IN THE HIGH COURT OF SOUTH AFRICA GAUTENG PROVINCIAL DIVISION, PRETORIA

In the matter between:	CASE NO:
THE HEALTH JUSTICE INITIATIVE	Applicant
And	
THE MINISTER OF HEALTH	First Respondent
THE INFORMATION OFFICER, NATIONAL DEPARTMENT OF HEALTH	Second Respondent
MINISTER OF COOPERATIVE GOVERNANCE	Third Respondent

FOUNDING AFFIDAVIT

I, the undersigned,

MARLISE RICHTER

do hereby make oath and state:

AND TRADITIONAL AFFAIRS

- I am a Senior Researcher with the Health Justice Initiative ("HJI"), a registered not-for-profit organisation and the applicant in this matter. I am duly authorised to depose to this affidavit and to institute these proceedings on the HJI's behalf as appears from the resolution marked as annex "HJI1".
- 2. Unless the context indicates otherwise, the facts set out in this affidavit are in my personal knowledge and are, to the best of my belief, true and correct. Where I make legal submissions, I do so on the advice of the HJI's legal representatives, which I accept as correct and good in law.

OVERVIEW OF APPLICATION

- 3. In these proceedings, the HJI seeks access to:
 - 3.1 The names of all expert advisors to the National Department of Health ("NDoH") on Covid-19 (irrespective of whether they serve on any Ministerial Advisory Committee/s);
 - 3.2 Copies of all advisories and recommendations made by the Ministerial Advisory Committee on Covid-19 ("the MAC") and the Ministerial Advisory Committee on Covid-19 Vaccines ("the V-MAC"), and/or others including those relating to options and recommendations for vaccinating people with co-morbidities (collectively, "the MAC advisories");
 - 3.3 Copies of all advisories and recommendations from the MAC and the V-MAC, regarding vaccine selection and priority group eligibility criteria from December 2020 to date (including any changes to such recommendations and advice) ("the prioritisation advice documents");
 - 3.4 The current, approved and/or draft risk and priority group framework used to make vaccine allocation and prioritisation decisions, and all submissions made in respect thereof ("the Prioritisation Framework");
 - 3.5 The recommendations and advisories concerning the use or non-use of the AstraZeneca-University of Oxford / Covishield vaccine and the decision to pause its use in South Africa; ("the AstraZeneca-University of Oxford records"); and
 - 3.6 A copy of the contract and details of the final sale or donation of the AstraZeneca - University of Oxford / Covishield vaccine, including all details cost recovery relating thereto (or lack thereof) ("the AstraZeneca--University of Oxford disposal documents").

- 4. The HJI requested access to these documents in terms of the Promotion of Access to Information Act 2 of 2000 ("PAIA"), on 20 July 2021. A copy of the request is attached as "HJI2". When the documents were not provided within the relevant time periods, it submitted an internal appeal against the deemed refusal on 9 September 2021. A copy of the internal appeal is attached as "HJI3". No response was received, and the internal appeal is deemed to have been dismissed. The HJI consequently has no choice but to approach this Court for access to the documents sought.
- 5. In addition, the HJI contends that the Minister of Health is constitutionally obliged to make all the expert advice and recommendations that he receives from the MAC and the V-MAC (or, indeed, **any other experts**) publicly available within a reasonable period of receipt. The HJI consequently seeks mandatory relief compelling the Minister of Health to publish such expert advice as he receives in relation to the Covid-19 pandemic, within a reasonable period of receipt, for as long as the pandemic continues.
- 6. In the context of a global pandemic (which has also been declared a national disaster), public disclosure is essential to transparency and access to information and acts as a safeguard against misinformation. It is vital to an appropriate public health response.

THE PARTIES

The Applicant

- The applicant is the HEALTH JUSTICE INITIATIVE ("HJI"), a registered not-forprofit organisation, established in July 2020, with registered offices at 41 Salt River Road, Community House, 2nd Floor, Salt River, Cape Town.
- 8. The HJI is a public health and law initiative dedicated to addressing the intersection between racial and gender inequality, on the one hand, and access to healthcare, on the other. The HJI's staff, board and reference advisory group

constitute a multi-disciplinary team with extensive experience in rights protection in the context of South Africa's dual health care system.

- 9. The HJI's focus areas include advocating for equitable health care, and access to affordable life-saving diagnostics and treatments, and against national profiteering particularly in the context of Covid-19, TB, and HIV. During the Covid-19 pandemic, the HJI has engaged in ongoing advocacy and lobbying regarding the conduct of the private sector in pricing personal protective equipment ("PPE"), and access to vaccines in South Africa (among others).
- 10. The HJI brings this application:
 - 10.1 in its own interest as an organisation that operates within, and promotes access to, the public healthcare system; and
 - 10.2 in the public interest. There is an obvious public interest in ensuring that the State's response to the Covid-19 pandemic is informed by expert input and is transparent.

The Respondents

- 11. The First Respondent is the MINISTER OF HEALTH ("Health Minister"), who is cited in his official capacity as head of the Ministry of Health in the national government, whose address is 1112 Voortrekker Road, Pretoria Townlands 351-JR, Pretoria within the jurisdiction of this honourable Court. The Minister is the person for whom the documents requested were prepared or to whom they were submitted.
- 12. The Second Respondent is the INFORMATION OFFICER OF THE NATIONAL DEPARTMENT OF HEALTH, whose address is 1112 Voortrekker Road, Pretoria Townlands 351-JR, Pretoria (within the jurisdiction of this honourable Court). He is cited in his official capacity as the officer designated to receive, deliberate upon, and determine requests for access to information, brought in terms of PAIA.

13. The Third Respondent is the MINISTER OF COOPERATIVE GOVERNANCE AND TRADITIONAL AFFAIRS ("COGTA Minister"), who is cited in her official capacity as the designated Minister responsible for the declaration of the Covid-19 pandemic as a national disaster, and for the issue of the regulations in relation thereto. Her address for service is 87 Hamilton Street, Arcadia, Pretoria.

FACTUAL BACKGROUND TO THE REQUESTS

The Covid-19 pandemic

- 14. On 30 January 2020, the World Health Organisation ("WHO") announced the outbreak of a novel coronavirus, Covid-19. The first official Covid-19 case was reported in South Africa on 5 March 2020. 6 days later, on 11 March 2020, the WHO declared the Covid-19 outbreak to be a pandemic.
- 15. On 15 March 2020, the COGTA Minister declared Covid-19 a national state of disaster in terms of section 27 of the Disaster Management Act. That declaration afforded the COGTA Minister (and, through her, the government) with extraordinary powers to address, contain and ameliorate the impact of the national disaster – including by substantially limiting constitutional rights, without first going through the ordinary legislative process.
- Among others, section 27(2) empowers the COGTA Minister, after consultation with the responsible Cabinet member, to make recommendations or issue directions or authorise the issue of directions concerning –

"(a) the release of any available resources of the national government, including stores, equipment, vehicles and facilities;

(b) the release of personnel of a national organ of state for the rendering of emergency services;

(c) the implementation of all or any of the provisions of a national disaster management plan that are applicable in the circumstances;

(d) the evacuation to temporary shelters of all or part of the population from the disaster-stricken or threatened area if such action is necessary for the preservation of life; (e) the regulation of traffic to, from or within the disaster-stricken or threatened area;

(f) the regulation of the movement of persons and goods to, from or within the disaster-stricken or threatened area;

(g) the control and occupancy of premises in the disaster-stricken or threatened area;

(h) the provision, control or use of temporary emergency accommodation;

(i) the suspension or limiting of the sale, dispensing or transportation of alcoholic beverages in the disaster-stricken or threatened area;

(*j*) the maintenance or installation of temporary lines of communication to, from or within the disaster area;

(k) the dissemination of information required for dealing with the disaster;

(I) emergency procurement procedures;

(m) facilitation of response and post-disaster recovery and rehabilitation;

(*n*) other steps that may be necessary to prevent an escalation of the disaster, or to alleviate, contain and minimise the effects of the disaster; or

(o) steps to facilitate international assistance."

- 17. Section 6 of the Disaster Management Act requires the COGTA Minister to prescribe a national disaster management framework, which takes into account, among others, the recommendations of the Intergovernmental Committee on Disaster Management. The Health Minister is the Chairperson of that Committee. The Health Minister and the COGTA Minister also both sit on the National Coronavirus Command Council ("NCCC") established by the President to coordinate Government's response to the Covid-19 pandemic.
- 18. Since the declaration of Covid-19 as a national disaster, the COGTA Minister has issued regulations in terms of section 27(2) of the Disaster Management Act, which have been amended from time to time. They prescribe and proscribe various activities, based on the lockdown 'alert level' which correspond to the degree of risk associated with the levels of Covid-19 infections at any given time. The Regulations associated with Alert level 5 include the most onerous

restrictions (requiring, in effect, that the overwhelming majority of the population remains at home most of the time), whilst restrictions are lightest (but are still in place) for alert level 1.

- 19. In terms of the Lockdown Regulations, as amended from time to time:
 - 19.1 Alert level 5 was in effect from midnight 26 March to 30 April 2020.
 - 19.2 Alert level 4 was in effect from 1 to 31 May 2020.
 - 19.3 Alert level 3 was in effect from 1 June to 17 August 2020.
 - 19.4 Alert level 2 was in effect from 18 August to 20 September 2020.
 - 19.5 Alert level 1 was in effect from 21 September to 28 December 2020.
 - 19.6 Adjusted alert level 3 was in place from 29 December 2020 until 28 February 2021.
 - 19.7 Adjusted alert level 1 was in place from 1 March 2021 to 30 May 2021.
 - 19.8 Adjusted alert level 2 was in place from 31 May to 15 June 2021.
 - 19.9 Adjusted alert level 3 was in place from 16 June 2021 to 27 June 2021.
 - 19.10 Adjusted alert level 4 was in place from 28 June to 25 July 2021.
 - 19.11 Adjusted alert level 3 was in place from 26 July to 12 September 2021.
 - 19.12 Adjusted alert level 2 was in place from 13 to 30 September 2021.
 - 19.13 Adjusted alert level 1 was in effect from 1 October 2021.
 - 19.14 The country has been on adjusted alert level 1 since 28 November 2021.The latest amendment to alert level 1 was Gazetted on 1 February 2022.
- 20. I emphasise that although the regulations enacted in terms of section 27(2) of the Disaster Management Act entail several serious limitations of certain constitutional rights, they have not been adopted in terms of the ordinary

regulatory process. Among others, they have not undergone the ordinary parliamentary debates and usual public comment process.

21. It is crucial that, for as long as Covid-19 remains a serious health threat and an issue of priority for the government, the measures imposed to manage the pandemic are predicated on sound, properly informed, publicly available information.

The Ministerial Advisory Committees

22. In the context of the Covid-19 pandemic – which is both a health threat in its own right, and a national disaster founded on a medical emergency – disaster management measures must be informed by expert medical information. It is obtained through the Health Minister who, in terms of section 91 of the National Health Act 61 of 2006, is empowered to establish and appoint ad hoc advisory and technical committees.

Establishment of the MAC on Covid-19

- 23. On around 30 March 2020, the Health Minister established the Ministerial Advisory Committee on Covid-19 ("the MAC"), under the terms of reference attached as "HJI4" and under the Chairmanship of Professor Salim Abdool Karim, an infectious Disease Epidemiologist, and the Director of the Centre for AIDS Programme of Research in South Africa.
- 24. The MAC provides high-level strategic advice to the Minister of Health in the management of Covid-19. Its role is purely advisory; it has no delegated powers to act on behalf of, or to commit, the Minister to any actions. Its Terms of Reference record its purpose and scope in this way:

Each of these Committees will review material and evidence available locally and internationally, as well as that which is provided by technical working groups supporting the National Department of Health (NDoH) on its COVID-19 response. It will provide the Minister of Health recommendations on: a) Case management of individuals infected with SARS-CoV-2 at all levels of the health care system. This includes:

a. Clinical management guidelines;

b. Selection of drugs on the Essential Medicines List;

c. Effective infection prevention and control interventions (health facilities and community level);

d. Flow of patients into the health system, such as from port authorities and the hospitality industry; and

e. Emergency services and disaster management response.

b) Public health interventions in the control and mitigation phases of an outbreak, such as social distancing measures, strategy for testing of case detection in communities and related isolation of cases and tracing and quarantine of their contacts, school, higher education and business closures, as well as national locked-down.

c) Communications strategies to optimize national community advocacy, awareness and education campaigns during an epidemic.

d) Research priorities into pathogenesis, clinical management (including presentation, diagnosis, and treatment modalities), disease modelling, and public health interventions. Particular emphasis on the interaction with our vulnerable HIV and NCD populations.

e) Economic impact to the health system and broader sectors within government, including issues of sector-wide procurement.

- 25. In turn, the MAC is divided into four committees, namely (a) pathologists and laboratory; (b) clinicians; (c) public health and (d) research. Each committee has its own chair and is tasked with reviewing local and international material and evidence, as well as information provided by the technical working groups supporting the NDoH, to provide the Minister with advice and recommendations on issues related to the pandemic. On 16 February 2022, the NDoH published the names of the 21 members of the MAC on the South African Coronavirus portal (sacoronavirus.co.za). The list is attached marked "HJI5".
- 26. The MAC and its sub-committees provide input, recommendations, and advice on a number of crucial aspects of Covid-19 and its management. Their advice and views are plainly considerations that should inform Government's response

to Covid-19, including its national disaster management response. They should, moreover, be publicly available, so that the public can understand and assess the basis on which the Health Minister, COGTA Minister, and government in general is taking their decisions, and satisfy itself that those decisions are based on sound advice, and are rational, reasonable and lawful.

27. Yet, the MAC advisories and recommendations have not always been made available as and when they are received. Some of the MAC advisories have been made publicly available on the NDoH's SA Coronavirus website (https://sacoronavirus.co.za/category/mac-advisories/) (as per the list attached as "HJI6") – but they have often been made available only well after the fact. We do not know if all MAC advisories received to date have been published– and invite the respondents expressly to confirm whether or not they have been.

The expansion of the MAC

 On 28 September 2020, the Health Minister announced changes to the Covid-19 MAC, to include more experts outside the biomedicine sector. A copy of this announcement to that effect is "HJI7". It pertinently states that:

> As we find ourselves in an extremely fortunate position of achieving effective transmission control, the true test lies in our ability to maintain low transmission rates. This requires a more wholistic approach to case management, preventative measures and public policy. It therefore became necessary to strengthen the MAC on Covid-19 so that it falls in line with its mandate to advise on effective mechanisms for the prevention of onward transmission of Covid-19.

> Recognising that the composition of the current MAC was focused on a biomedical approach, the Minister has taken a decision to augment the existing committee with various other experts from different sectors.

> In that regard, the reinforced MAC on Covid-19 consists of bio-medical practitioners; clinical experts; specialists in ethics; the nursing profession; social scientists; re-searchers; and community leaders to advise on interventions that should be considered in responding to the epidemic and to influence the behavioural change that is required to mitigate against the spread of Covid19.

The strengthened MAC will still maintain a degree of continuity, retaining many of the experts from the original clinical-biomedical MAC, including the incumbent chair Prof Abdool-Karim, Prof Marc Mendelson, Prof Sthembiso Mkhize, Prof Rudo Mathivha and Prof Nombulelo Magula, amongst others.

29. With its increased scope and participation, the MAC's advice presumably assumed greater importance in the government's decision-making. Yet, there was no concomitant increase in the NDoH's publication of its advice and recommendations for a substantial period of time.

The establishment of the V-MAC

- 30. After vaccines were developed, it quickly became clear that vaccination is essential to an effective response and management of the Covid-19 pandemic. The procurement, and fair and equitable distribution, of vaccines thus became an issue of significant public importance.
- 31. On 14 September 2020, the Health Minister announced the establishment of a MAC on the Coronavirus Vaccine (that is, the V-MAC). It is chaired by Professor Barry Schoub, a virologist and vaccinologist from South Africa. The V-MAC's role is to advise the Health Minister (and, through him, government) on developments relating to Covid-19 vaccines, and on access to and procurement of vaccines. A copy of the press release announcing the establishment of the V-MAC is attached as "HJI8". The HJI has been unable to locate a copy of its terms of reference.
- 32. The V-MAC operates in support of the MAC on Covid-19.
- 33. The V-MAC is an expert body constituted and tasked with advising the Health Minister on vaccines, the mainstay of the government's response to the Covid-19 pandemic. Its advice is plainly crucially relevant to any decision that the COGTA, NCCC, or Health Ministers – or government at large – makes in relation to their

Covid-19 response. Yet, the advice and recommendations of the V-MAC have not always been promptly published.

- 34. We do not know the total number of advisories prepared and submitted by the V-MAC or other advisors, to date. According to our records, between 25 August 2020 and 18 August 2021, a total of 120 advisories issued by the MAC (98) or the V-MAC (21) were published on the NDoH's SA Coronavirus website (<u>https://sacoronavirus.co.za/category/mac-advisories/</u>). The list of published advisories is already attached as "HJI6".
- 35. We again invite the respondents to disclose in answer:
 - 35.1 whether the 120 published advisories constitute the full gamut of advisories received between 25 August 2020 and 18 August 2021; and
 - 35.2 whether they have published all advisories received to date.

Other experts

- 36. During mid-2021, Professor Schoub gave a television interview to eNCA, stating that there are other 'advisors' to the NDoH outside of the MAC and the V-MAC. He specifically named Florian Kramner (an affiliate to DUKE University), David Montefiori (also affiliated with DUKE University), and Barney Graham (former National Institute of Health, USA). The interview is available at: https://www.youtube.com/watch?v=BHbJ7Fy-gjk.
- 37. We invite the respondents to disclose whether there are additional expert advisors, besides those appointed to the MAC and the V-MAC, who have made recommendations to the Health Minister and/or the COGTA Minister on issues relating to the management of the Covid-19 pandemic.

The prioritisation advice and framework

- 38. One of the crucial issues on which the V-MAC (and, possibly, the MAC, the South African Health Product Regulatory Authority ("SAHPRA"), South African Medical Research Council ("SAMRC") and others) would have been called on to give advice and recommendations is in respect of the vaccine rollout strategy – including what vaccines to procure, and how to decide in what order to make them available to the public and who to prioritise for vaccination.
- 39. In that regard, on 15 December 2020, the V-MAC signed an advisory titled Framework for Rational Allocation of Covid-19 vaccine in South Africa (a copy of which is attached as "HJI9" and which was published on the NDoH website on 3 January 2021). It recorded that:

Efficacy results from the Phase 3 Covid-19 vaccine trials are becoming available and more are expected in late 2020 / early 2021 and beyond. To date five vaccine trials have reported preliminary efficacy data ranging from 62–95%. In addition, the data suggest that these vaccines have no significant adverse events attributed to them.

Assuming that one or more of these vaccines are approved by SAHPRA, it is unlikely that there will be sufficient vaccines available for use beyond specific high-risk groups in the country before the end of the second quarter of 2021 and even then it is likely that only limited quantities of vaccine will be available.

40. That V-MAC advisory (dated 15 December 2020) recommended that the Health Minister adopt an accompanying draft "Framework for the Rational Allocation of Covid-19 vaccines in South Africa". The rationale for this recommendation was stated as follows:

Vaccine allocation will thus have to be based on a framework of prioritisation and need. The principles underpinning this Framework emphasises an evidence based approach and an ethical and moral perspective, including an African indigenous values context. The Framework will serve as a guide and will have to be adapted as new scientific information becomes available e.g.:

- information about specific characteristics of available vaccine/s,
- the benefit-risk assessment for different population sub-groups,

- the amount and pace of vaccine supply,
- the epidemiology at the time of vaccine introduction,
- clinical management,
- public health response, and
- economic and social impact of the pandemic.
- 41. The 'Draft Framework' was attached as 'annexure A' to the said advisory (dated 15 December 2020) and is attached as "HJI10". It recorded that:

Assuming that one or more of these vaccines are approved by SAHPRA, it is unlikely that there would be sufficient vaccines available for use beyond specific high-risk groups in the country before the end of the second quarter of 2021 and even then, it is likely that only limited quantities of vaccines will be available. Vaccine allocation will thus have to be based on a framework of prioritisation and need. The principles underpinning this framework emphasise an evidence based approach and an ethical and moral perspective, including an African indigenous values context.

- 42. The 'Draft Framework' was proposed to operate as a guide to the phased and fair allocation of vaccines domestically, taking into account available scientific information and the principle of *Ubuntu* (among others). It was also in alignment with the principles articulated by the WHO Strategic Advisory Group of Experts on Immunization (SAGE) which include 'human well-being; equal respect; global equity; national equity; reciprocity and legitimacy'. The 'Draft Framework' envisaged that prioritisation would be given to people:
 - 42.1 in roles considered to be essential for societal functioning;
 - 42.2 most at risk of infection and serious outcomes, for example, those in overcrowded living arrangements, multigenerational homes, with comorbid conditions; and
 - 42.3 most at risk of transmitting Covid-19 to others.
- 43. It proposed a three-phase approach, as follows:

- 43.1 *Phase 1:* to provide the vaccine to 1 250 000 front-line healthcare workers;
- 43.2 *Phase 2:* to provide the vaccine to a target population of:
 - 43.2.1 2 500 000 essential workers;
 - 43.2.2 1 100 000 persons living in congregate settings;
 - 43.2.3 5 000 000 persons who are over the age of 65 years; and
 - 43.2.4 8000000 persons who are over the age of 18 years and who have Covid-19 co-morbidities.
- 43.3 *Phase 3:* to provide the vaccine to about 22 500 000 persons who are all over the age of 18.
- 44. The priority groups in phase 2 were defined as follows:

Essential workers: Police officers, miners and workers in the security, retail food, funeral, teachers, banking and essential municipal and home affairs, border control and port health services.

Persons in congregate settings: Persons care homes, detention centers, shelters and prisons. In addition, people working in the hospitality and tourism industry, and educational institutions are also at risk.

Persons 60 years and older (5 000 000).

Persons older than 18 years with co-morbidities: Persons living with uncontrolled diabetics, chronic lung disease, poorly controlled cardiovascular disease, renal disease, HIV, tuberculosis and obesity.

- 45. As far as the HJI has been able to determine, the 'Draft Framework' proposed by the V-MAC was not formally adopted. We invite the Respondents to confirm this in answer.
- 46. The NDoH has provided some information in relation to government's vaccination strategy, in answering papers filed in the matter of *Solidarity and Another v Minister of Health and 16 Others* (case no 3623/21). According to those papers:

- 46.1 The V-MAC advised the NDoH to await the outcome of stage 3 clinical trial results for vaccines before it concluded any agreements with individual pharmaceutical manufacturers and recommended that *"specific high-risk groups be identified to receive the vaccine before the third quarter of 2021."* (The relevant advisory was not disclosed in the legal papers.) I should note that by 15 December 2020, Pfizer and Moderna had published their stage 3 clinical trial results, and AstraZeneca's stage 3 results were also published the same day.
- 46.2 In the *Solidarity* matter, the NDoH referred to high-risk groups which, it said, had been identified based on a framework of prioritisation and need. Paragraph 61 of the answering affidavit in the *Solidarity* matter stated the following in relation to the Prioritisation Framework:

"This included identifying, classifying and prioritising high-risk groups, such as:

61.1 Health Care workers: Health professionals, nurses, general health workers, care home workers, selected laboratory workers, and traditional healers.

61.2 Persons with co-morbidities and at risk for morbidity and mortality: These include persons 60 years and older, persons living with HIV, tuberculosis, diabetics, chronic lung disease, cardiovascular disease, renal disease, obesity, etc.

61.3 Persons in congregate or overcrowded settings: This group includes persons in prison, detention centres, shelters, and care homes. In addition people working in the hospitality and tourism industry, and educational institutions are also at risk.

61.4 Essential workers: This group includes police officers, miners, and workers in the security, retail food, funeral, travel, banking, and essential municipal and home affairs services.

It also emphasised that the introduction of a new vaccine into the immunisation programme provides an opportunity for health system strengthening and integration of health services. The Vaccine Strategy recorded that a National Technical Working Group for COVID-19 vaccine introduction had been established to plan and coordinate the vaccine introduction in line with the strategic objectives of the NDoH."

- 47. Extracts from the relevant answering affidavit are attached as "HJI11". Neither the Prioritisation Framework, nor the advice and recommendations on which it was based, have been attached to the *Solidarity* answering papers.
- 48. In other words, seemingly, the V-MAC advised, and the NDoH envisaged, making vaccines available based on a prioritisation framework that was needsbased, rather than only age-dependent.
- 49. On around 3 January 2021, the Health Minister formally announced the vaccination roll-out strategy, per the media statement attached as "HJI12". It was apparently developed in close collaboration with the V-MAC. Like the V-MAC advisory and draft framework, it envisaged a 3-phase rollout of vaccines:
 - first to healthcare workers,
 - then to essential workers, people in congregate settings, people over 60, and people over 18 with co-morbidities; and
 - finally, to the rest of the 18+ population.
- 50. Ultimately, and for reasons I address below, the vaccination of healthcare workers began on 17 February 2021 under the auspices of a clinical trial or study programme, the 'Sisonke Study', also regarded as 'phase 1' of the national rollout.
- 51. On 28 March 2021, the NDoH announced that it intended to commence with a mass vaccine rollout from May to October 2021, when phase 2 got underway. At that stage, it was envisaged that phase 2 would vaccinate "vulnerable groups, essential workers and the occupational health and safety stream". Phase 3 would commence in November 2021 and vaccinate anyone not covered in phases 1 and 2. A copy of that announcement is "HJI13".

- 52. Two days later, however, the Health Minister gave a slightly different report to Parliament. He said that Phase 2A (from 17 May to 31 July 2021) would target people over 60, that phase 2B (from August to 31 October 2021) would target people over the age of 40, prioritising those with co-morbidities and workers in high-risk settings, and phase 3 (from November onwards) would vaccinate the remainder. A report from the parliamentary monitoring group is "HJI14".
- 53. The Sisonke Study (Part 1) was completed on 15 May 2021, and phase 2 of the national vaccination rollout began on 17 May 2021, commencing with adults over 60.
- 54. On 16 May 2021, the Health Minister announced that phase 2 would provide vaccination to 'citizens over the age of 60'. No mention was made, or explanation given, for abandoning the previous plan also to prioritise essential workers, people in congregate settings and people with co-morbidities, for vaccination.
- 55. The vaccine roll-out that followed proceeded on age criteria, rather than the anticipated prioritisation. Vaccines were initially made available to healthcare workers (through the Sisonke Study), then to people over the age of 60, then to people in the age group 50-59, then the cohort of 35 to 49, then to 18 to 34 year-olds and, most recently, to 12 to 17 year-olds.
- 56. During this time, a cohort of teachers were also identified for a special vaccination programme using additional 'donated' stock from a vaccine manufacturer, in large part due to material delays in the overall supply provision by that manufacturer (Johnson & Johnson).
- 57. The NDoH also issued a Special Circular in July 2021 that 'permitted' certain categories of people to apply for permission to be vaccinated outside of the prevailing age cohort roll-out, the essential public sector programme or a workplace programme in other words, they could seek authorisation from the NDoH to 'jump the vaccine queue'. This circular was later retracted. A copy of that Special Circular is attached as "HJI15".

- 58. Neither the written framework underpinning the changes in the prioritisation approach, nor the advice nor recommendations on which it is based, have been made publicly available. The public is entirely in the dark as to when, why or how decisions were made on vaccine roll-out and prioritisation.
- 59. The public has a right to know on what basis the relevant Ministers and the government took these decisions. It is also entitled to know whether the expert advice of the MAC and the V-MAC was considered and followed and, if not, why it was departed from. Especially with new variants being detected, it is important to share information on how the country will manage vaccine supply in a timely manner.
- 60. Science around the pandemic is evolving at such a pace, so it is essential that government be kept abreast of, and take into account, rapidly evolving scientific knowledge. The only way that the public can be certain that government is listening to expert advice and making the appropriate decisions which are in line with the relevant and current scientific advice, is for it to share information from the experts more readily and speedily. Critically, the public has a right to know the roles of each advisor to the NDoH and their conflicts of interest (if any). That is particularly so where the decisions at issue involve vaccine selection and changes in selection, and severe restrictions on social, civil and political liberties, and where the ordinary legislative safeguards in place to protect the public, have been curtailed. The information sought is crucial to transparency and accountability and helps to mitigate confusion and hesitancy.

The Covishield vaccine roll out - and pausing it

- 61. On 7 January 2021, the Health Minister announced that a special order of the AstraZeneca-University of Oxford vaccine (Covishield) had been procured for healthcare workers in South Africa via the Serum Institute of India ("SII"), and that the first batch would be delivered during the course of January 2021. A copy of that statement is "HJI16"
- 62. According to the answering affidavit filed in the *Solidarity* matter (extracts of which are attached as "HJI17"):

- 62.1 Between September and December 2020, government had negotiated with the SII – which produces the AstraZeneca-University of Oxford vaccine against Covid-19 (also called Covishield) under licence – regarding the supply to South Africa. In terms thereof, 1 million doses would be delivered in early 2021.
- 62.2 In December 2020, a new Covid-19 variant (501Y.V2 variant or the Beta variant) was discovered. The efficacy of the AstraZeneca-University of Oxford vaccine had not been assessed in respect of this new variant.
- 62.3 The V-MAC considered whether the AstraZeneca-University of Oxford vaccine should be rolled out in the fact of the 501Y.V2 variant, and apparently sought advice from overseas experts (including the WHO, and experts form the United States and the United Kingdom whose details are not known to us). Their advice was reportedly that the vaccine was likely still to be effective against the 501Y.V2 variant. (The expert advice and the advisories in this regard have not been made public. It is not clear who exactly the international experts consulted were or what informed their assessment.)
- 62.4 On 22 January 2021, SAHPRA granted authorisation, in terms of section21 of the Medicines and Related Substances and Control Act, for the domestic use of Covishield.
- 62.5 SII caused one million doses of Covishield to be delivered to South Africa on or around 31 January 2021.
- 63. On 7 February 2021, the Health Minister, together with the head of SAMRC and members of the MAC and the V-MAC, announced, at a media briefing, that a decision had been taken to pause the rollout of the AstraZeneca-University of Oxford vaccine, based on the results of a preliminary study that showed substantially reduced protection against mild to moderate infections from the 501Y.V2 variant. (The media briefing is available on Youtube at: https://www.youtube.com/watch?v=Mfu-Bk7zuPY). The Minister of Health

briefed Parliament about the suspension of the AstraZeneca vaccine on 11 February 2021. A copy of the media statement is attached as **"HJI18"**.

- 64. In March 2021, the V-MAC submitted a <u>retrospective advisory</u> to the Health Minister, in which it recommended that the roll-out of the AstraZeneca-University of Oxford vaccine the Covishield vaccine "be suspended pending the release of data of the in-vivo efficacy against the 501Y.V2 variant" and that, "in the meantime, it is strongly recommended that urgent steps be taken to acquire alternate vaccines to replace the AstraZeneca vaccine". A copy of the retrospective advisory is attached as "HJI19". The (additional) information, recommendations and advice underpinning the decision to suspend the roll-out of the AstraZeneca-University of Oxford vaccine, if any, have not been made available.
- 65. By the stage that the retrospective advisory was issued, government had already decided to on-sell or donate the AstraZeneca-University of Oxford vaccine supply into, as far as we know, the African Union. The retrospective advisory also recorded that:

"This advisory was finalised on the 7th of February, of which NDoH officials were aware of.

It was never submitted as a formal advisory at the time as the VMAC was made aware that the AZ vaccines were to be sold to other country/ies in the African Union.

In hindsight, to ensure that there is a proper paper trail, this advisory is retrospectively being formally submitted to regularise the information conveyed in the advisory.

As it is only being submitted retrospectively, it was signed off on the date that the Committee recommended that it be submitted retrospectively to the NDoH, which was at the VMAC meeting on the 18th of March 2021."

66. On 21 March 2021, the NDoH confirmed the 'sale' of 1 million doses of the Covishield vaccine to the African Union 'for use by 14 member countries'. A copy of the relevant media statement is attached as "HJI20". A later media report

(attached as **"HJI21"**) suggests that the vaccine doses may instead have been donated. We invite the respondents to confirm the position in answer.

67. The terms and agreement on which such vaccines were on-sold or donated have never been made publicly available. HJI and the public are accordingly unaware of whether, and the extent to which, the state has been able to recoup its procurement costs. That is a matter of obvious public interest, given the expense of urgently procuring vaccines and whether there were any contractual restrictions on the ability of our government to sell or *donate* them especially.

THE REQUESTS FOR INFORMATION

- 68. The appointment of the MAC and the V-MAC, their and other experts' advice and the decisions made pursuant thereto, raise issues of clear public importance.
 - 68.1 It is a matter of comfort to the HJI that Government was seeking expert input to inform its approach to the Covid-19 pandemic and to the rollout of a vaccination strategy. But we believe that it was and is imperative that such expert advice be made publicly available in a timely way.
 - 68.2 This would not only foster transparency and help to combat misinformation; it would also allow the stakeholders and the public at large (including civil society organisations such as the HJI) to interrogate the reasonableness and lawfulness of decisions taken by the Government. That is particularly important where there have been suggestions in the media that government has been disregarding the expert advice procured, for no obvious reason. I attach one example of such reports as "HJI22".
 - 68.3 Such oversight is particularly necessary in the context of a global pandemic and a declared national disaster, where many of the checks and balances imposed by the ordinary legislative process do not apply. It is also consonant with the public's right to information (entrenched in section 32 of the Constitution) and the values of accountability and

transparency that bind the public administration (as stipulated in section 195 of the Constitution).

- 69. Despite the clear public interest in the MAC and V-MAC advisories, the prioritisation advice records, the Prioritisation Framework, the AstraZeneca-University of Oxford records (Covishield) and/or the AstraZeneca-University of Oxford decision (Covishield), those records have not been made fully publicly available.
- 70. The HJI has repeatedly sought to obtain access to this information, as follows:
- 71. On 9 March 2021, the HJI emailed the NDoH requesting it to "forward any MAC advisories published in the last two months, and that these are uploaded on the website" HJI also enquired about how many meetings of the MAC and the V-MAC had taken place from the beginning of 2021 to date. A copy of that email is marked annexure "HJI23".
- 72. On 10 March 2021, a representative of the NDoH responded in the email, already attached as "HJI23", stating:

"I am just working with our media liaison to see about what can be loaded to the website. We have an internal process where advisories are submitted to NDoH and the implementation of guidance as the deem appropriate is taken forward. Since the MAC only provides advice, we like to ensure that the department/s are afforded the opportunity to process and plan what is needed. (sic)"

- 73. On 23 March 2021, HJI sent the follow-up request as included in the email correspondence attached as "HJI23". The HJI again called for the publication of advisories issued since 11 January 2021 and information on how many MAC and V-MAC meetings had taken place since the beginning of the year. No response was received.
- 74. On 14 April 2021, the HJI wrote a formal letter to the NDoH (annexed as "HJI24") recording the comments of Professor Schoub (the V-MAC Chair) in the South

African Medical Journal (SAMJ) of 9 April 2021, responding to an earlier SAMJ article by Professors Venter and Madhi et al, where Professor Schoub stated:

"It is regrettable that there has been a lag in publicising these advisories on the Department of Health website. Nevertheless, the reasons have received fairly wide publicity in the media. Alternatively, I could simply have been approached for a response. I was not."

75. The HJI again requested that all MAC advisories be published and asked for reasons why they had not been publicly released to date. The letter, already annexed as "HJI24", stated further:

In a pandemic, transparency is imperative, and it is regrettable that we have had to resort to writing repeatedly to your offices for what should be a simple disclosure on the department's part, of information that is in the public interest.

Please note that in the interests of transparency we may publish this correspondence and any response/s received. We have also noted our correspondence with your office on the HJI's Vaccine Access Timeline that is available on our website.

- 76. Further follow-up emails were sent on 20 and 30 April, and 14 May 2021, reiterating the same requests. Those emails are included in the annexure already attached as "HJI23".
- 77. During May 2021, a selection of MAC advisories was published on the NDoH website. HJI noted as much in email correspondence already attached as "HJI23" but noted that others had still not been published including those relating to "vaccine selection, the rationale for the pausing the planned AstraZeneca roll-out, the selling on of the said vaccines, and the sequence of age and co-morbidity prioritisation within the Department of Health's Electronic Vaccination Data System (EVDS)".
- 78. On 22 June 2021, HJI reiterated its concerns and requests in a letter attached as "HJI25". The letter noted inter alia that:

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.

- 79. In that letter of 22 June 2021, the HJI invited the NDoH to make voluntary disclosure of the information sought in terms of section 15 of PAIA on three areas: broadly vaccine manufacturer contracts, expert advice, and prioritisation. Copies of that letter were also sent to the Information Officer of the Presidency, the Office of the speaker of the National Assembly and the CEO and Company Secretary of SAHPRA. (Paragraphs 7.2 and 7.3 of that letter are relevant to this application. Paragraph 7.1 of that letter deals with the disclosure of relevant vaccine contracts, which is the subject of a separate PAIA application before this Court).
- 80. On 29 July 2021, the HJI re-sent the letter, which the NDoH then acknowledged receipt of by e-mail. On 29 July 2021 the NDoH responded in a letter, attached as "HJI26". In respect of the MAC Advisories and other expert prioritisation recommendations, the letter merely stated that:

"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". 81. The HJI subsequently lodged a formal PAIA request on 20 July 2021 under reference number 002/NDoH/2021. It has already been attached as "HJI2".
HJI requested the following records:

A.) Expert Advice and Ministerial Advisory Committees Advisories on Covid-19:

1. A list of the names of all local and international expert advisors to the National Department of Health on Covid-19, irrespective of whether they also serve on a/ any Ministerial Advisory Committee ('MAC') for Covid-19.

2.i) Copies of all MAC and Ministerial Advisory Committee Covid-19 Vaccines ('VMAC') Advisories that are currently not in the public domain.

ii.) Copies of all memoranda and advisories from the MAC and VMAC that relate to options and recommendations for vaccinating all people with comorbidities.

3) Copies of all MAC, VMAC, National Department of Health, South African Health Product Regulatory Agency (SAHPRA), and/or any other expert recommendations and expert as well as ethic bodies/other professional or expert bodies written advice including from the South African Medical Research Council (SAMRC) and the South African Medical Association (SAMA), related to the vaccine selection and priority group eligibility criteria for South Africa from December 2020 to date, and copies of any changes in the respective recommendations/advice over this time period.

B.) Prioritisation and risk framework and principles:

1.) A copy of the written and current approved (or in draft form) risk and priority group framework or similar, and timeline, that the National Department of Health is at present using to vaccinate people in South Africa and in turn using to make vaccine allocation and prioritisation (eligibility) decisions.

2.) Copies of all submissions made by any other government department, trade union, political party, business body, organisations, medical schemes, statutory bodies or any other body, whether locally or internationally, on the issue of vaccine selection for South Africa; and also prioritisation of certain groups in South Africa ahead of others.

82. On 23 July 2021, HJI received an email from the NDoH acknowledging receipt of the formal PAIA request 002/NDOH/2021 ("HJI27"). (The reply of 29 July 2021, referred to in paragraph 80 above, responded to the earlier letter of 2 July 2021 but did not materially answer the PAIA request. It has already been attached as HJI26).

83. On 6 August 2021, HJI sent a letter to the Director General of the NDoH (attached as "HJI28") acknowledging, among others, that certain MAC advisories had been published on the NDoH website. The letter stated that:

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.

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.

And:

5.2 MAC advisories (Our PA/A 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.

84. No response was received to the PAIA request within the stipulated time period. Accordingly, the request was deemed to have been refused.

The internal appeal

- 85. On 9 September 2021, HJI lodged an internal appeal in terms of section 75 of PAIA against the deemed refusal of its request. The appeal has already been annexed as "HJI3".
- 86. The internal appeal was lodged in compliance with the prescribed requirements – that is, it was lodged within 60 days of the deemed refusal, delivered to the Respondents, and also contained the grounds upon which the appeal was based.
- 87. HJI has received no response to the internal appeal, and it is deemed, under section 27 of PAIA, to have been refused.

PROVISION OF THE DOCUMENTS SOUGHT

- 88. The Constitution demands that transparency must be fostered by providing the public with timely, accessible, and accurate information. Access to information is fundamental to the realisation of the other rights enshrined in the Bill of Rights.
- 89. The purpose of PAIA is to promote a culture of transparency and accountability in public and private bodies by giving effect to the right to access of information enshrined in the Constitution which allows the public to fully exercise and protect their rights. The need for transparency and accountability in a global pandemic and also in a declared state of disaster is all the more acute.
- 90. The HJI has made proper requests for access to the records in question and is entitled to be provided with the documents sought. There are no grounds for access being refused – nor have any been raised by the NDoH. At no point during HJI's efforts to gain the information sought, have the respondents claimed that the information enjoys exemption from disclosure – rightfully so, because the information sought does not fall within the ambit of any of the exclusions provided for in PAIA.

- 91. Even if there were statutory grounds for refusing disclosure of the records sought (which is denied), the public interest would render their production mandatory under section 46 of PAIA.
- 92. The HJI accordingly seeks an order setting aside the refusal to provide access to the records (to the extent that is necessary) and directing the First and Second Respondents to furnish those records within 10 days of any court order.

PUBLICATION OF ALL MAC / V-MAC / OTHER EXPERT ADVISORIES

- 93. The HJI also seeks an order directing the Health Minister, for as long as Covid-19 remains an issue of public importance (meaning, necessarily, for as long as its remains a declared national disaster and/or a pandemic and/or is endemic,) to publish advisories and/or recommendations received from the MAC, V-MAC and / or any other experts, in relation to Covid-19, on the NDoH website within 72 hours of receipt.
- 94. On a proper interpretation of section 12 of the National Health Act and/or section 22 of the National Disaster Management Act, those advisories and recommendations must be made publicly available to enable the public (including civil society) properly to understand and assess the basis on which the Covid-19 pandemic is being managed, and decisions (including in respect of the lockdown regulations and the vaccine roll-out) are being made, and rights and freedoms restricted.
- 95. In the absence of such publication, the public is unable meaningfully to interrogate the expert advice government is receiving, and the basis on which important decisions of policy and administration are being made. That is anathema to the value of transparency and accountability that govern the public administration (entrenched in section 195 of the Constitution) and does not best give effect to the right of access to information in section 32 of the Constitution. Transparency and access to information are particularly important in the context

of a declared national disaster, where the ordinary public participation rights entailed in the legislative process are curtailed.

96. Absent publication of the names of all advisors, advisories and recommendations, members of the public are unable to obtain them. Nor is there a reason why, as a general rule, they should be held confidential. They include, after all, the expert input and considerations on which public bodies and organs of state are exercising their powers.

CONCLUSION

97. For all the reasons set out above, the HJI seeks an order in terms of the notice of motion to which this affidavit is attached.

MARLISE RICHTER

I hereby certify that the deponent declares that the deponent knows and understands the contents of this affidavit and that it is to the best of the deponent's knowledge both true and correct. This affidavit was signed and sworn to before me at ______ on this _____ day of March 2022 and that the Regulations contained in Government Notice R1258 of 21 July 1972, as amended, have been complied with.

COMMISSIONER OF OATHS