

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

CASE NO: 19342/22

In the matter between :-

THE HEALTH JUSTICE INITIATIVE

Applicant

And

THE MINISTER OF HEALTH

1st Respondent

THE INFORMATION OFFICER

2nd Respondent

**NATIONAL DEPARTMENT
THE MINISTER OF SPORT, ARTS AND CULTURE**

3rd Respondent

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

4th Respondent

SOUTH AFRICAN MEDICAL RESEARCH COUNCIL

5th Respondent

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

6th Respondent

FILING SHEET

DOCUMENT: FIRST AND SECOND RESPONDENT'S ANSWERING AFFIDAVIT

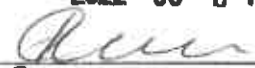
DATED at PRETORIA this 1st day of AUGUST 2022.


ATTORNEY FOR RESPONDENTS
STATE ATTORNEY PRETORIA
SALU BUILDING
316 THABO SEHUME STREET
CNR THABO SEHUME (ANDRIES) AND
FRANCIS BAARD (SCHOEMAN)
STREETS
PRIVATE BAG X94
PRETORIA, 0001
Ref: 0484/22/Z22
Tel: (012) 309 1578
Cell: 072 277 1908
E-mail: NaQongqo@justice.gov.za
Enq: N Qongqo

TO: THE REGISTRAR OF THE HIGH COURT
GAUTENG DIVISION
PRETORIA

AND
TO: APPLICANT'S ATTORNEYS
POWER SINGH INC
20 BAKER STREET, ROSEBANK
JOHANNESBURG, 21 96
TEL: 011 268 6881
FAX: 086 614 5818
Email: tara@powersigh.africa
tina@powersigh.africa
Ref: PSIHJ-202120

C/O CENTRE FOR CHILD LAW
FACULTY OF LAW
LAW BUILDING (ROOM 4 – 31)
UNIVERSITY OF PRETORIA
PRETORIA, 0002
TEL: 012 420 4502
FAX: 012 420 4499
Email: liesl.muller@up.ac.za
REF: LIESL MULLER

Centre for Child Law
Faculty of Law - University of Pretoria
2022 -08- 0 1
Signature: 
Name: <u>Portiso</u>

**IN THE HIGH COURT OF SOUTH AFRICA
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Case No.: 19342/22

In the matter between:

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THE MINISTER OF HEALTH

First Respondent

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Second Respondent

NATIONAL DEPARTMENT

Third Respondent

THE MINISTER OF SPORT, ARTS AND CULTURE

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

Sixth Respondent



FIRST AND SECOND RESPONDENTS' ANSWERING AFFIDAVIT

I, the undersigned,

DR NICHOLAS GILMOUR CRISP

do hereby make oath and state that:

1. I am the Deputy Director- General of the National Department of Health (NDoH). I am delegated to respond on behalf of the Director General who is the Designed Information Officer of the NDoH, having been designated in terms of the Promotion of Access to Information Act, 2000 (Act No. 2 of 2000) ("PAIA").
2. The facts contained in this affidavit fall within my personal knowledge, unless indicated otherwise by the context, and are furthermore, to the best of my belief both true and correct.
3. I am authorised to depose to this affidavit on behalf of the Minister of Health. The facts set out in this affidavit based on the information available to me in my capacity as the Deputy Director-General and as delegated by the information officer of the NDoH.
4. Where I make legal submissions, I do so on advice of the NDoH's legal representatives.
5. I accept such advice as correct. I have read the founding affidavit deposed to by

Fatima Hassan on behalf of the applicant, and wish to respond

6. I will not answer to each, and every allegation of fact or law set out in the founding affidavit. The fact that I do not answer respond to every allegation made in the founding affidavit should not be construed as admission that the allegation is true and correct.
7. I will confine my response to the issues falling with the NDoH's province.
8. Any allegation contained in the founding affidavit which is at variance with the averments I make in this affidavit is denied and the applicant is put to the proof thereof.

INFORMATION REQUESTED

9. The applicant's request is confined to the records under the auspices of Sisonke programme open-label, single-arm phase 3B implementation Study to monitor the Effectiveness of the Single-dose Ad26.Cov2. s COVID-19 Vaccine Among Health Care Workers in South Africa (VAC31518coV3012).
10. 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 General and/or Deputy Director Generals, sent to

- I. The National Department of Health (NDOH);The Minister of Health;**
- II. The South African Medical Research Council "SAMRC"),**
- III. The South African Health Product Regulatory Agency("SAHPPRA").**
- IV. The National Coronavirus Command Council ("NCCC");**
- V. Any other statutory or Covid -19 coordinating body in South Africa;**
- VI. Ministerial Advisory Committee on Covid – 19 ("MAC")**
- VII. Ministerial Advisory Committee on Covid – 19 "(MAC)" and**
- VIII. Ministerial Advisory Committee on Covid – 19 vaccines ("VMAC"), that requested permission to authorise and/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; and**
 - d) Cabinet members.**
 - 1. Copies of all respective response and regulatory and /or other approvals, waivers, or rejections.**
 - 2. Copies of all correspondence with**
 - i. the Department of sport, arts, and Culture**
 - ii. any national and/ or international sports bodies and/or**
 - iii. any local research bodies including any local research**

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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 2021.

- i. The list of all categories of persons offered and /or administered a vaccine under the auspices of Sisonke programme and any of its stock in April-June 2021.**
 - ii. A copy of all the list of all the provincial sites where the vaccines were administered for the Sisonke programme and from the any of its stock in April-June 2021.**
 - iii. A list of the sports bodies and codes, government departments, multilateral institutions and/ foreign embassies that participated and the total number of vaccines administered including the gender, disability, age, and occupational breakdown.**
- 11. I must state that this request is expansive in that it traverses wide range of areas, institutions, and departments. My observation is that the applicant is embarking on a fishing expedition. I am advised that the litigant who wishes to vindicate the constitutional right must identify the responsible authority with great precision.**
- 12. The applicant has failed to identify the responsible authority for the Sisonke programme in that it dragged every conceivable department into this litigation. It is common knowledge that Sisonke programme was a clinical trial to test the efficacy of a single dose of Johnson and Johnson vaccine on the Healthcare workers.**
- 13. These clinical trials were conducted by the South African Medical Research**

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Council ("SAMRC"). The information relating the Clinical trials resides with the ("SAMRC"). Some of the information about Sisonke is in the public domain. For example, the number of sites in the provinces, where the trials were conducted. The NDoH was not directly involved in the administration of Sisonke programme.

AD SERIATIM RESPONSE TO THE FOUNDING AFFIDAVIT

AD PARAGRAPHS 1 -3

14. Save to deny that the facts are true and correct, I have no knowledge of the contents thereof.

AD PARAGRAPHS 4 -5

15. The contents of these paragraphs are undisputed.

AD PARAGRAPH 6

16. I have no knowledge of the contents of these paragraphs.

AD PARAGRAPH 7

17. The contents of this paragraph are undisputed.

AD PARAGRAPHS 8- 10

18. Save to admit that a request was made to the department and an appeal was

subsequently lodged. I have no knowledge of the contents of these paragraphs.

AD PARAGRAPHS 11-15

19. I have no knowledge of the contents of these paragraphs.

AD PARAGRAPHS 16 to 23

20. The contents of these paragraphs are undisputed.

AD PARAGRAPHS 24 – 30

21. Save to admit that vaccines are 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 NDoH has no knowledge of the contents of these paragraphs.

AD PARAGRAPHS 31 to 37

22. The contents of these paragraphs are undisputed.

AD PARAGRAPHS 38 – 41

23. Save to state that the Sisonke Study concluded on 16 May 2021, the contents of these paragraphs are not in dispute.

AD PARAGRAPHS 42 – 45

24. I have no knowledge of the contents of these paragraphs.

AD PARAGRAPH 46

25. Save to admit that clinical studies are subject to guidelines and protocols, which require inclusion and exclusion criteria to be determined upfront and changes to be made after proper consideration by ethics committees and notice to SAHPRA. The First and Second Respondents have no knowledge of the contents of these paragraphs.

AD PARAGRAPH 47

26. Save to admit that a letter dated 27 May 2021, was sent by the Applicant to the First Respondent wherein they were noting their concerns and requesting information which is not in our disposal, Clinical trials were conducted by the South African Medical Research Council ("SAMRC") and the information relating the Clinical trials resides with the ("SAMRC").

AD PARAGRAPHS 48

27. The contents of this paragraph are undisputed.

AD PARAGRAPHS 49 - 55

28. I have no knowledge of the contents of these paragraphs.

AD PARAGRAPH 56

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29. The contents of this paragraph are undisputed.

AD PARAGRAPHS 57 – 60

30. I have no knowledge of the contents of these paragraphs.

AD PARAGRAPH 61

31. Save to state that in a letter dated 26 July 2021, the Director General advised the Applicant, 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. The department further advised the applicant that the request received from SASCOC through the Department of Sport, Arts and Culture ("DSAC") was forwarded to SAHPRA, regarding the expansion of the Sisonke Phase 3B Open Label Study to include Athletes in relation to the left – over Johnson and Johnson Vaccines. I have no knowledge of the balance of the contents of these paragraphs and can neither deny nor admit same.

AD PARAGRAPH 62.1

32. I have no knowledge of the contents of this paragraph.

AD PARAGRAPH 62.2

33. The contents of this paragraph are undisputed.

AD PARAGRAPHS 62.3 to 65

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34. Save to state that a letter to vaccinate the athletes travelling to Tokyo, was initiated by SASCOC, and addressed to the DSAC, I have no knowledge of the remainder of contents of these paragraphs and can neither deny nor admit same.

AD PARAGRAPH 66

35. The contents of this paragraph are undisputed. The NDoH sent a letter to the SAHPRA relating to the issues raised in the request. I attached hereto a copy of the letter and I marked it "NGC2". The contents of the letter are self-explanatory.

AD PARAGRAPH 66.2.

36. Save to admit that the applicant requested copies of all respective responses and regulatory and/or other approvals, waivers, and rejections in respect of information referred to in paragraph 66. 1 above. The department did not receive any responses, regulatory, approvals, waivers, rejections in respect of the requested permission to authorise and/prioritise individuals other than health care workers for vaccination under the Sisonke programme, including using any of its stock to vaccinate.

AD PARAGRAPH 66.3

37. The department has no copies of correspondences other than the request received from the department of Sports, Arts and Culture referred to in paragraph

Handwritten signature or initials in the bottom right corner of the page.

36 above.

AD PARAGRAPH 66.4

38. I have no knowledge of the categories of persons offered and/ or administered a vaccine under the auspices of the Sisonke programme and from any stock in April – June 2021. All sites where the vaccines were administered for the Sisonke programme and from any of its stock in April – June 2021 were reported by SAMRC. I also have no list of the sport bodies and codes, government departments, multilateral institutions and/or foreign embassies that participated and the total number of vaccines administered including the gender, race, disability, age, and occupational breakdown.

AD PARAGRAPH 67

39. The contents of this paragraphs are undisputed.

AD PARAGRAPH 68

40. The contents of this paragraphs are undisputed.

AD PARAGRAPHS 69 -72

41. I have no knowledge of the contents of these paragraphs.

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AD PARAGRAPHS 73 to 75

42. I have no knowledge of the contents of these paragraphs.

AD PARAGRAPHS 76 – 77

43. The contents of these paragraphs are undisputed.

AD PARAGRAPH 78

44. Save to admit that the request was made in terms of the PAIA. I have explained in the paragraph supra, that the department does not have in its possession the requested information save for the annexures attached herein. There is no basis to support this conclusion.

AD PARAGRAPHS 80 THEREOF

45. I deny that the disclosure is in the public interests.

AD PARAGRAPH 81 THEREOF

46. I deny the allegations contained in this paragraph.

CONCLUSION

I submit with respect that the applicant does not make out a case justifying the order sought. As a result, the application falls to be dismissed with costs. I submit further that there is no basis to apply the principles enunciated in the Biowatch decision

regarding cost. The applicant should pay the costs.



DEPONENT

The Deponent has acknowledged that he knows and understands the contents of this affidavit, which was signed and sworn to or solemnly affirmed before me at PRETORIA. on this the 29th day of July 2022, the regulations contained in Government Notice No. R1258 of 21 July 1972, as amended, and Government Notice No. R1648 of 19 August 1977, as amended, having been complied with.



COMMISSIONER OF OATHS

Full Names: CHRISTOPHER ANTHONY LEUKES

Capacity: DIRECTOR - LEGAL SERVICES

Designation:

Address: 22 Struben Street
Pretoria Central

CHRISTOPHER ANTHONY LEUKES
COMMISSIONER OF OATHS EX OFFICIO
DEPARTMENT OF EDUCATION
PRETORIA

SIGN:  DATE: 29/07/2022

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**DIRECTOR GENERAL
HEALTH
REPUBLIC OF SOUTH AFRICA**

PRETORIA
P.O. Box 2020, PRETORIA, 0001, 27th Floor, Citibus Building, Car Trade Station and Struben Street, PRETORIA, 0002 Tel (012) 305 9402 Fax (012) 305 9422
CAPE TOWN
P.O. Box 3070, CAPE TOWN, 8000, 105 Parliament Towers, Floor 014, 120 Fish Street, CAPE TOWN, 8000 Tel (021) 401 2040 Fax (021) 401 8804

Dr Bokumelo Semets-Makokotlela
Chief Executive Officer
South African Health Products Regulator (SAHPRA)
Building A
Loftus Park
402 Kirkness Street
Arcadia
Pretoria

E-mail: Bokumelo.Semets@saahpra.org.za

Dear Dr Semets-Makokotlela

RE: Request for Waiver of Sisonke Trial Requirements to Vaccinate Team South African to attend the Olympic Games in Tokyo, Japan

The above matter refers.

As you may be aware, various countries are preparing for the celebration of the Olympic Games in Tokyo which are scheduled to take place from 23 July to 8 August 2021. South Africa is also planning to send Team South Africa and a delegation to represent the country at the Games. This also includes attendance at the Paralympic Games scheduled for 24 August to 05 September 2021. The Olympic and Paralympic Games are the ultimate world stage for athletes to achieve the highest honour through an opportunity to participate in a sporting competition with the world's best athletes in their specific codes.

We understand that the International Olympic Committee has urged that where possible, Olympic and Paralympic teams be vaccinated in order to promote safe sport. Many countries have heeded to this call by vaccinating the delegation that would be attending the Olympics and Paralympics representing their countries. As the Government of South Africa, it would be imperative for us to also heed this call to ensure the health and safety of the South African delegation that will be attending the Games.

As you know, we had anticipated that by now we would have received the commercial Johnson&Johnson (J&J) vaccines in country which would make it easier to vaccinate the South African delegation since this is a single dose vaccine. Due to the fact that

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we have not received the commercial J&J doses we would like to request 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. We understand that some of the athletes need to start departing to Tokyo during the first week of June 2021 which makes it impossible for us to vaccinate the delegation with the Pfizer vaccine. We understand further that approximately 600 individuals would have to be vaccinated which includes the following categories: athletes, medical staff, coaches, team support, technical and media.

We trust that the above is in order and your favourable consideration of this request will be highly appreciated.

Kind Regards



Dr SSS Buthelezi
Director-General: Health
Date: 18/05/2021

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