

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

CASE NO:

In the matter between:

THE HEALTH JUSTICE INITIATIVE

Applicant

And

THE MINISTER OF HEALTH

First Respondent

**THE INFORMATION OFFICER,
NATIONAL DEPARTMENT OF HEALTH**

Second Respondent

THE MINISTER OF SPORT, ARTS AND CULTURE

Third Respondent

**THE INFORMATION OFFICER,
MINISTRY OF SPORT, ARTS AND CULTURE**

Fourth Respondent

SOUTH AFRICAN MEDICAL RESEARCH COUNCIL

Fifth Respondent

**THE INFORMATION OFFICER,
SOUTH AFRICAN MEDICAL RESEARCH COUNCIL**

Sixth Respondent

FOUNDING AFFIDAVIT

I, the undersigned,

MARLISE RICHTER

do hereby make oath and state:

1. I am the Senior Researcher of the Applicant – the Health Justice Initiative (“**HJI**”) – a registered not-for-profit organisation with registered offices at 41 Salt River Road, Community House, 2nd Floor, Salt River, Cape Town.

2. I am duly authorised to make this application and depose to this affidavit on behalf of the Applicant. A duly signed resolution by the Board of the HJI is attached marked as annexure “**HJI1**”.
3. The facts contained in this affidavit are true and correct, to the best of my knowledge and belief. Unless otherwise stated or indicated by context, they fall within my personal knowledge. Where I make submissions of law, I do so on the advice of the HJI’s legal representatives.

INTRODUCTION

4. On 17 February 2021, the Sisonke study (Part 1) commenced, kicking off the first nation-wide Covid-19 vaccination roll-out. The Sisonke study (Part 1) provided the Johnson & Johnson vaccine against Covid-19 (“the J&J vaccine”) to healthcare workers at a number of research sites across South Africa, as part of a phase 3B clinical trial.
5. Part 2 of the Sisonke study, relating to booster doses, has since commenced on 10 November 2021. It remains to be seen how that rollout will be handled. This application is limited to Part 1 of the study.
6. During or around April/ May 2021, the scope of the Sisonke study was somehow widened to provide for the vaccination of “*elite athletes*” – *and*, potentially, officials involved in sports administration – under its auspices. The HJI seeks information on how, when and on whose authority that occurred, and who that permission extended to.
7. To that end, the HJI made the following requests for records in terms of the Promotion of Access to Information Act 2 of 2000 (“PAIA”):
 - 7.1. The request attached as “**HJI2.1**” submitted to the Department of Health (“**NDoH**”) on 23 July 2021;
 - 7.2. The request attached as “**HJI2.2**” submitted to the Department of Sports, Arts and Culture on 28 July 2021;

- 7.3. The request attached as “**HJI2.3**” submitted to the South African Medical Research Council (“**SAMRC**”) on 23 July 2021.
8. The HJI also submitted a request to the South African Health Products Regulatory Authority (“SAHPRA”), which is attached as “**HJI2.4**”. We have since received a response to it, which I deal with below. As a result, we do not seek to compel records from SAHPRA.
9. None of the requests referred to in paragraph 7 above were granted. Accordingly, on 8 September 2021, the HJI submitted the following internal appeals in terms of section 75 of PAIA:
- 9.1. The internal appeal attached as “**HJI3.1**” to the NDoH;
- 9.2. The internal appeal attached as “**HJI3.2**” to the Department of Sports, Arts and Culture;
- 9.3. The internal appeal attached as “**HJI3.3**” to SAMRC.
10. None of those appeals generated a response and all are regarded as having been dismissed. The requested records have not been produced. The HJI accordingly applies, in terms of section 78 of PAIA, for an order directing production of the records requested.

THE PARTIES

The Applicant

11. The applicant is **THE HEALTH JUSTICE INITIATIVE**, a not-for-profit organisation established in 2020 and incorporated in accordance with the laws of South Africa.
12. The HJI is a dedicated public health and law initiative. Its mandate is to address 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.

13. The HJI's focus areas include advocating for equitable health care and access to affordable life-saving technologies. Since June 2020, the HJI has engaged in activities concerning, among other things, the conduct of the private sector in the pricing of personal protective equipment, and the lack of meaningful engagement and transparency from the state with regard to its vaccine plans, the transparency needed in vaccine procurement, and on the expert advice provided to government to manage the pandemic. The HJI has embarked on research, advocacy, and litigation strategies to advance various constitutional rights, including the right to access healthcare, life, equality, dignity, and access to information in the context of a pandemic. Our work throughout this time has included a special focus on the vaccine roll out in South Africa with an emphasis on evidence based decision making, transparency, accountability, and equity. In parallel to this application, the HJI brings two other PAIA applications, seeking information on the vaccination contracts entered into between government and the pharmaceutical companies, and on the expert advice provided to government regarding Covid-19, respectively.
14. The HJI brings this application in its own interest, as an organisation directly involved in the health sector and in promoting equitable access to medicines. The HJI has a clear interest in ensuring that various rights are respected, protected, and prompted during this unprecedented health crisis.
15. The HJI also brings this application on behalf of the South African public, and in the public interest.
 - 15.1. There is an obvious public interest in procuring the information necessary to assess how vaccinations were made available within the Sisonke study and how persons who are not health care workers were prioritised for vaccination ahead of, for example, essential workers and people with co-morbidities through that study and/or because of it. That information enables the public and civil society to hold the government and public bodies, including regulatory institutions, to account.
 - 15.2. There is a heightened need for transparency and accountability during a declared national disaster, and in a pandemic, where a number of the

usual checks and balances (including decision-making processes) have been curtailed.

16. The management of the current pandemic and also future pandemics require ethical, and evidence-based decision-making based on accepted public health principles in the context of scarce resources. Pandemic readiness requires that clear and transparent processes are put in place to ethically and fairly allocate scarce public goods to those who most urgently require it (in a transparent way). It also requires fair and principled precedent that is free from executive interference or vested or commercial/business interests, for the allocation of scarce resources in a time of crisis. is in the public interest.

The Respondents

17. The First Respondent is the **MINISTER OF HEALTH**, who is cited in his official capacity as head of the NDoH and whose address is 1112 Voortrekker Road, Pretoria Townlands 351-JR, Pretoria within the jurisdiction of this honourable Court.
18. 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.
19. The Third Respondent is the **MINISTER OF SPORTS, ARTS AND CULTURE**, who is cited in his official capacity as head of the Department of Sports, Arts and Culture and whose address is 202 Madiba Street, Pretoria, within the jurisdiction of this honourable Court.
20. The Fourth Respondent is **THE INFORMATION OFFICER OF THE MINISTRY OF SPORTS, ARTS AND CULTURE** whose address is 202 Madiba Street, Pretoria. 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.

21. The Fifth Respondent is the **SOUTH AFRICAN MEDICAL RESEARCH COUNCIL (“SAMRC”)**, whose address is 1 Soutpansberg Road, Pretoria, within the jurisdiction of this honourable Court. SAMRC is an established juristic person under section 2 of the South African Medical Research Council Act 58 of 1991. Its objects are, through research, development and technology transfer, to promote the improvement of the health and the quality of life of the South African population of the Republic. It also contributes to the strengthening of the country’s health systems by undertaking systematic reviews, health policy and health systems research to provide evidence for policy-makers, stakeholders and researchers.
22. The Sixth Respondent is the **INFORMATION OFFICER OF THE SAMRC**, whose address is 1 Soutpansberg Road, 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

BACKGROUND

The South African Covid-19 vaccine rollout

23. On 15 March 2020, the Covid-19 pandemic was declared a national state of disaster, in terms of section 27 of the Disaster Management Act. Since then, extraordinary measures have been taken to manage, address and ameliorate the impact of the pandemic.
24. It quickly became clear that vaccines would be an essential element of the global and domestic response to Covid-19, and that equitable access to vaccines, both globally and within South Africa, was a matter of crucial importance. The HJI wrote to the Minister of Health (as well as the Minister of Cooperative Governance and Traditional Affairs and to the National Disaster Management Centre) as early as 16 November 2020 calling for information and public

engagement on affordable access to, and equitable allocation of, Covid-19 vaccines. A copy of that letter, as well as the follow-up letters to it, are attached as “**HJI4.1**” to “**HJI4.3**”.

25. Our concerns were shared by a collective of scientists who, on 2 January 2021, issued an open letter to government suggesting that *Covid-19 vaccine inaction risks the biggest man-made health failure since the AIDS outbreak*” and calling on government to make its advice, and its vaccine plans, publicly available. A copy of that open letter is attached as “**HJI5**”.
26. On 3 January 2021, the Minister of Health announced South Africa’s Covid-19 vaccine strategy at a public press briefing. It proposed a three-phase vaccine rollout, with 1 250 000 front-line healthcare workers to be vaccinated in phase 1, which was anticipated to commence as early as February 2021. A copy of that press statement is “**HJI6**”.
27. Shortly thereafter, on 7 January 2021, the Minister of Health announced that an order of the Covishield (AstraZeneca – University of Oxford) vaccine had been procured for all healthcare workers in South Africa, and that the first batch would be delivered during the course of January 2021. A copy of that statement is “**HJI7**”.
28. Under section 14 of the Medicines and Related Substances Act 101 of 1965 (“**Medicines Act**”), no vaccine can be distributed or administered domestically unless SAHPRA had registered it or otherwise authorised its use under section 21 of the Medicines Act. SAHPRA authorised the use of the Covishield vaccine (the AstraZeneca–University of Oxford vaccine produced under licence by the Serum Institute of India) during January 2021.
29. The first consignment of the Covishield (AstraZeneca-University of Oxford) vaccine, for administration to front-line healthcare workers, was delivered on around 31 January 2021. Its arrival was announced in a press statement issued that day and attached as “**HJI8**”. Vaccination of healthcare workers was due to start shortly thereafter.

30. However, on 7 February 2021, a decision was taken by the NDoH to pause the rollout of the AstraZeneca-University of Oxford vaccine because the NDoH indicated that the results of a preliminary study suggested that it had lower efficacy against the 501Y.V2 variant, which was the dominant variant in South Africa at the time. (The expert advice and related information underpinning that decision is the subject of a separate PAIA application brought by the HJI before this Court.)

The introduction of the Sisonke Programme (Part 1)

31. Rapid arrangements were then made for healthcare workers to be vaccinated with the Johnson & Johnson vaccine (“J&J”) through a specially set up implementation study of that vaccine, on expedited timelines, for health care workers on the ‘frontline’.
32. The Sisonke Programme was an investigator-led study and collaboration between the NDoH, SAMRC and the Janssen Pharmaceutical group (the manufacturing group of the J&J vaccine), among others. It established an open-label, single arm Phase 3B implementation study, to monitor the effectiveness of a single-dose J&J vaccine among healthcare workers in South Africa. At the time:
 - 32.1. The Janssen Pharmaceutical group had submitted a dossier for consideration to SAHPRA for review of its J&J vaccine by mid-January 2021. The vaccine had at the time not yet been registered or authorised for use by SAHPRA.
 - 32.2. The phase 3 trial results for the J&J vaccine had been released globally on around 29 January 2021. They suggested that the J&J vaccine was safe and efficacious in preventing severe Covid-19 disease and death.
33. The immediate benefit of the Sisonke Programme was that in the first quarter of 2021, it made one dose of a J&J vaccine immediately available to healthcare workers in South Africa, whilst simultaneously allowing data to be gathered on the safety, efficacy and impact of vaccination on healthcare workers, compared

to the then-unvaccinated general population. At this point in the pandemic, there was a serious supply limitation of vaccines (what we term 'scarcity'), for healthcare workers and the general population in most global south countries. Supply deliveries for South Africa were similarly constrained.

34. The Sisonke Programme to vaccinate health care workers on the front line was a key and laudable achievement and helped to manage South Africa's containment of the Covid-19 pandemic at a time of increasing case numbers and globally, limited vaccine supplies. It was executed under very tight timeframes and under difficult conditions by committed researchers and healthcare workers. Our application on the decision-making and requests involved in the prioritisation of persons who were *not* healthcare workers, should not detract in any way from the importance and value of the programme for healthcare workers and those on the front line and who bore the brunt of wave after wave of infections, cases, and deaths in 2020 and 2021 in our country.
35. The earliest protocol for the study that we have found, describing its scope and its purpose, is attached as "**HJI9**". I highlight that the inclusion criteria, at the time, permitted only healthcare workers in the public and private sector, and the President to be vaccinated under the auspices of the Sisonke Programme. A subsequent amendment granted by SAHPRA included the vaccination of the President and Deputy President of South Africa, but not other cabinet members or government officials.
36. SAHPRA provided urgent study approval for the Sisonke Study (Part 1), as a phase 3B clinical trial and on the terms set out in **HJI9**, on 15 February 2021. A copy of the announcement of that approval is attached as "**HJI10**".
37. The Implementation of the Sisonke Study (Part 1) began two days later, on 17 February 2021. It aimed to administer between 350 000 and 500 000 doses of the J&J vaccine to healthcare workers by 15 May 2021, and thereafter to monitor them for a period of 24 months.

Expansion of Part 1 of the Sisonke Programme / Study

38. On 28 March 2021, the NDoH announced that it anticipated beginning phase 2 of the country's a mass vaccination roll-out programme from May 2021. The HJI understood that the general roll-out would not affect the Sisonke Programme since the latter's trial perimeters or terms were set by relevant ethics bodies and also SAHPRA, and the vaccines supplied to the Sisonke Programme were earmarked for it.
39. On 31 March 2021, the then Health Minister updated the Parliamentary Portfolio Committee on Health on both the Sisonke study and on plans for vaccine procurement. The press statement (attached as "HJI11") recorded that 251 707 healthcare workers had been vaccinated through the Sisonke Programme at that time.
40. The Sisonke Study (Part 1) concluded on 15 May 2021. The press statement issued at the time (and attached as "HJI12") recorded that it had vaccinated 478 733 individuals (although that figure was later updated to 479 760), and that the remainder of the 500 000 doses made available for the study would be used "*to conduct important studies and programmes that will help us to understand how the vaccines work for population groups such as persons living with HIV and other co-morbidities, elite athletes, pregnant and lactating women and other special groups*" (emphasis added).
41. The same press statement announced the commencement date of Phase 2 of the National Vaccination Programme as 17 May 2021, with vaccines being made available to "citizens 60 years and above", at 87 public and private vaccinations sites across the country.
42. Shortly thereafter, the media began reporting on the special vaccination of "*athletes*" ahead of their age cohort:
 - 42.1. A Daily Maverick article of 22 May 2021 (attached as "HJI13.1") reported that the South African Sports Confederation and Olympic Committee

(“Sascoc”) had been exploring vaccination options for “athletes” who were due to attend the Tokyo Olympics at the time.

- 42.2. A News 24/Sport24 article attached as “**HJI13.2**” reported that Sascoc had engaged with the NDoH and the Department of Sports, to roll out vaccines to the South African Olympic team, that a “test phase” had been conducted on 20 May 2021 and that a “full time rollout to athletes” would commence on 24 May 2021.
 - 42.3. A Daily Maverick article of 27 May 2021 (attached as “**HJI13.3**”) similarly reported that Olympic athletes had started to receive vaccines the previous Friday, 21 May 2021. So, too did the Business Insider in a 25 May 2021 article (attached “**HJI13.4**”) which also reported that a thousand doses of vaccine would be available to “rugby and Olympic stars”.
 - 42.4. Then, on 28 May 2021, both SuperSport and Daily Maverick reported that “every person in the Springbok rugby team” (including the players, management, and support staff) would be vaccinated for the “Lions series” in July 2020. The Daily Maverick article recorded that Professor Glenda Gray, the head of SAMRC, had confirmed that “athletes” were “receiving the Johnson & Johnson version [of the vaccine] from the Sisonke study, originally intended for healthcare workers”. Copies of the articles are attached as “**HJI13.5**” and “**HJI13.6**”.
43. The HJI was deeply concerned by these developments. Prioritising younger, healthy athletes into the Sisonke Programme and even perhaps other officials, including government officials effectively gave them special, privileged access to remaining clinical trial stock, seemingly as a consequence of political engagements. To the best of our knowledge, there was no plausible scientific ground, or public health basis, that warranted their inclusion in the trial, study and Programme. Elite athletes are, by definition, fit and healthy, are generally young, and are unlikely to have co-morbidities. They would seemingly be the least at risk of mortality and morbidity associated with Covid-19.

44. The expansion of the Sisonke Study to include elite athletes, sports officials, and perhaps even others, was particularly invidious at a time of extreme vaccine shortage when most of the vulnerable population remained without timely access to vaccines. (At the time, vaccines had not yet even been administered to the elderly, due to scarcity of supply.) The HJI considered the expansion to be without public health or scientific basis, and our only conclusion is that it was designed to pander to special, privileged interests pursuant, potentially, to executive interference. While we encourage vaccinations for everyone, when scarcity exists, vaccine access decisions cannot be made solely based on participation in local or global sporting or business or government events or based on who is more important for the economy, and at the expense of pressing public health considerations.
45. We were also concerned about how the changes to the Sisonke Programme had been brought about, and how access to the donated left-over stock would be prioritised as part of the National rollout programme which had limited access to sufficient supplies for everyone in the country at the very same time.
46. Clinical studies are subject to guidelines and protocols (including those published by the NDoH and SAHPRA attached as “HJI14”), which require inclusion and exclusion criteria to be determined up front, and for changes to be made only after proper consideration by ethics committees and notice to SAHPRA. We do not know how the Sisonke study protocol had been changed to include elite athletes.

The informal information requests

47. On 27 May 2021, the HJI sent an urgent letter to the Health Minister, SAMRC and SAHPRA noting our concerns and requesting information on:
 - (a) *Who approved the waiving of the study's eligibility criteria and what is the scientific and ethical basis for the decision?*
 - (b) *Who acts as Principal Investigator of the proposed elite athletes component of the Sisonke trial?*

- (c) *How will this study benefit our understanding of the efficacy and safety of the Janssen vaccine?*
- (d) *Which ethics committee approved the deviation from the protocol, on what basis was this decision made, and what rationale was provided for violating the principle of 'justice' in the four pillars of research ethics? Please provide copies of the ethics application and the decision of the ethics committee in question.*
- (e) *Was the Ministerial Advisory Committee (MAC) on Vaccines involved in this decision-making? Please provide us with a copy of its advisory on this matter as it is in the public interest that it be disclosed.*
- (f) *Please confirm the number of vaccines that are 'left-over' from the Sisonke trial and the expiry date.*
- (i) *In our calculation, there should be approximately 20 000 vaccines available.*
- (ii) *Please provide a detailed breakdown of the planned allocation of these particular vaccines and what other deviations of the Sisonke protocol are currently being considered or approved.*
- (iii) *This is particularly important because in a press interview on 13 May 2021, the co-investigator of the Sisonke trial, Professor Glenda Gray noted that the vaccines will only 'expire in one year'.*
- (iv) *In the SAMRC press release dated 25 May 2021, the SAMRC is oddly concerned about the 'urgency' with which to distribute the 'left-over' vaccines 'before they expire'.*
- (g) *Please clarify what is the scientific question being addressed for athletes here? Were any athletes vaccinated prior to approval from SAHPRA and the relevant ethics committees - if yes, how, when, and how is this justified? Please also confirm how many 'elite athletes' have already received the vaccine, their sporting code, age and gender.*
- (h) *What progress has been made in identifying and enrolling additional eligible groups, as described before ('sub-studies are*

ongoing to evaluate the vaccine further in pregnant and lactating women, in health workers living with HIV, older health workers and those with other co-morbidities')?

(i) *How is this being done now that enrolment in Sisonke via the EVDS has been terminated?*

48. In short, the HJI sought to establish how the expansion of access to the Sisonke Programme study and trial came about, who made the decision and what it was based on. We notified the recipients that if they did not provide the information sought, we would be forced to lodge a PAIA request. A copy of the letter is attached as “**HJI15**”.
49. To our great surprise, that same day (27 May 2021), HJI’s Board Chairperson, Dr Manjra received an unsolicited group phone call in his capacity as Chairperson of the HJI, which included, among others Professor Glenda Gray (the CEO / head of SAMRC), Dr Stavros Nicolaou (the then Chairperson of Cricket SA’s interim Board and a senior executive at a pharmaceutical company called Aspen), and Dr Fatima Mayet (an investigator on the Sisonke Programme study), in response to that letter. In that call, Professor Gray took exception to the HJI’s letter and tried to warn the HJI off making further inquiries. The tone of the call was aggressive, and its content threatening, inappropriate and irregular and, in our view, constitutes an attack on the work of civil society organisations in a pandemic. Her aggressive interaction with Dr Manjra on that call was laden with expletives and threatening of the HJI. Dr Manjra confirms the content of this paragraph in his accompanying confirmatory affidavit.
50. Following that phone call, the very next day, the SAMRC’s legal representative, Mzimhle Popo, provided a formal response to HJI’s letter (attached as “**HJI16**”).
- 50.1. The letter stated that the Sisonke Programme was distinct from South Africa’s National vaccine rollout programme, and that J&J doses received by SAMRC for the Sisonke study could be “*used for clinical trial purposes*” only.
- 50.2. It went on to record that SAMRC was not aware of the alleged prioritisation of athletes in the vaccine rollout and that “[w]ith the initiation

of the National Rollout of Vaccines on 17 May 2021 the large cohort Phase 3B open-label component of the health care worker trial was concluded and the Sisonke Study including relevance to the J and J vaccine was terminated from the EVDS system” although designated vaccination centres were involved in “the Phase 3B sub-study” on “selected participants who meet certain criteria”. The letter went on to state:

We applied to SAHPRA to waive the eligibility criteria to allow a specific set of athletic teams with a defined number of people to access vaccines that were imminently due to expire. The athletes were required to adhere to the study requirements. The process to enroll these athletes occurred at the clinical research sites and not at the designated government roll-out sites. SAHPRA's approval conditions will be followed at these research sites. Once we have completed this process there will be a report back to SAHPRA on the allocation of vaccines including wastage and expiration.

There are statutory entities/ committees that by law are allowed to rule on whether the study is ethically sound or not and, as far as the SAMRC is concerned, your institution is not one of them. While your institution has the right to the freedom of expression such a right must always be exercised responsibly. Your expressed opinion that the ethics of the study referred to in your letter are questionable is ill-informed and it is glaringly clear from the very letter is articulated in that it has no basis in fact. The SAMRC has adhered to all the regulatory requirements of the Sisonke Study. Therefore, all insinuations of impropriety that inhere in such ill-informed opinions are vigorously denied and utterly rejected as being irresponsible”. [emphasis added]

51. (SAHPRA’s actual approval process is dealt with below.)
52. The HJI was taken aback by the tone of the phone call, which we regard as abusive and threatening, as well as the content and tone of the SAMRC letter. In all of our work then and until now, where we have asked regulatory or statutory bodies and even companies to be transparent and accountable, including in

litigating against them (as is our right in a constitutional democracy), we have not been threatened, intimidated or shouted at. That kind of behaviour and conduct is not appropriate for a regulatory body that is publicly funded, nor would it be regarded as acceptable conduct of any entity, even a private corporation.

53. The claim that vaccines were made available to athletes, inter alia, because they were about to expire was squarely at odds with a statement made by Professor Gray quoted in a Polity article of 13 May 2021 and attached as “**HJI17**”, recording that vaccines were not due to expire for a year. Moreover, in the letter the SAMRC accused us of ignorance and being misinformed – when the very purpose of our letter had been to try and better inform ourselves.
54. I respectfully submit that the high-handed response – particularly coupled with the call made to the HJI’s Board Chairperson – was improper and fell far short of meeting the obligations of transparency and accountability imposed on the SAMRC by section 195 of the Constitution.
55. The HJI sent the letter attached as “**HJI18**” acknowledging receipt of the SAMRC response, noting the call made on 27 May 2021 and recording that we would first await responses from the Minister of Health, Minister of Sports, Arts and Culture and SAHPRA before responding further.
56. On 26 July 2021, the Director-General of Health, Dr Buthelezi, sent the letter attached marked “**HJI19**”. The letter noted:

*We would like to confirm that the National Department of Health was approached by the Department of Sports, Arts & Culture with a request to support the vaccination of athletes that would be attending the Tokyo Olympics Games that commenced in Japan on 23 July 2021. We also understood that the MRC would be obtaining SAHPRA’s approval to expand the Sisonke Phase 3B Open Label Study to include the Athletes in relation to the left-over Johnson & Johnson vaccines. The NDOH was supportive of this as it would ensure the health and safety of the South African delegation attending the **Tokyo Olympics**.*

It is essential to mention that the administration of the left over J&J vaccines to the athletes did not have any impact on the vaccine

rollout program of the country. The country has significantly increased daily vaccinations and sufficient vaccines have been secured to ensure that all persons in the republic will be vaccinated.
[emphasis added]

57. SAHPRA acknowledged receipt via email on 7 June 2021 but did not provide a formal response until mid-December 2021 and then again in early 2022 (see below).
58. No substantive response on this matter has been forthcoming from the Minister of Sports, Arts and Culture.
59. Matters remained very unclear, even after receipt of the responses from the SAMRC and the NDoH. At that time, HJI did not know, among others:
 - 59.1. at whose instance SAMRC had applied for the waiver;
 - 59.2. which “athletic teams” waiver had been applied for and/or had received vaccines;
 - 59.3. whether it was only the athletes themselves who had received the vaccines, or also their administrative, support and other staff;
 - 59.4. whether certain government officials had also been prioritised for early access (as we have been told by whistleblowers was the case);
 - 59.5. whether they were administered vaccines that were imminently to expire only; and
 - 59.6. What SAHPRA’s approval conditions were. (SAHPRA has since provided information on their approval, which I deal with below.)
60. The public has a right to know, among other things, who was given priority access to vaccination, and which ethics committees or regulatory bodies sanctioned this and whether there was any undue executive interference in the decision to do so. These issues have continued relevance and significance, given the ongoing need for booster shots and now also the availability of treatment options for Covid-19, against limited by global scarcity. Will people who were given priority

access in the original vaccine rollout be provided with booster shots ahead of the 5 million other people who got a J&J vaccine through the national programme who waited for their age turn? What precedent has been set for future allocation of scarce resources in a pandemic and generally for our health system?

The information and facts that have subsequently come to light

61. Given the continued uncertainty, the HJI submitted a range of PAIA requests (which I deal with in detail below). To date, only SAHPRA has responded to the request made to it. SAHPRA's response, and the accompanying documents, are attached as "**HJI20**". After further correspondence from the HJI on 8 February 2022, attached marked "**HJI21**", SAHPRA then provided further and additional information in a letter dated 15 February 2022, attached marked "**HJI22**".
62. The response from SAHPRA reveals that:
 - 62.1. On 16 May 2021, the SAMRC wrote to the CEO of SAHPRA urgently requesting a waiver to "*the eligibility criteria to include persons of high priority to the nation, including the Olympic and Para-Olympic Team to be included in the Sisonke Study using the Ad26 SARS-CoV-2 investigational vaccine*". The letter stated that the Director General of Health supported the use of J&J vaccines from the study to "*to support the nation*", and that "*The athletes would have received the Pfizer vaccine, and there is not enough time before they go to the Olympics to receive both doses [...] We request an expedited waiver to allow us to conclude the vaccinations this week, allowing the athletes to travel to [sic] abroad. We will send the list of vaccinated athletes and accompanying members of the team.*"
 - 62.2. The Director General of Health also sent a letter to SAHPRA on 18 May 2021 entitled "Request for Waiver of Sisonke Trial Requirements to Vaccinate Team South African to attend the Olympic Games in Tokyo, Japan". The letter only focused on Team South Africa's participation in the Olympics and Paralympic Games in Tokyo. The Director-General requested that "SAHPRA waives the Sisonke Trial requirements to allow

for the South African delegation attending the Games to be vaccinated with remaining doses from the Sisonke Trial” and that “*approximately 600 individuals would have to be vaccinated which includes the following categories: athletes, medical staff, coaches, team support, technical and media*”.

62.3. The information provided to HJI by SAHPRA indicates that the application for a deviation was considered by SAHPRA’s CTC (likely the SAHPRA Clinical Trials Committee) via round-robin. The content of the emails exchanged have been provided by SAHPRA, in an unattributed table that excludes email attachments. It demonstrates that the waiver application was unusual and discomfiting to at least some of SAHPRA’s personnel:

62.3.1. It is clear that a number of SAHPRA’s CTC members considered the category of “*persons of national interest*” as too wide a waiver, and at least two members objected to athletes, “*officials and spouses of officials, managers and other hangers-on*” being prioritised over ordinary citizens (see items 12 and 14 of the email table).

62.3.2. Others sought clarity on which vaccines would be used – particularly given that not all healthcare workers had been vaccinated at the time (items 25 and 26 of the email table).

62.3.3. As appears from the email table, other objections and concerns raised by the SAHPRA CTC members include:

62.3.3.1. the precedent set by ‘endless waivers to Sisonke’ (item 25 of the email table);

62.3.3.2. the ‘frivolity’ of the request and an objection to the ‘tone’ of the request (item 12 of the email table);
and

62.3.3.3. the 'implication of inequality' (item 14 of the email table).

62.4. An email – we believe, from the SAMRC – 'urged' a decision from the SAHPRA CEO and noted that "*at this stage we will not be able to amend the protocol and have it approved by Ethics we will forward them the waiver however if approved*" (emphasis added).

62.4.1. This seems to suggest that the SAMRC did not pursue a protocol amendment to the Sisonke study (as opposed to a waiver) as time would not allow for it. A protocol amendment would have required ethics committee oversight and guidance at the outset (before approaching SAHPRA). We presume that the ethics committee would ordinarily decide on who should have access to scarce doses of vaccine supplies in a time of a pandemic and ordinarily.

62.4.2. This email exchange that seemed to focus on the "South African Olympic Team going to Tokyo" as "persons of national interest" – was regarded by some SAHPRA CTC members as far too vague and therefore unacceptable" (item 19 of the email table).

62.4.3. Item 3 of the email table specifically refers to the possibility of a waiver to "members of the South African Olympic Team going to Tokyo".

62.5. Ultimately from this email exchange, it appears that SAHPRA was provided with a list of the individuals the SAMRC proposed be vaccinated, and that SAHPRA approved the 'waiver', but limited it to 'listed athletes and teams' but 'excluding spouses, officials' and others (items 28 and 29 of the email table and exchange). One member of the SAHPRA CTC recorded their opposition to the waiver approval (item 33 of the email table).

62.6. Neither the lists nor the draft approval letters referred to in the email exchange have been provided to the HJI.

62.7. On 19 May 2021, SAPHRA's CEO sent a short letter to SAMRC entitled "RE: Request to waive eligibility criteria to include persons of national interest". She noted that "SAHPRA recommends that the request be acceded to provided that:

All conditions of registration of the Johnson & Johnson/Janssen vaccine are also observed for the vaccinated persons, inclusive of, but not limited to, safety monitoring and reporting of the relevant safety outcomes to SAHPRA at specified intervals."

62.8. Notably, that letter did not refer confine approval to Olympic athletes nor did it expressly exclude spouses and officials. It is thus unclear who "the persons of the national interest" who were approved for vaccination were. Key to our request is thus the list of athletes provided by the SAMRC to SAHPRA. We wish to ascertain whether those individuals were only those who attended the Olympics, or also included those from other sports codes, and others who were not athletes. Also, ultimately whether the SAMRC can confirm that only those designated on the list received vaccines.

63. On 7 February 2022, the HJI requested SAHPRA to provide "a list of the categories of persons that SAHPRA authorised for vaccination under the Sisonke programme as well as using any Sisonke stock other than for those previously included as eligible in terms of the SAHPRA-approved protocol", which had previously not been disclosed.

64. On 15 February 2022, the CEO of SAHPRA responded that:

"the list of categories of athletes authorised by SAHPRA for vaccination are as follows:

- *Athletes*
- *Coaches*

- *Physiotherapists*
- *Doctors*
- *Other specific technical/essential members of the support team that accompanies the athletes”*

SAHPRA is not aware, nor did it authorise any additional categories of persons to be vaccinated under the Sisonke Programme.”

65. It thus remains a mystery, inter alia, who initiated the request to allocate vaccines to athletes and for which sports codes, and how many people in total were ultimately vaccinated under the waiver approval, whether they were all Olympic athletes and team members or whether other sports teams, and delegates and/or sports officials, others as well as government officials (civil servants) were also included, and at whose behest. These remain information that the public is entitled to know – particularly where multiple rounds of booster vaccinations may be required and especially where this may set an inappropriate and unethical precedent for future pandemics.

PAIA REQUESTS

The request to the NDoH

66. On 23 July 2021, a PAIA request was sent to the NDoH (already attached as **HJI2.1**). The HJI requested production of:

1. Copies of any emails and any other written requests, motivations and correspondence from either the National Department of Health or National Department of Sports, Arts and Culture and/or their respective Ministers, Deputy Ministers and/or their Director Generals and/or Deputy Director Generals, sent to

i. the South African Medical Research Council ('SAMRC')

ii. the South African Health Product Regulatory Agency ('SAHPRA')

iii. the National Coronavirus Command Council ('NCCC')

iv. any other statutory or Covid-19 coordinating body in South Africa

v. Ministerial Advisory Committee on COVID-19 ('MAC') and Ministerial Advisory Committee on COVID-19 vaccines ('VMAC') that requested permission to authorise and/or prioritise individuals other than health care workers for vaccination under the Sisonke programme, including using any of its stock to vaccinate

a. Professional athletes, sports people, sport coaches, and sports administrators from different sporting codes in South Africa

b. South African government officials

c. South African diplomatic staff

d. Cabinet members.

2. In respect of 1 above, copies of all respective responses and regulatory and/or other approvals, waivers or rejections.

3. Copies of all correspondence with

i. the Department of Sports, Arts and Culture

ii. any national and/or international sports bodies and/or

iii. any local research bodies including any local research ethics committees relating to the request and approval for professional athletes; sports officials; government officials or other persons to also be offered a vaccine through the Sisonke programme and its stock for the period April to June 2021.

4

i. The list of all categories of persons offered and/or administered a vaccine under the auspices of the Sisonke programme and from any of its stock in April - June 2021.

ii. A copy of the list of all the provincial sites where the vaccines were administered for the Sisonke programme and from any of its stock in April - June 2021.

iii. A list of the sports bodies and codes, government departments, multilateral institutions and/or foreign embassies that participated and the total number of vaccines administered including the gender, disability, age, and occupational breakdown.

67. No response was received within the statutorily prescribed period, and the request was deemed to have been refused.
68. On 8 September 2021, the HJI lodged the internal appeal already annexed as **HJI3.1**. It was also not responded to, and the internal appeal is regarded, under section 77(7) of PAIA, as having been dismissed.

The Department of Sports request

69. On 28 July 2021, the HJI submitted the PAIA request already attached as **HJI2.2** to the Department of Sports. It requested access to:

1. Copies of any emails and any other written requests, motivations, and correspondence including the respective dates, from the National Department of Sports, Arts and Culture and/or its Minister, Deputy Minister and/or the Director General and/or Deputy Director Generals, sent to:

i. the National Department of Health ('NDoH')

ii. the Minister of Health

iii. the South African Medical Research Council ('SAMRC')

iv. the South African Health Product Regulatory Agency ('SAHPRA')

v. the National Coronavirus Command Council ('NCCC')

vi. any other statutory or Covid-19 coordinating body in South Africa

vii. Ministerial Advisory Committee on COVID-19 ('MAC') and Ministerial Advisory Committee on COVID-19 vaccines ('VMAC')

viii. any provincial, national and/or international sports bodies including the International Olympics Committee (IOC) and the South African Sports Confederation and Olympic Committee (SASCOC) – that requested that artists, musicians, professional athletes, sports people, sport coaches, and sports administrators from different sporting codes in South Africa be included under the Sisonke programme, including using any of its stock for vaccination and/or prioritised otherwise.

2. *In respect of 1 above, copies of all respective responses and regulatory and/or other approvals, permissions, waivers and/or rejections.*

3.

i. The details or a list with the number of artists, musicians, professional athletes, sports people, sport coaches, and sports administrators from different sporting codes and/or other persons in the National Department of Sports, Arts and Culture that were offered and/or administered a vaccine under the auspices of the Sisonke programme, including using any of its stock in March - June 2021 or from any other vaccine programme, where they were given a vaccine outside of the age cohort prioritisation system determined by government.

ii. The provincial sites where the vaccines in 3.i. above were administered.

iii. The details or a list of all the art councils or bodies, sports bodies and codes that participated in 3.1 above and the total number of vaccines administered under the auspices of the Sisonke programme, including using any of its stock, or any other programme with the gender, race, disability, age, and occupational breakdown.

iv. The number of SASCOC officials and sports administrators who received a vaccination under the Sisonke programme but who did not travel to Japan to attend the Olympics.

4. Copies of any correspondence with the IOC and/or Pfizer in the period January - June 2021 regarding any offers of donations of vaccines for use by Olympic and Paralympic athletes.

70. On 29 July 2021, the Department of Sports Director General acknowledged receipt of the PAIA request and informed the HJI that the request had been forwarded to the relevant branch within the Department for consideration and response. That email correspondence is attached as “HJI23”.

71. No further response was received, and the request was deemed to have been refused.

72. The HJI lodged the internal appeal attached as **HJI3.2** on 9 September 2021. It was also not responded to and the internal appeal is regarded, under section 77(7) of PAIA, as having been dismissed.

The SAMRC request

73. On 23 July 2021, the HJI submitted a PAIA request to SAMRC (already attached as **HJI2.3**). It requested production of:

1. A copy of the request/s to all relevant ethics committees for any ethics amendment to the protocol of the Sisonke programme and copies of all ethics clearances and approvals, issued by any of the relevant ethics committees for the period April - June 2021.

2. A copy of the SAMRC request to the South African Health Product Regulatory Agency ('SAHPRA'), to waive or amend the eligibility criteria of the Sisonke programme in the period April - June 2021 where the request was to include any person other than for those previously included as eligible in terms of the SAHPRA approved protocol - including professional athletes, sports officials and government officials.

3. A copy of all responses from SAHPRA related to 1.) and 2.) above and a copy of its written approval/s.

4. A copy of any other written request that sets out the motivation and reasons for any request to amend, waive or change the eligibility criteria for inclusion in the Sisonke programme and for being a recipient of any stock from the Sisonke programme for the period April – June 2021.

5. Copies of all correspondence with the Ministers and the Director-Generals ('DGs') of the National Departments of Health and Arts, Culture and Sports; SAHPRA, South African Sports Confederation and Olympic Committee ('SASCOC'), the International Olympic Committee ('IOC') and/or any other statutory entity, sports body, and/or research or academic body, and/or ethics committee/s relating to the use of vaccines and vaccine stock from the Sisonke programme.

6. A list of the categories of persons other than health care workers and those previously included as eligible in terms of the SAHPRA-approved protocol that were offered and/or administered a vaccine

under the auspices of the Sisonke programme and from any of its stock in April - June 2021.

7. A list of all the places and sites where the vaccines in 6 above, were administered, and the sports bodies and codes, government departments, multilateral institutions and/or foreign embassies that participated and benefited from the Sisonke programme and / or its stock; and the total number of vaccines administered including the gender, disability, age, and occupational breakdown.

74. SAMRC acknowledged receipt of the request on 26 July 2021 (“**HJ124**”) but did not thereafter provide a substantive response.
75. On 8 September 2021, the HJI lodged the internal appeal attached as **HJ13.3** against SAMRC’s deemed refusal of the request. It was also not responded to, and the internal appeal is regarded as having been dismissed.

HJI IS ENTITLED TO THE INFORMATION REQUESTED IN TERMS OF PAIA

76. Section 32 of the Constitution provides for a right of access to information, which states that:

“(1) Everyone has the right of access to—

- a) any information held by the state; and*
- b) any information that is held by another person and that is required for the exercise or protection of any rights.”*

77. PAIA was enacted to give effect to the right of access to information, as envisaged in section 32(2) of the Constitution.
78. In terms of section 11(1) of PAIA, a requester must be given access to a record of a public body if two requirements are met. First, the request must comply with the procedural requirements in terms of PAIA and second, no ground of refusal, contemplated in Chapter 4 of PAIA, must apply. Each of those requirements were met in this case: the procedural requirements of PAIA have been complied with and no ground of refusal lawfully applies. Certainly, none has been identified by any of the Respondents, who bear the onus in this regard. It follows that the requested records must be produced.

79. Even if there was a basis to refuse access to the records sought (which is denied), their disclosure is manifestly in the public interest and is mandatory under section 46 of PAIA.

80. On either basis, I submit that the requested information falls to be disclosed.

CONCLUSION

81. The HJI accordingly asks for an order in terms of the notice of motion to which this affidavit is attached.

MARLISE RICHTER

I hereby certify 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 the ____ day of _____ 2022, and that the Regulations contained in Government Notice R.1258 of 21 July 1972, as amended by R1648 of 19 August 1977, and as further amended by R1428 of 11 July 1989, having been complied with.

COMMISSIONER OF OATHS