities.⁴ In the United States, each State orders doses from the Vaccine Tracking System, up to a limit decided at the federal level.⁵ Central governments also need to ensure that subnational authorities have sufficient funding and capacity to procure the necessary quantities of ancillary products such as syringes and gloves (National Academies of Sciences, Engineering, and Medicine, 2020^[13]).

Strengthening control mechanisms between national government entities, being each branch responsible for its actions towards the others, and moving beyond emergency rules will help increase support for vaccine policies seen as transparent, balanced and inclusive.

Instituting reliable and transparent legal provisions for the indemnification of vaccine manufacturers, and compensation for vaccine injury is another dimension influencing trust, since compensation provisions can theoretically provide some reassurance to those concerned about the risks of emergent side-effects. The introduction of indemnification and compensation provisions stems in part from the 1955 Cutter incident in the United States, in which certain batches of polio vaccine administered to the public contained live polio

⁴ <https://www.newtral.es/vacunas-covid-criterios-reparto-ccaa/20210119/>

⁵ <https://www.cdc.gov/vaccines/programs/vtrcks/index.html>.

virus, leading to over 250 cases of polio, many of which resulted in paralysis.⁶ While the incident led to more effective federal regulation of vaccines, it also prompted a wave of litigation for vaccine injuries, creating a disincentive for manufacturers to enter the vaccine market.

To address this disincentive, the US Government introduced the National Vaccine Injury Compensation Programme in 1986 to protect vaccine manufacturers from litigation that could threaten the continued development and manufacture of vaccines, and to provide compensation for injuries arising from adverse events following routine vaccinations.⁷ Later, the Public Readiness and Emergency Preparedness (PREP) Act of 2005 established a framework to deal with liability and compensation for injuries associated with vaccines and other countermeasures during the period of a declared pandemic or other public health emergency. Subsequently, in 2006 the International Federation of Pharmaceutical Manufacturers and Associations began advocating for broader indemnification provisions for vaccine-related adverse events in the context of pandemic responses (Halabi, Heinrich and Omer, 2020^[14]). Outside the United States, it has been reported that in its bilateral contracts, AstraZeneca has been granted protection against legal claims arising from its vaccine products in several countries.⁸

While 20 four countries currently have no-fault vaccine-injury compensation systems for routine immunisation (Mungwira et al., 2020^[15]), the World Health Organization recently agreed to underwrite a no-fault compensation plan for claims of serious side effects in 92 poorer countries due to receive COVID-19 vaccines via the COVAX sharing scheme.⁹ Vaccine injury compensation schemes that provide concomitant indemnification of vaccine manufacturers reduce, by design, the financial risks for manufacturers. These can, however, also be perceived as reducing the accountability of manufacturers with regard to the safety of their vaccines, and the rationale therefore needs to be conveyed carefully, particularly among population groups already sceptical about vaccine safety and effectiveness.

Values

Integrity and accountability in vaccine development are critical

Since the beginning of the COVID crisis, governments have had to make quick decisions and implement many unplanned measures to protect communities at risk. In the first months, the widespread use of direct awards as an exceptional measure to procure goods, services and works has drawn attention to potential integrity risks, most notably fraud and corruption, that could seriously weaken the effectiveness of government action if not correctly mitigated. Some instances of irregularities and allegations of corruption in the purchasing and supply of medicines have been reported, as well as other types of misbehaviours such as health professionals stockpiling medications, and a variety of online scams (OECD, 2020^[13]). Yet there has been little discussion on specific integrity risks related to the development and distribution of

⁶ <https://www.cdc.gov/vaccinesafety/concerns/concerns-history.html>.

⁷ <https://www.cdc.gov/vaccinesafety/concerns/concerns-history.html>.

⁸ <https://www.reuters.com/article/us-astrazeneca-results-vaccine-liability/astrazeneca-to-be-exempt-from-coronavirus-vaccine-liability-claims-in-most-countries-idUSKCN24V2EN>.

⁹ https://www.reuters.com/article/us-health-coronavirus-who-vaccines-compensation/who-vaccines-compensation-programme-for-covid-19-vaccines-is-a-world-first-idUSKBN2AM266?aid=6033fbb0ea66990001cf36d6&utm_campaign=trueanthem&utm_medium=trueanthem&utm_source=twitter; <https://www.who.int/news/item/22-02-2021-no-fault-compensation-programme-for-covid-19-vaccines-is-a-world-first>.



vaccines,¹⁰ and how these could affect people's trust in, and the effectiveness of, government vaccination strategies.

Public integrity refers to the consistent alignment of, and adherence to, shared ethical values, principles and norms for upholding and prioritising the public interest over private interests in the public sector (OECD, 2017^[14]). Integrity is a core institutional value and driver of trust. According to the OECD Trust Framework, the manner in which public institutions conduct themselves and the degree to which they can be trusted to safeguard the public interest play a key role in influencing the level of trust in them (OECD, 2017^[5]). In the context of vaccine development, four main integrity issues are critical for governments in building and enhancing trust.

Strengthening safeguards and accountability in the allocation of public funds and in emergency public procurement

The need to protect public health and ensure public service continuity has rendered public procurement a key priority for governments in developing their responses to the COVID-19 crisis.¹¹ The health emergency has prompted governments to make massive investments in R&D, and commit immense sums to the procurement of vaccines, treatments and diagnostics, both at the multilateral level (through the WHO ACT-Accelerator) and domestically. Although complete and accurate data are not yet available, governments of OECD countries have provided at least USD 13 billion in direct funding for R&D and building of manufacturing capacity for COVID-19 vaccines. This does not include additional billions allocated to advance purchase commitments for vaccines, and broader funding to prop up health systems, procure necessary supplies, and develop other health technologies to respond to the pandemic. Even larger sums – in the trillions of US dollars – have been allocated by governments to compensate for lost income and support struggling sectors of the economy. Such measures were taken very rapidly as the crisis unfolded in the first half of 2020.

Despite the rapid pace of the response, integrity and accountability safeguards must be observed when mobilising such exceptional public funds, to enhance trust and ensure that funds are allocated in the public's best interests. While the majority of OECD Governments had the necessary legal frameworks in place for emergency public procurement, they had to balance the need to procure large volumes of goods and services quickly, frequently from suppliers with whom they had not previously worked, and with the increased commercial and propriety risks associated with emergency procurement. In Canada, for example, emergency regulations allow direct procurement from non-prequalified suppliers (in the face of the pandemic, the government simply asked the private sector who could provide products such as facemasks, disinfectants, etc.). All decisions were documented, however, can be legally challenged, and are subject to audit. In the United States, the Coronavirus Aid, Relief, and Economic Security (CARES) Act of 2020 stipulates that the allocation of public funds to research and development of vaccines, and products developed with certain funds must be made available at a "fair and reasonable" price.

While these rapid procurement activities secured unprecedented volumes of essential supplies, the use of direct awards meant absence of competition in procurement, which is a crucial aspect in maintaining citizens' and business' trust in these processes. Without competition in the procurement process, in order to maintain the integrity of the purchasing activities, public buyers need to provide clear documentation on how they have considered and managed potential conflicts of interest or bias in their procurement decisions

¹⁰ <https://globalanticorruptionblog.com/2020/10/26/corruption-and-the-COVID-19-vaccine-the-looming-problem-of-distribution/>; <https://www.oecd.org/coronavirus/policy-responses/public-integrity-for-an-effective-COVID-19-response-and-recovery-a5c35d8c>.

¹¹ <http://www.oecd.org/coronavirus/policy-responses/stocktaking-report-on-immediate-public-procurement-and-infrastructure-responses-to-COVID-19-248d0646/>.



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and actions, publish their contract awards and contracts in a timely manner, and document due diligence checks carried out on suppliers and associated parties. The US Pandemic Response Accountability Committee, composed of independent inspectors, was created by the CARES Act to audit spending related to the response to COVID-19 to increase accountability and identify waste, and to investigate fraud and abuse in spending specifically related to the response to the coronavirus crisis.¹²

While the pandemic highlighted a number of procurement risks and associated mitigation measures, targeted efforts to increase a risk-based approach to public procurement existed prior to the crisis. Initially focusing on integrity threats, growing attention has been directed in recent years to tackle other risks that could significantly affect the outcome and impact of public procurement processes, including operational, financial, reputational, social and environmental and other contextual risks (OECD, 2019^[16]). The current exceptional circumstances of the pandemic also present an opportunity for international organisations and governments to permanently strengthen integrity and accountability safeguards and promote comprehensive risk management approaches within public procurement.

Promoting strong integrity standards in interactions between public officials and stakeholders

The second integrity issue in relation to COVID-19 vaccines relates to interactions between public officials and other actors. Stakeholders who participate in policy making processes, including representatives from the private sector and interest groups, can bring valuable insights to the policy debate. However, it is important to establish clear standards regarding the manner in which private interests influence and interact with policy makers, and to promote openness, integrity and fairness in order to maintain public trust. Otherwise there is a risk that some interests may have undue influence over the decision-making process and capture policies, to the detriment of the public interest.

A study of interest representation during COVID-19 found that lobbying activities increased during the crisis – especially concerning economic rescue packages – and that some actors enjoyed access advantages (Junk et al., 2020^[17]). Such an environment can favour stakeholders and sectoral interests with experienced and well-funded representatives,¹³ who already have access to key decision-makers and are able to sustain long-established relationships through phone calls, or other digital means.¹⁴

Recognising that using ethical principles to guide decision-making can enhance trust and solidarity and strengthen legitimacy and acceptability of measures to respond to the pandemic, in March 2020 the Irish Government developed an ethics framework for decision-making. The framework establishes ethical principles for decisions, and procedural values to guide the manner in which those decisions are made. Among the principles, fairness, for example, requires that resource allocation decisions are not made arbitrarily, and underscores that a fair decision is one that gives people an equal chance of benefiting from health care resources. Further, responsibility as a procedural value highlights that there should be an opportunity to revisit and revise decisions as new information becomes available, as well as mechanisms to address disputes and complaints. Additionally, in order to promote transparency and timely accountability in lobbying activities, the Office of the Commissioner of Lobbying of Canada ordered all

¹² <https://www.pandemicoversight.gov/>.

¹³ See, for example, Olson (2020^[57]) on corporate lobbying and conflicts of interest during the COVID-19 pandemic. Wouters et al. (2020^[58]) provide background on lobbying by the bio-pharmaceutical industry, which includes vaccine manufacturers.

¹⁴ <https://www.politico.eu/article/brussels-lobbying-goes-digital-because-of-coronavirus/>.



COVID-19 related activities to have digital tags, and included a keyword search capability in an online register of lobbyists, thereby facilitating timely scrutiny of the information by the public.¹⁵

Ensuring transparency and integrity of advisory bodies

Another element in building trust in vaccination strategies is ensuring transparency and integrity in special advisory bodies¹⁶ (such as scientific committees) (OECD, 2014_[16]). Many governments have established such entities to inform public decision-making in responding to the pandemic. There is some evidence that various industry sectors may engage with these bodies in order to influence regulatory processes, for example, by developing programmes “ostensibly intended to tackle health problems arising from the products they manufacture or distribute” (Mindell et al., 2012_[17]). For example, in the aftermath of the 2009 swine flu (A(H1N1) pandemic, scientific and public debates prompted accusations of commercial bias and that some governments and public institutions were misled into stockpiling a drug with limited efficacy. An analysis of how the Danish group of experts developed the plan to tackle the swine flu pandemic showed that they were lobbied by the industry directly and more subtly (Vilhelmsson and Mulinari, 2017_[20]). Recent investigations have shown that following reports of shortages in the United Kingdom, Spain, the Netherlands and Poland, the EU purchased and stockpiled a significant quantity of antivirals, despite limited evidence of their effectiveness (Hordijk and Patnaik, 2020_[21]). In general, advisory activities are excluded from influence frameworks. For example, only seven OECD countries made information publicly available on agendas, minutes and participants in advisory bodies in 2014, and in 2019 only 47% of OECD countries required public disclosure of the members of advisory bodies involved in regulatory processes at the national level (OECD, 2014_[18]).¹⁷ However, the European Commission Advisory Panel on COVID-19 is an example of a higher standard of transparency in the current pandemic. The group’s agenda and meeting reports are published online, thus supporting accountability to the public. In addition, minutes of meetings, participant submissions, and any external contributions received can be made available on request. The Advisory Committee of Immunization Practice (ACIP) in the United States, which develops recommendations on how to use vaccines, is another example of transparency. All discussions are streamed live and public comment is invited.¹⁸

More generally, some studies underline the positive role of “operational transparency” – when governments and public agencies disclose information regarding the way they work and the reasons for some decisions – in enhancing people’s trust in the processes and outcomes of public policies (Buell, 2019_[22]). Accordingly, raising awareness of the vaccine approval procedures followed by international and national regulatory bodies can contribute to enhancing trust in vaccines.

Fostering transparency and integrity in medical research

Lastly, governments need to ensure that information about, and results of research into treatments and vaccines are communicated transparently and comprehensively. In the COVID-19 vaccine development process several companies published their clinical trial protocols, but the results of key trials were initially

¹⁵ <https://lobbycanada.gc.ca/en/registration-and-compliance/COVID-19-emergency-funding-and-registration-requirements/>.

¹⁶ An advisory body or expert group refers to any committee, board, commission, council, conference, taskforce, or similar group, or any subcommittee or other subgroup thereof that provides governments with advice, expertise or recommendations. They are made up of public and/or private-sector members and/or representatives from civil society and may be put in place by the executive, legislative or judicial branches of government or government subdivisions.

¹⁷ <https://www.oecd.org/economy/reform/indicators-of-product-market-regulation/>.

¹⁸ <https://www.cdc.gov/vaccines/acip/meetings/index.html>.



communicated in headlines and via press releases,¹⁹ with little detail, prompting speculation²⁰ prior to publication and peer review about the underlying data. In addition, to date the rapid authorisations of vaccines by stringent regulators have been made mainly under emergency protocols, potentially creating perceptions that the assessments involved less than usual rigour,²¹ or were based on preliminary or incomplete data²² (See Box 2 above on how regulatory authorisation was expedited while safeguarding safety standards). The transition of these products to full authorisation, the peer-reviewed publication both of the results to date and of long term follow-up of subjects in ongoing clinical trials, and complete transparency of post-marketing data from Phase IV trials, routinely-collected datasets, and active and passive pharmacovigilance, should be paramount.

This degree of transparency was not always the norm prior to the COVID-19 pandemic. Several studies have shown that bio-pharmaceutical industry-funded clinical research is often subject to significant publication bias, favouring studies with positive results, as well as cherry-picking of evidence and marketing spin. (Smith, 2005^[23]; Lundh et al., 2017^[24]). However, since 2015, the European Medicines Agency (EMA) has instituted a policy of increasing transparency, publishing all clinical trial data submitted in pharmaceutical companies' regulatory submissions and assessed by its Committee for Human Medicinal Products (CHMP). In addition, for each submission the EMA publishes a European public assessment report on its website, providing the CHMP assessment of the data. During the COVID-19 crisis, regulatory authorities also instituted 'exceptional transparency' measures in the assessment of COVID-19 vaccines. For example, the EMA has published key documents following vaccine authorisation, including the complete version of the risk management plan and the vaccine clinical trial data reviewed in support of the authorisation.²³

In addition to ensuring transparency of clinical trial data, it is critical to try to avoid, or where unavoidable, manage, conflicts of interest between the different parties (e.g. researchers, pharmaceutical companies, governments) involved in vaccine development, as well as to strengthen the independence of researchers through funding and oversight mechanisms that insulate them from political and economic pressures. To that end, transparency requirements, together with clear institutional policies on industry sponsorship and conflicts of interest, are needed to preserve research integrity and independence.

The US National Institutes of Health (NIH) maintains a database containing a registry of clinical trials where the public can access a list of clinical studies specifically related to COVID-19. The US Food and Drug Administration (FDA) requires scientists and organisations that provide inputs to their processes to disclose their revenue sources and funding (Bowers and Cohen, 2018^[25]). Additionally, professional and industry associations have developed voluntary measures. For example, the American Psychiatric Association published a policy in 2007 requiring individuals involved in clinical trials, or in the revision of diagnosis and treatment protocols for mental disorders, to disclose any relationships with industry within three calendar years of their appointment, with updates to be provided annually for the duration of their participation (Wheeler and Cosgrove, 2013^[26]). In 2016, the European Federation of Pharmaceutical Industries and

¹⁹ For example <https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-conclude-phase-3-study-COVID-19-vaccine>.

²⁰ For example: <https://eu.usatoday.com/story/news/health/2020/11/09/pfizers-covid-vaccine-candidate-shows-90-effectiveness-early-test/6011925002/>.

²¹ For example: <https://www.nature.com/articles/d41586-020-03219-y>.

²² For example: <https://www.nature.com/articles/d41586-020-03441-8>.

²³ <https://www.ema.europa.eu/en/human-regulatory/overview/public-health-threats/coronavirus-disease-COVID-19/treatments-vaccines/COVID-19-vaccines-and-related-pages>.

Associations (EFPIA) implemented a voluntary code²⁴ similar to that of the Physician Payment Sunshine Act in the United States. The latter requires medical product manufacturers to disclose to the Centres for Medicare and Medicaid Services (CMS) any payments or other transfers of value made to physicians or teaching hospitals,²⁵ which are then published on a public website.²⁶

Institutional trust requires openness and community engagement

Open government refers to a culture of governance that promotes the principles of transparency, integrity, accountability, and stakeholder participation, in support of democracy and inclusive growth (OECD, 2017^[27]). Evidence from previous studies shows that in countries where low levels of openness were widely perceived by the public, increasing openness was a significant driver of institutional trust (OECD/KDI, 2018^[9]). In the context of the COVID-19 pandemic and vaccination campaigns, four actions are identified to ensure that government's actions are open to public scrutiny, and that public institutions engage with the population, especially those segments that are most hesitant to be vaccinated.

Proactively releasing timely information and data regarding vaccination strategies, modalities and accomplishments in disaggregated, user-friendly and open source formats

The COVID-19 pandemic has highlighted how a lack of clear information and timely data can cause uncertainty in decision-making and foster mistrust in the population. Ensuring the availability of timely and granular open source data on key issues, such as the number of people vaccinated, the number of doses administered, geographical coverage, and the number of people experiencing adverse reactions, will facilitate data analysis and dissemination in online trackers, news sites, etc.

Proactively releasing information that is up-to-date, reliable and easy to understand about procurement and funding of vaccines, in compliance with access to information laws, is also crucial for people outside government to have confidence in the effectiveness of government vaccination strategies and policies. However, supply contracts and the information therein contained, including delivery commitments, have generally remained confidential. Only very limited details about the procurement of vaccines were initially released by national authorities, with little or no disclosure of prices, delivery schedules and other contractual terms, or the financing of R&D, all of which are issues of public interest.

While some contracts were eventually published, these were heavily redacted, and only released after repeated requests by civil society organisations, or following disputes between governments and manufacturers over the timing, magnitude and nature of delivery commitments.²⁷ The absence of reliable and readily accessible information can leave much scope for speculation, false claims and controversies. Ultimately, it can also lead to an erosion of trust if there is a perception among the public, whether justified or not, that information is deliberately being obscured or withheld in order to evade accountability. The proactive release of all non-commercially sensitive details of contracts with vaccine manufacturers, on the

²⁴ <https://www.efpia.eu/relationships-code/the-efpia-code/>.

²⁵ The Physician Payments Sunshine Act (PPSA) is also known as section 6 002 of the Affordable Care Act (ACA) of 2010.

²⁶ <https://www.cms.gov/openpayments/>.

²⁷ The dispute between the EU and AstraZeneca on the timing and volume of vaccine deliveries is a case in point, though the eventual release of the heavily redacted contract resolved little of the conjecture surrounding the terms of the deal. The contract refers repeatedly to a requirement that AstraZeneca makes its "best reasonable effort" to manufacture and deliver vaccine doses according to the contract's schedule, prompting speculation as to whether in its negotiations the EU may have traded away certainty for price.

other hand, could not only help to build trust, but also reduce the burden that governments and the judiciary system are facing with increased volumes of access to information requests (UNESCO, 2020^[28]).

Enhancing transparent and coherent public communication to address misinformation and the 'infodemic'

Since its onset, the COVID-19 pandemic has been accompanied by an 'infodemic' (WHO, 2020^[29]) – an overabundance of information, whether accurate or not. Addressing it with determination is also crucial to enhancing trust.

Most of the problematic content circulated online (generally through social media) is based on manipulations of facts and unproven scientific theories. Scope for the dissemination of such content was opened by governments who, faced with scant and evolving scientific evidence, did not communicate decisively at the start of the pandemic (OECD, 2020^[30]). The mere fact of being exposed to 'science in the making', with evolving knowledge, and being exposed to debates in disciplines (e.g. epidemiology) that most people were not exposed to before the pandemic, can contribute to increase vaccine hesitancy due to lack of understanding. Cognitive overload is also a problem. As new information is being generated and disseminated at a fast pace, people can be overwhelmed and left unable to distil the most important principles that could guide their behaviour.

Social media platform algorithms tend to prompt users to consume content that is similar to what they have previously viewed, which may help create echo chambers. In non-moderated social media, even though the volume of content about COVID-19 from unreliable sources was relatively smaller than the content from reliable sources, the volume of reactions (e.g. likes, comments) to the former was larger (Cinelli et al., 2020^[31]). Several social media companies have reinforced their moderation policies, including removing misinformation²⁸ in 2020. Nevertheless, the majority of them do not have clear definitions of the types of content that need to be removed,²⁹ and few of them report how they perform content moderation or how users can contribute to it. More transparency would be needed regarding the activities of lobbyists and other actors seeking to influence national affairs on social media. The majority of governments have not established definitions of disinformation and misinformation, which would enhance a consistent content moderation policy across media platforms (OECD, forthcoming^[1]).

Effective and authoritative public communication can contribute to increased trust. Governments need to ensure that the public is able to access timely and accurate information from trusted sources about why vaccination is the only realistic means of achieving herd immunity in the medium term, and which is essential for the safe reopening of our societies and economies. For example, Belgium has delegated the task of delivering daily briefs to citizens to its crisis centre and scientific experts.³⁰ Governments can also learn from each other through sharing good communication practices. As part of its G7 Presidency, the UK Government, intends to launch a Global Vaccine Confidence Campaign to address health misinformation and build vaccine confidence through a comprehensive approach (Box 4).

²⁸ For example, Facebook published a policy on promoting accurate information across its platforms: <https://about.fb.com/news/2020/12/coronavirus/#misinformation-update>.

²⁹ A recent report by the OECD on approaches to terrorist and violent extremist content (TVEC) in online content-sharing services shows that the majority of platforms ban such content to a certain extent, the majority do not have a definition of TVEC and only five companies produce reports about how they moderate and remove such content (OECD, 2020^[30]).

³⁰ <https://www.ft.com/content/3d24b654-187e-4270-b051-acfc350498d2>.



Box 4. G7 Global Vaccine Confidence Campaign

As part of its G7 presidency, the United Kingdom is planning to launch a Global Vaccine Confidence Campaign together with G7 and partner countries, including the World Health Organization (WHO), OECD, and other international organisations as well as Cambridge University, Harvard University, and the London School of Hygiene and Tropical Medicine. The aim will be to raise vaccination confidence and build resilience of global audiences to vaccine misinformation. The campaign will rely on multiple channels and will be delivered together with G7 partners and external stakeholders.

The campaign will seek the endorsement of G7 countries, as well as an international network of government communicators, of evidence-based global standards to build confidence in public communication and address misinformation, which will be developed in partnership with the OECD and the University of Cambridge. Some of the findings will highlight the importance of informing rather than persuading (given that people are less receptive when they believe a communicator holds a hidden agenda), sharing all relevant pieces of information (not only those that fit with a narrative), disclosing uncertainties, and being open about the quality of the evidence supporting a claim, for example reporting survey sample sizes (Blastland et al., 2020^[32]).

The principles developed by the OECD will be informed by a range of practices covering specific communication activities; the enabling institution that define the organisation and co-ordination of the communication function within and outside of government; and the wider enabling ecosystem that supports timely and effective sharing of information and data.

Source: Blastland et al. (2020^[32]) "Five rules for evidence communication", *Nature*, Vol 587, pp. 362-364 <https://doi.org/10.1038/d41586-020-03189-1>

However, governments should also be open about residual uncertainties when communicating, given that omitting important pieces of information can foster distrust among the public once new evidence becomes available. Indeed, recent research shows that communicating uncertainty in news articles only produces a small decrease in trust in the numbers being reported and in the source of information (van der Bles et al., 202^[33]).

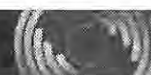
Efforts to increase people's ability to detect misinformation and their media and scientific literacy can contribute to reducing the uncertainty that drives vaccine hesitancy. Some countries, (e.g. Spain³¹) have begun monitoring disinformation campaigns in a systematic way, and have implemented action plans or laws in response. France, for example, passed a law against the manipulation of information in 2018.³² Other approaches include toolkits to help citizens detect false information. Other countries have created educational materials about disinformation. The Danish health authority has published a video on its website providing guidance on how to detect fake news, including, for example, by verifying whether it comes from an authoritative source and whether it is published in multiple outlets.³³ 'Pre-bunking' (also known as 'social inoculation') – exposing audiences to small doses of misinformation to explain their flawed reasoning – can help hesitant people overcome their fears about the COVID-19 vaccine (OECD, 2020^[33]). Together with the University of Cambridge, the UK Government has developed "Go Viral!",³⁴ a game to

³¹ <https://boe.es/boe/dias/2020/11/05/pdfs/BOE-A-2020-13663.pdf#BOEn>.

³² <https://www.gouvernement.fr/action/contre-la-manipulation-de-l-information>.

³³ <https://www.sst.dk/en/english/corona-eng/vaccination-against-COVID-19>.

³⁴ <https://www.goviralgame.com/>.



expose people to and educate them about the techniques used for spreading misinformation on social media.

Effective communication also entails sound knowledge of the various audiences (e.g. media consumption, languages spoken), partnerships with community leaders and subnational governments to overcome barriers to information, and empathy (OECD, 2020^[30]; OECD, 2020^[34]). In many countries ethnic minorities are reported to be more vaccine hesitant. Moreover, a recent study showed that, in Ireland and the United Kingdom, population groups that are resistant to taking vaccines against COVID-19 resort to social media as a source of information more than vaccine-accepting segments, and have lower levels of trust in information coming from news agencies, government agencies and health care professionals. People who are unwilling to be vaccinated were also found to hold stronger religious beliefs (Murphy et al., 2021^[35]).

Various strategies can be effective in stimulating demand for vaccination among hesitant population groups (see, for example, Evans and French (2021^[36])), many of which are already being used by some governments in OECD countries. In Israel, the Ministry of Health launched a public relations campaign to encourage vaccination among ultra-orthodox Jewish communities. Religious leaders of some of these groups communicated the importance of being vaccinated to their members, including sharing pictures of their own vaccinations. In the United Kingdom, the Department for Digital, Culture, Media and Sport launched a campaign to tackle false vaccine information shared amongst ethnic minority communities, providing a toolkit with content designed to be shared via WhatsApp and Facebook community groups, as well as Twitter, YouTube and Instagram. The campaign is fronted by trusted local community figures such as religious leaders, clinicians and others who provide simple tips on how to spot misinformation and what to do to stop its spread in short, shareable videos.³⁵ Box 5 provides other examples of good practices in public communications by governments.

Box 5. Good practices in public communications during the COVID-19 pandemic

Leveraging the use of behavioural science to increase vaccine confidence in Canada

Impact Canada led the implementation of the World Health Organization (WHO) Behavioural Insights data collection tool, which was applied in several waves, surveying around 2000 Canadians on key behavioural areas including public risk perceptions, information sources and vaccine confidence. The findings revealed that citizens who trust the government correspond to those who trust vaccines.

In addition, Impact Canada analysed over 125 sources of information to gain insights on successful COVID-19 international communication campaigns and policy responses. The results showed that demonstrating efficacy, evoking emotional responses, emphasising collective action and adaptiveness, making social norms salient, and addressing pandemic fatigue were effective ways of communicating.

Chatbots and call-contact centre in Estonia and Slovenia

Estonia's Communication Unit established an automated Chatbot with nearly a thousand questions related to the COVID-19 crisis on multiple aspects, and is embedded in several public websites. In an effort to cater to minorities, the content is also translated into Russian and English. Slovenia's government set up a call-contact centre for citizens seeking information and answers, as well allowing them to express their fears and worries while talking to someone knowledgeable, trustworthy and understanding. The calls are answered by medical students at the University of Ljubljana, under the professional supervision of doctors at the Clinic for Infectious Diseases and Febrile Conditions who receive training and updated information to respond to these calls.

³⁵ <https://dcmsblog.uk/check-before-you-share-toolkit/>.



The Slovenian National Institute of Public Health also created a user friendly website (<https://www.cepimose.si/>), which provides information regarding vaccines, including about how they were developed and approved, about vaccination in general, and an FAQ section. It also features an interactive tool with vaccination data and other health advice.

Partnerships with influencers in Finland and Korea

Finland's Prime Minister's Office, in collaboration with the National Emergency Supply Agency and the private sector partnered with social media influencers to provide clear and relevant information for younger audiences that can be harder to reach through traditional channels. Following a comprehensive influencer mapping, over 1 800 Finnish influencers helped the government share reliable information on health measures to empower and engage citizens in the fight against COVID-19. A follow-up survey conducted revealed that: "94% of followers felt they got enough information and instructions about coronavirus via influencers with the over half saying influencer communication affected their behaviour" and "97% of respondents consider the COVID-19 information shared by influencers reliable".

During the pandemic, the Korean Ministry of Health and Welfare launched the "Thanks Challenge" on Instagram, with the aim of expanding the reach of awareness raising efforts around COVID-19 measures. The initiative invited citizens to share a picture of themselves at home to promote social distancing and "stay at home" measures. Celebrities and influencers also took part in the campaign and helped the government disseminate official information about the disease and its symptoms.

Targeted messaging through social media in Italy

During the second wave of the pandemic, a key priority was to address COVID-related messages to selected audiences that appeared to be the most reluctant to follow the rules set by the Italian Government in order to limit the spread of the virus: wear a mask, maintain social distancing and wash your hands. As such, the Presidency of the Council of Ministers implemented a multi-platform campaign on major social media channels focused on these three elements, with ad-hoc messages for selected audiences such as youth, or small and medium business owners. Studies concluded that a 3-week campaign on Facebook and Instagram led to a 2.4 percentage point increase in remembering the advertising campaign and a 1.5 point increase in compliance with the three rules.

Source: OECD (2020^[37]), The COVID-19 crisis: A catalyst for government transformation?, <https://doi.org/10.1787/1d0c0788-en>;
 OECD (2020^[34]), Building resilience to the COVID-19 pandemic, the role of centres of government, <https://doi.org/10.1787/893d2961-en>;
 Media Pool (2020), Combating coronavirus together by sharing reliable information, available online at <https://pinhelsinki.fi/en/combating-coronavirus-together-by-sharing-reliable-information>;
 World Bank (2020), Co-ordinating pandemic responses from the centre of government: Why country context matters, <https://blogs.worldbank.org/governance/co-ordinating-pandemic-responses-centre-government-why-country-context-matters>.

The OECD has facilitated a number of in-depth conversations on the role of communication and government efforts to build trust in vaccines, with an OECD Forum Series event³⁶ exploring the importance of effective communication to tackle the "infodemic" and a high-level event³⁷ taking stock the challenges posed by misinformation in the covid context and providing an opportunity for participants to share experiences and communication good practices.

³⁶ <https://oecd-events.org/public-health-and-misinformation>.

³⁷ <https://oecd.ukqovernment.live/schedule>.

Engaging the public when developing vaccination strategies

Governments need to listen to people's concerns and the reasons why they do not trust the approved vaccines against COVID-19, and cater to their need for reassurance. While vaccine hesitancy is characterised by mistrust in experts (Stecula, Kuru and Jamieson, 2020^[36]), this is unrelated to their competence or technical knowledge of the subject, but rather to perceptions that experts do not act in good faith (Eiser et al., 2009^[35]). For this reason, one-way communication about the benefits of vaccination will not suffice in convincing people to modify their views. Instead, allowing vaccine-hesitant people to express their views, expressing empathy, and dealing with resistance without antagonism, are effective ways of promoting behaviour change (Gagneur et al., 2018^[40]). Following this approach, the Economic, Social and Environmental Council of France produced a website³⁸ to ask citizens about the reasons why they are or are not willing to be vaccinated.

To sustain or restore confidence in vaccines, a thorough understanding is needed of each citizen's specific vaccine concerns, historical experiences, religious or political affiliation, and socio-economic status. For example, in the United States, African-Americans are less willing to be vaccinated than other groups (Reiter, Pennell and Katz, 2020^[41]). This distrust may be linked to personal or vicarious, negative experiences with the health care system and other public services, as well as current and historical abuses of power (e.g. lack of informed consent) towards these groups. Evidence shows that African-Americans tend to experience lower communication quality (such as information-giving and participatory decision-making) with physicians, especially with non-African American physicians. (Johnson Shen et al., 2018^[42]). Underprivileged groups are also more exposed to COVID-19 because of their living conditions and/or occupations (which may prevent them from isolating at home or sustaining effective social distancing in the workplace), and have less access to safety nets should they become severely ill (OECD, 2020^[43]). More generally, these population groups also tend to have poorer access to health care, which contributes to the limited impact of existing recommendations. Another example is low MMR coverage in minority populations of London boroughs.³⁹ All of these factors combined contribute to scepticism about government recommendations. This calls specifically for engagement of the communities in the development and implementation of public health strategies addressing their needs as well as for broadening of all of the governmental services involved.

Clearly explained and communicated decisions about vaccination strategies are also necessary to increase vaccination acceptance. Demand for COVID-19 vaccines will continue to exceed supply for several months (OECD, 2021^[44]). Many countries must therefore prioritise the administration of limited vaccine stocks. Clarity in how these decisions are made is essential to gaining the public's trust in government action. For instance, health workers and workers in essential services are particularly exposed as they are at the 'frontline' of the fight against the pandemic. Also, the elderly and people with co-morbidities have higher probability of developing severe forms of the disease, and these groups have seen much higher mortality rates than the rest of the population. It is widely recognised that immunising these groups first would contribute to alleviating pressure on health systems. Communication efforts on why these two groups are in almost all countries seen as priority population would facilitate acceptance and foster trust in intentions.

Successful vaccination campaigns require extensive and well-managed community engagement. All population groups need to be involved in the design and implementation of grassroots initiatives that will build trust in vaccines, and strengthen relationships between communities and their governments, particularly for marginalised or underserved segments of the population.⁴⁰ In the case of COVID-19, this requires a specific emphasis on addressing issues of concern regarding the speed of development and of approval of the vaccines (see Box 2).

³⁸ <https://participez.lecese.fr/>.

³⁹ <https://www.london.gov.uk/press-releases/assembly/concern-about-londons-low-vaccination-rate>.

⁴⁰ <https://www.who.int/publications/i/item/WHO-2019-nCoV-vaccination-community-engagement-2021.1>.

Governments can partner with, and support community organisations in order to leverage existing structures to vaccinate the population, achieve a clearer understanding of barriers and enablers to vaccination for specific communities, and empower community leaders, who are better positioned to instil confidence in vaccines. Employers (Milkman et al., 2011^[45]), co-workers (Chapman and Coups, 1999^[46]), and family members and friends (Takahashi et al., 2003^[47]) play an important role in influenza vaccination uptake in adults. Physician recommendation has also consistently shown to increase vaccination rates for other diseases (Brewer and Fazekas, 2007^[48]). The Rapid Community Assessment, developed by the American Centre for Disease Control and Prevention, provides health officials with five-steps guidance to assess what communities think about COVID-19 vaccines, identify community leaders and trusted messengers, and prioritise potential intervention strategies to increase confidence in and uptake of COVID-19 vaccine (Centers for Disease Control and Prevention, 2021^[49]).

When done appropriately, community engagement increases the likelihood that communities lead on issues that affect them, use services, and build resilience. Community engagement expands the influence of local actors, facilitates access to and understanding of information, enables and promotes the right to provide feedback on the received services, and builds on existing local capacities. In the United States, recent pilot programmes in California offer relevant lessons in the value of community engagement (Mondal, 2021^[50]). For example, a longitudinal cohort study that began in 1999 as an examination of the effects of pesticide use on farmworkers across California's Central Valley recently shifted to investigating the impacts of COVID-19. In its latest report, researchers found that in October 2021, 20% were SARS-CoV-2 antibody positive, but as many as half expressed reluctance to accept a COVID-19 vaccine, as they did not trust the government. Investigators quickly realised that building trust in vaccination among the cohort would require inclusive community participation.

There is an expectation that the more the public are involved in decisions regarding the approval and delivery of vaccines, the more likely they will accept vaccination. Deliberative democracy⁴¹ is gaining traction as a way of addressing pressing policy problems, in areas such as urban planning, health and environment (OECD, 2020^[51]). These processes are generally successful when they are asked to address moral dilemmas (such as whether to implement 'vaccine passports') and given sufficient time to weigh arguments and evidence. For example, in the case of Scotland, a citizens' panel was set up to evaluate the governments' response to COVID-19, weighing evidence from experts in fields ranging from epidemiology to law and economy, and provide a report to the Parliament's COVID-19 committee.⁴²

Consulting and engaging citizens and local communities will also help to develop the vaccination strategy most adapted to the local context, thus overcoming some of the logistical challenges and vaccination hesitancy. For example, Canada's COVID-19 immunisation plan involves collaboration between the Federal Government; the provinces; the territories; First Nations, Inuit and Métis leaders; and municipal governments, among others.⁴³ The United Kingdom's COVID-19 vaccine delivery plan takes a local, community-led approach, with partnerships between national government, local authorities, national health system, local directors of public health, local health and well-being boards, voluntary, and community and faith sectors.⁴⁴

⁴¹ By representative deliberative democratic processes it is meant processes that involve a group of randomly selected people, broadly representative of society, who are provided with the time and evidence to deliberate on a policy issue and propose collective, informed recommendations to public decision makers.

⁴² <https://www.parliament.scot/newsandmediacentre/116952.aspx>.

⁴³ <https://www.canada.ca/content/dam/phac-aspc/documents/services/diseases/2019-novel-coronavirus-infection/canadas-reponse/canadas-COVID-19-immunisation-plan-en.pdf>.

⁴⁴ <https://www.gov.uk/government/publications/COVID-19-vaccination-uptake-plan/uk-COVID-19-vaccine-uptake-plan>.



Our Ref: 001/NDoH/2021

19 July 2021

Information Officer:

Director General Dr Sandile Buthelezi

Per Email: dg@health.gov.za

Deputy Information Officer:

Mr Justinos Motalaota

Per Email: justinos.motalaota@health.gov.za

Dear Dr Buthelezi and Mr Motalaota

Request for information pursuant to the Promotion of Access to Information Act 2000 - Vaccine Contracts and Information

We refer to our previous correspondence in this matter, wherein the Health Justice Initiative (HJI) requested specific information related to the Covid-19 pandemic. Our requests have not been acknowledged and/or fully responded to.

Therefore, please find enclosed a completed **FORM A** request for access to information pursuant to the *Promotion of Access to Information Act 2 of 2000* (PAIA).

In order for us to undertake our work effectively, we request that you respond to this request as expeditiously as possible.



We submit that a review of PAIA reveals that there are no applicable grounds of refusal that may arise in respect of the records sought and we note further the provisions of section 46 of PAIA which provides for mandatory disclosure in the public interest.

Moreover, we remind you of the guidance from the Constitutional Court in *President of the Republic of South Africa and Others v M&G Media Limited* [2011] ZACC 32, in which the Constitutional Court explained that:

1. The scheme of PAIA is such that information must be disclosed unless it is exempt from disclosure, in circumstances where the exemptions must be narrowly construed.
2. It is indeed the holder of the information that bears the onus of establishing that a refusal of access to information is justified under PAIA.
3. A bare denial will not suffice to justify a refusal.
4. There is no discretion to withhold information that is not protected, and the unprotected material must be disclosed despite any other provision of PAIA, unless it cannot be reasonably severed from the protected portions.

Annexure A is a letter of authorisation from the Health Justice Initiative (HJI).

Please find enclosed the relevant attachments in relation to the above-mentioned request.

Kindly advise of the amount of the request fee to be paid and provide us with the bank details so that we can attend to the payment accordingly.

Yours sincerely,



Dr Marlise Richter

Marlise@healthjusticeinitiative.org.za

info@healthjusticeinitiative.org.za

A handwritten signature in black ink, appearing to be 'Marlise Richter'.



J750

REPUBLIC OF SOUTH AFRICA

FORM A
REQUEST FOR ACCESS TO RECORD OF PUBLIC BODY
(Section 18(1) of the Promotion of Access to Information Act, 2000 (Act No. 2 of 2000))
[Regulation 6]

FOR DEPARTMENTAL USE

Reference number:

Request received by (state rank,
name and surname of information officer/deputy information officer) on (date)
at (place).

Request fee (if any): R

Deposit (if any): R

Access fee: R

.....
SIGNATURE OF INFORMATION OFFICER/DEPUTY INFORMATION OFFICER

A. Particulars of public body

The Information Officer/Deputy Information Officer

Information Officer:
Director General Dr Sandile Buthelezi (Information Officer)
By email: dg@health.gov.za

Deputy Information Officer:
Justinos Motalaota
By email: justinos.motalaota@health.gov.za;

B. Particulars of person requesting access to the record

(a) The particulars of the person who requests access to the record must be given below.
(b) The address and/or fax number in the Republic to which the information is to be sent, must be given.
(c) Proof of the capacity in which the request is made, if applicable, must be attached.

Full names and surname: Marlise Richter

Identity number: [REDACTED]

Postal address: 2nd Floor Community House: 41 Salt River Road, Salt River, Cape Town South Africa 7925

Telephone number: ([REDACTED]) Fax number: (.....)

E-mail address: marlise@healthjusticeinitiative.org.za and info@healthjusticeinitiative.org.za

Capacity in which request is made, when made on behalf of another person:

Dr Richter is a Senior Researcher at the Health Justice Initiative. She has been authorised to submit a request on behalf of the Health Justice Initiative in the public interest.

C. Particulars of person on whose behalf request is made

This section must be completed ONLY if a request for information is made on behalf of another person.

Full names and surname: Not applicable

Identity number:

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D. Particulars of record

(a) Provide full particulars of the record to which access is requested, including the reference number if that is known to you, to enable the record to be located.
(b) If the provided space is inadequate, please continue on a separate folio and attach it to this form. The requester must sign all the additional folios.

1. Description of record or relevant part of the record:

See next page:
.....
.....



Covid-19 Vaccine Contracts:

1A.) Copies of all Covid-19 vaccine procurement contracts, and Memoranda of Understanding, and agreements including with the following parties and/or duly authorised licensed representative/s of:

- a. Janssen Pharmaceuticals / Johnson & Johnson.
- b. Aspen Pharmacare.
- c. Pfizer.
- d. Serum Institute of India / Cipla.
- e. Sinovac/Coronavac
- f. Any other vaccine manufacturer / licensee.
- g. The African Union Vaccine Access Task Team (AU AVATT).
- h. 'COVAX' (with the Global Vaccine Alliance – GAVI /other)
- i. The Solidarity Fund.

1B.) Copies of all Covid-19 vaccine negotiation meeting outcomes and/or minutes, and correspondence, including with the following parties and/or duly authorised licensed representative/s of:

- a. Janssen Pharmaceuticals / Johnson & Johnson.
- b. Aspen Pharmacare.
- c. Pfizer.
- d. Serum Institute of India / Cipla.
- e. Sinovac/Coronavac
- f. Any other vaccine manufacturer / licensee.
- g. The African Union Vaccine Access Task Team (AU AVATT).
- h. 'COVAX' (with the Global Vaccine Alliance – GAVI /other)
- i. The Solidarity Fund.

A handwritten signature in black ink is located in the bottom right corner of the page. Below the signature is a solid black rectangular redaction box.

2. Reference number, if available:

3. Any further particulars of record:
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E. Fees

- (a) A request for access to a record, other than a record containing personal information about yourself, will be processed only after a request fee has been paid.
- (b) You will be notified of the amount required to be paid as the request fee.
- (c) The **fee payable for access** to a record depends on the form in which access is required and the reasonable time required to search for and prepare a record.
- (d) If you qualify for exemption of the payment of any fee, please state the reason for exemption.

Reason for exemption from payment of fees:

Not applicable
.....
.....
.....
.....

F. Form of access to record

If you are prevented by a disability to read, view or listen to the record in the form of access provided for in 1 to 4 below, state your disability and indicate in which form the record is required.

Disability: Not applicable	Form in which record is required:
Mark the appropriate box with an X .	
NOTES:	
(a) Compliance with your request for access in the specified form may depend on the form in which the record is available.	
(b) Access in the form requested may be refused in certain circumstances. In such a case you will be informed if access will be granted in another form.	
(c) The fee payable for access to the record, if any, will be determined partly by the form in which access is requested.	

1. If the record is in written or printed form:				
<input checked="" type="checkbox"/>	copy of record*		inspection of record	
2. If record consists of visual images - (this includes photographs, slides, video recordings, computer-generated images, sketches, etc.):				
	view the images	<input checked="" type="checkbox"/>	copy of the images*	transcription of the images*

3. If record consists of recorded words or information which can be reproduced in sound:					
x	listen to the soundtrack (audio cassette)		transcription of soundtrack* (written or printed document)		
4. If record is held on computer or in an electronic or machine-readable form:					
	printed copy of record*	x	printed copy of information derived from the record*		copy in computer readable form* (stiffy or compact disc)

*If you requested a copy or transcription of a record (above), do you wish the copy or transcription to be posted to you? Postage is payable.	YES <input checked="" type="checkbox"/>	NO
	Please email	

Note that if the record is not available in the language you prefer, access may be granted in the language in which the record is available.

In which language would you prefer the record? English

G. Notice of decision regarding request for access

You will be notified in writing whether your request has been approved / denied. If you wish to be informed in another manner, please specify the manner and provide the necessary particulars to enable compliance with your request.

How would you prefer to be informed of the decision regarding your request for access to the record?

Via email correspondence at marlise@healthjusticeinitiative.org.za and info@healthjusticeinitiative.org.za

Signed at Cape Town this day 19th of July year 2021



.....
SIGNATURE OF REQUESTER /
PERSON ON WHOSE BEHALF REQUEST IS MADE

Appendix A:

19 July 2021

To whom it may concern

Letter of Authorisation: Health Justice Initiative (HJI)

To the extent that a letter of authority is requested, this is to confirm that Dr Marlise Richter is duly authorised to submit a request in terms of the *Promotion of Access to Information Act of 2000* on behalf of the Health Justice Initiative.

Yours sincerely,

*Fatima Hassan***Fatima Hassan****Director: Health Justice Initiative**



REPUBLIC OF SOUTH AFRICA

FORM B
NOTICE OF INTERNAL APPEAL
(Section 75 of the Promotion of Access to Information Act, 2000 (Act No. 2 of 2000))
[Regulation 8]

STATE YOUR REFERENCE NUMBER: 001/NDoH/2021

A. Particulars of public body

The Information Officer/Deputy Information Officer:

Information Officer:
Actig Director-General Dr Nicholas Crisp (Information Officer)
By email: dg@health.gov.za

Deputy Information Officer
Justinos Motalaota
By email: justinos.motalaota@health.gov.za

B. Particulars of requester/third party who lodges the internal appeal

- (a) The particulars of the person who lodge the internal appeal must be given below.
- (b) Proof of the capacity in which appeal is lodged, if applicable, must be attached.
- (c) If the appellant is a third person and not the person who originally requested the information, the particulars of the requester must be given at C below.

Full names and surname: Marlise Richter

Identity number: [REDACTED]

Postal address: 2nd Floor Community House, 41 Salt River Road, Salt River, Cape Town South Africa 7925

Telephone number: [REDACTED] Fax number: (.....)

E-mail address: marlise@healthjusticeinitiative.org.za and info@healthjusticeinitiative.org.za

Capacity in which an internal appeal on behalf of another person is lodged: N/A

C. Particulars of requester

This section must be completed ONLY if a third party (other than the requester) lodges the internal appeal.

Full names and surname: N/A

Identity number: [Grid of 13 empty boxes]

D. The decision against which the internal appeal is lodged

Mark the decision against which the internal appeal is lodged with an X in the appropriate box:

x	Refusal of request for access
	Decision regarding fees prescribed in terms of section 22 of the Act
	Decision regarding the extension of the period within which the request must be dealt with in terms of section 26(1) of the Act
	Decision in terms of section 29(3) of the Act to refuse access in the form requested by the requester
	Decision to grant request for access

E. Grounds for appeal

If the provided space is inadequate, please continue on a separate folio and attach it to this form. You must sign all the additional folios.

State the grounds on which the internal appeal is based:

Please refer to the next pages
.....
.....
.....
.....
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State any other information that may be relevant in considering the appeal:

Please refer to the next pages
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.....
.....
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Grounds for appeal:

On 19 July 2021, the Health Justice Initiative (HJI) submitted a request to the National Department of Health (the Department) in terms of the Promotion of Access to Information Act 2 of 2000 (PAIA) (See Appendix 1). The request pertained to COVID-19 vaccine contracts. It followed our correspondence dated 22 June 2021 (see Appendix 2). In response to that letter and the PAIA request, on 29 July 2021 the Department requested additional time to consult with relevant parties (see Appendix 3). In correspondence dated 6 August 2021, HJI granted an extension until 25 August 2021 (see Appendix 4).

In terms of section 47(2) of PAIA the Department had until 13 August 2021 to notify the relevant third parties. In terms of section 49(1) of PAIA the Department had until 12 September 2021 to make a decision and advise the third parties and the requester accordingly.

To date, the requested information has not been provided despite the relevant time periods having lapsed. It is on the basis of this deemed refusal that HJI now lodges this internal appeal.

We await your urgent response to this request for information in the public interest. This is all the more pressing because of the recent revelations concerning aspects included in an agreement between the Government of South Africa and a vaccine manufacturer, Johnson & Johnson / Janssen. In terms of a report by the *New York Times*^[1] (see Appendix 5), it is alleged that South Africa is paying comparatively inflated rates for vaccines, that a broad indemnification against liability was granted and that the inclusion of an export waiver has prevented South Africa from restricting the export of vaccines filled and finished here. The inclusion of such clauses may have an adverse effect on South Africa's national vaccine roll-out programme and may undermine certain constitutional obligations of the state.

To the extent that no response is received, HJI will have no choice but to consider its further recourse before the appropriate forum.

Other relevant information:

For ease of reference, a copy of the initial PAIA request is enclosed together with this internal appeal together with relevant correspondence.

^[1] Rebecca Robbins and Benjamin Mueller "Covid Vaccines Produced in Africa Are Being Exported to Europe" *New York Times* 16 August 2021, Available: <https://www.nytimes.com/2021/08/16/business/johnson-johnson-vaccine-africa-exported-europe.html>

A black rectangular redaction box covers the signature area. Below the redaction, there is a handwritten signature in blue ink.

F. Notice of decision on appeal

You will be notified in writing of the decision on your internal appeal. If you wish to be informed in another manner, please specify the manner and provide the necessary particulars to enable compliance with your request.

State the manner: N/A

Particulars of manner:

Signed at Cape Town this day 15 of September year 2021



SIGNATURE OF APPELLANT

FOR DEPARTMENTAL USE:

OFFICIAL RECORD OF INTERNAL APPEAL:

Appeal received on (date) by

(state rank, name and surname of information officer/deputy information officer).

Appeal accompanied by the reasons for the information officer's/deputy information officer's decision and, where applicable, the particulars of any third party to whom or which the record relates, submitted by the information officer/deputy information officer on (date) to the relevant authority.

OUTCOME OF APPEAL:

DECISION OF INFORMATION OFFICER/DEPUTY INFORMATION OFFICER CONFIRMED/NEW DECISION SUBSTITUTED

NEW DECISION:

DATE RELEVANT AUTHORITY

RECEIVED BY THE INFORMATION OFFICER/DEPUTY INFORMATION OFFICER FROM THE RELEVANT AUTHORITY ON (date):

Our Ref: 001/NDoH/2021

19 July 2021

Information Officer:

Director General Dr Sandile Buthelezi

Per Email: dg@health.gov.za**Deputy Information Officer:**

Mr Justinos Motalaota

Per Email: justinos.motalaota@health.gov.za

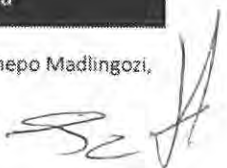
Dear Dr Buthelezi and Mr Motalaota

Request for information pursuant to the Promotion of Access to Information Act 2000 - Vaccine Contracts and Information

We refer to our previous correspondence in this matter, wherein the Health Justice Initiative (HJI) requested specific information related to the Covid-19 pandemic. Our requests have not been acknowledged and/or fully responded to.

Therefore, please find enclosed a completed **FORM A** request for access to information pursuant to the *Promotion of Access to Information Act 2 of 2000 (PAIA)*.

In order for us to undertake our work effectively, we request that you respond to this request as expeditiously as possible.



We submit that a review of PAIA reveals that there are no applicable grounds of refusal that may arise in respect of the records sought and we note further the provisions of section 46 of PAIA which provides for mandatory disclosure in the public interest.

Moreover, we remind you of the guidance from the Constitutional Court in *President of the Republic of South Africa and Others v M&G Media Limited* [2011] ZACC 32, in which the Constitutional Court explained that:

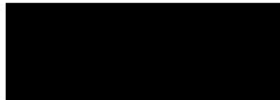
1. The scheme of PAIA is such that information must be disclosed unless it is exempt from disclosure, in circumstances where the exemptions must be narrowly construed.
2. It is indeed the holder of the information that bears the onus of establishing that a refusal of access to information is justified under PAIA.
3. A bare denial will not suffice to justify a refusal.
4. There is no discretion to withhold information that is not protected, and the unprotected material must be disclosed despite any other provision of PAIA, unless it cannot be reasonably severed from the protected portions.

Annexure A is a letter of authorisation from the Health Justice Initiative (HJI).

Please find enclosed the relevant attachments in relation to the above-mentioned request.

Kindly advise of the amount of the request fee to be paid and provide us with the bank details so that we can attend to the payment accordingly.

Yours sincerely,



Dr Marlise Richter

Marlise@healthjusticeinitiative.org.za

info@healthjusticeinitiative.org.za

A handwritten signature in black ink, appearing to be 'Marlise Richter', located in the bottom right corner of the page.



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REPUBLIC OF SOUTH AFRICA

FORM A
REQUEST FOR ACCESS TO RECORD OF PUBLIC BODY
 (Section 18(1) of the Promotion of Access to Information Act, 2000 (Act No. 2 of 2000))
 [Regulation 6]

FOR DEPARTMENTAL USE

Reference number:

Request received by (state rank,
 name and surname of information officer/deputy information officer) on (date)
 at (place).

Request fee (if any): R

Deposit (if any): R

Access fee: R

.....
SIGNATURE OF INFORMATION OFFICER/DEPUTY INFORMATION OFFICER**A. Particulars of public body**

The Information Officer/Deputy Information Officer

Information Officer:
 Director General Dr Sandile Buthelezi (Information Officer)
 By email: dg@health.gov.za

Deputy Information Officer:
 Justinos Motalaota
 By email: justinos.motalaota@health.gov.za;

B. Particulars of person requesting access to the record

(a) The particulars of the person who requests access to the record must be given below.
(b) The address and/or fax number in the Republic to which the information is to be sent, must be given.
(c) Proof of the capacity in which the request is made, if applicable, must be attached.

Full names and surname: Marlise Richter

Identity number: [REDACTED]

Postal address: 2nd Floor Community House; 41 Salt River Road, Salt River, Cape Town South Africa 7925

Telephone number: [REDACTED] Fax number: (.....)

E-mail address: marlise@healthjusticeinitiative.org.za and info@healthjusticeinitiative.org.za

Capacity in which request is made, when made on behalf of another person:

Dr Richter is a Senior Researcher at the Health Justice Initiative. She has been authorised to submit a request on behalf of the Health Justice Initiative in the public interest.

C. Particulars of person on whose behalf request is made

This section must be completed ONLY if a request for information is made on behalf of another person.

Full names and surname: Not applicable

Identity number:

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D. Particulars of record

(a) Provide full particulars of the record to which access is requested, including the reference number if that is known to you, to enable the record to be located.
(b) If the provided space is inadequate, please continue on a separate folio and attach it to this form. The requester must sign all the additional folios.

1. Description of record or relevant part of the record:

See next page:
.....
.....



Covid-19 Vaccine Contracts:

1A.) Copies of all Covid-19 vaccine procurement contracts, and Memoranda of Understanding, and agreements including with the following parties and/or duly authorised licensed representative/s of:

- a. Janssen Pharmaceuticals / Johnson & Johnson.
- b. Aspen Pharmacare.
- c. Pfizer.
- d. Serum Institute of India / Cipla.
- e. Sinovac/Coronavac
- f. Any other vaccine manufacturer / licensee.
- g. The African Union Vaccine Access Task Team (AU AVATT).
- h. 'COVAX' (with the Global Vaccine Alliance – GAVI /other)
- i. The Solidarity Fund.

1B.) Copies of all Covid-19 vaccine negotiation meeting outcomes and/or minutes, and correspondence, including with the following parties and/or duly authorised licensed representative/s of:

- a. Janssen Pharmaceuticals / Johnson & Johnson.
- b. Aspen Pharmacare.
- c. Pfizer.
- d. Serum Institute of India / Cipla.
- e. Sinovac/Coronavac
- f. Any other vaccine manufacturer / licensee.
- g. The African Union Vaccine Access Task Team (AU AVATT).
- h. 'COVAX' (with the Global Vaccine Alliance – GAVI /other)
- i. The Solidarity Fund.



2. Reference number, if available:

3. Any further particulars of record:
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E. Fees

- (a) A request for access to a record, other than a record containing personal information about yourself, will be processed only after a request fee has been paid.
- (b) You will be notified of the amount required to be paid as the request fee.
- (c) The fee payable for access to a record depends on the form in which access is required and the reasonable time required to search for and prepare a record.
- (d) If you qualify for exemption of the payment of any fee, please state the reason for exemption.

Reason for exemption from payment of fees:

Not applicable
.....
.....
.....
.....

F. Form of access to record

If you are prevented by a disability to read, view or listen to the record in the form of access provided for in 1 to 4 below, state your disability and indicate in which form the record is required.

Disability: Not applicable	Form in which record is required:
Mark the appropriate box with an X.	
NOTES:	
(a) Compliance with your request for access in the specified form may depend on the form in which the record is available.	
(b) Access in the form requested may be refused in certain circumstances. In such a case you will be informed if access will be granted in another form.	
(c) The fee payable for access to the record, if any, will be determined partly by the form in which access is requested.	

1. If the record is in written or printed form:					
x	copy of record*		inspection of record		
2. If record consists of visual images - (this includes photographs, slides, video recordings, computer-generated images, sketches, etc.):					
	view the images	x	copy of the images*		transcription of the images*

FORM A: REQUEST FOR ACCESS TO RECORD OF PUBLIC BODY

3. If record consists of recorded words or information which can be reproduced in sound:					
<input checked="" type="checkbox"/>	listen to the soundtrack (audio cassette)	<input type="checkbox"/>	transcription of soundtrack* (written or printed document)	<input type="checkbox"/>	<input type="checkbox"/>
4. If record is held on computer or in an electronic or machine-readable form:					
<input type="checkbox"/>	printed copy of record*	<input checked="" type="checkbox"/>	printed copy of information derived from the record*	<input type="checkbox"/>	copy in computer readable form* (stiffy or compact disc)

*If you requested a copy or transcription of a record (above), do you wish the copy or transcription to be posted to you? Postage is payable.	YES <input checked="" type="checkbox"/>	NO <input type="checkbox"/>
	Please email	
Note that if the record is not available in the language you prefer, access may be granted in the language in which the record is available.		
In which language would you prefer the record? English		

G. Notice of decision regarding request for access

You will be notified in writing whether your request has been approved / denied. If you wish to be informed in another manner, please specify the manner and provide the necessary particulars to enable compliance with your request.
--

How would you prefer to be informed of the decision regarding your request for access to the record?

Via email correspondence at marlise@healthjusticeinitiative.org.za and info@healthjusticeinitiative.org.za

Signed at Cape Town this day 19th of July year 2021

.....
SIGNATURE OF REQUESTER /
PERSON ON WHOSE BEHALF REQUEST IS MADE



Appendix A:

19 July 2021

To whom it may concern

Letter of Authorisation: Health Justice Initiative (HJI)

To the extent that a letter of authority is requested, this is to confirm that Dr Marlise Richter is duly authorised to submit a request in terms of the *Promotion of Access to Information Act of 2000* on behalf of the Health Justice Initiative.

Yours sincerely,

*Fatima Hassan***Fatima Hassan****Director: Health Justice Initiative**

22 June 2021

National Department of Health

Acting Minister Mmamoloko Kubayi-Ngubane
Director General Dr Sandile Buthelezi (Information Officer)

Copies to:

The Presidency

Information Officer

National Assembly

The Office of the Speaker

SAHPRA

The CEO
Company Secretary

Dear Acting Minister Mmamoloko Kubayi-Ngubane and Director-General Dr Sandile Buthelezi

RE: REQUEST FOR THE VOLUNTARY DISCLOSURE AND AUTOMATIC AVAILABILITY OF NECESSARY PUBLIC INFORMATION DURING THE COVID-19 PANDEMIC

1. The Health Justice Initiative (**HJI**) is a dedicated public health and law initiative addressing the intersection between racial and gender inequality with a special focus on access to life-saving diagnostics, treatment and vaccines for COVID-19, TB and HIV.
2. Since November 2020 we have written on numerous occasions to the National Department of Health ("Department") and other relevant Ministries requesting information pertaining to the COVID-19 pandemic in order to foster transparency, disclosure and improved engagement and communication. This includes correspondence on the national vaccine programme, including on matters related to the acquisition, procurement, selection and prioritisation.
3. Our correspondence has been copied to relevant government departments and in certain cases also addressed/copied to statutory bodies including the South African Health Products Regulatory Authority (**SAHPRA**) and also, Parliament.



4. Aside from a single delayed and short response from the Director-General of Health on 8 March 2021, there has not been a detailed response from the Department to the many questions that we and our legal representatives have raised in our various correspondence during this pandemic, nor any significant disclosure of information, as has been requested. This is regrettable.

Open procurement and voluntary disclosure of information

5. As you are aware, section 217(1) Constitution requires that when an organ of state contracts for goods and services, it must do so in accordance with a system which is “**fair, equitable, transparent, competitive and cost-effective**”. In addition, section 15 of the Promotion of Access to Information Act 2 of 2000 (**PAIA**) enables the voluntary disclosure and automatic availability of records, *without* a person having to request access in terms of PAIA and without a fee.
6. Due to the ongoing public health crisis occasioned by the Covid-19 pandemic and also allegations of corruption in the health care sector, there is an urgent need for the voluntary disclosure and automatic availability of any and all information pertaining to the government’s Covid-19 response, particularly as it relates to the national vaccine programme. This is squarely a matter of public interest, which warrants openness and accountability from the government and a state-led approach to information-sharing.

Information that should be voluntarily disclosed and automatically accessible

7. Based on the foregoing, we request that the following information is voluntarily disclosed and made automatically accessible, free of charge:

- 7.1. **Copies of all Covid-19 vaccine procurement and supply contracts, agreements, meeting outcomes and/or minutes, and correspondence** including with the following parties and/or duly authorised licensed representatives of:

- 7.1.1. Johnson & Johnson.
 7.1.2. Aspen.
 7.1.3. Pfizer.
 7.1.4. Serum Institute of India / Cipla.
 7.1.5. Any other vaccine manufacturer / licensee.

- 7.1.6. The African Union Vaccine Access Task Team (AU AVATT).
- 7.1.7. 'COVAX' (with the Global Vaccine Alliance – GAVI /Other).

We have previously raised that notwithstanding private corporations, including those detailed above, reportedly requesting non-disclosure agreements (**NDAs**), there is a constitutional duty on the state to ensure open, transparent, and competitive procurement.

In addition, Section 231(3) of the Constitution, which pertains to international agreements, requires that such agreements be tabled in the National Assembly and the National Council of Provinces within a reasonable time.

We note that our correspondence in this regard has remained unacknowledged and unanswered.

- 7.2. **Copies of all and any outstanding MAC Vaccine Advisories**, including any other form of written advice to the Ministry of Health related to vaccine selection and age and/or other prioritisation factors from January 2021 to date, including any advice communicated by the Chairperson and / or Members of the MAC Vaccine Advisory Committee and / or SAHPRA, and any other form of communication to the Ministry of Health related to:

- 7.2.1. the decision and / or other advice on vaccine selection and specifically, pausing the use of the AstraZeneca (AZ) vaccine in South Africa and to donate and / or sell it;
- 7.2.2. the prioritisation of people over 60 years old and / or those with comorbidities;
- 7.2.3. the prioritisation of 'elite' athletes and sport officials, South African government officials and diplomats / others;
- 7.2.4. the prioritisation of teachers and school support staff / others.

We have repeatedly requested the publication of all MAC Advisories since 9 March 2021, yet not all advisories are publicly available as at 21 June 2021.

- 7.3. **Copies of all correspondence with and/or from SAHPRA, and/or any other entity and/or research or academic body and/or ethics committees** relating to the *request and approval* for 'elite' athletes to be prioritised, ahead of elderly and

other at-risk populations, for vaccine administration.

We note that our correspondence in this regard has also remained unanswered.

8. We request that the voluntary disclosures are made, or reasons for non-disclosure are given, by no later than **2 July 2021**, failing which we will formally submit relevant Promotion of Access to Information Act (PAIA) requests, if applicable, and/or pursue any other recourse that may be available to us. We hope that this will not have to be the case.
9. We sincerely hope that this letter and the request for the voluntary disclosures lead to meaningful and transparent engagements with the state and that the relevant stakeholders open channels for co-operation on these issues, which are far-reaching and will remain in the public interest for the foreseeable future.

We look forward to hearing from you.

Sincerely,



Fatima Hassan (Director)





DIRECTOR GENERAL
HEALTH
REPUBLIC OF SOUTH AFRICA

PRETORIA

Private Bag X828, PRETORIA, 0001, 27th Floor, Civitas Building, Cnr Thabo Sehume and Struben Street, PRETORIA, 0002 Tel (012) 395 8402 Fax (012) 395 8422

CAPE TOWN

P.O. Box 3875, CAPE TOWN, 8000, 103 Parliament Towers, Room 615, 120 Plain Street, CAPE TOWN, 8000 Tel (021) 461 2040 Fax (021) 461 6864

Attention: Ms Fatima Hassan
Director of Health Justice Initiative

E-mail: Althea@healthjusticeinitiative.org.za

Dear Ms Hassan

RE: REQUEST FOR VOLUNTARY DISCLOSURE AND AUTOMATIC AVAILABILITY OF NECESSARY PUBLIC INFORMATION DURING THE COVID-19 PANDEMIC

We refer to the above matter and to your correspondence dated 22 June 2021 addressed to the Information Officer of the National Department of Health.

We wish to advise you that following the receipt of your correspondence and in line with the Promotion of Access to Information Act 2 of 2000 (PAIA), we have resolved to:

- notify the vaccine manufacturers and distributors of your request for us to disclose the Vaccine Acquisition Agreements; and
- invite the vaccine manufacturers and distributors to make written or oral representations as to whether the request for access should be granted or refused (in whole or in part).

Given the need to consider their responses and then make an appropriate decision, we request your indulgence for us to revert with a formal response.

Kindly note that all advisories of the MAC on Vaccines can be found on the website of the sacoronavirus which is www.sacoronavirus.co.za

We trust that the above is in order and we look forward to hearing from you.

Kind Regards


Dr SSS Buthelezi
Director-General: Health
Date: 29/07/2021



6 August 2021

To:

Dr SSS Buthelezi
Director General: National Department of Health
 By email: dg@health.gov.za

Copy to:

Mr Justinos Motalaota
Deputy Information Officer: National Department of Health
 Per email: justinos.motalaota@health.gov.za

Dear Dr Buthelezi

**Health Justice Initiative's requests for information - Vaccine Contracts, Expert
 Advisories, Prioritisation Decisions**

1. Please convey our congratulations to the newly appointed Minister of Health, Dr Joe Phaahla.
2. We acknowledge receipt of your letter dated 29 July 2021.
3. As you will be aware, further to our letter dated 22 June 2021, and in the absence of any timely response, the Health Justice Initiative submitted three formal requests in terms of the Promotion of Access to Information Act 2 of 2000 ("PAIA") to the National Department of Health ("NDoH") in the public interest for which we duly received relevant acknowledgements of receipt, for two of the requests.
4. These three PAIA requests relate to: (1) all vaccine contracts (2) details about the Ministerial Advisory Committee/s (MAC) and its Advisories; and (3) prioritisation decisions including for the Sisonke programme.
5. Accordingly, we draw your attention to the following:
 - 5.1 **Vaccine Contracts (Our PAIA Ref: 001/NDoH/2021):** With regard to the vaccine contracts, we have noted your intention to consult with the vaccine manufacturers and distributors. We note further that, in terms of section 26 of PAIA, there is no basis to extend the time period for a PAIA request in order to consult with private bodies. However, we are amenable to granting you a one-



week extension, until **25 August 2021**, to respond to our request. We further request that we be given access to any of the submissions made by the vaccine manufacturers and distributors in this regard, so as to inform any further steps that may need to be taken.

- 5.2 **MAC advisories (Our PAIA Ref: 002/NDoH/2021):** We note our appreciation for some of the MAC advisories that have been made public thus far, although this information has been difficult to navigate in the absence of a contents list. Moreover, we emphasise that this does not respond in full to our PAIA request, dated 20 July 2021. For instance, we have not been provided with the relevant names relating to “all local and international expert advisors to the National Department of Health on Covid-19” as requested. We trust that full disclosure will be made in accordance with our PAIA request within the 30-day prescribed period, and by no later than **19 August 2021**.
- 5.3 **Sisonke programme (Our PAIA Ref: 003/NDoH/2021):** Your letter of 29 July 2021 does not address our PAIA request for information related to the Sisonke programme, dated 23 July 2021 (this request has not yet been formally acknowledged). We trust that full disclosure will be made in accordance with our PAIA request within the 30-day prescribed period, and by no later than **22 August 2021**.
6. Given the inherent urgency and public interest in these requests for information – as well as the constitutional rights and values of access to information, openness, transparency, and accountability – it is imperative that this information be made available without delay. We highlight that these requests are made in the context of the ongoing pandemic and a vaccine supply chain that is not always reliable. We are therefore not amenable to granting any further extensions in order to respond to our respective PAIA requests.
7. We trust that we will receive a response in accordance with the time periods set out above, if not, kindly note that we will have no option but to consider our further legal options in order to compel disclosure of this information in the public interest.

We await to hear from you.

Yours sincerely,



Fatima Hassan

Director – Health Justice Initiative



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.

By Rebecca Robbins and Benjamin Mueller

Aug. 16, 2021

Johnson & Johnson's Covid vaccine was supposed to be one of Africa's most important weapons against the coronavirus.

The New Jersey-based company agreed to sell enough of its inexpensive single-shot vaccine to eventually inoculate a third of the continent's residents. And the vaccine would be produced in part by a South African manufacturer, raising hopes that those doses would quickly go to Africans.

That has not happened.

South Africa is still waiting to receive the overwhelming majority of the 31 million vaccine doses it ordered from Johnson & Johnson. It has administered only about two million Johnson & Johnson shots. That is a key reason that fewer than 7 percent of South Africans are fully vaccinated — and that the country was devastated by the Delta variant.

At the same time, Johnson & Johnson has been exporting millions of doses that were bottled and packaged in South Africa for distribution in Europe, according to executives at Johnson & Johnson and the South African manufacturer, Aspen Pharmacare, as well as South African government export records reviewed by The New York Times.

Glenda Gray, a South African scientist who helped lead Johnson & Johnson's clinical trial there, said companies needed to prioritize sending doses to poorer countries that were involved in their production. "It's like a country is making food for the world and sees its food being shipped off to high-resource settings while its citizens starve," she said.

Many Western countries have kept domestically manufactured doses for themselves. That wasn't possible in South Africa because of an unusual stipulation in the contract the government signed this year with Johnson & Johnson. The confidential contract, reviewed by The Times, required South Africa to waive its right to impose export restrictions on vaccine doses.

Popo Maja, a spokesman for the South African 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."

Johnson & Johnson had always planned for some vaccines produced by Aspen to leave Africa, but it has never disclosed how many doses it was actually exporting. The export records reviewed by The Times show that Johnson & Johnson shipped 32 million doses in recent months, although that does not capture the full number that have left South Africa.

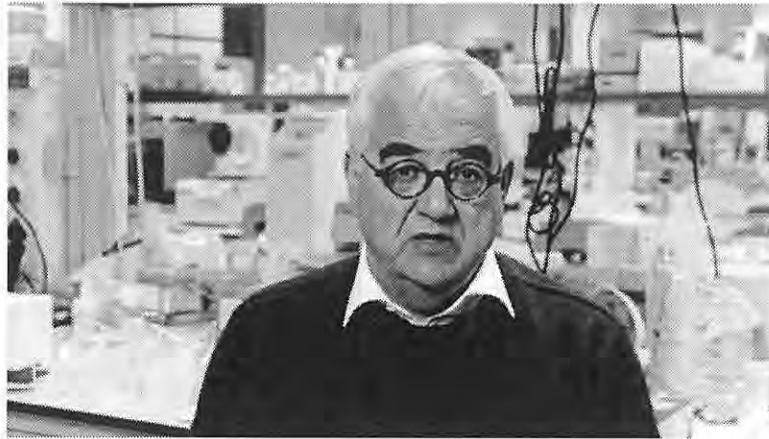
Germany in April received shots produced by Aspen, a spokesman for Germany's health ministry said. In June and July, Spain received more than 800,000 doses, according to the country's health ministry.

Critics say the shortfall in South Africa partly reflects a power imbalance between a giant company and a desperate country.

"The disproportionate amount of power that Johnson & Johnson has exercised is really concerning," said Fatima Hassan, a human rights lawyer in South Africa. "It is harming our efforts to get speedy supplies into the system."

The picture is bleak across the continent. While several African countries received small initial shipments of Johnson & Johnson doses last week, they are a sliver of the 400 million doses that the African Union has ordered or has the option to order for its member countries. About 2 percent of Africans are fully vaccinated.

Johnson & Johnson's chief scientific officer, Dr. Paul Stoffels, said the Aspen plant is part of a production network in which vaccines are routinely shipped between countries for manufacturing, quality inspection and delivery.



Dr. Paul Stoffels, Johnson & Johnson's chief scientific officer, says the Aspen plant is part of a global production network. Janssen Vaccines, via Reuters

"We have done our best to prioritize South Africa as much as we can," he said. He noted that Johnson & Johnson early this year provided about 500,000 doses to vaccinate South African health care workers. He said the Aspen plant would exclusively supply doses to African countries later this year.

Aspen is responsible for the final stage of vaccine production, a process known as "fill and finish." The company receives mass quantities of the vaccine, bottles it into vials and then packages it for final inspections and delivery.

Some of Aspen's doses were never used because of worries they might have been contaminated at the Baltimore plant that handled their first stage of production, according to Johnson & Johnson and Aspen executives. The problems at that plant, run by Emergent BioSolutions, wreaked havoc on Johnson & Johnson's vaccine supplies, leading the company to fall behind on orders all over the world.

The Coronavirus Pandemic ›

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- The pandemic was the No. 1 issue for many voters in California's recall election.
- The E.U. will create an agency to guide its response to future pandemics.

Stephen Saad, Aspen's chief executive, blamed the lack of South African doses on the Emergent plant. He said Aspen could not control where its doses were sent, but "I would have liked to see it all go to Africa."

Aspen is now finishing doses that were made at a plant in the Netherlands, with 40 percent of those doses going to Europe and the remaining 60 percent to Africa through the end of September. Previously, the plan was for only 10 percent to go to the continent, but the European Union agreed to change the distribution in light of South Africa's crisis, said Daniel Ferrie, a spokesman for the European Commission.

South Africa's vaccination campaign has accelerated in recent weeks, thanks largely to Pfizer doses ordered by the government and shots donated by the United States. But about four million of the country's 60 million residents are fully vaccinated.

That left the population vulnerable when a third wave of cases crested over the country. At times in recent months, scores of Covid-19 patients at Helen Joseph Hospital in Johannesburg were waiting in the emergency department for a bed, and the hospital's infrastructure struggled to sustain the huge volumes of oxygen being piped into patients' lungs, said Dr. Jeremy Nel, an infectious-disease doctor there.

"The third wave, in terms of the amount of death we saw, was the most heartbreaking, because it was the most avoidable," Dr. Nel said. "You see people by the dozens dying, all of whom are eligible for a vaccine and would've been among the first to get it."



Dr. Jeremy Nel, an infectious-disease doctor in Johannesburg. Gulshan Khan for The New York Times

Critics say South Africa's government shares blame for the low rate of vaccinations. Early on, the government relied on a [United Nations-backed clearinghouse for vaccines](#) that has fallen behind on deliveries. South Africa was slow to enter negotiations with manufacturers for its own doses. In January, a [group of vaccine experts warned](#) that the government's "lack of foresight" could cause "the greatest man-made failure to protect the population since the AIDS pandemic."

Johnson & Johnson's deal with Aspen was [announced in November](#). Aspen's facility in Gqeberha, on South Africa's southern coast, was the first site in Africa to produce Covid vaccines. (Other companies subsequently announced plans to produce vaccines on the continent.)

Understand Vaccine and Mask Mandates in the U.S.

- **Vaccine rules.** On Aug. 23, the Food and Drug Administration [granted full approval to Pfizer-BioNTech's coronavirus vaccine](#) for people 16 and up, paving the way for an increase in mandates in both the public and private sectors. Private companies have been [increasingly mandating vaccines](#) for employees. Such mandates are [legally allowed](#) and have been upheld in court challenges.
- **Mask rules.** The Centers for Disease Control and Prevention in July [recommended](#) that all Americans, regardless of vaccination status, wear masks in indoor public places within areas experiencing outbreaks, a reversal of the guidance it offered in May. [See where the C.D.C. guidance would apply](#), and where [states have instituted their own mask policies](#). The battle



South African officials hailed Aspen's involvement as indispensable.

Aspen "belongs to us as South Africans, and it is making lifesaving vaccines," South Africa's president, Cyril Ramaphosa, [said](#) during a visit to Aspen's plant in March. He said he had pushed Johnson & Johnson to prioritize the doses made there for Africans.

"I want them now," Mr. Ramaphosa added. "I've come to fetch our vaccines."



President Cyril Ramaphosa, right, and other South African officials touring the Gqeberha plant in March. Getty Images

The Johnson & Johnson vaccine became even more important in February when the results of a clinical trial suggested that the vaccine from AstraZeneca offered little protection from mild or moderate infections caused by the Beta variant that was circulating in South Africa.

Weeks later, Johnson & Johnson and the government signed a contract for 11 million doses. South Africa ordered another 20 million doses in April. That would be enough to vaccinate about half the country.

South Africa agreed to pay \$10 per dose for the 11 million shots, according to the contract. That was the same price that the United States paid and slightly more than the \$8.50 that the European Commission agreed to pay. The South African contract prohibited the government from banning exports of the vaccine, citing the need for doses to “move freely across national borders.”

Mr. Maja, the South African health ministry spokesman, said that absent that stipulation, the government might have stopped vaccine doses from leaving the country.

But the requirement put South Africa at a disadvantage compared with other places that were producing Covid vaccines.

The European Union introduced export controls this year to conserve scarce supplies. India halted exports produced by the Serum Institute, which was supposed to be a major vaccine supplier to poor countries. In the United States, officials said they didn’t ban exports, but they didn’t need to. The combination of the extensive vaccine production on American soil and the high prices the U.S. government was willing to pay meant that companies made the delivery of shots for Americans a priority.

Other benefits for Johnson & Johnson were embedded in the South African contract.

While such contracts typically protect companies from lawsuits brought by individuals, this one shielded Johnson & Johnson from suits by a wider range of parties, including the government. It also imposed an unusually high burden on potential litigants to show that any injuries caused by the vaccine were the direct result of company representatives engaging in deliberate misconduct or failing to follow manufacturing best practices.

“The upshot is that you have moved almost all of the risk of something being wrong with the vaccine to the government,” said Sam Halabi, a health law expert at Georgetown University who reviewed sections of the South African contract at the request of The Times.

Mr. Halabi said the contract’s terms appeared more favorable to the pharmaceutical company than other Covid vaccine contracts he had seen. South African officials have said Pfizer, too, sought aggressive legal protections.

The contract said Johnson & Johnson would aim to deliver 2.8 million doses to South Africa by the end of June, another 4.1 million doses by the end of September and another 4.1 million doses by the end of December. (The government expects the 20 million additional doses to be delivered by the end of this year, Mr. Maja said.)

The company has so far fallen far short of those goals. As of the end of June, South Africa had received only about 1.5 million of the doses from its order. The small number of doses that have been delivered to the African Union were on schedule.

The difficulties in procuring doses have revealed the limits of fill-and-finish sites, which leave countries dependent on vaccines from places like the European Union or the United States, said Dr. Salim Abdool Karim, who until March was co-chairman of South Africa’s ministerial advisory committee on Covid.

“Ultimately,” he said, “the solution to our problem has to be in making our own vaccines.”

Lynsey Chutel and Choe Sang-Hun contributed reporting.

Correction: Aug. 16, 2021

An earlier version of a picture caption with this article reversed the identifications of two South African officials. President Cyril Ramaphosa is on the right, and the health minister at the time, Dr. Zweli Mkhize, is on the left.

Rebecca Robbins joined The Times in 2020 as a business reporter focused on covering Covid-19 vaccines. She has been reporting on health and medicine since 2015. [@RebeccaDRobbins](#)

Benjamin Mueller is a United Kingdom correspondent for The New York Times. Before that, he had been a police and law enforcement reporter on the Metro desk since 2014. [@benjmueller](#)

A version of this article appears in print on , Section B, Page 1 of the New York edition with the headline: Africa Needs Vaccines. So Why Is It Exporting?



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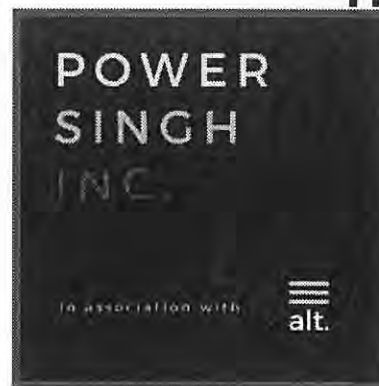
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Date: 8 December 2021

Your ref:

Our ref: PSIHJ-202120

TO: DR MATHUME JOSEPH PHAAHLA

Minister of Health

National Department of Health

Email: minister@health.gov.za

Dear Dr. Phaahla

HIGH COURT PROCEEDINGS FOR THE DISCLOSURE OF COVID VACCINE AGREEMENTS AND RELATED INFORMATION

1. We act for the Health Justice Initiative ("HJI"). HJI is a public health and law initiative dedicated to addressing inequities in access to healthcare through research, advocacy, and legal action. It works to ensure a more inclusive and equitable public health system that includes access to lifesaving diagnostics, treatment, and vaccines.
2. In terms of the Promotion of Access to Information Act ("PAIA"), HJI has sought access from the Department of Health to:
 - 2.1. the various agreements that the South African government, through its National Department of Health, has concluded with pharmaceuticals manufacturers and/or their licensees, the African Union Vaccine Task Team, COVAX and/or the Solidarity Fund for the domestic supply of Covid-19 vaccines; and

// **Directors:** A Singh B.Comm., LL.B. (UP), MJ Power B.A., LL.B., LL.M. (Wits) | **Senior Associate:** T Power B.A., LL.B., LL.M. (Wits).
Associates: T Davis B.A. (RU), LL.B. (UCT), S Khumalo LL.B. (Wits) | **Office Manager:** J Rashid | **Technology Officer:** K Nwana.
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A handwritten signature in black ink, appearing to be 'J. Rashid', is located in the bottom right corner of the page.

- 2.2. the meeting outcomes, minutes, and/or correspondence relating to the negotiation thereof (collectively, "the records").
3. The Department's information officer failed to grant our client's request, and your office failed to respond to or uphold its internal appeal.
4. Our client accordingly intends to apply to court for disclosure of the records. It wishes to join the National Department of Health's counterparties to the relevant negotiations and agreements, since they may have an interest in that application.
5. To that end, please could you provide us with the names and details of each of the vaccine manufacturers, licensees, Funds, trusts, and other entities that the Department negotiated and/or concluded vaccine-related agreements with.
6. We hope to avoid further unnecessary delay but are mindful of office closures during the end of year break. We accordingly request your response by no later than 7 January 2022.

Yours faithfully,



POWER SINGH INC.

Per: Tara Davis | *Associate*

E-mail: tara@powersingh.africa



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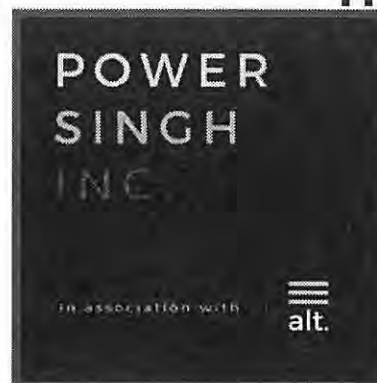
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Date: 8 December 2021**Your ref:****Our ref:** PSIHJ-202120**TO: JANSSEN PHARMACEUTICA SOUTH AFRICA**

Johnson & Johnson Campus

2 Medical Road, Midrand

Gauteng

South Africa

Email: JGCC_EMEA@its.jnj.com

Dear Madam / Sir

HIGH COURT PROCEEDINGS FOR THE DISCLOSURE OF COVID VACCINE AGREEMENTS AND RELATED INFORMATION

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2. In terms of the Promotion of Access to Information Act ("PAIA"), HJI has sought access from the National Department of Health (NDOH) to:
 - 2.1. the various agreements that the South African government, through its National Department of Health, has concluded with pharmaceuticals manufacturers and/or their licensees, the African Union Vaccine Task Team, COVAX and/or the Solidarity Fund for the domestic supply of Covid-19 vaccines; and

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A handwritten signature in black ink, appearing to be "S. J.", is located in the bottom right corner of the page.

- 2.2. the meeting outcomes, minutes, and/or correspondence relating to the negotiation thereof (collectively, "the records").
3. The NDOH failed to provide our client with access to the records, either in response to its initial request or pursuant to the internal appeal it lodged thereafter.
4. Our client accordingly intends to apply to court for disclosure of the records. It wishes to join the NDOH's counterparties to the relevant negotiations and agreements, since they may have an interest in that application.
5. It is clear from information in the public domain that the NDOH negotiated with and/or concluded agreement(s) with your group of companies in respect of the supply of Covid-19 vaccines. We have, however, been unable to ascertain which entity in the group acted as the NDOH's counterparty.
6. In the circumstances and to enable proper joinder, please advise us which entity in the group was the NDOH's counterparty to the negotiations and any ultimate agreement(s), and provide us with a South African address at which we may serve the application on them.
7. We hope to avoid unnecessary delay, but are mindful of office closures during the end of year break. We accordingly request your response by no later than 7 January 2022.

Yours faithfully,



POWER SINGH INC.

Per: Tara Davis | *Associate*

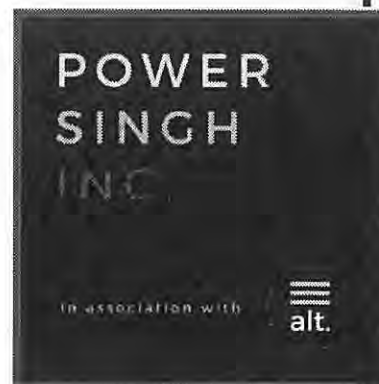
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Date: 8 December 2021

Your ref:

Our ref: PSIHJ-202120

TO: PFIZER SOUTH AFRICA

85 Bute Lane
Sandton
South Africa
Email: SouthAfricaInformationOfficer@pfizer.com

Dear Madam / Sir

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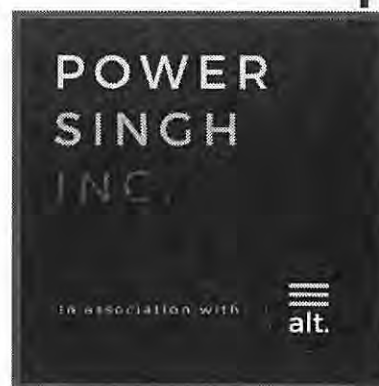
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Date: 8 December 2021**Your ref:****Our ref:** PSIHJ-202120**TO: SERUM INSTITUTE OF INDIA PVT. LTD**

212/2, Hadapsar, Off Soli Poonawalla Road

Pune 411028

India

Email: contact@seruminstitute.com

Dear Madam / Sir

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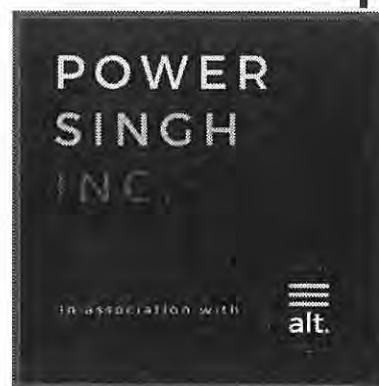
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Date: 8 December 2021**Your ref:****Our ref:** PSIHJ-202120**TO: GAVI, THE VACCINE ALLIANCE**

Global Health Campus

Chemin du Pmmier 40

1218 Le Grand-Saconnex

Switzerland

Email: info@gavi.org | covax@gavi.org

Dear Madam / Sir

HIGH COURT PROCEEDINGS FOR THE DISCLOSURE OF COVID VACCINE AGREEMENTS AND RELATED INFORMATION

1. We act for the Health Justice Initiative ("HJI"). HJI is a public health and law initiative dedicated to addressing inequities in access to healthcare through research, advocacy, and legal action. It works to ensure a more inclusive and equitable public health system that includes access to lifesaving diagnostics, treatment, and vaccines.
2. In terms of the Promotion of Access to Information Act ("PAIA"), HJI has sought access from the National Department of Health (NDOH) to:
 - 2.1. the various agreements that the South African government, through its National Department of Health, has concluded with pharmaceuticals manufacturers and/or their licensees, the African Union Vaccine Task Team, COVAX and/or the Solidarity Fund for the domestic supply of Covid-19 vaccines; and

// **Directors:** A Singh B.Comm., LL.B. (UP), MJ Power B.A., LL.B., LL.M. (Wits) | **Senior Associate:** T Power B.A., LL.B., LL.M. (Wits).
Associates: T Davis B.A. (RU), LL.B. (UCT), S Khumalo LL.B. (Wits) | **Office Manager:** J Rashid | **Technology Officer:** K Nwana.
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A handwritten signature in black ink, appearing to be 'SC' or similar initials, located at the bottom right of the page.

- 2.2. the meeting outcomes, minutes, and/or correspondence relating to the negotiation thereof (collectively, "the records").
3. The NDOH failed to provide our client with access to the records, either in response to its initial request or pursuant to the internal appeal it lodged thereafter.
4. Our client accordingly intends to apply to court for disclosure of the records. It wishes to join the NDOH's counterparties to the relevant negotiations and agreements, since they may have an interest in that application.
5. It is clear from information in the public domain that the NDOH negotiated with and/or concluded agreement(s) with Gavi / the COVAX Facility for the supply of vaccines.
6. In the circumstances and to enable proper joinder, please advise us which entity was the NDOH's counterparty to the negotiations and any ultimate agreement(s), and provide us with a South African address at which we may serve the application on them.
7. We hope to avoid unnecessary delay, but are mindful of office closures during the end of year break. We accordingly request your response by no later than 7 January 2022.

Yours faithfully,



POWER SINGH INC.

Per: Tara Davis | *Associate*

E-mail: tara@powersingh.africa



// POWER SINGH INCORPORATED

LPC Reg. No: F18433 | CIPC Reg. No: 2018/071686/21

Public Interest Law.

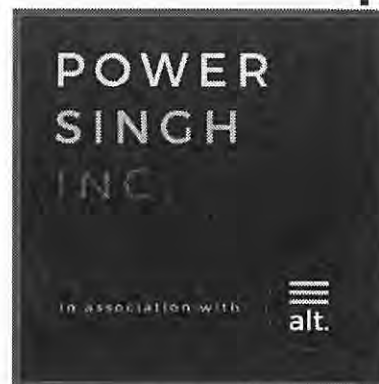
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Date: 11 January 2022

Your ref:

Our ref: PSIHJ-202120

TO: DR MATHUME JOSEPH PHAAHLA

Minister of Health

National Department of Health

Email: minister@health.gov.za | justinos.motalaota@health.gov.za

Dear Madam / Sir

REQUEST FOR RESPONSE

1. We act for the Health Justice Initiative ("HJI").
2. Our letter of 8 December 2021 refers wherein we requested the names and details of each of the vaccine manufacturers, licensees, Funds, trusts and other entities that the Department negotiated and/or concluded vaccine-related agreements with.
3. We requested a response by 7 January 2022, which time has now lapsed. To date, we have not received a response.
4. Kindly provide us with a response by no later than the close of business on **Friday, 14 December 2022.**

// **Director:** MJ Power B.A., LL.B., LL.M. (Wits) | **Senior Associate:** T Power B.A., LL.B., LL.M. (Wits)
Associates: T Davis B.A. (RU), LL.B. (UCT), S Khumalo LL.B. (Wits) | **Office Manager:** J Rashid | **Technology Officer:** K Nwana.
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A handwritten signature in black ink, appearing to be the initials "JS" followed by a stylized flourish.

Yours faithfully,



POWER SINGH INC.

Per: Tara Davis | *Associate*

E-mail: tara@powersingh.africa



101
"HJI11"

// POWER SINGH INCORPORATED

LPC Reg. No: F18433 | CIPC Reg. No: 2018/071686/21

Public Interest Law.

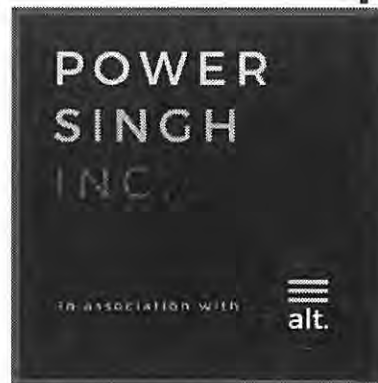
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Date: 11 January 2022

Your ref:

Our ref: PSIHJ-202120

TO: JANSSEN PHARMACEUTICA SOUTH AFRICA

Johnson & Johnson Campus

2 Medical Road, Midrand

Gauteng

South Africa

Email: JGCC_EMEA@its.jnj.com | RA-JACZA-MedInfo@ITS.INI.com

Dear Madam / Sir

REQUEST FOR RESPONSE

1. We act for the Health Justice Initiative ("HJI").
2. Our letter of 8 December 2021 refers wherein we requested the name and service address of the entity within your group that contracted with the South African government, through its National Department of Health, for the supply of Covid-19 vaccines.
3. We requested a response by 7 January 2022, which time has now lapsed. To date, we have not received a response.
4. Kindly provide us with a response by no later than the close of business on **Friday, 14 December 2022.**

// Director: MJ Power B.A., LL.B., LL.M. (Wits) | Senior Associate: T Power B.A., LL.B., LL.M. (Wits)

Associates: T Davis B.A. (RU), LL.B. (UCT), S Khumalo LL.B. (Wits) | Office Manager: J Rashid | Technology Officer: K Nwana.

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A handwritten signature in black ink, appearing to be 'S. Power' or similar, located at the bottom right of the page.

Yours faithfully,



POWER SINGH INC.

Per: Tara Davis | *Associate*

E-mail: tara@powersingh.africa



// POWER SINGH INCORPORATED

LPC Reg. No: F18433 | CIPC Reg. No: 2018/071686/21

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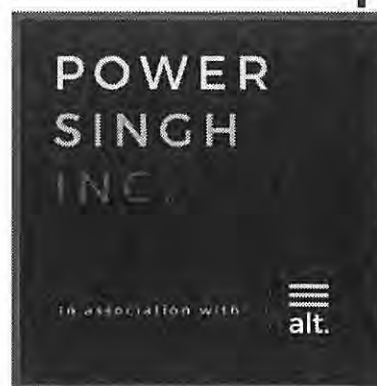
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Date: 11 January 2022

Your ref:

Our ref: PSIHJ-202120

TO: SERUM INSTITUTE OF INDIA PVT. LTD
212/2, Hadapsar, Off Soli Poonawalla Road
Pune 411028
India
Email: contact@seruminstitute.com

Dear Madam / Sir

REQUEST FOR RESPONSE

1. We act for the Health Justice Initiative ("HJI").
2. Our letter of 8 December 2021 refers wherein we requested the name and service address of the entity within your group that contracted with the South African government, through its National Department of Health, for the supply of Covid-19 vaccines.
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// Director: MJ Power B.A., LL.B., LL.M. (Wits) | Senior Associate: T Power B.A., LL.B., LL.M. (Wits)
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Yours faithfully,



POWER SINGH INC.

Per: Tara Davis | *Associate*

E-mail: tara@powersingh.africa



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Public Interest Law.

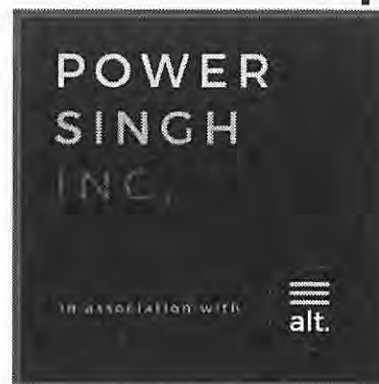
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Date: 11 January 2022

Your ref:

Our ref: PSIHJ-202120

TO: GAVI, THE VACCINE ALLIANCE

Global Health Campus

Chemin du Pommier 40

1218 Le Grand-Saconnex

Switzerland

Email: info@gavi.org | covax@gavi.org

Dear Madam / Sir

REQUEST FOR RESPONSE

1. We act for the Health Justice Initiative ("HJI").
2. Our letter of 8 December 2021 refers wherein we requested the name and service address of the entity that contracted with the South African government, through its National Department of Health, for the supply of Covid-19 vaccines.
3. We requested a response by 7 January 2022, which time has now lapsed. To date, we have not received a response.
4. Kindly provide us with a response by no later than the close of business on **Friday, 14 December 2022.**

// **Director:** MJ Power B.A., LL.B., LL.M. (Wits) | **Senior Associate:** T Power B.A., LL.B., LL.M. (Wits)

Associates: T Davis B.A. (RU), LL.B. (UCT), S Khumalo LL.B. (Wits) | **Office Manager:** J Rashid | **Technology Officer:** K Nwana.
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A handwritten signature in black ink, appearing to be 'T Power', is located in the bottom right corner of the page.

Yours faithfully,



POWER SINGH INC.

Per: Tara Davis | *Associate*

E-mail: tara@powersingh.africa



Tara Davis

From: South Africa Information Officer <SouthAfricaInformationOfficer@pfizer.com>
Sent: Friday, 07 January 2022 13:03
To: Tara Davis; South Africa Information Officer
Cc: 'Tina Power'
Subject: RE: [EXTERNAL] [PSIHJ] Correspondence to Pfizer South Africa

Good Day,

I trust this email finds you well.

The information you request is itself confidential and protected from disclosure, and cannot be provided.

Kind Regards,
Pfizer Information Officer

From: Tara Davis <tara@powersingh.africa>
Sent: Wednesday, December 8, 2021 2:27 PM
To: South Africa Information Officer <SouthAfricaInformationOfficer@pfizer.com>
Cc: 'Tina Power' <tina@powersingh.africa>
Subject: [EXTERNAL] [PSIHJ] Correspondence to Pfizer South Africa

Dear Madam / Sir

PSIHJ-202120: HIGH COURT PROCEEDINGS FOR THE DISCLOSURE OF COVID VACCINE AGREEMENTS AND RELATED INFORMATION

1. We act for the Health Justice Initiative.
2. Kindly find the attached correspondence marked for your attention.
3. Kindly acknowledge receipt.

Yours faithfully

Tara Davis

Power Singh Inc

3, Soveraile, 201 Victoria Road, G & B (Pretoria) G & B (JHB)



e tara@powersingh.africa

t +2711 266 6881

w powersingh.africa

a First Floor, 20 Baker Street, Rosebank, South Africa, 2196



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Handwritten signature or initials, possibly 'S. H.' or similar, written in black ink.

Tara Davis

From: Justinos Motalaota <justinos.motalaota@health.gov.za>
Sent: Tuesday, 11 January 2022 10:24
To: Tara Davis
Cc: Ayanda Ngubo
Subject: Re: [PSIHJ-202120] Follow-up Correspondence

Good morning Tara,

We hereby acknowledge receipt of your instant correspondence.

Kindly be informed that as per confidential agreements, the National Department of Health is not at liberty to divulge such details/information.

Best Regards

Justinos

From: Tara Davis <tara@powersingh.africa>
Sent: Tuesday, 11 January 2022 09:43
To: Minister <minister@health.gov.za>; Justinos Motalaota <justinos.motalaota@health.gov.za>
Cc: 'Tina Power' <tina@powersingh.africa>
Subject: RE: [PSIHJ-202120] Follow-up Correspondence

Dear Dr. Phaahla

PSIHJ-202120: REQUEST FOR RESPONSE

1. We act for the Health Justice Initiative and refer to our previous correspondence of 8 December 2021, attached for ease of reference.
2. Kindly find attached correspondence marked for your attention.
3. Kindly acknowledge receipt.

Yours faithfully

Tara Davis

Power Singh Inc.

Attorneys-Admitted (PSA) & (PFA) (Pretoria, South Africa)



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From: Tara Davis <tara@powersingh.africa>
Sent: Wednesday, 08 December 2021 13:59
To: 'minister@health.gov.za' <minister@health.gov.za>
Cc: 'Tina Power' <tina@powersingh.africa>
Subject: [PSIHJ-202120] Correspondence

Dear Dr. Phaahla

PSIHJ-202120: HIGH COURT PROCEEDINGS FOR THE DISCLOSURE OF COVID VACCINE AGREEMENTS AND RELATED INFORMATION

1. We act for the Health Justice Initiative.
2. Kindly find the attached correspondence marked for your attention.
3. Kindly acknowledge receipt.

Yours faithfully

Tara Davis

Power Singh Inc.

Associate Attorney (RSA) B.A. (Rhodes), LL.B. (UCT)



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w powersingh.africa

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A handwritten signature in black ink, appearing to be "Tara Davis".

CORONAVIRUS

Pfizer backs down over 'unreasonable' terms in South Africa vaccine deal

Madlen Davies Rosa Furmeaux 19 Apr 2021



The priority for Africa is to achieve herd immunity for Covid-19, the head of the Africa Centres for Disease Control and Prevention (Africa CDC) said at a weekly briefing on Thursday. (Photo by Vincent Kalut / Photonews via Getty Images)

Pfizer has backed down over its controversial demand that the South African government put up sovereign assets guaranteeing an indemnity against the cost of any future legal cases, the Bureau of Investigative Journalism can reveal.

During Covid-19 vaccine negotiations, the company sought indemnity against civil claims from citizens who had experienced adverse vaccine effects — meaning that the government would have to cover the costs instead.

On Wednesday, South African Health Minister Zweli Mkhize, voiced frustrations about “difficult and sometimes unreasonable” terms his country’s government had been presented with during contract negotiations with vaccine manufacturers, including Pfizer.

In a briefing letter sent ahead of his appearance at the parliamentary health committee, Mkhize said one condition in particular demanded by Pfizer was “too risky” — that the country put up sovereign assets as potential collateral.

Internationally Pfizer wanted indemnity

In its negotiations to provide vaccines to countries worldwide, Pfizer has asked governments for wide-ranging indemnity protection against any civil claims a citizen might file.

This means that if Pfizer were to be sued by someone who had suffered a rare adverse effect from the vaccine, then the government, not the company, would have to pay for legal costs and compensation.

This would apply even if the case were brought due to the company's own acts of negligence, fraud or malice.

In other negotiations, Pfizer went further. The company required some Latin American governments to put up sovereign assets, including federal bank reserves, embassy buildings or military bases — as a guarantee against indemnifying the cost of future legal cases. This was reported by the Bureau in February and picked up by more than 25 media organisations worldwide.

Pfizer told the Bureau: "Pfizer and BioNTech have no intention of interfering with any country's diplomatic, military, or culturally significant assets."

Unredacted draft contracts between Pfizer and the Dominican Republic, Albania and Peru show that the company sought to be indemnified against problems at any step of the supply chain — including packaging, manufacturing and storage. Experts told the Bureau it was "unreasonable" to require governments to pick up the bill for any negligence by Pfizer.

In South Africa's case, Mkhize said the clauses "posed a potential risk to our assets and fiscus [public purse]". He described how Pfizer's late demand caused delays in the discussions, which in turn put back the anticipated vaccine-delivery dates.

Mkhize wrote that the government was "relieved" when Pfizer eventually conceded and removed the "problematic term". He added: "As the government, we 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."

A level playing field

Experts have raised concerns that Pfizer and some other big pharma companies have demanded complete confidentiality during the recent vaccine negotiations, which would prevent the public from knowing about issues including indemnity protection and price. In South Africa, there are fears that any such secrecy clauses could undo public trust built up by years of anti-corruption work.

"I think it is important that this [sovereign assets] clause has been taken out," said Georg Neumann of the not-for-profit organisation Open Contracting Partnership.

"When contracts are negotiated in secret, companies have the power to dictate the terms. And I think what we're seeing here is that transparency — when contracts with other countries have been made public — has improved that balance and created a bit more of a level playing field."

A contract for 30-million doses of Pfizer vaccine has now been signed at \$10 a dose. Nearly two million doses are scheduled to arrive in South Africa in May and 2.5-million in June. The government has made down payments in its deals with Pfizer and Johnson & Johnson, which are not refundable under any circumstance.

"This is another onerous term that we had to concede as manufacturers were not prepared for it to be removed," Mkhize wrote.

Yousuf Vawda, a professor at the University of KwaZulu-Natal's law school, said: "While Pfizer appears to have dropped its demand on sovereign assets, it has still insisted on the indemnity and no-fault compensation commitments ... Such conduct must be condemned in the strongest terms, as they are holding governments to ransom and delaying the rollout of vaccination."

More talk as Covid-19 tally rises

Pfizer told the Bureau: "Pfizer and BioNTech seek the same kind of indemnity and liability protections they have in the US in all of the countries that have asked to purchase our vaccine, consistent with the applicable local laws.

"In markets that do not have the legal or legislative protections that are available in the US, we work with governments to find mutually agreeable solutions, including contractual indemnity clauses."

The delayed Pfizer deal arrives as South Africa is facing a third wave of Covid-19. In total, the country has recorded nearly 1.6-million cases and more than 53 000 deaths.

Its response has been complicated because current vaccines appear to be less effective against the dominant variant circulating in the country. Less than a quarter of the country's 1.2-million frontline health workers have been vaccinated, using doses donated by Johnson & Johnson. However, its roll-out has been suspended to investigate a potential link to blood clots. South Africa decided to sell or donate 1.5-million doses of the AstraZeneca/Oxford vaccine when a small study suggested the jab might not adequately prevent mild or moderate illnesses in patients with the country's dominant variant.



National Treasury is taking a hard line on the indemnification of pharmaceutical companies against vaccine “adverse events”, potentially putting the lives of huge numbers of South Africans at risk, frustrating the Department of Health (DOH) and complicating the negotiations with vaccine producers.



Listen to this article

0:00 / 5:48 1X

The indemnification of pharmaceutical companies against “serious adverse events” during the vaccination process is internationally regarded as a vital precursor to the widespread roll-out of vaccines and forms part of all the current existing contracts.

Normally, pharmaceutical companies can insure against the risk of some of its vaccines causing harm which typically happens in a minuscule proportion of cases. But the astronomical size of the Coronavirus vaccine roll-out means even this tiny risk could turn into a huge financial risk to the producers of vaccines.

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news, analysis, and opinions you need
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Consequently, governments which have already signed contracts with vaccine producers normally include a clause indemnifying the producers and try hard to find workarounds to ensure that the world can effectively start combatting the virus outbreak.

In South Africa, however, there is a complication – the indemnification of companies that contract with government is prohibited in the normal course of events by Section 66 of the Public Finance Management Act (PFMA).

Speaking during a briefing with the SA National Editors' Forum, Treasury Director-General Dondo Mogajane complained about “onerous clauses” the pharmaceutical companies wanted health officials to sign.

Mogajane complained that the pharmaceutical companies were “holding a gun to our heads”. “And then when things go wrong, you will blame government and say government or Treasury had an issue”. He called for companies to “play fair”.

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From Treasury's perspective, it is attempting to ensure contractual legality and equity, possibly mindful of the long battle with pharmaceutical companies over the HIV vaccine and intellectual property rights, which was eventually won by people living with HIV.

But from the perspective of the DOH, the Covid-19 crisis is a different situation entirely, and it considers Treasury's attitude to be a kind of absurd dunderheadedness which is putting hundreds of thousands of lives at risk.

According to one observer with intimate knowledge of the negotiations, Treasury doesn't seem to appreciate that there is nothing forcing pharmaceutical companies to provide vaccines to South Africa. On the contrary, they have hundreds of alternative buyers desperate for their products. For SA in these circumstances to insist on pharmaceutical companies accepting the full risk contrary to the normal practice around the world is an act of monumental stupidity, said the observer.

It's also hypocritical since SA did suspend the Public Finance Management Act's indemnity requirements during the Soccer World Cup, indemnifying the Fédération Internationale de Football Association (Fifa) from a wide array of potential risks. The comparison plays badly for SA, which is now apparently in the invidious position of being quite happy to suspend the PFMA for soccer games but is not prepared to do so to save the lives of thousands of its citizens.

While section 66 does, in general, prohibit different branches of government from indemnifying service and product providers, it

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does **allow** the Treasury to suspend this clause with the explicit, written permission of the Treasury.

But DOH officials have faced enormous difficulty getting this sign-off, which was also apparently the reason why SA was late in paying its contribution of the Covax facility, the attempt to coordinate an international response to the vaccine issue by the international Vaccine Alliance, Gavi.

Covax recognised early the issue of indemnity could potentially be a stumbling block to quick vaccine delivery, and has established a workaround which essentially entails a general fund that can be claimed against in the event of “serious adverse events”.

SA already has comparable examples with the Compensation for Occupational Injuries and Diseases Act and the Road Accident Fund. Another workaround could be to utilise part of the Solidarity Fund

But importantly, Covax and Gavi both operate from the basis that there really is no alternative but to indemnify the vaccine providers.

In a recent dispute over vaccine delivery, the European Union took the unusual step of publishing a redacted version of the contract (<https://ec.europa.eu/commission/presscorner/de>) it signed with pharma company AstraZeneca, which includes a very explicit liability exemption.

It is understood that the same kind of clause is likely to be in contracts with the Serum Institute of India, which SA has already signed for emergency use after it became clear the SA government was behind the international curve on buying vaccines.

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At the time of publication, neither Treasury nor the DOH had responded to *Business Maverick's* questions on the indemnity issue. Their comments will be added if and when they are received.

BM/DM

Information pertaining to Covid-19, vaccines, how to control the spread of the virus and potential treatments is ever-changing. Under the South African Disaster Management Act Regulation 11(5)(c) it is prohibited to publish information through any medium with the intention to deceive people on government measures to address COVID-19. We are therefore disabling the comment section on this article in order to protect both the commenting member and ourselves from potential liability. Should you have additional information that you think we should know, please email letters@dailymaverick.co.za

We have to work harder

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QUESTIONS ASKED OF DEPT AFTER REPORT THAT J&J SHIPPING SA-MADE JABS TO EUROPE

The New York Times is reporting due to an unusual stipulation in the contract that our government signed with Johnson and Johnson, South Africa has waived its right to impose export restrictions on vaccines.



Vials and syringes of the Johnson and Johnson Janssen COVID-19 vaccine are displayed for a photograph at a Culver City Fire Department vaccination clinic on 5 August 2021, in California. Picture: Patrick T. Fallon/AFP

[Coronavirus \(https://ewn.co.za/topic/coronavirus\)](https://ewn.co.za/topic/coronavirus) [COVID-19 \(https://ewn.co.za/topic/covid-19\)](https://ewn.co.za/topic/covid-19) [Health Department \(https://ewn.co.za/topic/health-department\)](https://ewn.co.za/topic/health-department)
[Mia Lindeque \(https://ewn.co.za/contributors/mia-lindeque\)](https://ewn.co.za/contributors/mia-lindeque) | 5 months ago (153 days ago)

JOHANNESBURG - It's being reported that Johnson & Johnson has been exporting millions of vaccine doses that were bottled and packaged here in South Africa for distribution in Europe.

According to the *New York Times* (<https://www.nytimes.com/2021/08/16/business/johnson-johnson-vaccine-africa-exported-europe.html>) the New Jersey-based company agreed to sell enough of its single-shot vaccines to eventually inoculate a third of Africans against COVID-19.

South Africa was still waiting for the majority of the 31 million shots ordered from the manufacturer.

South Africa has been hoping that if the vaccine is produced in part by a South African manufacturer, these Johnson and Johnson jabs would quickly go to African countries, much like many Western nations that have kept locally manufactured doses for themselves.

But this appears not to be the case. The *New York Times*'s reporting due to an unusual stipulation in the contract that our government signed with Johnson and Johnson, South Africa has waived its right to impose export restrictions on vaccines.

The publication is quoting the Health Department spokesperson Popo Maja as saying that government is not happy with the requirements in the contract, but was not in a position to refuse the deal, because it came down to sign the contract or get no vaccines.

Eyewitness News has tried to contact Maja to clarify questions around this report, but he has not yet been available for comment.

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Coronavirus

🕒 This article is more than **11 months old**

South Africa paying more than double EU price for Oxford vaccine

Health ministry quotes says premium is because government did not pay into research and development effort

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Helen Sullivan *and agencies*

🐦 @helenrsullivan

Fri 22 Jan 2021 02:43 GMT

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 \$5.25 (€4.32) each - nearly two and a half times the amount paid by most European countries.

European Union members will pay \$2.16 (€1.78) for AstraZeneca's shots, according to information leaked by a Belgian minister on Twitter.

AstraZeneca France told AFP in November that its shots would be capped at €2.50 (around \$3) per dose "to provide vaccines to the widest population, with as fair access as possible".

It did not immediately respond to requests for comment on the health ministry's price quote.

To date South Africa has recorded more than 1.3 million cases of coronavirus and 38,800 deaths.

South Africa's deputy director general of health Anban Pillay said via text message: "The National Department of Health confirms that the price \$5.25 is what was quoted to us."

Pillay told the local Business Day newspaper the higher price was because other countries contributed to research and development.

"The explanation we were given for why other high-income countries have a lower price is that they have invested in the [research and development], hence the discount on the price," Pillay said.

Around 2,000 South Africans participated in clinical trials for the vaccine in 2020.

Bilateral deals between wealthier governments and coronavirus vaccine manufacturers have raised concern over price rises and lack of supply for low- and middle-income countries.

The World Health Organization (WHO) has warned against "vaccine nationalism" and "price gouging".

South Africa's AstraZeneca vaccine order is part of 20m secured doses to be delivered in the first half of 2021.

The WHO-backed Covax facility is expected to provide shots for 10% of the population between April and June.

Other vaccines will be provided via the African Union and bilateral contracts with suppliers that have not yet been disclosed.

The SII was also set to supply 100m doses of the vaccine to the African Union for \$3 each, Reuters reported.

Opposition groups have criticised South Africa's inoculation strategy. "Reports today indicate that ... government will have to spend double what some other countries are paying for their vaccines," the main opposition Democratic Alliance party said, blaming poor planning and delayed negotiations.

The trade union Solidarity and the prominent rights group Afriforum jointly announced plans to launch a legal battle against the government over lack of transparency. "The government's non-disclosure of information is further proof why it cannot be trusted with a monopoly regarding the purchasing and distribution of Covid-19 vaccines," Afriforum said.

South Africa is battling with a second wave of infections fuelled by a new coronavirus variant deemed more infectious by scientists.

The government aims to vaccinate two-thirds of its population - around 40 million out of nearly 60 million people - to achieve herd immunity by the end of 2021.

As 2022 begins, and you're joining us from South Africa, there's a new year resolution we'd like you to consider. We'd like to invite you to join more than 1.5 million people in 180 countries who have taken the step to support us financially - keeping us open to all, and fiercely independent.

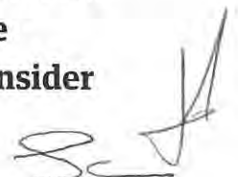
The year is already shaping up to be hectic, with a cluster of elections (France, Brazil, the US to say the least), economic pinch points, the next phase of the pandemic, the gathering climate emergency and the first 'winter World Cup'.

More ominously, independent media faces a critical year, with autocrats across the world rolling back press freedoms, shutting down newspapers such that free, impartial information is becoming the exception rather than the rule.

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Africa

South Africa says non-refundable downpayments among onerous vaccine terms



By Alexander Winning and Wendell Roelf

4 minute read



Country has signed big vaccine deals with J&J, Pfizer

Minister says manufacturers made difficult demands

Paused J&J rollout on Tuesday over U.S. blood clot reports

Minister signals pause may be short-lived



CAPE TOWN, April 14 (Reuters) - South Africa agreed to onerous conditions like non-refundable downpayments to secure COVID-19 vaccines from Johnson & Johnson (J&J) (JNJ.N) and Pfizer (PFE.N), its health minister said on Wednesday, describing terms vaccine manufacturers had demanded as "difficult and sometimes unreasonable".

The country worst-hit by the pandemic on the African continent in terms of coronavirus infections and deaths is counting on the single-dose J&J and double-shot Pfizer vaccines to ramp up immunisations after a slow start. It has signed deals with the two firms for a combined 61 million doses, enough to vaccinate 46 million people out of its population of 60 million.

"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," Health Minister Zweli Mkhize told a parliamentary committee about vaccine negotiations, adding procurement efforts were now largely concluded.

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Mkhize did not give a value for the non-refundable payments, which are in the spotlight after South Africa paused use of the J&J vaccine on Tuesday to investigate a potential link to rare blood clots - following the lead of U.S. regulators. **read more**

Mkhize reiterated on Wednesday the pause was likely to be short-lived.

J&J and Pfizer did not immediately respond to requests for comment.

Mkhize said Pfizer initially wanted "sole discretion to determine additional terms and guarantees for us to fulfil indemnity obligations" but had backed down after "intense negotiations".



He said J&J was holding out for a letter from the trade minister expressing support for its investment in local pharmaceutical company Aspen (**APNJ.J**), which will be making J&J doses under licence.

South Africa is setting up a no-fault compensation fund to indemnify the manufacturers against third-party claims, Mkhize continued.

J&J SUSPENSION

Opinion among ordinary South Africans appears divided over whether South Africa was right to pause use of the J&J vaccine.

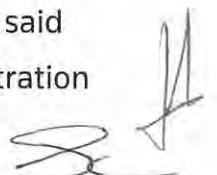
"I think it's a little bit premature given the fact that we have had no local reports in terms of the blood clots, but ... what happens in the U.S. tends to influence what happens in the rest of the world," Johannesburg resident Ntokozo Mhlongo told Reuters TV in the city's financial district Sandton.

Around 290,000 doses of the J&J vaccine have been given in South Africa in a study targeting up to 500,000 health workers.

Mkhize said officials were still expecting the first batch of commercial doses from J&J later this month and they were not considering terminating their contract.

The suspension was the latest setback for South Africa's immunisation efforts, after it ditched plans to kick-start vaccinations with AstraZeneca's (**AZN.L**) shot in February. A trial showed that vaccine had greatly reduced efficacy against the dominant local coronavirus variant. **read more**

Regulator SAHPRA said on Wednesday it had found no major safety concerns with the J&J shot after reviewing data from the research study that started in February. It said further data were being obtained from J&J and the U.S. Food and Drug Administration and that reviewing that could take a few days.



Mkhize said South Africa was paying \$10 per dose for the J&J and Pfizer vaccines and talks were continuing over Russian and Chinese shots.

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Additional reporting by Shafiek Tassiem; Editing by Joe Bavier and Mark Potter

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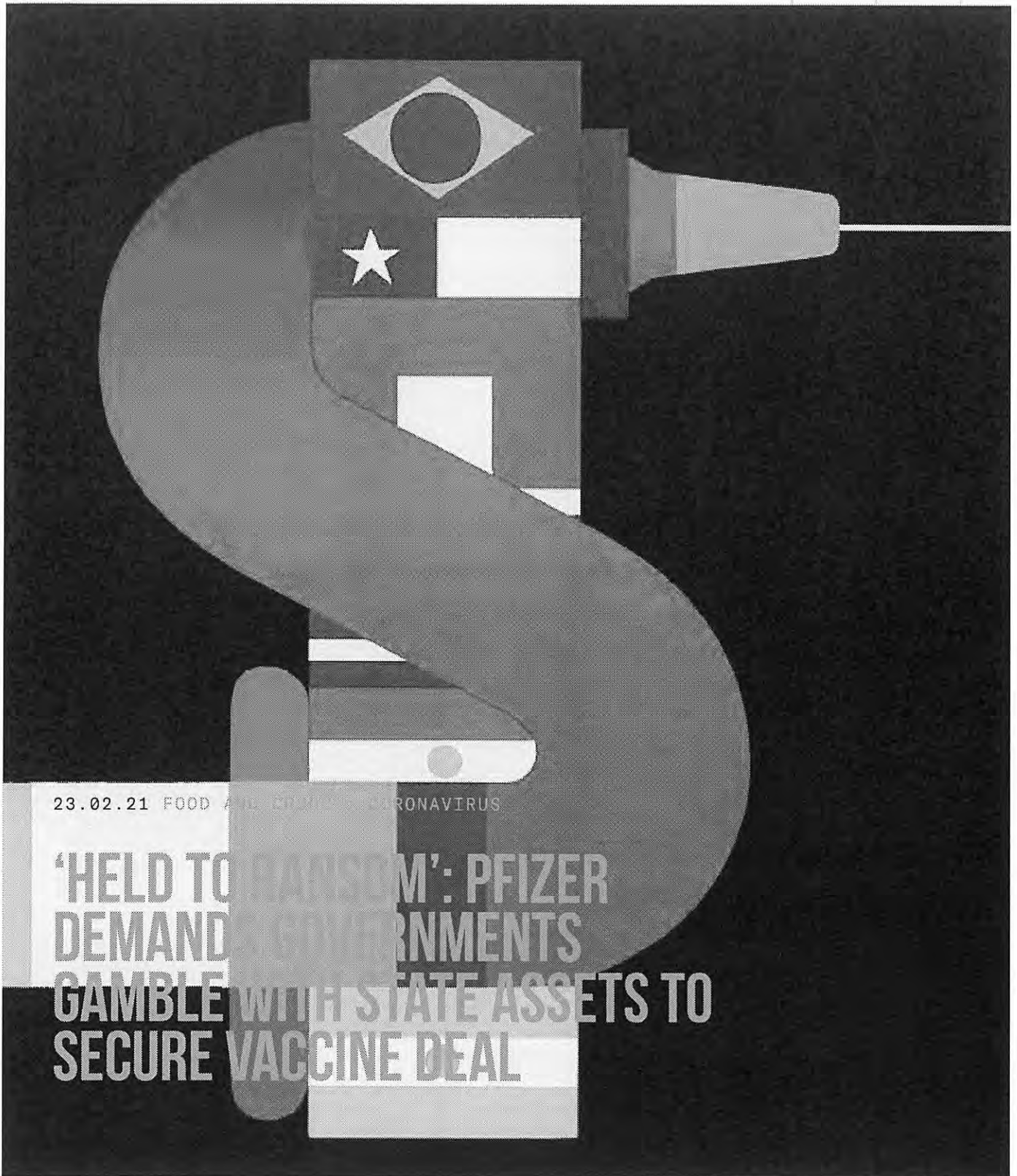
The detainees that Djokovic left behind

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Africa

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Published February 23 2021

By Madlen Davies, Rosa Furneaux, Iván Ruiz, Jill Langlois

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Pfizer has been accused of “bullying” Latin American governments in Covid vaccine negotiations and has asked some countries to put up sovereign assets, such as embassy buildings and military bases, as a guarantee against the cost of any future legal cases, the Bureau of Investigative Journalism can reveal.

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.

Officials from Argentina and the other Latin American country, which cannot be named as it has signed a confidentiality agreement with Pfizer, said the company’s negotiators demanded additional indemnity against any civil claims citizens might file if they experienced adverse effects after being inoculated. In Argentina and Brazil, Pfizer asked for sovereign assets to be put up as collateral for any future legal costs.

One official who was present in the unnamed country’s negotiations described Pfizer’s demands as “high-level bullying” and said the government felt like it was being “held to ransom” in order to access life-saving vaccines.

Campaigners are already warning of a “vaccine apartheid” in which rich Western countries may be inoculated years before poorer regions. Now, legal experts have raised concerns that Pfizer’s demands amount to an abuse of power.

Terms

Indemnity When a government agrees to cover any compensation costs that may arise from citizens bringing civil cases relating to serious adverse effects after a vaccine.



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or delivered the wrong vaccine.

Adverse effect An untoward medical occurrence that happens as a result of receiving a vaccine or medicine. Can lead to injury, disability or death.

“Pharmaceutical companies shouldn't be using their power to limit life-saving vaccines in low- and middle-income countries,” said Professor Lawrence Gostin, director of the World Health Organization’s Collaborating Center on National and Global Health Law. “[This] seems to be exactly what they're doing.”

Protection against liability shouldn't be used as “the sword of Damocles hanging over the heads of desperate countries with a desperate population,” he added.

Pfizer has been in talks with more than 100 countries and supranational organisations, and has supply agreements with nine countries in Latin America and the Caribbean: Chile, Colombia, Costa Rica, Dominican Republic, Ecuador, Mexico, Panama, Peru, and Uruguay. The terms of those deals are unknown.

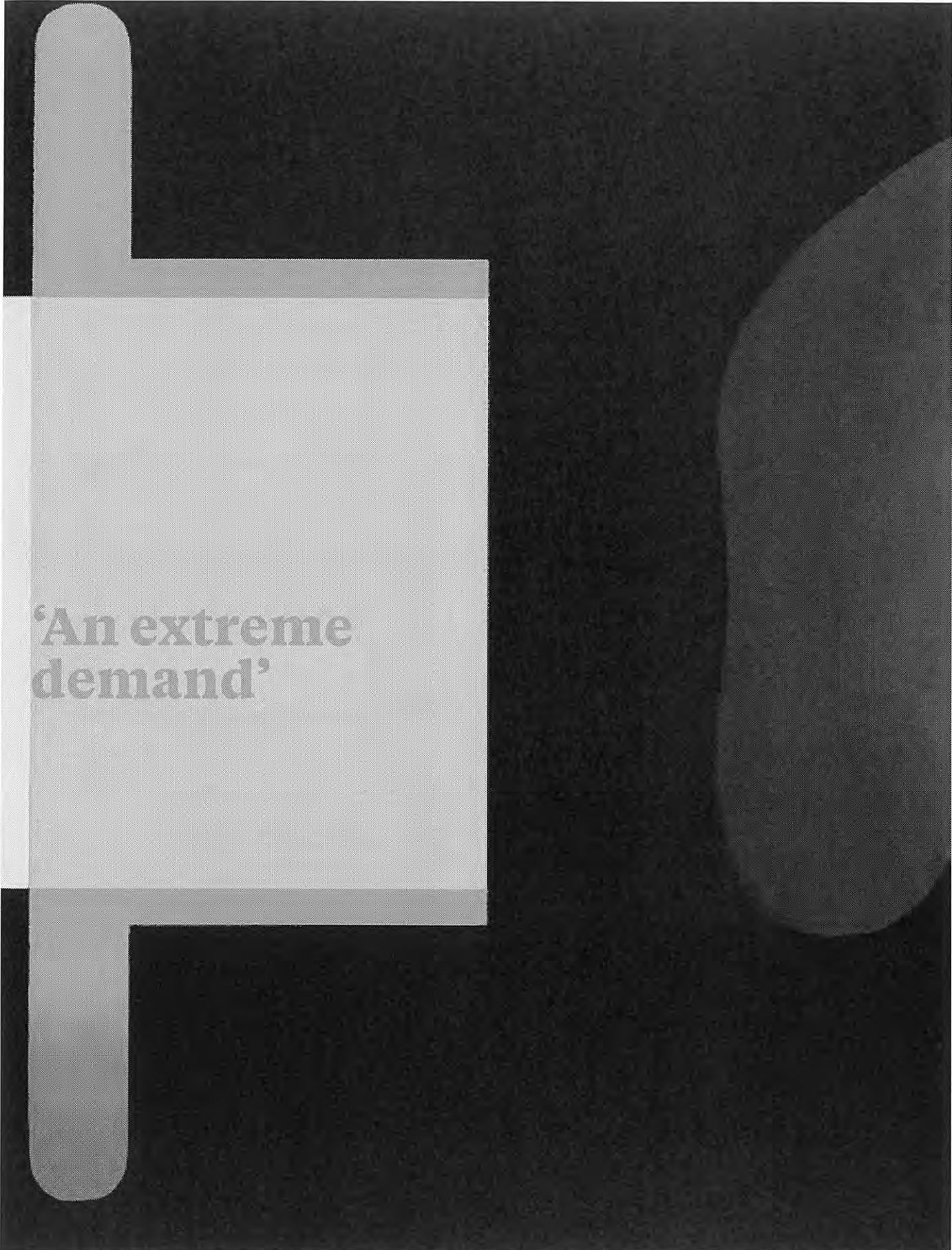
Pfizer told the Bureau: “Globally, we have also allocated doses to low- and lower-middle-income countries at a not-for-profit price, including an advance purchase agreement with Covax to provide up to 40 million doses in 2021. We are committed to supporting efforts aimed at providing developing countries with the same access to vaccines as the rest of the world.” It declined to comment on ongoing private negotiations.

Most governments are offering indemnity – exemption from legal liability – to the vaccine manufacturers they are buying from. This means that a citizen who suffers an adverse effect after being vaccinated can file a claim against the manufacturer and, if successful, the government would pay the compensation. In some countries people can also apply for compensation through specific structures without going to court.

This is fairly typical for vaccines administered in a pandemic. In many cases adverse effects are so rare that they do not show up in clinical trials and only become apparent once hundreds of thousands of people have received the vaccine (a 2009 [H1N1 flu vaccine](#), for example, was eventually linked to narcolepsy). Because manufacturers have developed vaccines quickly and because they protect everyone in society, governments often agree to cover the cost of compensation.

However, the government officials from Argentina and the unnamed country who spoke to the Bureau felt Pfizer's demands went beyond those of other vaccine companies, and beyond those of Covax, an organisation created to ensure low-income countries can access vaccines, which is also requiring its members to indemnify manufacturers. This presents an additional burden for some countries because it

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'An extreme
demand'

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Pfizer asked for additional indemnity from civil cases, meaning that the company would not be held liable for rare adverse effects or for its own acts of negligence, fraud or malice. This includes those linked to company practices – say, if Pfizer sent the wrong vaccine or made errors during manufacturing.

“Some liability protection is warranted, but certainly not for fraud, gross negligence, mismanagement, failure to follow good manufacturing practices,” said Gostin.

“Companies have no right to ask for indemnity for these things.”

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Dr Mark Eccleston-Turner, a lecturer in global health law at Keele University, said Pfizer and other manufacturers have received government funding to research and develop the vaccines and are now pushing the potential costs of adverse effects back on to governments, including those in low- and middle-income countries. (Pfizer’s partner BioNTech was given \$445m by the German government to develop a vaccine and the US government agreed a deal in July to pre-order 100m doses for nearly \$2bn, before the vaccine had even entered phase three trials. Pfizer expects to make sales of \$15bn worth of vaccines in 2021.)

“Pfizer misbehaved with Argentina. Its intolerance with us was tremendous” – Ginés González García, former minister of health

In Eccleston-Turner’s opinion, it looks like Pfizer “is trying to eke out as much profit and minimise its risk at every juncture with this vaccine development then this vaccine rollout. Now, the vaccine development has been heavily subsidised already. So there’s very minimal risk for the manufacturer involved there.”



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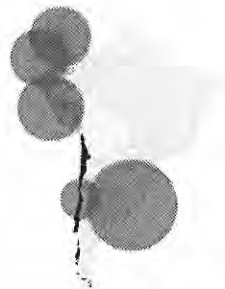
ARGENTINA MINISTRY OF HEALTH

The Argentinian Ministry of Health began negotiating with the company in June and President Alberto Fernández held a meeting with Pfizer Argentina’s CEO the following month. During subsequent meetings Pfizer asked to be indemnified against the cost of any future civil claims. Although this had never been done before, Congress passed a new law in October allowing for it. However, Pfizer was not happy with the phrasing of the legislation, according to an official from the president’s office. The government believed Pfizer should be liable for any acts of negligence or malice. Pfizer, said the official, disagreed.

The government did offer to amend the existing law to make it clear “negligence” meant problems in the distribution and delivery of the vaccines. But Pfizer was still not satisfied. It asked the government to amend the legislation through a new decree; Fernández refused.

Pfizer’s deals in South America

Several countries have purchased millions of vaccines from Pfizer, but the terms of the contracts are secret



Source: [Duke University](#) • Note: These figures do not include doses through Covax

TBIJ via Flourish

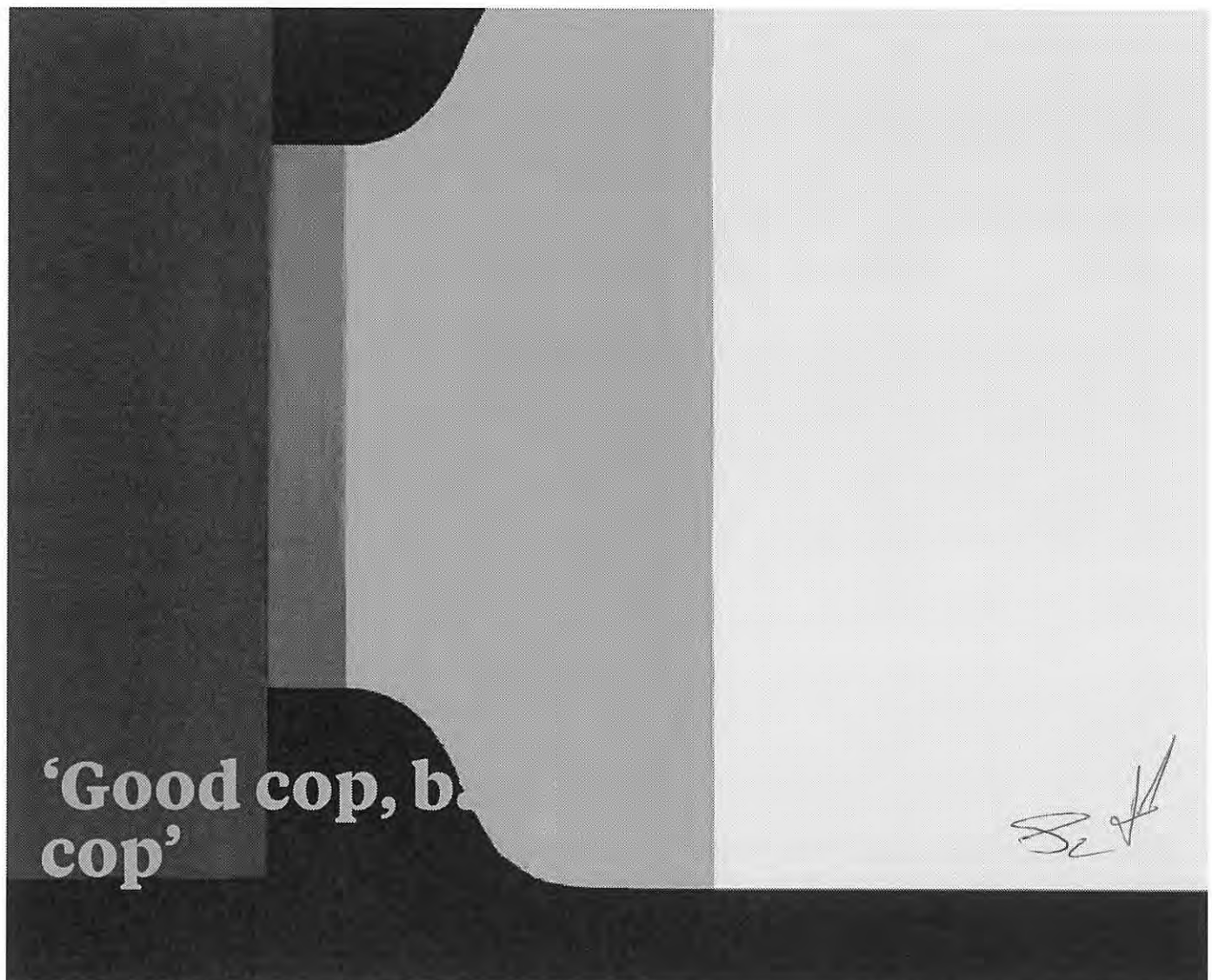
“Argentina could compensate for the vaccine’s adverse effects, but not if Pfizer makes a mistake,” said the official, who has detailed knowledge of the negotiations. “For example, what would happen if Pfizer unintentionally interrupted the vaccine’s cold

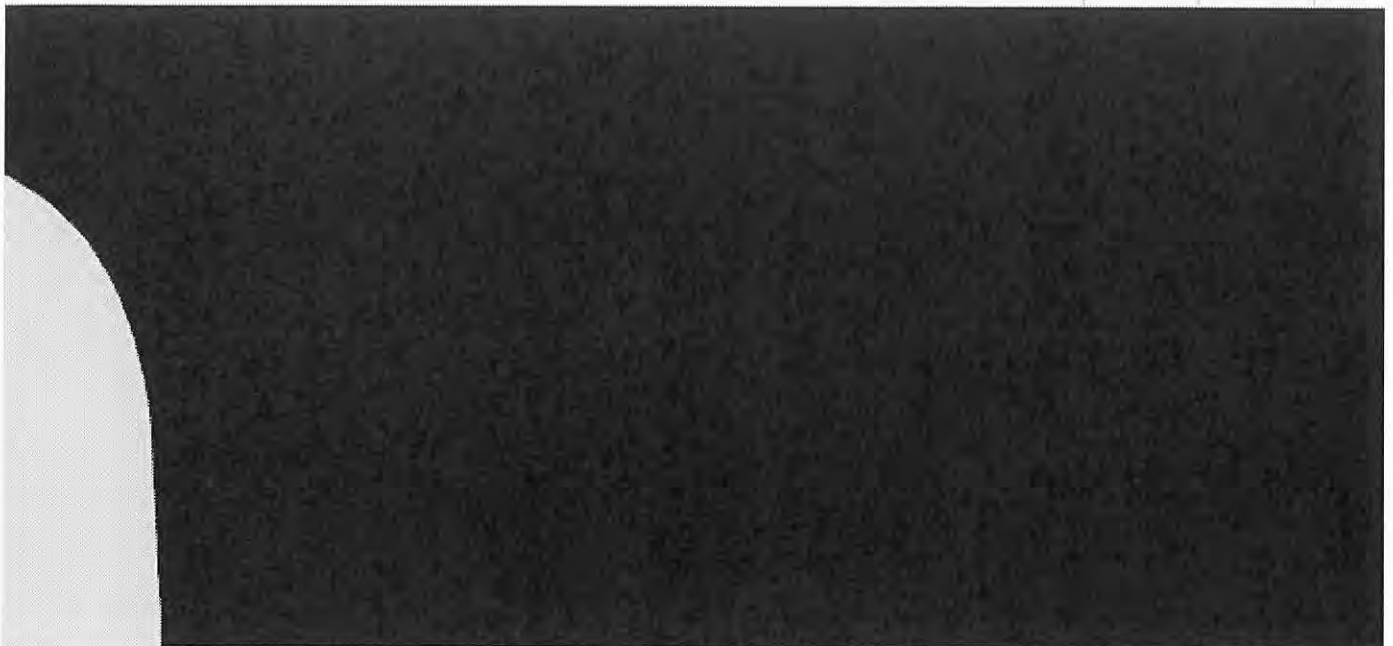
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The official said talks soon became tense and complicated: “Instead of giving in on some points, Pfizer demanded more and more.” In addition to the changes in the new law, it asked Argentina to take out international insurance to pay for potential future cases against the company (countries were also asked to do this during the H1N1 outbreak).

In late December, Pfizer made another unexpected request: that the government put up sovereign assets – which might include federal bank reserves, embassy buildings or military bases – as collateral.

“We offered to pay for millions of doses in advance, we accepted this international insurance, but the last request was unusual: Pfizer demanded that the sovereign assets of Argentina also be part of the legal support,” the official said. “It was an extreme demand that I had only heard when the foreign debt had to be negotiated, but both in that case and in this one, we rejected it immediately.”





The failed negotiations mean Argentinian citizens, unlike those in neighbouring countries, do not have access to Pfizer's vaccine, leaving them with Russia's Sputnik V vaccine, AstraZeneca's vaccine and those delivered through Covax. The government is also negotiating to acquire vaccines from Moderna, Sinopharm and CanSino.

"Pfizer misbehaved with Argentina," said Ginés González Garcia, Argentina's former minister of health. "Its intolerance with us was tremendous." (González Garcia resigned at the weekend after allegations that VIPs had been allowed to jump the queue for vaccines.)

The same demands were made of Brazil's Ministry of Health. Pfizer asked to be indemnified and asked the ministry to put up sovereign assets as collateral, as well as create a guarantee fund with money deposited in a foreign bank account. In January, the ministry refused these terms, describing the clauses as "abusive".

An official from another Latin American country, which cannot be named, described talks unfolding similarly. They said the government began negotiating with Pfizer in July, before the vaccine was approved. There was a perception that Pfizer's negotiators had a "good cop, bad cop" routine, with the "bad cop" pressing the government to buy more doses.

"[At that time] there was not a single drug or vaccine in the world with this kind of technology that had been shown to be safe and effective ... You had this lady putting pressure saying: 'Buy more, you're going to kill people, people are going to die because of you,'" the official said.

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Negotiations became fraught when the company asked for additional indemnity. The government had never awarded any kind of indemnity before and did not want to waive liability, but Pfizer said this was non-negotiable. Negotiations continued and eventually a deal was signed, but after a delay of three months.

As Pfizer has only 2 billion doses to sell across the world this year – apparently on a first come, first served basis – the official is angry about a delay that likely pushed the country further back in the queue.

One of the reasons the government wanted Pfizer's vaccines was because the company said they could be delivered quickly. Yet in the contract, Pfizer wanted to reserve the right to modify the schedule. There was no room for negotiation. "It was take it or leave it," said the official.

The official said: "Five years in the future when these confidentiality agreements are over you will learn what really happened in these negotiations."

Pfizer told the Bureau: "Pfizer and BioNTech are firmly committed to working with governments and other relevant stakeholders to ensure equitable and affordable access to our Covid-19 vaccine for people around the world."

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"HJI22"

PFIZER'S POWER

Zain Rizvi

Access to Medicines Program

October 19, 2021



A handwritten signature in black ink, appearing to be "Zain Rizvi".

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This report was written by Zain Rizvi, law and policy researcher in Public Citizen's Access to Medicines Program. It was edited by Peter Maybarduk, director of the Access to Medicines Program, Rhoda Feng, editor in the Communications Program, Brook Baker, Professor of Law at Northeastern University, and Zain Jinnah, an international lawyer. Luz Marina Umbasia Bernal in the Access to Medicines Program also provided critical input.

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A handwritten signature in black ink, appearing to be 'SC', is written over the page number '2'.

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INTRODUCTION

In February, Pfizer was accused of “bullying” governments in COVID vaccine negotiations in a groundbreaking story by the Bureau of Investigative Journalism.¹ A government official at the time noted, “Five years in the future when these confidentiality agreements are over you will learn what really happened in these negotiations.”²

Public Citizen has identified several unredacted Pfizer contracts that describe the outcome of these negotiations. The contracts offer a rare glimpse into the power one pharmaceutical corporation has gained to silence governments, throttle supply, shift risk and maximize profits in the worst public health crisis in a century. We describe six examples from around the world below.³

Table 1: Select Pfizer Contracts Reviewed⁴

Purchaser	Date	Type	Doses	Price Per Dose	Total Cost
Albania	Draft ⁵	Draft Definitive Agreement	500,000	\$12	\$6 million
Brazil	03/15/21 ⁶	Definitive Agreement	100 million	\$10	\$1 billion
Colombia	02/02/21 ⁷	Definitive Agreement	10 million	\$12	\$120 million
Chile	12/01/20 ⁸	Definitive Agreement (Redacted)	10 million	Redacted	Redacted

¹ Madlen Davies, Rosa Furneaux, Iván Ruiz, Jill Langlois, ‘Held to Ransom’: Pfizer Demands Governments Gamble with State Assets to Secure Vaccine Deal, Bureau of Investigative Journalism (Feb 23 2021), <https://tinyurl.com/t2z39a63>.

² *Id.*

³ While there are similarities across the contracts, each agreement is unique. The specific examples outlined below should not read as reflective of other contracts.

⁴ In several cases, governments signed additional deals with Pfizer. We reviewed select contracts that were publicly available.

⁵ Albania-Pfizer Contract Draft, (“Albania Draft Contract”), (Jan. 6 2021) <https://www.documentcloud.org/documents/20616251-albanian-pfizer-covid-19-vaccine-contract>. The final provisions of the agreement may have differed from this draft. However, given similarities between this draft and the other reviewed agreements, we believe the modifications, if any, were likely not substantial. The contract was first leaked on Twitter, and then shared widely in the press.

⁶ Brazil-Pfizer Contract (“Brazil Contract”), (March 15 2021) <https://aurores.org/wp-content/uploads/2021/08/Brazil-Pfizer.pdf>. The contract was leaked online and later covered by The Guardian in August. See e.g., <https://tinyurl.com/yupsz2j4>.

⁷ Colombia-Pfizer Contract (“Colombia Contract”), (Feb. 2 2021), <https://www.nodal.am/wp-content/uploads/2021/08/DOCUMENTO.pdf>. The contract was leaked in the Colombian Media in August. <https://tinyurl.com/4vswvrz4>. It is currently referenced in the UNICEF Vaccine Market Dashboard.

⁸ Chile-Pfizer Contract (“Chile Contract”) (Dec. 1 2021), <https://www.chiletransparente.cl/wp-content/uploads/2021/07/Acuerdo-de-fabricacion-y-suministro-PFIZER.pdf>. A Chilean transparency initiative published a redacted version of the contract.

Dominican Republic	10/29/20 ⁹	Binding Term Sheet ¹⁰	8 million	\$12	\$96 million
European Commission	11/20/20 ¹¹	Custom Advance Purchase Agreement	200 million	\$18.6 ¹²	\$3.7 billion
Peru	09/17//20 ¹³	Binding Term Sheet	10 million	\$12	\$120 million
United States	07/21/20 ¹⁴	Custom Advance Purchase Agreement (Redacted)	100 million	\$19.5	\$1.95 billion
United Kingdom	10/12/20 ¹⁵	Custom Advance Purchase Agreement (Redacted)	30 million	Redacted	Redacted

Pfizer's demands have generated outrage around the world, slowing purchase agreements and even pushing back the delivery schedule of vaccines.¹⁶ If similar terms are included as a condition to receive doses, they may threaten President Biden's commitment to donate 1 billion vaccine doses.¹⁷

High-income countries have enabled Pfizer's power through a favorable system of international intellectual property protection.¹⁸ High-income countries have an obligation to rein in that monopoly power. The Biden administration, for example, can call on Pfizer to renegotiate existing commitments and pursue a fairer approach in the future. The administration can further rectify the power imbalance by sharing the vaccine recipe, under the Defense Production Act, to allow multiple producers to expand vaccine

⁹ Dominican Republic-Pfizer Contract ("D.R. Contract") (Oct. 29 2020), <https://www.keionline.org/35485>. Knowledge Ecology International obtained the contract through a freedom of information law request.

¹⁰ The text was subject to the approval of the Dominican Republican National Congress, which reportedly approved the text with no objections. Pfizer and AstraZeneca, *The Game of Contracts with Small Print*, Dominican Today, <https://tinyurl.com/yhasn7um>.

¹¹ European Commission-Pfizer Contract ("E.C. Contract") (Nov. 20 2020), <https://tinyurl.com/3bph89wy>. The Italian public broadcaster RAI published the EC Contract in April.

¹² 15.5 EUR.

¹³ Peru-Pfizer Contract ("Peru Contract") (Sept. 17 2020), <https://tinyurl.com/y2ap74xz>. The Bureau of Investigative Journalism published the contract.

¹⁴ United States-Pfizer Contract ("U.S. Contract") (July 21 2020), <https://tinyurl.com/4k5i7d5u>. The contract is available on the U.S. Department of Health and Human Services website.

¹⁵ United Kingdom-Pfizer Contract ("U.K. Contract") (Oct. 10 2020), <https://tinyurl.com/ym4pk3tw>. This likely is the definitive agreement that follows on from initial agreement announced in July. The contract is available on the U.K government website.

¹⁶ Madlen Davies, Rosa Furneaux, Pfizer backs down over "unreasonable terms" in South Africa vaccine deal (April 19 2021), <https://tinyurl.com/tmys9u2c>. ("He described how Pfizer's late demand caused delays in the discussions, which in turn put back the anticipated vaccine delivery dates."). See also the impasse in Philippines. Philippines receives side letter from Pfizer; WHO sees resolution of 'impasse' soon (Feb 23. 2021), <https://tinyurl.com/3fs8z3cb> ("The delivery of 117,000 Pfizer-BioNTech doses, initially expected in mid-February, was delayed by concerns on indemnification.").

¹⁷ White House, FACT SHEET: President Biden Announces Historic Vaccine Donation: Half a Billion Pfizer Vaccines to the World's Lowest-Income Nations (June 10 2021), <https://tinyurl.com/he8bm9tk>

¹⁸ Peter Drahos and John Braithwaite, *Information Feudalism: Who Owns the Knowledge Economy?* (2007) (tracing the role of Pfizer in advocating for a system of international patent protection).

supplies.¹⁹ It can also work to rapidly secure a broad waiver of intellectual property rules (TRIPS waiver) at the World Trade Organization.²⁰ A wartime response against the virus demands nothing less.

PFIZER'S POWER

1. Pfizer Reserves the Right to Silence Governments.

In January, the Brazilian government complained that Pfizer was insisting on contractual terms in negotiations that were “unfair and abusive.”²¹ The government pointed to five terms that it found problematic, ranging from a sovereign immunity waiver on public assets to a lack of penalties for Pfizer if deliveries were late. The Bureau of Investigative Journalism soon published a scathing story on Pfizer’s vaccine negotiations.²²

Less than two months later, the Brazilian government accepted a contract with Pfizer that contains most of the same terms that the government once deemed unfair.²³ Brazil waived sovereign immunity; imposed no penalties on Pfizer for late deliveries; agreed to resolve disputes under a secret private arbitration under the laws of New York; and broadly indemnified Pfizer for civil claims.²⁴

The contract also contains an additional term not included in other Latin American agreements²⁵ reviewed by Public Citizen: The Brazilian government is prohibited from making “any public announcement concerning the existence, subject matter or terms of

¹⁹ Zain Rizvi, Jishian Ravinthiran, Amy Kapczynski, Sharing The Knowledge: How President Joe Biden Can Use The Defense Production Act To End The Pandemic Worldwide, Health Affairs Blog (August 6, 2021), <https://www.healthaffairs.org/doi/10.1377/hblog20210804.101816/full/>

²⁰ Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).

²¹ Madlen Davies, Rosa Furneaux, Iván Ruiz, Jill Langlois, ‘Held to Ransom’: Pfizer Demands Governments Gamble with State Assets to Secure Vaccine Deal, Bureau of Investigative Journalism (Feb 23 2021), <https://tinyurl.com/t2z39a63>.

²² *Id.*

²³ One clause that appears to have changed is the number of doses supplied by Pfizer. It is also not clear whether Brazil developed a foreign bank guarantee fund.

²⁴ Brazil Contract, footnote 6, Article 9.4 (Waiver of Sovereign Immunity), pg. 45, Article 2.6 (Delivery Delays), pg. 34, Article 9.4 (Waiver of Sovereign Immunity) pg. 45, Article 3.1 (Indemnification by Purchaser), pg. 43, respectively.

²⁵ The other Latin American contracts reviewed contain a more limited nondisclosure obligation. For example, under the Colombia contract, neither Pfizer nor Colombia can “use the name, trade name, service marks, trademarks, trade dress or logos of the other Party in publicity releases, advertising or any other publication, without the other Party’s prior written consent in each instance.” This does not appear to prohibit the government from talking about the contract, as long as it is not a “publicity release, advertising, or any other publication.”

[the] Agreement” or commenting on its relationship with Pfizer without the prior written consent of the company.²⁶ Pfizer gained the power to silence Brazil.

Brazil is not alone. A similar nondisclosure provision is contained in the Pfizer contract with the European Commission and the U.S. government.²⁷ In those cases, however, the obligation applies to both parties.

For example, neither Pfizer nor the U.S. government can make “any public announcement concerning the existence, subject matter or terms of this Agreement, the transactions contemplated by it, or the relationship between the Pfizer and the Government hereunder, without the prior written consent of the other.”²⁸ The contract contains some exceptions for disclosures required by law. It is not clear from the public record whether Pfizer has elected to prohibit the U.S. from making any statements thus far. The E.C. cannot include in any announcement or disclosure the price per dose, the Q4 2020 volumes, or information that would be material to Pfizer without the consent of Pfizer.²⁹

2. Pfizer Controls Donations.

Pfizer tightly controls supply.³⁰ The Brazilian government, for example, is restricted from accepting Pfizer vaccine donations from other countries or buying Pfizer vaccines from others without Pfizer’s permission.³¹ The Brazilian government also is restricted from

²⁶ Brazil Contract, Article 12.3 (Publicity), pg. 32 (“Purchaser shall not make, or permit any person to make, any public announcement concerning the existence, subject matter or terms of this Agreement, the wider transactions contemplated by it, or the relationship between the Parties (except as required by Law, and subject to the protections set forth in Section 10.1), without the prior written consent of Pfizer (such consent not to be unreasonably withheld or delayed)”.

²⁷ E.C. Contract, footnote 11, Article II.10 (Announcements and Publicity), pg. 36.

²⁸ U.S. Contract, footnote 14, Article 11.11 (Announcements), pg. 25.

²⁹ E.C. Contract, footnote 11, Article II.10 (Announcements and Publicity), pg. 36.

³⁰ For example, Colombia is also required to distribute the vaccine only in its territory. Colombia Contract, footnote 7, Article 4.6 (Diversion Issues), pg. 23 (“All Product delivered to Purchaser shall be: (a) stored securely by Purchaser; and (b) distributed by Purchaser only in Colombia in a secure manner appropriate to the transportation route and destination, in each case (a) and (b) to guard against and deter theft, diversion, tampering, substitution (with, for example, counterfeits) resale or export out of Colombia, and to protect and preserve the integrity and efficacy of the Product.”).

³¹ Brazil Contract, footnote 6, Article 2.1 (f) (Agreement to Supply), pg. 31 (“Purchaser, including any related Person or any agents of Purchaser, covenants to exclusively obtain all of its supply of any Vaccine of Pfizer, BioNTech or their respective Affiliates intended for the prevention of the human disease COVID-19 (including the Product) either (i) directly from Pfizer or from Pfizer through the COVAX Facility, or (ii) from a Third Party, whether by donation, resale or otherwise, only if Purchaser has obtained Pfizer’s prior written consent. Any breach of this Section 2.1(f) shall be deemed an uncurable material breach of this Agreement, and Pfizer may immediately terminate this Agreement pursuant to Section 6.2. For clarity, nothing in this Section 2.1(f) shall prevent Purchaser from purchasing competing vaccine products of any Third Party.”).

donating, distributing, exporting, or otherwise transporting the vaccine outside Brazil without Pfizer's permission.³²

The consequences of noncompliance can be severe. If Brazil were to accept donated doses without Pfizer's permission, it would be considered an "uncurable material breach" of their agreement, allowing Pfizer to immediately terminate the agreement.³³ Upon termination, Brazil would be required to pay the full price for any remaining contracted doses.³⁴

3. Pfizer Secured an "IP Waiver" for Itself.

The CEO of Pfizer, Albert Bourla, has emerged as a strident defender of intellectual property in the pandemic. He called a voluntary World Health Organization effort to share intellectual property to bolster vaccine production "nonsense" and "dangerous."³⁵ He said President Biden's decision to back the TRIPS waiver on intellectual property was "so wrong."³⁶ "IP, which is the blood of the private sector, is what brought a solution to this pandemic and it is not a barrier right now," claims Bourla.³⁷

But, in several contracts, Pfizer seems to recognize the risk posed by intellectual property to vaccine development, manufacturing, and sale. The contracts shift responsibility for any intellectual property infringement that Pfizer might commit to the government purchasers. As a result, under the contract, Pfizer can use anyone's intellectual property it pleases—largely without consequence.

At least four countries are required "to indemnify, defend and hold harmless Pfizer" from and against any and all suits, claims, actions, demands, damages, costs, and expenses related to vaccine intellectual property.³⁸ For example, if another vaccine maker sued

³² Brazil Contract, footnote 6, Article 4.6 (Diversion Issues), pg. 38 ("Purchaser shall not directly or indirectly resell, donate, distribute, export or otherwise transport the Product outside the Territory without Pfizer's prior written consent.")

³³ Brazil Contract, footnote 6, Article 2.1 (f) (Agreement to Supply), pg. 31.

³⁴ Brazil Contract, footnote 6, Article 6.2 (Termination for Cause), pg. 27 ("In the event that this Agreement is terminated by Pfizer under this Section 6.2, Purchaser shall pay within thirty (30) days of the date of notice of termination of this Agreement the full Price for all Contracted Doses less amounts already paid to Pfizer as of such date.")

³⁵ Ed Silverman, Pharma leaders shoot down WHO voluntary pool for patent rights on Covid-19 products, STAT (May 28 2020), <https://www.statnews.com/pharmalot/2020/05/28/who-voluntary-pool-patents-pfizer/>

³⁶ U.S. Backs Waiver of Intellectual Property Protection for Covid-19 Vaccines, Wall Street Journal (May 6 2021), <https://www.wsj.com/articles/u-s-backs-waiver-of-intellectual-property-protection-for-covid-19-vaccines-11620243518>

³⁷ WTO delays decision on waiver on COVID-19 drug, vaccine rights (Dec. 10 2020), <https://www.reuters.com/article/us-health-coronavirus-wto-idUSKBN28K2WL>

³⁸ This extends to all civil claims, including adverse effects. That has been detailed elsewhere: Madlen Davies, Rosa Furneaux, Iván Ruiz, Jill Langlois, 'Held to Ransom': Pfizer Demands Governments Gamble

Pfizer for patent infringement in Colombia, the contract requires the Colombian government to foot the bill. At Pfizer's request, Colombia is required to defend the company (i.e., take control of legal proceedings.)³⁹ Pfizer also explicitly says that it does not guarantee that its product does not violate third-party IP, or that it needs additional licenses.

Pfizer takes no responsibility in these contracts for its potential infringement of intellectual property. In a sense, Pfizer has secured an IP waiver for itself. But internationally, Pfizer is fighting similar efforts to waive IP barriers for all manufacturers.⁴⁰

4. Private Arbitrators, not Public Courts, Decide Disputes in Secret.

What happens if the United Kingdom cannot resolve a contractual dispute with Pfizer? A secret panel of three private arbitrators—not a U.K court—is empowered under the contract to make the final decision.⁴¹ The arbitration is conducted under the Rules of Arbitration of the International Chamber of Commerce (ICC). Both parties are required to keep everything secret:

The Parties agree to keep confidential the existence of the arbitration, the arbitral proceedings, the submissions made by the Parties and the decisions made by the arbitral tribunal, including its awards, except as required by Law and to the extent not already in the public domain.⁴²

The Albania draft contract and Brazil, Chile, Colombia, Dominican Republic, and Peru agreements require the governments to go further, with contractual disputes subject to ICC arbitration applying New York law.⁴³

with State Assets to Secure Vaccine Deal, Bureau of Investigative Journalism (Feb 23 2021), <https://tinyurl.com/t2z39a63>.

³⁹ Colombia Contract, footnote 7, Article 8.2 (Assumption of Defense), pg. 31.

⁴⁰ Pfizer signed the letter opposing the TRIPS waiver sent to President Biden in March, for example. PhRMA Letter Opposing TRIPS Waiver to President Biden (March 5 2021), <https://patentdocs.typepad.com/files/2021-03-05-phrma-letter.pdf>

⁴¹ U.K. Contract, footnote 15, Article 23 (Dispute Resolution) pg. 36. ("The arbitration award shall be final and binding on the Parties, and the parties undertake to carry out any award without delay. Judgment upon the award may be entered by any court having jurisdiction of the award or having jurisdiction over the relevant party or its assets.")

⁴² *Id.*

⁴³ Article on Governing Law. Albania Draft Contract pg. 34, Brazil Contract pg. 45, Chile Contract pg. 29, Colombia Contract pg. 43, DR Contract pg. 17, Peru Contract pg. 9.

While ICC arbitration involving states is not uncommon, disputes involving high-income countries and/or pharmaceuticals appear to be relatively rare.⁴⁴ In 2012, 80% of state disputes were from Sub-Saharan Africa, Central and West Asia, and Central and Eastern Europe.⁴⁵ The most common state cases were about the construction and operation of facilities.⁴⁶ In 2020, 34 states were involved in ICC arbitrations.⁴⁷ The nature of state disputes is not clear, but only between 5 to 7% of all new ICC cases, including those solely between private parties, were related to health and pharmaceuticals.⁴⁸

Private arbitration reflects an imbalance of power. It allows pharmaceutical corporations like Pfizer to bypass domestic legal processes. This consolidates corporate power and undermines the rule of law.

5. Pfizer Can Go After State Assets.

The decisions reached by the secret arbitral panels described above can be enforced in national courts.⁴⁹ The doctrine of sovereign immunity can sometimes, however, protect states from corporations seeking to enforce and execute arbitration awards.

Pfizer required Brazil, Chile, Colombia, the Dominican Republic, and Peru to waive sovereign immunity.⁵⁰ In the case of Brazil, Chile and Colombia, for example, the government “expressly and irrevocably waives *any right of immunity* which either it or its assets may have or acquire in the future” to enforce any arbitration award (emphasis

⁴⁴ Our analysis is limited by a lack of transparency.

⁴⁵ Arbitration Involving States and State Entities under the ICC Rules of Arbitration – Report of the ICC Commission on Arbitration and ADR (2012), <https://iccwbo.org/publication/arbitration-involving-states-state-entities-icc-rules-arbitration-report-icc-commission-arbitration-adr/>, pg. 4.

⁴⁶ Arbitration Involving States and State Entities under the ICC Rules of Arbitration – Report of the ICC Commission on Arbitration and ADR (2012), <https://iccwbo.org/publication/arbitration-involving-states-state-entities-icc-rules-arbitration-report-icc-commission-arbitration-adr/>, pg. 4.

⁴⁷ 194 state-owned entities were also involved. ICC Dispute Resolution 2020 Statistics, <https://iccwbo.org/publication/icc-dispute-resolution-statistics-2020/> pg. 11. See also, an analogous mechanism known as investor-state dispute resolution, which is based on international law as opposed to contract: Global Trade Watch, Table of Foreign Investor-State Cases and Claims Under NAFTA and Other U.S. “Trade Deals” (Jan. 15 2021), <https://www.citizen.org/article/table-of-foreign-investor-state-cases-and-claims-under-nafta-and-other-u-s-trade-deals/>

⁴⁸ ICC Dispute Resolution 2020 Statistics, <https://iccwbo.org/publication/icc-dispute-resolution-statistics-2020/> pg. 17.

⁴⁹ United Nations Convention on the Recognition and Enforcement of Foreign Arbitral Awards (New York, 10 June 1958) (“Each Contracting State shall recognize arbitral awards as binding and enforce them in accordance with the rules of procedure of the territory where the award is relied upon, under the conditions laid down in the following articles.”)

⁵⁰ Article on Waiver of Sovereign Immunity. The language differs in some of the contracts. Brazil Contract, pg. 45, Chile Contract pg. 24, Colombia Contract pg. 36, DR Contract pg. 17, Peru Contract pg. 9.

added).⁵¹ For Brazil, Chile, Colombia, and the Dominican Republic, this includes “immunity against precautionary seizure of any of its assets.”⁵²

Arbitral award enforcement presents complex questions of law that depend on the physical location and type of state asset.⁵³ But the contract allows Pfizer to request that courts use state assets as a guarantee that Pfizer will be paid an arbitral award and/or use the assets to compensate Pfizer if the government does not pay.⁵⁴ For example, in U.S. courts, these assets could include foreign bank accounts, foreign investments, and foreign commercial property, including the assets of state-owned enterprises like airlines and oil companies.⁵⁵

6. Pfizer Calls the Shots on Key Decisions.

What happens if there are vaccine supply shortages? In the Albania draft contract and the Brazil and Colombia agreement, Pfizer will decide adjustments to the delivery schedule based on principles the corporation will decide. Albania, Brazil, and Colombia “shall be deemed to agree to any revision.”⁵⁶

Some governments have pushed back on Pfizer’s unilateral authority for other decisions. In South Africa, Pfizer wanted to have the “sole discretion to determine additional terms and guarantees for us to fulfill the indemnity obligations.”⁵⁷ South Africa deemed this “too risky” and a “potential risk to [their] assets and fiscus.”⁵⁸ After delays, Pfizer reportedly conceded to remove this “problematic term.”⁵⁹

⁵¹ *Id.*

⁵² *Id.*

⁵³ In the U.S., the governing statute is the Foreign Sovereign Immunities Act (FSIA). 28 U.S.C § 1602. Sovereign property used for commercial activity can be used to execute a judgment based on an arbitral award if the state has waived immunity. Property belonging to an instrumentality of a foreign state engaged in commercial activity can also be used. 28 U.S.C § 1610. However, certain kinds of foreign sovereign property are absolutely immune from award attachment and execution. This includes property belonging to the foreign central bank or monetary authority and property used for military purposes. 28 U.S.C §1611.

⁵⁴ Under FSIA, this is known as “attachment prior to the entry of judgment” and can be done if the state waives this kind of immunity and “the purpose of the attachment is to secure satisfaction of a judgment that has been or may ultimately be entered against the foreign state.” 28 U.S.C § 1610

⁵⁵ Other jurisdictions may handle these questions differently, potentially exposing other types of sovereign assets. These assets may also be vulnerable in settlement negotiations.

⁵⁶ Albania Draft Contract, pg. 14. Brazil Contract, pg. 22. Colombia Contract, pg. 15.

⁵⁷ Pfizer Backs Down Over Unreasonable Terms in South Africa Vaccine Deal (April 19 2021), <https://www.thebureauinvestigates.com/stories/2021-04-19/pfizer-backs-down-over-asset-seizing-clause-in-south-africa-vaccine-deal>.

⁵⁸ *Id.*

⁵⁹ *Id.*

But others have not been as successful. As a condition to entering into the agreement, the Colombian government is required to “demonstrate, in a manner satisfactory to Suppliers, that Suppliers and their affiliates will have adequate protection, as determined in *Suppliers’ sole discretion*” (emphasis added) from liability claims.⁶⁰ Colombia is required to certify to Pfizer the value of the contingent obligations (i.e., potential future liability), and to start appropriating funds to cover the contingent obligations, according to a contribution program.⁶¹

Pfizer’s ability to control key decisions reflects the power imbalance in vaccine negotiations. Under the vast majority of contracts, Pfizer’s interests come first.

A BETTER WAY

Pfizer’s dominance over sovereign countries poses fundamental challenges to the pandemic response. Governments can push back. The U.S. government, in particular, can exercise the leverage it holds over Pfizer to require a better approach. Empowering multiple manufacturers to produce the vaccine via technology transfer and a TRIPS waiver can rein in Pfizer’s power. Public health should come first.

⁶⁰ Colombia Contract, footnote 7, Article 8.5 (Privileges and Immunities), pg. 32. This includes but is not limited to funding state contractual contingency funds.

⁶¹ *Id.*





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Johnson & Johnson Confirms Advance Purchase Agreement with the Government of the Republic of South Africa for Janssen's COVID-19 Vaccine Candidate

MAR 01, 2021

Media Statement February 28, 2021

Janssen Pharmaceutica NV, one of the Janssen Pharmaceutical Companies of Johnson & Johnson (NYSE: JNJ) ("the Company"), has entered into an agreement with the Government of the Republic of South Africa to supply 11 million doses of its COVID-19 vaccine candidate, Ad26.COVS.2.S. The availability of the vaccine candidate is subject to its successful development and regulatory approval. The vaccine will be provided at a global not-for-profit basis for emergency pandemic use. Additionally, to ensure equitable distribution, in December 2020, the Company entered into an agreement in principle with Gavi, the Vaccine Alliance (Gavi) in support of the COVAX Facility. Johnson & Johnson and Gavi expect to enter into an Advance Purchase Agreement (APA) that would provide up to 500 million doses of the Janssen vaccine to COVAX through 2022. At this time, 190 countries have joined the COVAX Facility, including South Africa.¹ The COVAX Facility is a global mechanism for pooled procurement and distribution of COVID-19 vaccines in 190 participating countries, including 92 lower-income countries. The Facility is an important mechanism for promoting equitable access in lower-income countries that can significantly increase their chances of securing successful vaccines.

These collaborations are part of Johnson & Johnson's commitment to ensuring widespread global access to its COVID-19 vaccine candidate upon authorization, on a not-for-profit basis for emergency pandemic use. Recognising the global demand for COVID-19 vaccines, Johnson & Johnson is working tirelessly to further expand the available doses, once authorized.

Regulatory Filings



initiated in several countries worldwide.

Janssen's COVID-19 Vaccine Candidate

The Company's COVID-19 vaccine candidate leverages the AdVac® vaccine platform, a unique and proprietary technology that was also used to develop and manufacture Janssen's European Commission-approved Ebola vaccine regimen and construct its investigational Zika, RSV, and HIV vaccines.^{3,4,5,6,7}

On January 29, the Company announced topline data from the Phase 3 ENSEMBLE study clinical trial, which found that the single-dose Janssen COVID-19 vaccine candidate met all primary and key secondary endpoints. In December 2020, the Company began to submit Phase 2 data to the South African Health Products Regulatory Authority, per rolling submission to the European Medicines Agency, and additional data will be submitted as it becomes available.

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Notice to Investors Concerning Forward-Looking Statements

This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995 regarding development of a potential preventive vaccine for COVID-19. The reader is cautioned not to rely on these forward-looking statements. These statements are based on current expectations of future events. If underlying assumptions prove inaccurate or known or unknown risks or uncertainties materialize, actual results could vary materially from the expectations and projections of the Janssen Pharmaceutical Companies, and/or Johnson & Johnson. Risks and uncertainties include, but are not limited to: challenges and uncertainties inherent in product research and development, including the uncertainty of clinical success and of obtaining regulatory approvals; uncertainty of commercial success; manufacturing difficulties and delays; competition, including technological advances, new products and patents attained by competitors; challenges to patents; product efficacy or safety concerns resulting in product recalls or regulatory action; changes in behavior and spending patterns of purchasers of health care products and services; changes to applicable laws and regulations, including global health care reforms; and trends toward health care cost containment. A further list and descriptions of these risks, uncertainties and other factors can be found in Johnson & Johnson's Annual Report on Form 10-K for the fiscal year ended January 3, 2021, including in the sections captioned "Cautionary Note Regarding Forward-Looking Statements" and "Item 1A. Risk Factors," and in the company's most recently filed Quarterly Report on Form 10-Q, and the company's subsequent filings with the Securities and Exchange Commission. Copies of these filings are available online at www.sec.gov,

A handwritten signature in black ink, appearing to be "J. Janssen", is located in the bottom right corner of the page.



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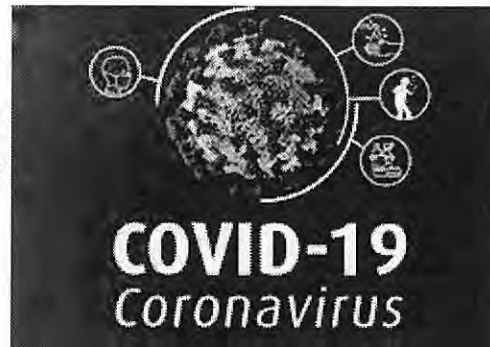
PRESS RELEASES

Parliament, Wednesday, 31

March 2021 – The Portfolio

Committee on Health received an update from the Minister of Health, Dr Zweli Mkhize, and the Department of Health on the Johnson & Johnson clinical trials, vaccines

procurement and progress on the vaccination roll-out programme.



Briefing the committee, Minister Mkhize said South Africa has secured 10 million Covid-19 vaccine doses from Johnson & Johnson and that the government had successfully pushed for a further 20 million doses. Government is now negotiating the terms for the additional vaccines. In total, the Minister said South Africa has 31 million doses of the Johnson & Johnson vaccine in the pipeline and an additional 20 million doses from Pfizer.

The committee was informed that advanced negotiations are taking place with other pharmaceutical manufacturers, such as Sputnik, Sinopharm and Sinovac.

The committee expressed concern about the delays in the implementation, as well as the deviation in the vaccine roll-out figures. Members of the committee said that the department had made commitments and set targets for the roll-out of the vaccines,

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but these have not been met. The committee questioned whether the revised targets will be met and what measures are in place to ensure this.

The committee also heard that to date 251 707 healthcare workers have been vaccinated under the Sisonke Protocol.

Committee Chairperson Dr Sibongiseni Dhlomo congratulated Ministerial Advisory Committee co-chair Professor Kholeka Mlisana on her appointment after the departure of Professor Salim Abdool Karim to focus on his HIV research.

ISSUED BY THE PARLIAMENTARY COMMUNICATION SERVICES ON BEHALF OF THE CHAIRPERSON OF THE PORTFOLIO COMMITTEE ON HEALTH, DR SIBONGISENI DHLOMO.

For media enquiries or interviews with the Chairperson, please contact the committee's Media Officer:

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Vaccine roll-out & preparedness for third wave; Digital Vibes contract investigation; with Acting Minister & Deputy Minister | PMG



Vaccine roll-out & preparedness for third wave; Digital Vibes contract investigation; with Acting Minister & Deputy Minister

17 June 2021

Chairperson: Dr S Dhlomo (ANC)

Meeting Summary

Video:
Audio:

The Committee met virtually with the Department of Health to receive updates on the investigation into the Digital Vibes contract, and on the management of the COVID-19 pandemic.

The Committee had also requested a legal opinion about the applicability of the sub judice rule. In a prior meeting, the ANC had invoked the rule to foreclose discussion about the Digital Vibes contract and to justify the Minister's absence from the briefing. The legal opinion concluded that the Digital Vibes matter was not sub judice. The matter was under investigation but not before a court, and in any case the sub judice rule would have to be measured against the importance of parliamentary oversight.

Despite this legal opinion, the ANC remained convinced that the Committee should not interrogate the Digital Vibes matter until the Special Investigating Unit (SIU) had concluded its investigation. In addition, ANC Members claimed it would be inappropriate for the Committee to summon the Minister while he was on special leave. However, the DA, EFF, and FF+ were united in their demand that the Minister should appear before the Committee. They believed that the Minister was being shielded from accountability and that the Committee was being disabled in its oversight functions.

The Department of Health reported that the Auditor-General had suspected Digital Vibes of overcharging, and that the Department had subsequently appointed Ngubane, a private firm, to investigate. That investigation had found various irregularities. The tender and bidding process had been in contravention of the Public Finance Management Act, and there had been irregularities in the appointment process, including non-disclosure of conflicts of interest by members of the bid committees. Digital Vibes had also been paid R35 million for COVID-19-related work that had not been included in the contract at the time the work was done. The total sum paid to Digital Vibes – R150 million – was deemed irregular, and R37 million constituted fruitless and wasteful expenditure. The Department was awaiting the SIU's final report before taking further steps in disciplinary processes and in recovering funds. Several individuals were implicated in the internal report, but the Department could not yet reveal their identities, especially because the SIU might add further charges.

The ANC expressed satisfaction with the Department's report, but opposition parties were uniformly disappointed. Members wanted to hear details about the purported irregularities in the procurement process, and about how the Department had outsourced communication functions that should have been handled internally. They also wanted to know whether the Minister had approved the Digital Vibes contract and whether he had benefited from it personally. The DA, EFF, and FF+ maintained that the Minister should be required to answer these questions before the Committee.

The Chairperson decided to approach parliamentary office-bearers about meeting with the SIU in early July, when its investigation would be finalised. He also undertook to seek further advice about the legality of summoning a minister on special leave, though parliamentary legal services had assured the Committee that such a summons was within its powers and up to its discretion.

On COVID-19, the Department reported that cases had increased by 50% over the last week, for a total of 95 772 active cases. The effective reproduction rate (R) of the virus was estimated at 1.25. Four provinces had entered their third wave of infections, with Gauteng the current epicentre, but all showed a troubling rise in cases and hospitalisations. The country's public and private hospitals accommodated a total of 114 421 hospital beds, including 5 616 ICU beds. In the current week, 6.5% of all beds and 25.9% of ICU beds were occupied by COVID-19 patients. At the same time, field hospitals in the provinces were being decommissioned, because the Department did not think they were needed. The Department was also confident that its oxygen supplies would be sufficient to cope with the third wave.

The Department said that 1.97 million people had been vaccinated to date, although most of them had received only the first dose of the two-dose Pfizer vaccine. The Department was unlikely to vaccinate more than 60% of persons older than 60 before the end of June, well below its target. The vaccination roll-out had primarily been hampered by delays in vaccine procurement. However, another concern was a decline in the pace of registrations. The Department was therefore reviewing the protocols for walk-ins at its 576 vaccination sites, 31 million doses of the Johnson &

11/19/21, 9:41 AM

Vaccine roll-out & preparedness for third wave; Digital Vibes contract investigation; with Acting Minister & Deputy Minister | PMG

Johnson vaccine and 31,39 million doses of the Pfizer vaccine had been secured, including 1.39 million through COVAX. Deliveries of the first batches were expected to begin the next day. Johnson & Johnson vaccines arriving over the next week would be used for an ambitious programme in the basic education sector, which would target half a million persons in that sector over a period of ten days.

Members raised several matters arising from their oversight visits, including the continued closure of Charlotte Maxeke Academic Hospital and water shortages at health care facilities. They asked about the provision of oxygen to day hospitals and district hospitals, especially in rural areas. Also of concern was the decommissioning of field hospitals and the renewed spread of COVID-19 at schools.

However, the vaccination roll-out dominated the discussion about COVID-19. Though the Department claimed that the roll-out would accelerate rapidly when vaccines began arriving, Members remained concerned about its pace. They criticised the Department's failure to meet its vaccination targets and urged the Department to admit such failures to the Committee and to the public. They pushed the Department to provide new and realistic targets, taking into account the delays thus far and the loss of two million contaminated vaccines. Members also wanted more detailed updates about the Sputnik and Sinovac vaccines, which they thought should be a crucial part of the vaccination plan. Finally, they raised problems with the electronic vaccination data system (EVDS), which experienced delays and which they said assigned people to inaccessible vaccination sites, especially in rural areas. Given these problems with EVDS, they were concerned that the approach to walk-ins was inconsistent across vaccination sites.

Meeting report

Ms E Wilson (DA), Ms M Hlengwa (IFP), and Ms M Sukers (ACDP) sent apologies. The acting Minister had also communicated a request to be excused after an hour, to attend a meeting with the President.

The Chairperson reminded Members that the Committee meeting constituted a meeting of the National Assembly (NA) for official purposes. Thus NA rules, including the rules of debate, and as well as the rules for virtual sittings, applied. Members enjoyed the same powers and privileges as in a sitting of the NA. Anything said during the meeting was considered to have been said before the NA and could be ruled upon accordingly. All Members should mute their microphones unless recognised by the Chairperson, and should refrain from making unnecessary points of order or interjections.

Legal opinion: Application of the *sub judice* rule in the Digital Vibes matter

The Chairperson reminded Members of the context in which a legal opinion had been sought. Dr Zweli Mkhize, Minister of Health, had declined to attend the Committee's last meeting with the national Department of Health (NDOH), on . The night before that meeting, Minister Mkhize had told the Chairperson over telephone that he had received legal advice not to appear before the Committee in connection with the Digital Vibes matter. The Chairperson had accepted this explanation and had communicated it to the Committee. He had not been able to seek legal advice prior to the meeting, because it had begun at 8 a.m. Some Members had "reluctantly accepted" Minister Mkhize's explanation. During that meeting, the sub judice rule had been raised. The sub judice issue, however, was an "add-on" – it had not been the reason for Minister Mkhize's absence. During the meeting, the Committee had decided to seek a legal opinion to clarify its powers. The legal opinion had subsequently been sent in writing to all Members.

Adv Siviwe Njikela, Senior Legal Advisor: Office of Constitutional and Legal Services, Parliament, presented the legal opinion. The legal services unit had been given a narrow brief. The Committee had asked for advice on whether the sub judice rule applied to a matter under investigation by the South African Police Service (SAPS) or by the Special Investigating Unit (SIU). He could not comment on the legal advice received by Minister Mkhize, because he had not been privy to it.

Adv Njikela said that the sub judice rule had a long history in law, but had generally been used under jury systems, to promote the administration of justice. The rule had been established in response to the concern that laypersons in juries – who had to make findings of fact on matters before a court – should be protected from external influence. However, South Africa had abandoned the jury system long ago. Justice was now administered by judges, who were trained in the law and in adjudication. The Constitution and other laws guaranteed the independence and impartiality of judges.

In the post-Apartheid constitutional dispensation, *Midi Television* the Supreme Court of Appeal (SCA) had considered the interpretation of the sub judice rule in the post-Apartheid constitutional dispensation. *Midi Television* concerned an eTV television programme which discussed a specific case that was pending before court at the time. The SCA's judgement provided guidelines on the application of the sub judice rule. First, the rule applied only if there was a demonstrable and substantial risk of prejudice to the administration of justice. Mere conjecture or speculation that prejudice might occur was not sufficient – substantive evidence had to be provided. Moreover, a court had to determine whether the disadvantage of curtailing the free

COVID-19 vaccine agreements

Publicly announced supply agreements, as well as manufacturing agreements between companies

To expand a visual, hover over the visual and select the focus mode icon

Hold down CTRL to select multiple filters

View option

Bilateral/multilateral agreements

By country/group and vaccine developer

By country/group and manufacturer

By vaccine developer

By manufacturer

Agreements table

Resold/swapped agreements

Population coverage



Deal date	Country/territory/group	Deal type	Vaccine developer	Manufacturer	Vaccine name	Distributor	Committed \$	Secured doses	Optioned doses	Status	Source
07/01/2021	South Africa	Bilateral	(Beijing) Serum Institute of India	(Beijing) Serum Institute of India	Covishield			1,000,000		Formalized	
18/01/2021	South Africa	Bilateral	Janssen Pharmaceuticals	Janssen	Ad26.COV 2.5			11,000,000	20,000,000	Formalized	
07/04/2021	South Africa	Bilateral	Pfizer BioNTech	Pfizer/BioNTech	Comirnaty			20,000,000		Formalized	
14/04/2021	South Africa	Bilateral	Pfizer BioNTech	Pfizer/BioNTech	Comirnaty			10,000,000		Formalized	
28/04/2021	South Africa	Bilateral	Gamaleya Research Institute	Gamaleya Research Institute	Sputnik V			10,000,000		In discussion	
28/04/2021	South Africa	Bilateral	Sinopharm (Beijing)	Sinopharm (Beijing)	BBIBP-CorV			10,000,000		In discussion	
29/01/2021	Sri Lanka	Bilateral	Pfizer BioNTech	Pfizer/BioNTech	Comirnaty			5,000,000		Formalized	
19/02/2021	Sri Lanka	Bilateral	Serum Institute of India	Serum Institute of India	Covishield			1,500,000		Formalized	
17/03/2021	Sri Lanka	Bilateral	Gamaleya Research Institute	Gamaleya Research Institute	Sputnik V			13,000,000		Formalized	
15/05/2021	Sri Lanka	Bilateral	Sinopharm (Beijing)	Sinopharm (Beijing)	BBIBP-CorV			13,000,000		Formalized	
07/08/2020	Switzerland	Bilateral	Moderna	Moderna	Spikevax			13,500,000		Formalized	



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ASPEN ANNOUNCES AGREEMENT WITH JOHNSON & JOHNSON TO MANUFACTURE INVESTIGATIONAL COVID-19 VACCINE CANDIDATE

By [Shauneen Beukes](https://www.aspenpharma.com/author/shauneen-beukes/) | Nov 2, 2020 | Comments Off

Durban, South Africa – Aspen is pleased to announce that one of its wholly-owned South African subsidiaries, Pharmacare Limited (which trades as "Aspen Pharmacare"), has entered into a preliminary agreement with Janssen Pharmaceuticals, Inc., and Janssen Pharmaceutica NV, two of the Janssen Pharmaceutical Companies of Johnson & Johnson, for the technical transfer and proposed commercial manufacture of their COVID-19 vaccine candidate, JNJ-78456563 (previously referred to as JNJ-78456563-COV2-S).



The vaccine candidate is currently undergoing clinical trials. Aspen Pharmacare will perform formulation, filling and secondary packaging of the vaccine for supply to Johnson & Johnson. This agreement is still subject to the successful completion of the relevant technology transfer activities and finalisation of certain commercial manufacturing terms.

Aspen Pharmacare has agreed to provide the necessary capacity required for the manufacture of Johnson & Johnson’s COVID-19 vaccine candidate at its existing sterile facility in Port Elizabeth, South Africa.

Aspen has invested in excess of R3 billion in the facility together with the high technology equipment and systems that will be used to manufacture state-of-the-art sterile drugs and vaccines, packaged into vials, ampoules and pre-filled syringes. The production area where it is intended that the vaccine candidates will be manufactured has capacity to produce more than 300 million doses per annum. The facility has accreditation from a range of international regulatory authorities and provides lifesaving medicines to both the domestic and international markets. It was part of the first flagship investments announced at the President’s inaugural South African Investment conference. Stephen Saad, Aspen Group Chief Executive said “We have invested globally in our sterile capability and are determined to play a role in the manufacture of vaccines to add to our proud track record of making contributions to humanity in times of global pandemics. This has included, *inter alia*, being a leading global supplier for antiretrovirals for the treatment of HIV/AIDS, multi-drug-resistant-TB products and COVID-19-related treatments such as anaesthetics and dexamethasone. We have been selected as a vaccine partner by Johnson & Johnson and this project will receive priority focus. We are particularly pleased to be given the opportunity of providing assistance for patients in need across the world from our South African base.”



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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.

By Rebecca Robbins and Benjamin Mueller

Aug. 16, 2021

Johnson & Johnson's Covid vaccine was supposed to be one of Africa's most important weapons against the coronavirus.

The New Jersey-based company agreed to sell enough of its inexpensive single-shot vaccine to eventually inoculate a third of the continent's residents. And the vaccine would be produced in part by a South African manufacturer, raising hopes that those doses would quickly go to Africans.

That has not happened.

South Africa is still waiting to receive the overwhelming majority of the 31 million vaccine doses it ordered from Johnson & Johnson. It has administered only about two million Johnson & Johnson shots. That is a key reason that fewer than 7 percent of South Africans are fully vaccinated — and that the country was devastated by the Delta variant.

At the same time, Johnson & Johnson has been exporting millions of doses that were bottled and packaged in South Africa for distribution in Europe, according to executives at Johnson & Johnson and the South African manufacturer, Aspen Pharmacare, as well as South African government export records reviewed by The New York Times.

Glenda Gray, a South African scientist who helped lead Johnson & Johnson's clinical trial there, said companies needed to prioritize sending doses to poorer countries that were involved in their production. "It's like a country is making food for the world and sees its food being shipped off to high-resource settings while its citizens starve," she said.

Many Western countries have kept domestically manufactured doses for themselves. That wasn't possible in South Africa because of an unusual stipulation in the contract the government signed this year with Johnson & Johnson. The confidential contract, reviewed by The Times, required South Africa to waive its right to impose export restrictions on vaccine doses.

Popo Maja, a spokesman for the South African 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."

Johnson & Johnson had always planned for some vaccines produced by Aspen to leave Africa, but it has never disclosed how many doses it was actually exporting. The export records reviewed by The Times show that Johnson & Johnson shipped 32 million doses in recent months, although that does not capture the full number that have left South Africa.

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.

Critics say the shortfall in South Africa partly reflects a power imbalance between a giant company and a desperate country.

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"The disproportionate amount of power that Johnson & Johnson has exercised is really concerning," said Fatima Hassan, a human rights lawyer in South Africa. "It is harming our efforts to get speedy supplies into the system."

The picture is bleak across the continent. While several African countries received small initial shipments of Johnson & Johnson doses last week, they are a sliver of the 400 million doses that the African Union has ordered or has the option to order for its member countries. About 2 percent of Africans are fully vaccinated.

Johnson & Johnson's chief scientific officer, Dr. Paul Stoffels, said the Aspen plant is part of a production network in which vaccines are routinely shipped between countries for manufacturing, quality inspection and delivery.

Dr. Paul Stoffels, Johnson & Johnson's chief scientific officer, says the Aspen plant is part of a global production network. Janssen Vaccines, via Reuters

"We have done our best to prioritize South Africa as much as we can," he said. He noted that Johnson & Johnson early this year provided about 500,000 doses to vaccinate South African health care workers. He said the Aspen plant would exclusively supply doses to African countries later this year.

Aspen is responsible for the final stage of vaccine production, a process known as "fill and finish." The company receives mass quantities of the vaccine, bottles it into vials and then packages it for final inspections and delivery.

Some of Aspen's doses were never used because of worries they might have been contaminated at the Baltimore plant that handled their first stage of production, according to Johnson & Johnson and Aspen executives. The problems at that plant, run by Emergent BioSolutions, wreaked havoc on Johnson & Johnson's vaccine supplies, leading the company to fall behind on orders all over the world.

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Stephen Saad, Aspen's chief executive, blamed the lack of South African doses on the Emergent plant. He said Aspen could not control where its doses were sent, but "I would have liked to see it all go to Africa."

Aspen is now finishing doses that were made at a plant in the Netherlands, with 40 percent of those doses going to Europe and the remaining 60 percent to Africa through the end of September. Previously, the plan was for only 10 percent to go to the continent, but the European Union agreed to change the distribution in light of South Africa's crisis, said Daniel Ferrie, a spokesman for the European Commission.

South Africa's vaccination campaign has accelerated in recent weeks, thanks largely to Pfizer doses ordered by the government and shots donated by the United States. But about four million of the country's 60 million residents are fully vaccinated.

That left the population vulnerable when a third wave of cases crested over the country. At times in recent months, scores of Covid-19 patients at Helen Joseph Hospital in Johannesburg were waiting in the emergency department for a bed, and the hospital's infrastructure struggled to sustain the huge volumes of oxygen being piped into patients' lungs, said Dr. Jeremy Nel, an infectious-disease doctor there.

"The third wave, in terms of the amount of death we saw, was the most heartbreaking, because it was the most avoidable," Dr. Nel said. "You see people by the dozens dying, all of whom are eligible for a vaccine and would've been among the first to get it."



Dr. Jeremy Nel, an infectious-disease doctor in Johannesburg. Gulshan Khan for The New York Times

Critics say South Africa's government shares blame for the low rate of vaccinations. Early on, the government relied on a United Nations-backed clearinghouse for vaccines that has fallen behind on deliveries. South Africa was slow to enter negotiations with manufacturers for its own doses. In January, a group of vaccine experts warned that the government's "lack of foresight" could cause "the greatest man-made failure to protect the population since the AIDS pandemic."

Johnson & Johnson's deal with Aspen was announced in November. Aspen's facility in Gqeberha, on South Africa's southern coast, was the first site in Africa to produce Covid vaccines. (Other companies subsequently announced plans to produce vaccines on the continent.)

The Coronavirus Pandemic: Key Things to Know

The latest Covid data in the U.S. As the Omicron surge caused case counts to reach record highs and hospitalizations to surpass last winter's peak, here's what the data suggests about the variant's potential toll. Reports of falling infection rates in parts of the U.S., meanwhile, hint that a national peak may be approaching.

South African officials hailed Aspen's involvement as indispensable.

Aspen "belongs to us as South Africans, and it is making lifesaving vaccines," South Africa's president, Cyril Ramaphosa, said during a visit to Aspen's plant in March. He said he had pushed Johnson & Johnson to prioritize the doses made there for Africans.

"I want them now," Mr. Ramaphosa added. "I've come to fetch our vaccines."

President Cyril Ramaphosa, right, and other South African officials touring the Gqeberha plant in March. Getty Images

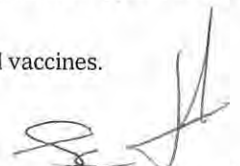
The Johnson & Johnson vaccine became even more important in February when the results of a clinical trial suggested that the vaccine from AstraZeneca offered little protection from mild or moderate infections caused by the Beta variant that was circulating in South Africa.

Weeks later, Johnson & Johnson and the government signed a contract for 11 million doses. South Africa ordered another 20 million doses in April. That would be enough to vaccinate about half the country.

South Africa agreed to pay \$10 per dose for the 11 million shots, according to the contract. That was the same price that the United States paid and slightly more than the \$8.50 that the European Commission agreed to pay. The South African contract prohibited the government from banning exports of the vaccine, citing the need for doses to "move freely across national borders."

Mr. Maja, the South African health ministry spokesman, said that absent that stipulation, the government might have stopped vaccine doses from leaving the country.

But the requirement put South Africa at a disadvantage compared with other places that were producing Covid vaccines.



11/19/21, 2:21 PM

Vaccine trials, procurement & roll-out programme update; with Minister & Deputy Minister | PMG

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Vaccine trials, procurement & roll-out programme update; with Minister & Deputy Minister

Health

28 April 2021

Chairperson: Mr S Dhlomo (ANC)

Meeting Summary

COVID-19 Updates

Video

In this virtual meeting, the Department of Health updated the Portfolio Committee on Health on Covid-19 Epidemiology, Surveillance and Vaccine Roll-Out. The Department provided South Africa's epidemiology and surveillance of Covid-19. An update was provided on the South African Covid-19 Modelling Consortium's preliminary findings on anticipating the third wave. An update on the vaccination rollout plan was also given. This explained in detail the vaccines supply pipeline, vaccination sites and the vaccine dose allocation. It was indicated that the Sisonke Trail was expected to be finalised by the middle of May. An update on the no-fault compensation fund was also given to the Committee. The Department updated the Committee on the Electronic Vaccination Data System registrations. The cumulative number of cases reported in South Africa on 26 April 2021 was 1 576 320. Nationally, the cumulative number of recoveries increased by 0.05% in the past 24 hours to 1 501 880. This represented a recovery rate of 95.3%. There were currently 20 254 active cases in the country. The national case fatality rate (CFR) as of 26 April 2021 was 3.4%. The total cumulative number of deaths was 54 186.

The Committee was concerned about the situation in India. It was asked of the Department what regulations and steps were it putting in place to ensure that South Africa did not have a spike in infections like in India? Why did the Minister want to wait before another crisis and then put restrictions on travellers that were travelling from India to South Africa? Members asked if the Minister could confirm if there had been any serious side-effects or any deaths reported of people who had received the Johnson and Johnson vaccine in South Africa? The Committee discussed the rollout of phase two of vaccinations. Would phase two start during phase one? Would phase one first be fully completed before phase two started? Would the 292 000 healthcare workers that was vaccinated with the Johnson and Johnson vaccine be monitored for any side-effects? Would the total number of 3357 vaccination facilities across the country be enough to administer the vaccines and were they duly prepared to do these vaccinations? When would the members of the Committee receive a final list of the vaccination facilities? Since phase two entailed the vaccination of citizens over 60 years older the members asked questions about the Department preparedness to assist the elderly. What programmes were being put in place to assist the elderly in registration? It was asked if there would there be home calls for elderly registration or do they need to physically do it at a clinic? The members also raised the issue of the regulations for the no-fault compensation fund. It was asked why the public was only given four days to comment and give inputs on these regulations? Why was there so much haste to establish this fund? It was said that the short amount of time given for public comment could amount to an undermining of the democratic process. The members of the Committee raised concern about the Department's prediction on when South Africa would be entering a third wave. It was asked if the third wave would be more severe than the others? It was asked if the Department would act appropriately and timeously with regard to the third wave? A Member asked how many private applications have been done for the private purchase of vaccines? This had been allowed and the Committee needed to know if any applications had been made. What were the Government regulations with regards to that? It was noted that many people could not return to their places of work or to their studies because they needed to be vaccinated in advance. Was there no way that provision could be made

<https://pmg.org.za/committee-meeting/32735/>

1/21

11/19/21, 2:21 PM

Vaccine trials, procurement & roll-out programme update; with Minister & Deputy Minister | PMG

for somebody who could produce a contract or an acceptance into a university to have them included in this vaccine rollout sooner rather than later? The Committee wanted to know how medical schemes and healthcare providers were going to make financial provisions for the vaccine rollout. How did the Department define the price to recover the vaccine and the associated logistical costs from the medical schemes? How would the private healthcare providers, such as pharmacies, be compensated for dispensing vaccines to state patients?

Meeting report

The Chairperson welcomed the Department of Health, members of the Committee, the media and members of the public to the meeting. He thanked the Committee Secretariat for finding time for the Committee to respect the commitment made of having fortnightly updates from the Minister. That was the item for today's meeting. He would be guided if there were any other items on the agenda. One of the items on the agenda were the minutes that were outstanding. He thanked the team that worked very hard to ensure the Committee and Department sat in these meetings. He asked that the meeting start with a moment of silence to remember a colleague, Ms Jacqueline Mofokeng, who was laid to rest with her daughter the previous day. It was a very tragic incident. A day before she passed on she had lost her daughter. The following day she had also succumbed to Covid-19.

[The Committee held a moment's silence for her and all South Africans lost to Covid-19].

The Committee Secretariat read out the members present in the meeting and the apologies.

The Chairperson recognised the Minister, Deputy Minister and Director General of the Department of Health. He thanked the Minister for finding time to update the Committee. The Minister updated the Committee a fortnight ago and was detailed in response to the things that were worrying the Committee. Some of the issues were work-in-progress. The Committee made a specific request that it be updated on the vaccine plan and updates on Sinopharm and Sputnik. The Committee was excited to learn that today the Department would be restarting with the vaccine trial. The Department needed to tell the Committee why it was restarting today. It was always indicated to the Committee that the suspension of the trial was not going to be very long. The Department needed its scientists to guide it and provide advice. The Department needed to comment on its readiness to go to the provinces. The Department also needed to provide an update on the registration process of South African citizens who were older than 60. Those were the main items that would be discussed in the meeting. Thereafter, the Committee would deal with its in-house programme. After the presentation the Chairperson would allow the members to ask clarity seeking questions, to make comments and engage with the Minister.

Mr A Shaik Emam (NFP) said he would be boarding a flight in 30 minutes. He had sent some written questions to the Committee to be asked to the Department.

The Chairperson said he would read Mr Shaik Emam's questions.

Mr P Van Staden (FF+) said he also had questions for the Minister after he was finished with the presentation.

The Chairperson handed over to the Minister to update the Committee.

Remarks by Minister

Dr Zweli Mkhize, Minister of the Department of Health, appreciated the opportunity to share some of the issues that relate to the vaccine rollout programme. There would be times when there would be lots of details and there would be times where there were not a lot of details. It all depended on where the Department was with the process. He said that a number of issues that the Committee previously raised had been cleared. The matter that related to the contracts with Johnson and Johnson had been resolved. The contract had been signed. The



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More Pfizer vaccines for SA

Wednesday, April 14, 2021

Health Minister, Dr Zweli Mkhize, has announced that South Africa has secured an additional 10 million COVID-19 Pfizer vaccines.

Speaking in Parliament, Mkhize told the Health Portfolio Committee on Wednesday that this will increase the total number of the two-dose vaccine to 30 million.

"We can now guarantee that the number of people that will be vaccinated with Pfizer has increased from 10 to 15 million."

The Minister said the first batch of over 300 000 vials of these shots are expected to arrive in the country on 3 May 2021, while the rest of the consignment will be delivered weekly.

However, he said both the Pfizer and Johnson & Johnson (J&J) agreements, which both cost US\$10 per vaccine, have non-refundable clauses.

"The agreements state that down payments that have been made in advance by the department shall not be refundable by the manufacturer to us in any circumstances.

"This is another onerous term that we had to settle for," the Minister told the committee.

Meanwhile, he said government has received an email from J&J, stating that they will not sign off the 20 million doses until they receive a letter from the Trade, Industry and Competition Minister, expressing support for the local investment that they made in Aspen Pharmacare.

"We've been taken aback by this, as there are clauses in the agreement that express this support and acknowledge that this production will not just be limited

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to South Africa and the continent, but also targeted for the global market," said Mkhize.

Last month, President Cyril Ramaphosa and his Deputy, David Mabuza, visited the Aspen Pharmicare sterile manufacturing facility, where millions of vaccine shots are produced in Gqeberha, Eastern Cape.

"Our support for this production in our country was publicly made... J&J said if we don't give them this letter, we're making their global leadership nervous and to them, we've not shown our political will to support them," said Mkhize.

He acknowledged that government has had to navigate through difficult and sometimes unreasonable terms.

"I can also assure that we haven't been sleeping on the job," Mkhize said.

J&J vaccine suspended

Meanwhile, South Africa has suspended the rollout of the Johnson & Johnson (J&J) COVID-19 vaccine as a precautionary measure.

This comes after the United States Food and Drug Administration (FDA) and Centres for Disease Control and Prevention (CDC) paused the rollout of the vaccine following reports of a rare clotting condition in six people out of 6.8 million doses administered.

However, a final decision on the suspension is expected in the next few days.

Addressing media on Tuesday night, Mkhize was confident that in an unlikely event that the J&J rollout is completely halted, the country would still be able to proceed with phase two of the vaccination programme.

"We are confident that the rollout of Johnson & Johnson will resume and so, with 30 million doses of Johnson & Johnson and 30 million doses of Pfizer secured, we now have enough doses to exceed the 40 million we were targeting this year," he said. – [SAnews.gov.za](https://www.sanews.gov.za)

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HEALTH

These are the vaccines South Africa could get

Tshepo Mathe 4 Jan 2021



A lab technician wearing a full body protection suit inspects a bottle containing growth media for virus production during coronavirus vaccine research at the Valneva SA laboratories in Vienna, Austria. (Photo: Akos Stiller/Bloomberg via Getty Images)

Covid-19 cases have been increasing rapidly but Health Minister Zweli Mkhize has assured the public that the government is pulling out all the stops to ensure the country gets vaccines.

The total reported cases have risen to more than a million, 29 577 people have died and about 900 000 have recovered from Covid-19.

The vaccine is expected to play a critical role in controlling the pandemic. The government plans to vaccinate a minimum of 67% of the population (about 40-million people) to achieve herd immunity — when most of the population is resistant to an infectious disease — by the end of this year.

Countries in Europe started vaccinating people at the end of 2020, but South Africa is yet to do so. Mkhize informed the nation on Sunday that the government is “mindful of the urgency, particularly as we feel the impact of the second wave we are currently experiencing” and to this end has “set up structures to expedite financing, sourcing and procurement”.

He added that there were critical factors — such as availability, level of efficacy and safety record — to consider when deciding which vaccine to use.

Last year the department of health and the ministerial advisory committee had discussions with potential vaccine suppliers.

Pfizer

Its vaccine has 95% efficacy. But a patient needs two doses, and it must be stored at -70°C.

AstraZeneca

The vaccine has been approved by the United Kingdom and India's drugs controller general. It has a 70% efficacy rate through two doses. The largest manufacturer is the Serum Institute of India, which has partnered with Cipla SA, itself 100% owned by Cipla India. This vaccine is likely to be widely used because it has stability at between 2°C to 8°C.

Johnson and Johnson

The vaccine will be submitted for approval this month. It is a single dose vaccine, which makes it more cost-effective and easier to administer.

Moderna

The vaccine has been approved by the Food and Drug Administration in the United State. It is a two-dose vaccine, which must be stored at -20°C. But the department of health said the company does not expect to submit a dossier to the South African Health Products Regulatory Authority.

Mkhize said the government plans to roll out vaccinations in three phases, starting with the most vulnerable people. The first phase will target 1.25-million healthcare workers. The second phase will target: 2.5-million other essential workers (for example the police service, mines, retail food sector, banks, municipalities), 1.1-million people in congregate settings such as prisons and care homes, five million people older than 60, and eight million people older than 18 years who have comorbidities. The third phase will involve vaccinating 22.5-million people over the age of 18.

By the end of the third phase, 40.35-million citizens (or 67.25% of the population) would be immunised against Covid.

In a statement on 22 December 2020, the health department and the Solidarity Fund announced that they had made a payment of R283-million through the Covax programme to secure a vaccine for 10% of the population. Mkhize said on Sunday the Covax programme is expected to deliver the vaccine at the beginning of the second quarter.

The R283-million represents 15% of the total cost, but Mkhize said the outstanding amount to be paid had been allocated.

Outside the Covax programme, Mkhize said the government was in negotiations with various companies to acquire vaccines "hopefully as early as February 2021", but much will "depend on the success of [the] current bilateral negotiations".

He said the government has embarked on public and private partnerships to finance the acquisition of the vaccines. The Solidarity Fund will collect funds and expedite controlled procurement processes.

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Minister Mkhize says SA will receive first batch of COVID-19 vaccine in January

Jan 7th, 2021 | In The Media

Health Minister Dr Zweli Mkhize has announced that the country will be receiving the first batch of vaccine this month and another next month and the Astra Zeneca jab will be given to healthcare workers. He says priority will be given to the more than one million health workers for both the private and the public sector. Mkhize was briefing the portfolio committee on Health on the roll out strategy of the COVID-19 vaccine.

Minister Mkhize says SA will receive first batch of COVID-19 vaccine in ...

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Covid-19 vaccines

South Africa halts rollout of AstraZeneca vaccine

Preliminary data find no effect on mild or moderate disease caused by local variant



The South African government had been planning to begin jabs for frontline health workers this month using 1.5m doses of the AstraZeneca vaccine © AP

Joseph Cotterill in Johannesburg and Donato Paolo Mancini in Rome FEBRUARY 8 2021

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South Africa has moved to halt its rollout of the Oxford/AstraZeneca vaccine after preliminary and limited evidence showed it failed to protect against mild and moderate forms of disease caused by a coronavirus variant first detected in the country.

Distribution of the AstraZeneca jab, scheduled to begin this month, would be put on hold to study its effects including on severe cases in more detail “until the scientists give us clear indications as to what we need to do”, Zweli Mkhize, South Africa’s health minister, said on Sunday.

A small trial led by Oxford university and South Africa's Wits university found that the AstraZeneca vaccine had low efficacy against milder illness with the 501Y.V2 variant, according to findings first reported by the Financial Times on Saturday. The paper, which has not yet been peer reviewed, did not study the jab's effects on stopping severe illness.

The South African government had been planning to begin jabs for frontline health workers this month using 1.5m doses of the AstraZeneca vaccine that are being supplied by India's Serum Institute. It will now accelerate rollout of other vaccines it has ordered.

"We can still proceed with this rollout, but we need to do it wisely with a stepped approach," said Salim Abdool Karim, chairman of South Africa's ministerial advisory committee on Covid-19.

What these results tell us is that we need to do everything we can to reduce circulation of the virus and delay mutations that may reduce the efficacy of existing vaccines

World Health Organization

Drugmakers and scientists have been racing to understand how far the 501Y.V2 variant may reduce the effectiveness of some vaccines because it has become dominant in South Africa and similar strains are being detected elsewhere in the world.

Recent results for vaccines produced by Novavax and Johnson & Johnson have shown less effectiveness against 501Y.V2 than against other forms, but showed complete protection against severe Covid-19 regardless of the variant.

South Africa is planning to accelerate rolling out the J&J single-shot vaccine to health workers after results showed that it offers strong protection against severe Covid-19 with 501Y.V2, said Glenda Gray, leader of J&J's local trial.

The country has so far secured 9m J&J doses and 20m doses of Pfizer's vaccine. "What will be available to the health workers will be those vaccines" in the coming weeks, Mkhize said.

J&J's vaccine uses a similar design to AstraZeneca's, which raises hopes that the latter is also effective against severe Covid-19, said Shabir Madhi, leader of the South African study.

AstraZeneca on Saturday said the South African study was limited by the fact that subjects were predominantly young, healthy adults and that numbers were small. No deaths or hospitalisations were recorded in the study, which involved more than 2,000 people with a median age of 31.

The drugmaker said it believed its vaccine could still protect against severe disease caused by the 501Y.V2 variant, which has a mutation, E484K, that appears to neutralise antibodies. The mutation has also been detected in variants in Brazil and, in limited numbers, in the UK.

AstraZeneca also said it believed other immune responses, such as T-cells, could offer protection against the worst of the disease when caused by this variant. The South African study was not designed to measure this response, and no data were available. However, initial data indicated those responses remained intact against the South African variant, AstraZeneca said.

Shabir Madhi, who has led AstraZeneca's clinical trials in the country, told South African radio on Monday that he still believed the shot would play a role in "protecting against severe disease". The suspension of the rollout was intended "to give the scientific community in South Africa a bit more time to interrogate the data," Mr Madhi said.

Both Oxford and AstraZeneca said they had begun tweaking their vaccine with a view to making it available in the autumn, if necessary. Late on Sunday, they had not responded to a request for comment on South Africa's decision.

The World Health Organization told the Financial Times it was important to determine effectiveness in preventing moderate and severe cases, given the South African trial's small sample size and the low risk of severe disease to the participants.

"What these results tell us is that we need to do everything we can to reduce circulation of the virus and delay mutations that may reduce the efficacy of existing vaccines," the WHO said. "It also seems increasingly clear that manufacturers will have to adjust to the Covid-19 viral evolution, taking into account the latest variants for future booster shots."





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Media Statement

21 March 2021

The Minister of Health, Dr Zweli Mkhize, is pleased to announce that the sale of the Astra Zeneca vaccines that we had acquired has been concluded. In the past weeks the Department has had to ensure that all member states identified by the AU vaccine acquisition team as recipients of the vaccines, are compliant and have obtained all regulatory approvals, permits and licenses to roll out the vaccines in their respective countries.

The Minister can confirm that the full purchase amount was received by the Department on Monday last week. The AU and South African teams then ensured that all logistical arrangements are in place for the shipment of the vaccines. The Minister is pleased to announce that the first batch of vaccines that is being delivered will benefit 9 member states. The balance will be collected this week to be delivered to 5 other countries.

Issued by the Ministry of Health


Further queries:

Dr. Lwazi Manzi

MLO Ministry of Health

0826788979

75,000 Doses Of AstraZeneca Vaccine Arrived Yesterday

 CORONAVIRUS APRIL 9, 2021

WRITTEN BY: AINSWORTH MORRIS



PHOTO: MICHAEL SLOLEY

Jamaica yesterday (April 8) received its third shipment of AstraZeneca vaccine to help in its fight against the coronavirus (COVID-19).

The shipment, totalling 75,000 doses, arrived at the Noman Manley International Airport, and came through the African Medical Supply Platform.

The first shipment was donated by the Indian Government and the second

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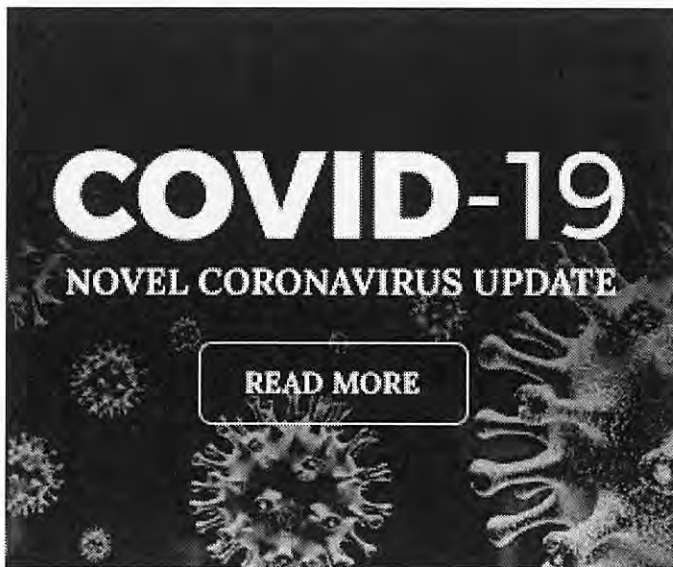


Accepting the shipment, Minister of Health and Wellness, Dr. the Hon. Christopher Tufton, thanked the Government and people of South Africa and the African Medical Supply Platform for the donation.

“This shipment is going to be used for our [vaccination] blitz exercise, starting this weekend. As early as tomorrow, we’re going to be dispatching. The intention is to inoculate as many persons as possible, hopefully well over 50,000. We are doing 60 years and over, and we are including now our teachers and we are also including our hotel workers,” Minister Tufton said.

“We have another shipment coming in this month from COVAX. Approximately 50,000 doses should come in about the third week of April, and possibly another shipment for 20,000,” he said.

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SA makes down payment for COVID-19 vaccine

Tuesday, December 22, 2020

South Africa has made a down payment to secure the COVID-19 vaccine for 10% of the country's population.

"The National Department of Health and the Solidarity Fund are pleased to announce that a down payment of US \$19.2 million USD (R283 million) has been made to GAVI (the Vaccine Alliance) to secure South Africa's entry into the COVAX facility," the department and fund said in a statement on Tuesday.

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 six 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.

Minister of Health, Dr Zweli Mkhize, has hailed this milestone as the epitome of excellence in health service delivery through multilateralism.

"It is a privilege to oversee a process that has brought together government, international partners and business for the sole purpose of delivering quality health care to the people of South Africa.

"This is what we have been advocating for when we speak of multi-sectoral collaboration, and it is gratifying to see this spirit being harnessed for the good of our people, Africans and the global village," Mkhize said.

Solidarity Fund chairperson, Gloria Serobe, said there can be no doubt that a COVID-19 vaccine will play an important role in helping South Africa manage the

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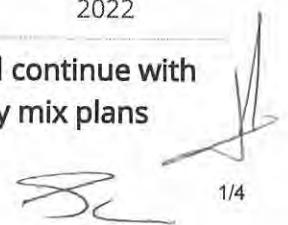
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“The Solidarity Fund was set up for exactly this purpose – to be additive to the work of government and assist in initiatives and programmes that have the greatest impact in the fight against the pandemic. The fund is grateful to be in a position to assist at this crucial juncture,” Serobe said.

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The Department of Health’s Director-General, Dr Sandile Buthelezi, has thanked the Solidarity Fund for providing the financial support that has enabled the country to meet the down payment obligations, as required in terms of the agreement.

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“The Department of Health will make additional payments in relation to vaccines delivered under the COVAX facility as they fall due over the next year,” Buthelezi said. – SAnews.gov.za

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THE COVAX FACILITY: INTERIM DISTRIBUTION FORECAST – latest as of 3 February 2021

INTRODUCTION

In line with initial guidance delivered on 22 January, and building on the publication of the [2021 COVAX global and regional supply forecast](#), the COVAX Facility is pleased to share the following forecast on early availability of doses of the Pfizer-BioNTech vaccine and the AstraZeneca/Oxford vaccine to Facility participants, subject the caveats listed below.

This document contains information on indicative distribution of 240 million doses of the AstraZeneca/Oxford vaccine, licensed to Serum Institute of India (SII) – hereinafter “AZ/SII” and 96 million doses of the AstraZeneca/Oxford vaccine, under the advance purchase agreement between Gavi, the Vaccine Alliance and AstraZeneca – hereinafter “AZ”, for Q1 & Q2 2021.

It also contains an overview of exceptional first round allocation of 1.2 million doses of the WHO Emergency Use Listing (EUL)-approved Pfizer-BioNTech vaccine – hereinafter “Pfizer-BioNTech”, for Q1 2021.

It is important to note additional doses of both these products will be available to the COVAX Facility in 2021.

ASTRAZENECA/OXFORD VACCINE: INDICATIVE DISTRIBUTION, Q1 & Q2 2021

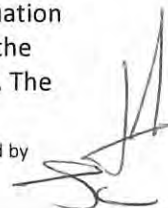
What is an “indicative distribution”?

This indicative distribution is intended to provide interim guidance to Facility participants – offering a planning scenario to enable preparations for the final allocation of the number of doses each participant will receive in the first rounds of vaccine distribution. It is therefore **non-binding and may be subject to change**, due to the caveats outlined below. Nevertheless, COVAX partners believe the publication of this information, which has now been shared with all economies participating in the COVAX Facility, marks an important first step in providing governments and public health leaders with the information they need to put in place practical steps for the provision of early doses and a successful national roll out of vaccines.

Overview of the Process

It is important to note that WHO EUL has not yet been granted for the AstraZeneca vaccine¹ – although evaluation processes are [currently underway](#). Pending these final decisions, and based on current estimates of supply, the COVAX Facility has provided an indicative distribution for each Facility participant, covering Q1 and Q2 2021. The

¹ Three WHO Emergency Use Listing (EUL) evaluations are currently underway in relation to the AstraZeneca/Oxford vaccine: for doses manufactured by AstraZeneca, SK Bioscience, and Serum institute of India.



COVAX Interim Distribution Forecast

As of 3 February 2021

final allocation of the AstraZeneca vaccine(s) will be undertaken following process and governance outlined to and agreed upon by all Facility participants, and will be subject to the validation of the Independent Allocation of Vaccine Group (IAVG).

It is important to underscore that the indicative distribution is based on current communication of estimated availability from manufacturers. In this regard, it is likely the distribution may need to be adjusted in light of circumstances that are difficult to anticipate and variables that are constantly evolving.

Caveats

In order to understand the indicative distribution and future final allocation of this vaccine, it is important to consider the following:

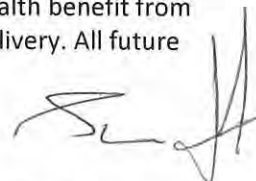
- The actual allocation will only be announced once a product is granted the WHO EUL, and this indicative distribution information does not imply or pre-suppose that this vaccine will be granted WHO EUL;
- The indicative distribution takes into account current estimation of supply volumes.² The supply volume may vary due to manufacturing/and or operational constraints, and this will have an impact on the doses that will be allocated to countries;
- No doses will be allocated in the final allocation if a participant is deemed not ready (for AMC countries), which may cause variations in the quantities allocated to the other participants;
- The exact delivery after allocation will depend on the sequence of countries in the shipment plan, the time taken to place the purchase order, legal / regulatory obligations, as well as the supplier's lead time and related logistics;
- If during this period different products become available, this indicative distribution will need to be adjusted as different products may be allocated to a Facility participant and therefore the quantities indicated for the AstraZeneca/Oxford vaccine (both AZ/SII and AZ) may be altered.

PFIZER-BIONTECH VACCINE: EXCEPTIONAL FIRST ROUND DISTRIBUTION, Q1 2021

Overview of the Process

COVAX currently anticipates 1.2 million doses of the Pfizer-BioNTech vaccine will be available to the COVAX Facility in Q1 2021, subject to the completion of additional agreements, and will be complemented by the larger volumes of the AstraZeneca/Oxford vaccine available to the Facility during the same time period. Additional volumes of doses of the Pfizer-BioNTech vaccine will be available in the second quarter and beyond, per the signed advance purchase agreement between Gavi and Pfizer-BioNTech for up to 40 million doses.

As a result, an exceptional process of distribution was undertaken to ensure maximum public health benefit from the smaller volume of doses of the Pfizer-BioNTech vaccine anticipated to be available for Q1 delivery. All future allocation rounds will follow the standard Facility approach.



² 5% of H1 2021 doses were removed off the supply schedule from AZ/SII and AZ, subtracted from doses anticipated to be available in Q2 2021. This will be used for the Humanitarian and Contingency Buffers, if approved.

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On 6 January, COVAX offered the opportunity to all Facility participants who had not already opted-out of this product to express their interest in accessing an initial limited volume of the ultra-cold chain vaccine from Pfizer-BioNTech. As of the deadline of 18 January, the Facility had received 72 submissions (36 Advance Market Commitment participants and 36 self-financing participants). Six regional review committees (composed of staff from WHO, UNICEF, Gavi and members of Gavi's Independent Review Committee) undertook a technical assessment of the applications to make readiness recommendations.

Given the limited doses, the complexities related to rolling-out a vaccine requiring ultra-cold chain, and to ensure maximum public health impact, a decision was made to limit the number of countries for first deliveries of the Pfizer-BioNTech vaccine in order to enable successful distribution and delivery. Building on the principles of fairness, transparency, and equity for this exceptional early delivery allocation process, all Facility participants expressing interest in early deliveries of Pfizer-BioNTech and assessed as ready by the six regional review committees were divided by regional bloc – as per the six WHO regions – and by their Participant status (whether Self-Financing or AMC).

Based on the limited quantity of doses available, the list of participants was pared down via a WHO-led review process as follows, and based on information available as of 29 January:

- (1) Participant readiness: The majority of participants who applied were assessed to be ready.
- (2) Whether or not the participant had already initiated vaccination: As the intent of this initial roll-out was to allow participants to introduce a vaccine, it was stipulated that Participants that have initiated their COVID vaccination programme as of 29 January will not be included in the first exceptional allocation round for the Pfizer-BioNTech vaccine.
- (3) Self-financing participants' pricing preferences: If doses were within the price point indicated in their Facility application.
- (4) Assessment of risk of health care worker exposure: This is the key impact that this early exceptional distribution is aiming for, and as communicated to COVAX Participants on 6 January. As there is no direct measure of that exposure, a combination of indicators/data were used as a proxy, including mortality rates over the last 28 days.

Caveats

Final supply of these doses is subject to:

- Negotiation and execution of additional agreements required;
- Confirmation of acceptance and enforceability of product handling requirements;
- Confirmation of AMC country readiness; and
- Confirmation of WHO EUL regulatory acceptance by participating countries.



COVAX Interim Distribution Forecast

As of 3 February 2021

OVERVIEW BY FACILITY PARTICIPANT

Total doses cover, on average, 3.3% of the total population of the 145 participants receiving doses from at least one manufacturer in the list detailed below. This is in line with the Facility target to reach at least 3% population coverage in all countries in the first half of the year, enough to protect the most vulnerable groups such as health care workers.

Participants that do not appear in the list below have either exercised their rights to opt-out, have not submitted vaccine requests, or have not yet been allocated doses.

Notes of clarification

- For AZ/SII and AZ indicative distribution, delivery is estimated to begin as of late February, subject to WHO EUL, manufacturing supply capacity and completion of pre-requisites, as outlined in the related caveats section, above.
- For AZ/SII, indicative distribution doses specify contracted number of doses for Q1 + Q2 (first half – H1) supply, with 35-40% available in Q1 and 60-65% available in Q2.
- For AZ, range reflects H1 supply. Of the 170 million doses available via the advance purchase agreement between Gavi and AstraZeneca, 15% is anticipated to be available in Q1 and 42% available in Q2 – or 56%³ overall in H1. Further supply is planned for the second half of the year.
- For Pfizer-BioNTech, doses are those anticipated for Q1 supply, pending successful satisfaction of caveats listed in the relevant section above.

WHO Region	Participant	SFP/AMC	# doses – AZ/SII (indicative distribution)	# doses – AZ/SKBio (indicative distribution)	# doses – Pfizer-BioNTech (exceptional allocation)
EMRO	Afghanistan	AMC	3,024,000	-	-
EURO	Albania	SFP	-	141,600	-
AFRO	Algeria	AMC	-	2,200,800	-
EURO	Andorra	SFP	-	26,400	-
AFRO	Angola	AMC	2,544,000	-	-
PAHO	Antigua and Barbuda	SFP	-	40,800	-
PAHO	Argentina	SFP	-	2,275,200	-
EURO	Armenia	SFP	-	146,400	-

³ Actual numbers are 14.7% in Q1, 41.7% in Q2 totalling 56.4% in H1.

COVAX Interim Distribution Forecast

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EURO	Azerbaijan	SFP	-	506,400	-
PAHO	Bahamas	SFP	-	100,800	-
EMRO	Bahrain	SFP	-	100,800	-
SEARO	Bangladesh	AMC	12,792,000	-	-
PAHO	Barbados	SFP	-	100,800	-
PAHO	Belize	SFP	-	100,800	-
AFRO	Benin ⁴	AMC	936,000	-	-
SEARO	Bhutan	AMC	108,000	-	5,850
PAHO	Bolivia	AMC	900,000	-	92,430
EURO	Bosnia and Herzegovina	SFP	-	153,600	23,400
AFRO	Botswana	SFP	-	117,600	-
PAHO	Brazil	SFP	-	10,672,800	-
WPRO	Brunei Darussalam	SFP	-	100,800	-
AFRO	Burkina Faso	AMC	1,620,000	-	-
AFRO	Cabo Verde	AMC	108,000	-	5,850
WPRO	Cambodia	AMC	1,296,000	-	-
AFRO	Cameroon	AMC	2,052,000	-	-
PAHO	Canada	SFP	-	1,903,200	-
AFRO	Central African Republic	AMC	372,000	-	-
AFRO	Chad	AMC	1,272,000	-	-
PAHO	Chile	SFP	-	957,600	-

⁴ Participation pending final evaluation of vaccine request submitted to the COVAX Facility.

COVAX Interim Distribution Forecast

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PAHO	Colombia	SFP	-	2,553,600	117,000
AFRO	Comoros	AMC	108,000	-	-
AFRO	Congo, Dem. Rep.	AMC	6,948,000	-	-
AFRO	Congo, Rep.	AMC	420,000	-	-
PAHO	Costa Rica	SFP	-	254,400	-
AFRO	Cote d'Ivoire	AMC	2,040,000	-	-
EMRO	Djibouti	AMC	108,000	-	-
PAHO	Dominica	AMC	-	28,800	-
PAHO	Dominican Republic	SFP	-	542,400	-
PAHO	Ecuador	SFP	-	885,600	-
EMRO	Egypt, Arab Rep.	AMC	-	5,138,400	-
PAHO	El Salvador	AMC	-	324,000	51,480
AFRO	Eswatini	AMC	108,000	-	-
AFRO	Ethiopia	AMC	8,928,000	-	-
WPRO	Fiji	AMC	-	100,800	-
AFRO	Gambia, The	AMC	180,000	-	-
EURO	Georgia	SFP	-	184,800	29,250
AFRO	Ghana	AMC	2,412,000	-	-
PAHO	Grenada ⁵	AMC	-	45,600	-
PAHO	Guatemala	SFP	-	847,200	-
AFRO	Guinea	AMC	1,020,000	-	-
AFRO	Guinea-Bissau	AMC	144,000	-	-

⁵ See footnote 4, above.



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PAHO	Guyana	AMC	-	100,800	-
PAHO	Haiti ⁶	AMC	876,000	-	-
PAHO	Honduras	AMC	-	496,800	-
SEARO	India	AMC	97,164,000	-	-
SEARO	Indonesia	AMC	-	13,708,800	-
EMRO	Iran	SFP	-	4,216,800	-
EMRO	Iraq	SFP	-	2,018,400	-
PAHO	Jamaica	SFP	-	146,400	-
EMRO	Jordan	SFP	-	511,200	-
AFRO	Kenya	AMC	4,176,000	-	-
WPRO	Kiribati	AMC	-	48,000	-
SEARO	Korea, Dem. People's Rep.	AMC	1,992,000	-	-
EURO	Kosovo	AMC	-	100,800	-
EURO	Kyrgyz Republic	AMC	504,000	-	-
WPRO	Lao PDR	AMC	564,000	-	-
EMRO	Lebanon	SFP	-	340,800	-
AFRO	Lesotho	AMC	156,000	-	-
AFRO	Liberia	AMC	384,000	-	-
EMRO	Libya	SFP	-	343,200	-
AFRO	Malawi	AMC	1,476,000	-	-
WPRO	Malaysia	SFP	-	1,624,800	-

⁶ See footnote 4, above.



COVAX Interim Distribution Forecast

As of 3 February 2021

SEARO	Maldives	AMC	108,000	-	5,850
AFRO	Mali	AMC	1,572,000	-	-
WPRO	Marshall Islands	AMC	-	24,000	-
AFRO	Mauritania	AMC	360,000	-	-
AFRO	Mauritius	SFP	-	100,800	-
PAHO	Mexico	SFP	-	6,472,800	-
WPRO	Micronesia, Fed. Sts.	AMC	-	48,000	-
EURO	Moldova	AMC	-	156,000	24,570
EURO	Monaco	SFP	-	7,200	-
WPRO	Mongolia	AMC	-	163,200	25,740
EURO	Montenegro	SFP	-	84,000	-
EMRO	Morocco	AMC	-	1,881,600	-
AFRO	Mozambique	AMC	2,424,000	-	-
SEARO	Myanmar	AMC	4,224,000	-	-
AFRO	Namibia	SFP	-	127,200	-
WPRO	Nauru	SFP	-	7,200	-
SEARO	Nepal	AMC	2,256,000	-	-
WPRO	New Zealand	SFP	-	249,600	-
PAHO	Nicaragua	AMC	504,000	-	-
AFRO	Niger	AMC	1,872,000	-	-
AFRO	Nigeria	AMC	16,008,000	-	-
EURO	North Macedonia	SFP	-	103,200	-
EMRO	Oman	SFP	-	254,400	-



COVAX Interim Distribution Forecast

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EMRO	Pakistan	AMC	17,160,000	-	-
PAHO	Panama	SFP	-	216,000	-
WPRO	Papua New Guinea	AMC	684,000	-	-
PAHO	Paraguay	SFP	-	357,600	-
PAHO	Peru	SFP	-	1,653,600	117,000
WPRO	Philippines	AMC	-	5,500,800	117,000
EMRO	Qatar	SFP	-	144,000	-
WPRO	Republic of Korea	SFP	-	2,596,800	117,000
AFRO	Rwanda	AMC	996,000	-	102,960
WPRO	Samoa	AMC	-	79,200	-
AFRO	Sao Tome and Principe	AMC	96,000	-	-
EMRO	Saudi Arabia	SFP	-	1,747,200	-
AFRO	Senegal	AMC	1,296,000	-	-
EURO	Serbia	SFP	-	345,600	-
AFRO	Sierra Leone	AMC	612,000	-	-
WPRO	Singapore	SFP	-	288,000	-
WPRO	Solomon Islands	AMC	108,000	-	-
EMRO	Somalia	AMC	1,224,000	-	-
AFRO	South Africa	SFP	-	2,976,000	117,000
AFRO	South Sudan	AMC	864,000	-	-
SEARO	Sri Lanka	AMC	1,692,000	-	-
PAHO	St. Kitts and Nevis	SFP	-	21,600	-

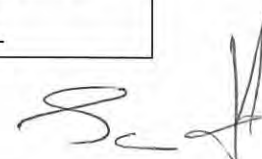
COVAX Interim Distribution Forecast

As of 3 February 2021

PAHO	St. Lucia ⁷	AMC	-	74,400	-
PAHO	St. Vincent and the Grenadines	AMC	-	45,600	-
EMRO	Sudan	AMC	3,396,000	-	-
PAHO	Suriname	SFP	-	79,200	-
EMRO	Syrian Arab Republic ⁸	AMC	1,020,000	-	-
EURO	Tajikistan	AMC	732,000	-	-
SEARO	Timor-Leste	AMC	-	100,800	-
AFRO	Togo	AMC	636,000	-	-
WPRO	Tonga	AMC	-	43,200	-
PAHO	Trinidad and Tobago	SFP	-	100,800	-
EMRO	Tunisia	AMC	-	592,800	93,600
WPRO	Tuvalu	AMC	-	4,800	-
AFRO	Uganda	AMC	3,552,000	-	-
EURO	Ukraine	AMC	-	2,215,200	117,000
PAHO	Uruguay	SFP	-	172,800	-
EURO	Uzbekistan	AMC	2,640,000	-	-
WPRO	Vanuatu	AMC	-	100,800	-
PAHO	Venezuela	SFP	-	1,425,600	-
WPRO	Vietnam	AMC	-	4,886,400	-
EMRO	West Bank and Gaza	AMC	-	240,000	37,440
EMRO	Yemen, Rep.	AMC	2,316,000	-	-

⁷ See footnote 4, above.

⁸ Additional doses are allocated for distribution through UN partners given unique country context.



COVAX Interim Distribution Forecast

As of 3 February 2021

AFRO	Zambia	AMC	1,428,000	-	-
AFRO	Zimbabwe ⁹	AMC	1,152,000	-	-
Non-UN	Non-UN Member States	N/A	-	1,303,200	-

NOTES

- Document was edited 3 February 2021 to add footnote 3, and clarification of related numbers.
- Document was edited 5 February 2021 to add footnote 9.



⁹ Participation pending submission of vaccine request to the COVAX Facility.



THE PRESIDENCY
REPUBLIC OF SOUTH AFRICA (L)

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Statement by President Cyril Ramaphosa on progress in the national effort to contain the COVID-19 pandemic, Union Buildings, Tshwane

27 June 2021 - 12:00am



Fellow South Africans,

Our former President Nelson Mandela once wrote:

"I have walked that long road to freedom. I have tried not to falter; I have made missteps along the way.

"But I have discovered the secret that after climbing a great hill, one only finds that there are many more hills to climb".

As a country, we have faced two devastating waves of coronavirus infections.

We have overcome these by responding swiftly and decisively, and by acting together to contain the spread of the virus and protect ourselves, our families and our communities.

We now face another great challenge, another hill to climb.

Twelve days ago, I addressed you to warn that a new and deadly third wave of infections had begun in a number of our provinces, and was spreading.

The average number of daily new infections was more than doubling, hospital admissions were rising, and deaths from COVID-19 were increasing by nearly 50 per cent.

As I address you this evening, the situation has gotten worse.

Along with many other countries in Africa, South Africa is seeing a massive resurgence of infections.

The Africa Centres for Disease Control and Prevention reports that a third wave of the disease is underway on the continent.

To date, African Union Member States have reported over 5.2 million cases and over 138,000 deaths from COVID-19.

The COVID-19 virus that descended on our country in March last year has been continuing to mutate, creating new variants.

Our scientists tell us that COVID-19 virus has many variants. Last year, we experienced the Beta variant.

In addition, we now have the Delta variant.

This variant was first detected in India at the end of March this year, and is now found in 85 countries.

The Delta variant spread like wildfire in India in an alarming manner.

The Delta variant has now been detected in five of our provinces, namely the Eastern Cape, Free State, Gauteng, KwaZulu-Natal and Western Cape.

The evidence we have is that the Delta variant is rapidly displacing the Beta variant, which has been dominant in our country until now.

We are concerned about the rapid spread of this variant.

Firstly, because it is more transmissible than previously circulating viruses, meaning it is easier to catch through person-to-person contact.

It is thought to be twice as contagious as the Beta variant.

Secondly, because it is more contagious, it can infect far more people.

As with the previous variants, you can pass it on without even knowing you have it. Thirdly, there is now emerging scientific evidence that people previously infected with the Beta variant do not have full protection against the Delta variant, and may get re- infected.

Fourthly, because it is much more contagious, the measures we have so far adopted to contain the spread of the virus may no longer be sufficient to reduce transmission.

There is also much we do not know about this variant.

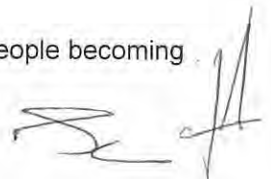
For example, it is not clear that it causes more severe symptoms. Preliminary data from other countries suggests that it is not more severe.

Reports from some countries, including on our continent, also suggest that infections and clinical illness in children may be more common with the delta variant, even as the overall rate of infection remains substantially lower than in adults.

The rapid spread of this variant is extremely serious.

Even if it is not more severe, the rate at which people are infected could lead to many more people becoming ill and requiring treatment at the same time.

We need to take extra precautions.



As of today, the 7-day average of new daily cases nationally has overtaken the peak of the first wave in July last year, and will soon overtake the peak of the second wave we experienced in January this year.

Gauteng now accounts for more than 60 per cent of new cases in the country.

With the exceptions of the Northern Cape and Free State, infections are rising rapidly in all other provinces.

We also must remain vigilant in the Northern Cape and Free State, which may experience a second spike of cases if the new variant spreads there as well.

We must all be worried about what we are seeing unfold before our very eyes.

Every one of us has a friend, a family member or a colleague who has been infected. There are few in our country who have not had to bury a family member, a friend or a loved one who lost their lives to this disease.

We are in the grip of a devastating wave that by all indications seems like it will be worse than those that preceded it.

The peak of this third wave looks set to be higher than the previous two. The 1st wave lasted 15 weeks. The 2nd wave lasted 9 weeks.

We don't know how long this one will last, but indications are that it could last longer. I know that is the last thing many of you want to hear.

We have all had to endure great hardship over the past year and a half.

We may have thought that with life slowly returning to normal, we could take a more casual approach to the public health regulations.

Perhaps we are fed up with wearing a mask on public transport and decide to keep it off one day. When we see nobody objects or complains, we stop wearing it.

We go to social gatherings with a mask on, but take it off once we are inside.

When we meet our friends and loved ones we hug, kiss and shake hands, believing ourselves and them to be safe.

We continue to accept invitations to social gatherings and parties, and host our own. The difficult truth is that complacency comes at a high price.

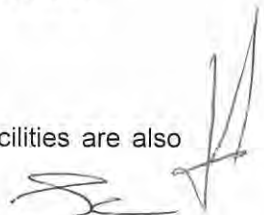
We must maintain our guard and continue to be careful at all times.

We must follow the public health regulations that are there for our own safety and the safety of others.

Safeguarding the capacity of our health facilities to cope with rising infections is a priority.

In several provinces, our public health facilities are stretched to their limits, and private facilities are also buckling under the strain.

Even as our hospitals have made extraordinary efforts to accommodate patients, ICU beds are in short supply.



What we are seeing is that the existing containment measures in place are not enough to cope with the speed and scale of new infections.

In considering what new measures we have to take we have drawn on international best practice and scientific data from studies across the world.

Our priority is to break the chain of transmission by reducing person-to-person contact and thereby help to flatten the curve.

Based on scientific advice we received from the Ministerial Advisory Committee and further consultation with our provinces and metros and traditional leaders, and on the recommendation of the National Coronavirus Command Council, Cabinet has decided that the country should move to Adjusted Alert Level 4.

Cabinet decided that to ensure that our response is appropriate and proportionate to the current situation, the additional restrictions we are announcing this evening will be in place for the next 14 days.

We will assess the impact of these interventions after 14 days to determine whether they need to be maintained or adjusted.

Therefore, the following measures are to be in place across the country from tomorrow, Monday, the 28th of June 2021 to Sunday, the 11th of July 2021:

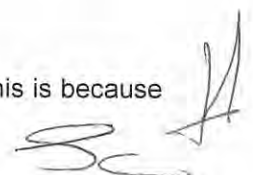
- All gatherings – whether indoors or outdoors – are prohibited. These include religious, political, cultural and social gatherings.
- Funerals and cremations are permitted, but attendance may not exceed 50 people and all social distancing and health protocols must be observed.
- Night vigils, after-funeral gatherings and 'after-tears' gatherings are not allowed.
- Public spaces, such as beaches and parks, will remain open. However, no gatherings will be permitted.
- A curfew will be in place from 9pm to 4am, and all non-essential establishments will need to close by 8pm.
- The sale of alcohol both for on-site and off-site consumption is prohibited.

Our Ministerial Advisory Committee has advised that the limited restrictions previously imposed were not that effective and that a prohibition will ease the pressure that is placed on hospital services by alcohol-related emergency incidents.

- Because of the burden of infections in Gauteng, travel in and out of the province for leisure purposes will be prohibited. This does not include work, business or commercial travel, transit through airports or for the transport of goods.

If you are currently not in your place of residence, you will be allowed to return home to or from Gauteng.

- Visits to old age homes, care facilities and other 'congregant settings' will be restricted.
- Restaurants and other eateries will only be permitted to sell food for take-away or delivery. This is because it is not possible for patrons to wear masks while eating or drinking in these establishments.



The closure of schools and other educational institutions for the winter holidays will be brought forward. 193

Schools will start closing from this Wednesday, the 30th of June, and all schools will be expected to be closed by the end of the week, on Friday.

Contact classes at tertiary institutions will end by Wednesday, the 30th of June, with limited access to the institutions.

Residences will however remain open.

The Ministers of Basic Education and Higher Education, Science and Innovation will provide further details on these arrangements.

The measures that we are putting in place now are designed to allow as much economic activity to continue as possible, while containing the spread of the virus.

Most businesses will continue to operate at full capacity and should not be affected. Our focus is on limiting social contacts while preserving the economy.

I want to emphasise that it remains mandatory for every person to wear a face mask that always covers their nose and mouth when in public spaces.

It is a criminal offence not to do so.

The owners and managers of public buildings, centres, shops, restaurants, taxis and buses all have a responsibility to ensure that people on their premises or in their vehicles wear masks.

All employers must allow their staff to work from home wherever possible, and should postpone all non-essential travel and workplace gatherings.

Government will also be putting in place measures to reduce physical attendance of its employees at workplaces while limiting the disruption of government activities and services.

As we implement these restrictions, we are continuing to work to strengthen the capacity of our health system.

In Gauteng, the loss of significant capacity due to the ongoing closure of the

Charlotte Maxeke Hospital is adding strain to other hospitals.

We are doing everything we can to provide additional bed capacity and speed up the re-opening of Charlotte Maxeke hospital.

At present, Gauteng has made available 830 additional beds by postponing elective surgery and another 400 beds constructed with alternative building technology that are now being activated.

We have been engaging with the producers of medical oxygen to increase their production to accommodate the anticipated increase in cases.

We are constantly monitoring PPE stocks and medicine stock availability so that we can intervene where we see declines in stock levels.



The Gauteng Department of Health is recruiting additional human resources to support increased workload.

The Solidarity Fund has provided R16 million to support the recruitment and placement of additional nurses in Gauteng hospitals to complement the military health team that has been deployed.

To ensure there is sufficient hospital bed space we have to reprioritise service provision to ensure there is capacity to treat those with severe cases of COVID-19.

We are forging ahead with our rapidly expanding national vaccination programme.

The programme has picked up significant momentum with key milestones being achieved as we move forward.

As of midnight yesterday, nearly 2.7 million people in South Africa had received a vaccine dose.

In the last week, the daily vaccination rate surpassed 100,000.

In the last three days, we have received an additional 1.2 million doses of the Johnson & Johnson vaccine and 1.4 million doses of the Pfizer vaccine through the COVAX facility.

With these additional supplies, we will be able to rapidly increase the rate of vaccination this week and in the weeks that follow.

In line with our national roll-out plan, over 950,000 health care workers have now been vaccinated across the country and the registration and vaccination of this cohort continues.

The second phase of our roll out has also gone well with the drive for the registration and vaccination of the over 60 year old group continuing to yield good results.

Whilst we have yet to reach all of the estimated 5 million citizens in this group, each province has now embarked on social mobilisation drives to assist our elderly to register and receive their vaccination.

To date 3.8 million people have been registered on the electronic vaccination database.

The national vaccination programme will continue along three defined streams. The first stream is the general population according to age groups.

The next cohort of 50 to 59 year olds can begin registration on the 1st of July and vaccination of this group will begin on the 15th of July.

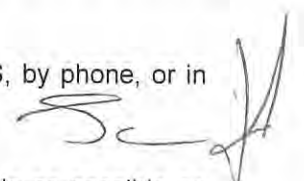
The second stream has already commenced with people working in the basic education sector, with 184,000 vaccinations recorded to date.

The third stream is focusing on police and other security personnel. We will start to vaccinate this group on the 5th of July.

The fourth stream is through workplace programmes in key economic sectors such as mining, manufacturing and the taxi industry.

I want to call on all who are eligible to register for a vaccine whether it is online, via SMS, by phone, or in person.

We will continue to work with our social partners and communities to reach as many people as possible as



quickly as we can.

Fellow South Africans,

There is still a lot of misinformation being circulated about the COVID-19 vaccine. False stories are being spread on WhatsApp groups, on social media, and by word of mouth about the COVID-19 vaccine, claiming that the vaccine is not safe, that it can make you sick, or that it doesn't work.

I have said it before, and I wish to say it again: please think long and hard before you press share or send.

Please consider the harm you may be causing.

You are spreading panic, fear and confusion at a time when we can ill-afford it.

The scientific evidence before us shows that vaccines work. They are safe. They are effective, and they save lives.

If you have any questions about the vaccine, if you are unsure in any way, please consult the information being provided by the Department of Health and from doctors.

You may also have questions as to whether the vaccines currently being used are effective in preventing severe illness or hospitalisation from the new variant.

There is evidence that the vaccines we are using in South Africa are effective against the delta variant.

The Vaccine Ministerial Advisory Committee will continue to consider all data at its disposal and will adapt its advice as and when new evidence emerges.

We must also remember that some vaccinated people may still become infected, regardless of variant, because no vaccine is 100% effective.

Where vaccinated people do get infected, the symptoms tend to be mild.

The most important thing is that any of the vaccines we are rolling out will protect you against severe disease, hospitalisation and, most importantly, death.

I also want to remind the South African people that we must continue to follow the public health guidelines even if we are vaccinated.

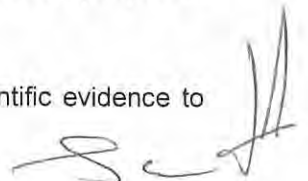
Throughout this pandemic, our national response has been led by dedicated medical professionals, healthcare workers and scientists.

We owe them all a debt of gratitude for their professionalism and their dedication.

It is therefore extremely distressing when political leaders launch personal attacks against such people for doing the job they have been assigned to do.

We must remember that SAHPRA is an independent regulator that focuses only on scientific evidence to ensure safety, quality and efficacy in the interest of public health.

SAHPRA must be allowed to do its job without intimidation or political influence so that when vaccines are approved the public can be confident that the vaccines are safe, of good quality and will work.



Fellow South Africans,

Since our country reported its first case of this deadly virus, we have understood that we are all in this together.

As much as we had hoped this pandemic would pass quickly, we know the reality to be vastly different.

There may be uncertainty over the trajectory of the pandemic, but there is one thing that is certain.

We can and we must continue to protect ourselves in the best way we know how.

The tried and tested public health measures that have been in place remain our best chance at fighting this pandemic.

They are not complicated, difficult or expensive.

Whatever inconvenience they may be to us, they are certainly better than becoming seriously ill and needing hospitalisation.

We must always wear a mask in public.

We must regularly wash or sanitise our hands.

We must always keep a safe distance from others. Unless it is necessary, please remain at home.

If you are sick and have even mild COVID-19 symptoms, you must isolate yourself, including from your immediate household.

If you have been exposed to someone infected with COVID-19 you have to quarantine for ten days.

If you test positive, notify the people you have come into contact with so they can protect themselves and others.

We are all responsible not just for our own health, but for the health of those around us.

While this pandemic may seem overwhelming, we can do something about it. Through the choices we make, we can help to contain it.

We have come so far. We have weathered this storm for nearly a year and a half. We have overcome many hurdles and setbacks.

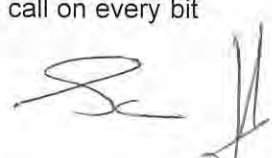
We are still standing, because we are a resilient people that has overcome the worst many times in our history.

Now a third wave is gathering in strength and force.

Once again, we find ourselves at a defining moment in our fight against this disease. Let us call on every bit of strength we have, let us summon our reserves of courage,

and hold firm until this wave, too, passes over us. We will recover.

We have climbed many hills before, and we will climb this one too. We will do so by working together, as we



have always done.

I say so because I believe in you, the South African people.

I know that you will continue to do what is right and what needs to be done.

And I know that no matter how difficult things become, we never, never give up. May God bless South Africa and protect her people.

I thank you.

The Presidency Profiles

[President Cyril Ramaphosa \(/profiles/president-cyril-ramaphosa%3A-profile\)](/profiles/president-cyril-ramaphosa%3A-profile)

[Deputy President David Mabuza \(/profiles/deputy-president-david-mabuza%3A-profile\)](/profiles/deputy-president-david-mabuza%3A-profile)

[Minister Mondli Gungubele \(/profiles/minister-mondli-gungubele-0\)](/profiles/minister-mondli-gungubele-0)

[Minister Maite Nkoana-Mashabane \(/profiles/minister-maite-nkoana-mashabane%3A-profile\)](/profiles/minister-maite-nkoana-mashabane%3A-profile)

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[Director General & Secretary of Cabinet Phindile Baleni \(/profiles/director-general-and-secretary-cabinet-phindile-baleni\)](/profiles/director-general-and-secretary-cabinet-phindile-baleni)

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22 June 2021

National Department of Health

Acting Minister Mmamoloko Kubayi-Ngubane
Director General Dr Sandile Buthelezi (Information Officer)

Copies to:

The Presidency

Information Officer

National Assembly

The Office of the Speaker




SAHPRA

The CEO
Company Secretary

Dear Acting Minister Mmamoloko Kubayi-Ngubane and Director-General Dr Sandile Buthelezi

RE: REQUEST FOR THE VOLUNTARY DISCLOSURE AND AUTOMATIC AVAILABILITY OF NECESSARY PUBLIC INFORMATION DURING THE COVID-19 PANDEMIC

1. The Health Justice Initiative (**HJI**) is a dedicated public health and law initiative addressing the intersection between racial and gender inequality with a special focus on access to life-saving diagnostics, treatment and vaccines for COVID-19, TB and HIV.
2. Since November 2020 we have written on numerous occasions to the National Department of Health ("Department") and other relevant Ministries requesting information pertaining to the COVID-19 pandemic in order to foster transparency, disclosure and improved engagement and communication. This includes correspondence on the national vaccine programme, including on matters related to the acquisition, procurement, selection and prioritisation.
3. Our correspondence has been copied to relevant government departments and in certain cases also addressed/copied to statutory bodies including the South African Health Products Regulatory Authority (**SAHPRA**) and also, Parliament.

 healthjusticeinitiative.org.za |  @HealthJusticeIn |  info@healthjusticeinitiative.org.za

Reference Advisory Group: Dr Francois Venter, Phumi Mtetwa, Dr Francois Bonnici, Phumeza Mlungwana, Dr Els Torreale, Prof Tshapo Madilingozi, Justice Kate O'Regan, Noncedo Madubedube, Dr Shuaib Manjra

Board: Dr Shuaib Manjra, Noncedo Madubedube, Fatima Hassan



4. Aside from a single delayed and short response from the Director-General of Health on 8 March 2021, there has not been a detailed response from the Department to the many questions that we and our legal representatives have raised in our various correspondence during this pandemic, nor any significant disclosure of information, as has been requested. This is regrettable.

Open procurement and voluntary disclosure of information

5. As you are aware, section 217(1) Constitution requires that when an organ of state contracts for goods and services, it must do so in accordance with a system which is “**fair, equitable, transparent, competitive and cost-effective**”. In addition, section 15 of the Promotion of Access to Information Act 2 of 2000 (**PAIA**) enables the voluntary disclosure and automatic availability of records, *without* a person having to request access in terms of PAIA and without a fee.
6. Due to the ongoing public health crisis occasioned by the Covid-19 pandemic and also allegations of corruption in the health care sector, there is an urgent need for the voluntary disclosure and automatic availability of any and all information pertaining to the government’s Covid-19 response, particularly as it relates to the national vaccine programme. This is squarely a matter of public interest, which warrants openness and accountability from the government and a state-led approach to information-sharing.

Information that should be voluntarily disclosed and automatically accessible

7. Based on the foregoing, we request that the following information is voluntarily disclosed and made automatically accessible, free of charge:

- 7.1. **Copies of all Covid-19 vaccine procurement and supply contracts, agreements, meeting outcomes and/or minutes, and correspondence** including with the following parties and/or duly authorised licensed representatives of:

- 7.1.1. Johnson & Johnson.
 7.1.2. Aspen.
 7.1.3. Pfizer.
 7.1.4. Serum Institute of India / Cipla.
 7.1.5. Any other vaccine manufacturer / licensee.

- 7.1.6. The African Union Vaccine Access Task Team (AU AVATT).
- 7.1.7. 'COVAX' (with the Global Vaccine Alliance – GAVI /Other).

We have previously raised that notwithstanding private corporations, including those detailed above, reportedly requesting non-disclosure agreements (**NDAs**), there is a constitutional duty on the state to ensure open, transparent, and competitive procurement.

In addition, Section 231(3) of the Constitution, which pertains to international agreements, requires that such agreements be tabled in the National Assembly and the National Council of Provinces within a reasonable time.

We note that our correspondence in this regard has remained unacknowledged and unanswered.

- 7.2. **Copies of all and any outstanding MAC Vaccine Advisories**, including any other form of written advice to the Ministry of Health related to vaccine selection and age and/or other prioritisation factors from January 2021 to date, including any advice communicated by the Chairperson and / or Members of the MAC Vaccine Advisory Committee and / or SAHPRA, and any other form of communication to the Ministry of Health related to:

- 7.2.1. the decision and / or other advice on vaccine selection and specifically, pausing the use of the AstraZeneca (AZ) vaccine in South Africa and to donate and / or sell it;
- 7.2.2. the prioritisation of people over 60 years old and / or those with comorbidities;
- 7.2.3. the prioritisation of 'elite' athletes and sport officials, South African government officials and diplomats / others;
- 7.2.4. the prioritisation of teachers and school support staff / others.

We have repeatedly requested the publication of all MAC Advisories since 9 March 2021, yet not all advisories are publicly available as at 21 June 2021.

- 7.3. **Copies of all correspondence with and/or from SAHPRA, and/or any other entity and/or research or academic body and/or ethics committees** relating to the *request and approval* for 'elite' athletes to be prioritised, ahead of elderly and

other at-risk populations, for vaccine administration.

We note that our correspondence in this regard has also remained unanswered.

8. We request that the voluntary disclosures are made, or reasons for non-disclosure are given, by no later than **2 July 2021**, failing which we will formally submit relevant Promotion of Access to Information Act (PAIA) requests, if applicable, and/or pursue any other recourse that may be available to us. We hope that this will not have to be the case.
9. We sincerely hope that this letter and the request for the voluntary disclosures lead to meaningful and transparent engagements with the state and that the relevant stakeholders open channels for co-operation on these issues, which are far-reaching and will remain in the public interest for the foreseeable future.

We look forward to hearing from you.

Sincerely,



Fatima Hassan (Director)





DIRECTOR GENERAL
HEALTH
REPUBLIC OF SOUTH AFRICA

PRETORIA
Private Bag X828, PRETORIA, 0001, 27th Floor, Civitas Building, Cnr Thabo Sehume and Struben Street, PRETORIA, 0002 Tel (012) 395 8402 Fax (012) 395 8422
CAPE TOWN
P.O. Box 3875, CAPE TOWN, 8000, 103 Parliament Towers, Room 615, 120 Plain Street, CAPE TOWN, 8000 Tel (021) 461 2040 Fax (021) 461 6864

Attention: Ms Fatima Hassan
Director of Health Justice Initiative

E-mail: Althea@healthjusticeinitiative.org.za

Dear Ms Hassan

**RE: REQUEST FOR VOLUNTARY DISCLOSURE AND AUTOMATIC AVAILABILITY OF
NECESSARY PUBLIC INFORMATION DURING THE COVID-19 PANDEMIC**

We refer to the above matter and to your correspondence dated 22 June 2021 addressed to the Information Officer of the National Department of Health.

We wish to advise you that following the receipt of your correspondence and in line with the Promotion of Access to Information Act 2 of 2000 (PAIA), we have resolved to:

- notify the vaccine manufacturers and distributors of your request for us to disclose the Vaccine Acquisition Agreements; and
- invite the vaccine manufacturers and distributors to make written or oral representations as to whether the request for access should be granted or refused (in whole or in part).

Given the need to consider their responses and then make an appropriate decision, we request your indulgence for us to revert with a formal response.

Kindly note that all advisories of the MAC on Vaccines can be found on the website of the sacoronavirus which is www.sacoronavirus.co.za

We trust that the above is in order and we look forward to hearing from you.

Kind Regards

Dr SSS Buthelezi
Director-General: Health
Date: 29/07/2021

6 August 2021

To:

Dr SSS Buthelezi
Director General: National Department of Health
By email: dg@health.gov.za

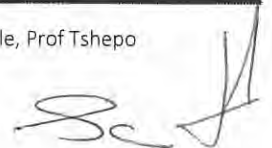
Copy to:

Mr Justinos Motalaota
Deputy Information Officer: National Department of Health
Per email: justinos.motalaota@health.gov.za

Dear Dr Buthelezi

**Health Justice Initiative's requests for information - Vaccine Contracts, Expert
Advisories, Prioritisation Decisions**

1. Please convey our congratulations to the newly appointed Minister of Health, Dr Joe Phaahla.
2. We acknowledge receipt of your letter dated 29 July 2021.
3. As you will be aware, further to our letter dated 22 June 2021, and in the absence of any timely response, the Health Justice Initiative submitted three formal requests in terms of the Promotion of Access to Information Act 2 of 2000 ("PAIA") to the National Department of Health ("NDoH") in the public interest for which we duly received relevant acknowledgements of receipt, for two of the requests.
4. These three PAIA requests relate to: (1) all vaccine contracts (2) details about the Ministerial Advisory Committee/s (MAC) and its Advisories; and (3) prioritisation decisions including for the Sisonke programme.
5. Accordingly, we draw your attention to the following:
 - 5.1 **Vaccine Contracts (Our PAIA Ref: 001/NDoH/2021):** With regard to the vaccine contracts, we have noted your intention to consult with the vaccine manufacturers and distributors. We note further that, in terms of section 26 of PAIA, there is no basis to extend the time period for a PAIA request in order to consult with private bodies. However, we are amenable to granting you a one-



week extension, until **25 August 2021**, to respond to our request. We further request that we be given access to any of the submissions made by the vaccine manufacturers and distributors in this regard, so as to inform any further steps that may need to be taken.

- 5.2 **MAC advisories (Our PAIA Ref: 002/NDoH/2021):** We note our appreciation for some of the MAC advisories that have been made public thus far, although this information has been difficult to navigate in the absence of a contents list. Moreover, we emphasise that this does not respond in full to our PAIA request, dated 20 July 2021. For instance, we have not been provided with the relevant names relating to “all local and international expert advisors to the National Department of Health on Covid-19” as requested. We trust that full disclosure will be made in accordance with our PAIA request within the 30-day prescribed period, and by no later than **19 August 2021**.
- 5.3 **Sisonke programme (Our PAIA Ref: 003/NDoH/2021):** Your letter of 29 July 2021 does not address our PAIA request for information related to the Sisonke programme, dated 23 July 2021 (this request has not yet been formally acknowledged). We trust that full disclosure will be made in accordance with our PAIA request within the 30-day prescribed period, and by no later than **22 August 2021**.
6. Given the inherent urgency and public interest in these requests for information – as well as the constitutional rights and values of access to information, openness, transparency, and accountability – it is imperative that this information be made available without delay. We highlight that these requests are made in the context of the ongoing pandemic and a vaccine supply chain that is not always reliable. We are therefore not amenable to granting any further extensions in order to respond to our respective PAIA requests.
7. We trust that we will receive a response in accordance with the time periods set out above, if not, kindly note that we will have no option but to consider our further legal options in order to compel disclosure of this information in the public interest.

We await to hear from you.

Yours sincerely,



Fatima Hassan

Director – Health Justice Initiative



13 September 2021

URGENT

To:

Dr Nicholas Crisp

Acting Director General: National Department of Health

By email: dg@health.gov.za

And:

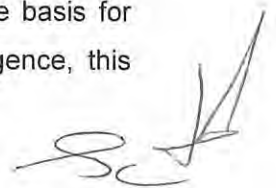
Mr Justinos Motalaota

Deputy Information Officer: National Department of Health

By email: justinos.motalaota@health.gov.za

**Health Justice Initiative's requests for information - Vaccine Contracts – 25 August
2021 time extension has expired**

1. We refer to our previous correspondence in this matter and, in particular, our letter dated 22 June 2021, your response thereto dated 29 July 2021, and our response dated 6 August 2021, as well as our request in terms of the Promotion of Access to Information Act 2 of 2000 (PAIA) dated 23 July 2021 (with reference 001_NDOH_2021). We note that:
 - 1.1. In your letter dated 29 July 2021, your offices requested additional time for the Department to consult with relevant parties.
 - 1.2. In our reply to that request, dated 6 August 2021, we set out the basis for granting an extension until **25 August 2021**. Despite this indulgence, this deadline has not been met.



- 1.3. It is our understanding that by the time we received your correspondence on 29 July 2021, you had already notified the relevant third parties in accordance with section 47(2) of PAIA. However, in any event, in terms of section 47(2) of PAIA, the latest date on which you could have notified the third parties is 13 August 2021.
- 1.4. Thereafter, in terms of section 49(1) of PAIA, the information officer must, as soon as reasonably possible, but in any event within 30 days after every third party is informed, make a decision and advise the third party *and the requester* accordingly. We take the view that this 30-day period expired on 12 September 2021.
2. We are aware that the Department is addressing multiple issues in this pandemic. Notwithstanding, we believe that sufficient and reasonable time has been afforded for the release of the relevant vaccine contracts even if the provisions of sections 47 to 49 of PAIA are considered to be applicable here, and that it is of pressing public interest and importance that they be released in full form, publicly.
3. This is because in the last weeks, the New York Times (NYT) revealed certain extremely concerning aspects of just one of the agreements entered into between the South African government (Department) and a vaccine manufacturer – Johnson & Johnson / Janssen that we mentioned in our correspondence of 22 June 2021 and in our PAIA request of 23 July 2021.
4. The NYT report includes *inter alia* that in the case of Johnson & Johnson / Janssen:
 - 4.1. That South Africa is paying more for its vaccines than certain European countries.
 - 4.2. That the South African government was ‘forced’ to agree to an *export waiver* in its agreement, and for the purpose of benefiting a separate agreement that Aspen Pharmaceuticals entered into with Johnson & Johnson / Janssen that effectively prevents the South African government from taking any measures to prevent or restrict the export of vaccines from South Africa (a measure many other countries have adopted in a pandemic).



- 4.3. This has meant that at least 32 million vaccines were filled and finished in South Africa (Aspen), while the country was facing wave 3, to benefit Europe, with perhaps millions more leaving our shores (confirmed by the Department's spokesperson to the NYT).
- 4.4. This directly and adversely affects/ed South Africa's national vaccine roll-out programme (and that of Africa).
- 4.5. That the South African government also granted a broad indemnification against liability to Johnson & Johnson / Janssen.
5. We note that on the face of it, several of these provisions reported on by the NYT may undermine certain constitutional obligations of the state.
6. All the vaccine-related contracts must therefore be disclosed and if necessary, be amended. Against this backdrop, in a pandemic, it is disappointing that all of the vaccine-related contracts have not yet been made publicly available.
7. Accordingly, we wish to let you know that we will be filing an internal appeal by **Wednesday, 15 September 2021** and will not be in a position to agree to any further time extensions.
8. Kindly also note that should the appeal not be successfully resolved, we will without further notice file an application to the High Court for the disclosure of all vaccine-related contracts.

Sincerely,



Fatima Hassan – Director

