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

NOTICE OF MOTION

KINDLY TAKE NOTICE that the Applicant intends to make application to this Court, on a date to be determined by the Registrar, for an order in the following terms —

- 1. To the extent necessary, setting aside and declaring invalid:
 - 1.1. the failure by the First and/or Second Respondent to provide access to the information requested by the Applicant in its request attached hereto as "A";

- 1.2. the failure by the Third and/or Fourth Respondent to provide access to the information requested by the Applicant in its request attached hereto as "B";
- 1.3. the failure by the Fifth and/or Sixth Respondent to provide access to the information requested by the Applicant in its request attached hereto as "C":
- Directing the First to Sixth Respondents, respectively, to supply the Applicant, within 10 days of the date of order, with copies of each of the records requested in annexures A, B and C respectively;
- 3. Directing that the costs of this application are to be paid jointly and severally by any Respondents who oppose it;
- 4. Further and/ or alternative relief.

TAKE NOTICE FURTHER that the founding affidavit of **MARLISE RICHTER** and the confirmatory affidavit of **DR SHUAIB MANJRA** will be used in support of this application.

TAKE NOTICE FURTHER that the Applicant has appointed the offices of POWER SINGH INC., C/O CENTRE FOR CHILD LAW, FACULTY OF LAW, LAW BUILDING (ROOM 4 – 31), UNIVERSITY OF PRETORIA, PRETORIA, as the address at which they will accept service of all notices and processes in these proceedings. The Applicant's attorneys will also accept electronic service at the following email addresses: tara@powersingh.africa and tina@powersingh.africa.

TAKE NOTICE FURTHER that if you intend opposing this application, you are required:

- a) to notify the Applicant's attorneys in writing, within fifteen (15) days of receipt of this application, and in such notice to appoint an address at which you will accept notice and service of all documents in these proceedings; and
- b) within fifteen (15) days of delivering such notice, deliver your answering affidavit, if any, together with any relevant documents.

TAKE NOTICE FURTHER that if no such notice of intention to oppose is delivered, this application will be made on a date to be set by the Registrar or so soon thereafter as counsel may be heard.

DATED at **JOHANNESBURG** on the 31st day of **MARCH 2022**.

POWER SINGH INC.

Attorneys for the Applicant 20 Baker Street, Rosebank JOHANNESBURG, 2196

Tel: +27 11 268 6881 Fax: +27 86 614 5818

Email: tara@powersingh.africa;

tina@powersingh.africa

Ref: PSIHJ-202120 C/O Centre for Child Law

Faculty of Law

Law Building (Room 4 – 31)

University of Pretoria

PRETORIA, 0002

Tel: +27 12 420 4502

Fax: +27 12 420 4499

Email: liesl.muller@up.ac.za

Ref: Liesl Muller

TO: THE REGISTRAR

High Court of South Africa Gauteng Division PRETORIA

AND TO: THE MINISTER OF HEALTH

First Respondent
Dr AB Xuma Building
1112 Voortrekker Road
Pretoria Townlands 351 -JR
Pretoria

AND TO: THE MINISTER OF HEALTH

First Respondent
Dr AB Xuma Building
1112 Voortrekker Road
Pretoria Townlands 351 -JR

Pretoria

AND TO: THE INFORMATION OFFICER

NATIONAL DEPARTMENT OF HEALTH

Second Respondent
Dr AB Xuma Building
1112 Voortrekker Road
Pretoria Townlands 351 -JR

Pretoria

AND TO: THE MINISTER OF SPORT, ARTS AND CULTURE

Third Respondent VWL Building 202 Madiba Street

Pretoria

AND TO: THE INFORMATION OFFICER

MINISTRY OF SPORT, ARTS AND CULTURE

Fourth Respondent

VWL Building

202 Madiba Street

Pretoria

AND TO: SOUTH AFRICAN MEDICAL RESEARCH COUNCIL

Fifth Respondent 1 Soutpansberg Road

Pretoria

AND TO: INFORMATION OFFICER

SOUTH AFRICAN MEDICAL RESEARCH COUNCIL

Sixth Respondent
1 Soutpansberg Road

Pretoria



Our Ref: 003/NDoH/2021

23 July 2021

Information Officer:

Director General Dr Sandile Buthelezi

Per Email: dg@health.gov.za

Deputy Information Officer:

Mr Justinos Motalaota

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

Dear Dr Buthelezi and Mr Motalaota

Request for information pursuant to the Promotion of Access to Information Act 2000 -Sisonke programme

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

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

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

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

We also request this information because due to the unique and pressing circumstances that faced the country at the time, the Sisonke programme and the national rollout remain deeply connected: government has and still reports the total number of people vaccinated in South Africa as the total of the Sisonke programme and the national roll out; all government dashboards and data issued shows this number as well, and under the Johnson & Johnson (Janssen) totals, while the national figures do not include the small number of people vaccinated in other clinical, placebo-controlled trials who received other active vaccines in SA. This underscores that the Sisonke programme was indeed different.

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

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

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

Vidte

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

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

Yours sincerely,

Dr Marlise Richter

Marlise@healthjusticeinitiative.org.za

info@healthjusticeinitiative.org.za







J750

REPUBLIC OF SOUTH AFRICA

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

FOR DEPARTMENT	TAL USE
	Reference number:
Request received by	(state rank,
name and surname of	of information officer/deputy information officer) on
at	(place).
Request fee (if any):	R
Deposit (if any):	R
Access fee:	R
SIGNATURE OF INF	FORMATION OFFICER/DEPUTY INFORMATION OFFICER

A. Particulars of public body

The Information Officer/Deputy Information Officer

Information Officer:

Director General Dr Sandile Buthelezi (Information Officer)

By email: dg@health.gov.za

Deputy Information Officer:

Justinos Motalaota

By email: justinos.motalaota@health.gov.za;

B. Particulars of person requesting access to the record

Full names and surname:

Identity number:

(a) The particulars of the person who requests access to the record must be given below.

(c) Proof of the capacity in which the request is made, if applicable, must be attached.

Marlise Richter

(b) The address and/or fax number in the Republic to which the information is to be sent, must be given.

Postal address:	2nd Floor Community House; 41 Salt River Road, Salt River, Cape Town South Africa 7925
Telephone number:	Fax number: ()
E-mail address:	marlise@healthjust.ceinitiative.org.za and info@healthjusticeinitiative.org.za
Capacity in which request	s made, when made on behalf of another person:
Dr Richter is a Senior Resea Health Justice Initiative in th	rcher at the Health Justice Initiative. She has been authorised to submit a request on behalf of the e public interest.
	n whose behalf request is made leted ONLY if a request for information is made on behalf of another person.
Full names and surname:	Not applicable
Identity number:	
D. Particulars of record	
to you, to enable the	is inadequate, please continue on a separate folio and attach it to this form. The requester
Description of record or r See next page:	elevant part of the record:
	7

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))

- 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.

Middle

2. Reference	number, if available:					
3. Any furthe	er particulars of record:					
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FORM A: REQUEST FOR ACCESS TO RECORD OF PUBLIC BODY

3. If record	consists of recorded words o	r inforn	nation which can be reproduced	in soun	d:		
х	listen to the soundtrack (audio cassette)		transcription of soundtrack* (written or printed document)				
4. If record	is held on computer or in an	electro	nic or machine-readable form:				
	printed copy of record*	X	printed copy of information derived from the record*		copy in compute readable form* (stiffy or compac		
	n to be posted to you?	of a re	cord (above), do you wish the co	opy or	YES X Please email	NO	
Note that if record is av		the lan	guage you prefer, access may b	e grant	ed in the language	e in whic	h the
In which lar	nguage would you prefer the	record?	English				
G. Notice of	decision regarding reques	t for a	ccess				
			est has been approved / denied the necessary particulars to er				
How would y	ou prefer to be informed of the	ne deci	sion regarding your request for a	access t	o the record?		
Via email cor	respondence at marlise@healthj	usticeir	utiative.org.za and info@healthjust	iceinitiat	ive.org.za		
Signed at	ape Town		this day ^{19th} of	y		year	1
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Appendix A:
19 July 2021
To whom it may concern
Letter of Authorisation: Health Justice Initiative (HJI)
To the extent that a letter of authority is requested, this is to confirm that Dr Marlise Richter is duly authorised to submit a request in terms of the <i>Promotion of Access to Information Act of 2000</i> on behalf of the Health Justice Initiative.
Yours sincerely,
Fatima Hassan
Fatima Hassan
Director: Health Justice Initiative



Our Ref: 001/NDSAC/2021

28 July 2021

Information Officer:

Director-General: Mr Vusumusi Mkhize

Per Email: directorgeneral@dac.gov.za

Dear Mr Mkhize

Request for information pursuant to the Promotion of Access to Information Act 2000 - the Sisonke Covid-19 vaccination programme

We are writing to request specific information on government's response to the Covid-19 pandemic and the Department of Sports, Arts and Culture's ('the Department') role in it. It has come to our attention that the Department requested the prioritisation of artists. musicians, professional athletes, sports people, sport coaches, and sports administrators from different sporting codes in South Africa ahead of the general population, to be specially included in the Sisonke programme and prioritised in the national roll out.

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

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

We also request this information because due to the unique and pressing circumstances that faced the country at the time, the Sisonke programme and the national Covid-19 vaccine rollout remain deeply connected: government has and still reports the total number of people vaccinated in South Africa as the total of the Sisonke programme and the national rollout; all government dashboards and data issued shows this number as well, and under the Johnson & Johnson (Janssen) totals, while the national figures do not include the small number of people vaccinated in other clinical, placebo-controlled trials who received other active vaccines in South Africa. This underscores that the Sisonke programme was indeed different.

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

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

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2.It is indeed the holder of the information that bears the onus of establishing that a refusal of access to information is justified under PAIA.

3.A bare denial will not suffice to justify a refusal.

4. There is no discretion to withhold information that is not protected, and the unprotected material must be disclosed despite any other provision of PAIA, unless it cannot be reasonably severed from the protected portions.

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

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

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

Yours sincerely,

Dr Marlise Richter

Marlise@healthjusticeinitiative.org.za

info@healthjusticeinitiative.org.za



J750

REPUBLIC OF SOUTH AFRICA

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

FOR DEPARTMENT	TAL USE
	Reference number:
	Neighblide number
Request received by	(state rank,
name and surname	of information officer/deputy information officer) on
at	(place).
Request fee (if any):	R
Deposit (if any):	R
Access fee:	R
SIGNATURE OF INF	FORMATION OFFICER/DEPUTY INFORMATION OFFICER

A. Particulars of public body

The Information Officer/Deputy Information Officer

Information Officer: Director-General: Mr Vusumusi Mkhize Per Email: directorgeneral@dac.gov.za

B. Particulars of person requesting access to the record

Full names and surname:

Identity number:

Postal address:

(a) The particulars of the person who requests access to the record must be given below.

(c) Proof of the capacity in which the request is made, if applicable, must be attached.

Marlise Richter

(b) The address and/or fax number in the Republic to which the information is to be sent, must be given.

2nd Floor Community House 41 Salt River Road Salt River, Cape Town

Telephone number:	(Fa	x numb	er: (نيست)	بخين	وبيسو	والمراجعة
E-mail address:	marlis	se@healthju	sticeinitia	ative.org.z	a and in	fo@he	althjusti	ceinitia	tive.org	za	ana.	253424143441
Capacity in which reque	st is made,	when made	e on beh	alf of and	ther pe	erson:						
Dr Richter is a Senior Res Health Justice Initiative in			stice Initi	ative. She	has bee	n autho	rised to	submit	a reque	st on b	ehalf o	f the
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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))

- 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.

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FORM A: REQUEST FOR ACCESS TO RECORD OF PUBLIC BODY

2. Reference	number, it available:					
3. Any furthe	r particulars of record:					
E. Fees						
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Mark the ap	ppropriate box with an X .					
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			any, will be determined partly by	the for	m in which access is requ	ested.
4 15 **						
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X	copy of record*		inspection of record			
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	view the images	x	copy of the images*		transcription of the images*	

FORM A: REQUEST FOR ACCESS TO RECORD OF PUBLIC BODY

3. If record	consists of recorded words o	r inforn	nation which can be reproduced	in soun	d:			
X	listen to the soundtrack (audio cassette)		transcription of soundtrack* (written or printed document)					
4. If record	is held on computer or in an	electro	nic or machine-readable form:					
	printed copy of record*	Х	printed copy of information derived from the record*		copy in o readable (stiffy or	form*		
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	n to be posted to you?	of a re	cord (above), do you wish the co	opy or	YES	X	NO	
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In which lar	nguage would you prefer the	ecord?	P English					
G. Notice of	decision regarding reques	t for a	ccess					
			est has been approved / denied the necessary particulars to er					
How would y	ou prefer to be informed of th	e deci	sion regarding your request for a	access t	o the reco	ord?		
Please email	marlise@healthjusticeinitiative.	org.za a	nd info@healthjusticeinitiative.org.	za				
Signed at	ape Town		this day28th o	f	July		year	2021

SIGNATURE OF REQUESTER /
PERSON ON WHOSE BEHALF REQUEST IS MADE



Appendix A:
19 July 2021
To whom it may concern
Letter of Authorisation: Health Justice Initiative (HJI)
To the extent that a letter of authority is requested, this is to confirm that Dr Marlise Richter is duly authorised to submit a request in terms of the <i>Promotion of Access to Information Act of 2000</i> on behal of the Health Justice Initiative.

Fatima Hassan

Fatima Hassan

Yours sincerely,

Director: Health Justice Initiative



Our Ref: 001/SAMRC/2021

23 July 2021

Information Officer:

The President & Chief Executive Officer, Prof Glenda Gray

Per Email: glenda.gray@mrc.ac.za

Deputy Information Officer

Ms Nikiwe Momoti

Per Email: nikiwe.momoti@mrc.ac.za

Deputy Information Officer

Dr Alfred Thutloa

Per Email: alfred.thutloa@mrc.ac.za

Dear Prof Gray, Ms Momoti and Dr Thutloa

Request for information pursuant to the Promotion of Access to Information Act 2000 -Sisonke programme

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

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We also request this information because due to the unique and pressing circumstances that faced the country at the time, the Sisonke programme and the national rollout remain deeply connected: government has and still reports the total number of people vaccinated in South Africa as the total of the Sisonke programme and the national roll out; all government dashboards and data issued shows this number as well, and under the Johnson & Johnson (Janssen) totals, while the national figures do not include the small number of people vaccinated in other clinical, placebo-controlled trials who received other active vaccines in SA. This underscores that the Sisonke programme was indeed different.

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

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

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

Yours sincerely,

Dr Marlise Richter

Marlise@healthjusticeinitiative.org.za

info@healthjusticeinitiative.org.za



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REPUBLIC OF SOUTH AFRICA

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

FOR DEPARTMENT	TAL USE
	Reference number:
Request received by	v
name and surname	of information officer/deputy information officer) on
at	(place).
Request fee (if any):	R
Deposit (if any):	R
Access fee:	R
SIGNATURE OF INF	FORMATION OFFICER/DEPUTY INFORMATION OFFICER

A. Particulars of public body

The Information Officer/Deputy Information Officer

Information Officer - The President & Chief Executive Officer

Prof Glenda Gray

Per Email: glenda.gray@mrc.ac.za

Deputy Information Officer

Ms Nikiwe Momoti

Per Email: nikiwe.momoti@mrc.ac.za

Deputy Information Officer

Dr Alfred Thutloa

Per Email: alfred.thutloa@mrc.ac.za

B. Particulars of person requesting access to the record

Full names and surname:

Identity number:

(a) The particulars of the person who requests access to the record must be given below.

(c) Proof of the capacity in which the request is made, if applicable, must be attached.

Marlise Richter

(b) The address and/or fax number in the Republic to which the information is to be sent, must be given.

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E-mail address:	marlise@	healthjus	ticeiniti	ative.org.za	and inf	o@hea	lthjusti	ceiniti	ative.org	za		54010300
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'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))

- 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 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.



FORM A: REQUEST FOR ACCESS TO RECORD OF PUBLIC BODY

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FORM A: REQUEST FOR ACCESS TO RECORD OF PUBLIC BODY

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G. Notice of	decision regarding reques	t for a	ccess					
You will be notified in writing whether your request has been approved / denied. If you wish to be informed in another manner, please specify the manner and provide the necessary particulars to enable compliance with your request.								
	•		sion regarding your request for a		o the record?			
Signed at this day23rd ofJuly year								

SIGNATURE OF REQUESTER /
PERSON ON WHOSE BEHALF REQUEST IS MADE



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Appendix A:			

19 July 2021

To whom it may concern

Letter of Authorisation: Health Justice Initiative (HJI)

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

Yours sincerely,

Fatima Hassan

Fatima Hassan

Director: Health Justice Initiative

Reference Advisory Group: Dr Francois Venter, Phumi Mtetwa, Dr Francois Bonnici, Phumeza Mlungwana, Dr Els Torreele, Prof Tshepo Madlingozi,

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:

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".
- The facts contained in this affidavit are true and correct, to the best of my 3. 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

- On 17 February 2021, the Sisonke study (Part 1) commenced, kicking off the first 4. 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.
- Part 2 of the Sisonke study, relating to booster doses, has since commenced on 5. 10 November 2021. It remains to be seen how that rollout will be handled. This application is limited to Part 1 of the study.
- During or around April/ May 2021, the scope of the Sisonke study was somehow 6. 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.
- To that end, the HJI made the following requests for records in terms of the 7. Promotion of Access to Information Act 2 of 2000 ("PAIA"):
 - The request attached as "HJI2.1" submitted to the Department of Health 7.1. ("NDoH") on 23 July 2021;
 - The request attached as "HJI2.2" submitted to the Department of 7.2. Sports, Arts and Culture on 28 July 2021:

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- 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.
- 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

- 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.

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- 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.
- 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

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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 scare 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.

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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.

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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

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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**".
- 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.

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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 "HJ!11") 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 "HJ!12") 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

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- ("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.

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- 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?

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- (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'.
- Please clarify what is the scientific question being addressed for (g) 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

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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

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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

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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".

- The information provided to HJI by SAHPRA indicates that the 62.3. 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 hangerson" 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).

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- 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 dislosed.
- 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

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- 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

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- 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.

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- 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.

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

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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 SAHPRAapproved 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 ("HJI24") but did not thereafter provide a substantive response.
- 75. On 8 September 2021, the HJI lodged the internal appeal attached as HJI3.3 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.

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- 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

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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 <u>CAPE Town</u> on this the day of <u>March</u> 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 gomplied with.

COMMISSIONER OF OATHS

KSHETHRA NAIDOO

Commissioner of Oaths, Ex Officio Practising Attorney, R.S.A 2rd Floor, Sedgwick House 24 Bloem Street, Cape Town Tel. 021 204 0591

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NPC: 2020/779556/08 41 Salt River Road Community House 2nd Floor Salt River Cape Town 7925

RESOLUTION 7: DECEMBER 2021

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

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

_day of January Signed at Cape Town, South Africa on this the 10th Dr Shuaib Manjra Chairperson

Noncedo Madubedube

Board Member







⊕ healthjusticeinitiative.org.za | ₹7 @HealthJusticeIn | □ □ info@healthjusticeinitiative.org.za



2021.



Our Ref: 003/NDoH/2021

23 July 2021

Information Officer:

Director General Dr Sandile Buthelezi

Per Email: dg@health.gov.za

Deputy Information Officer:

Mr Justinos Motalaota

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

Dear Dr Buthelezi and Mr Motalaota

Request for Information pursuant to the Promotion of Access to Information Act 2000 -Sisonke programme

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

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

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







healthjusticeinitiative.org.za | [7] @Healthjusticeln | [7] info@healthjusticeinitiative.org.za

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

We also request this information because due to the unique and pressing circumstances that faced the country at the time, the Sisonke programme and the national rollout remain deeply connected: government has and still reports the total number of people vaccinated in South Africa as the total of the Sisonke programme and the national roll out; all government dashboards and data issued shows this number as well, and under the Johnson & Johnson (Janssen) totals, while the national figures do not include the small number of people vaccinated in other clinical, placebo-controlled trials who received other active vaccines in SA. This underscores that the Sisonke programme was indeed different.

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

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

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

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

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

Yours sincerely,

Dr Marlise Richter

Marlise@healthjusticeinitiative.org.za

info@healthjusticeinitiative.org.za

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REPUBLIC OF SOUTH AFRICA

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

FOR DEPARTME	NTAL USE	
	Reference r	number:
Request received	by	(state rank,
name and surname	e of information officer/deputy information officer) on	(date)
at		(place)
Request fee (if any	/): R	
Deposit (if any):	R	
Access fee:	R	
SIGNATURE OF I	NFORMATION OFFICER/DEPUTY INFORMATION OFFICER	

A. Particulars of public body

The Information Officer/Deputy Information Officer

Information Officer:

Director General Dr Sandile Buthelezi (Information Officer)

By email: dg@health.gov.za

Deputy Information Officer:

Justinos Motalaota

By email: justinos.motalaota@health.gov.za;

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B. Particulars of person requesting access to the record

(a) The particulars of the person who requests access to the record must be given below.

(b) The address and/or fax	number in the Republic to which the information is to be sent, must be given. which the request is made, if applicable, must be attached.	
Full names and surname:	Marlise Richter	
Identity number:		
Postal address:	2nd Floor Community House; 41 Salt River Road, Salt River, Cape Town South Africa 7925	
Telephone number:		
E-mail address:	marlise@healthjusticeinitiative.org.za and info@healthjusticeinitiative.org.za	
Capacity in which request is	s made, when made on behalf of another person:	
Dr Richter is a Senior Resear Health Justice Initiative in th	rcher at the Health Justice Initiative. She has been authorised to submit a request on behalf of the e public interest.	
C. Particulars of person or	n whose behalf request is made	
This section must be compl	leted ONLY if a request for information is made on behalf of another person.	
Full names and surname:	Not applicable	
Identity number:		
D. Particulars of record		
to you, to enable the r	is inadequate, please continue on a separate folio and attach it to this form. The requeste	
Description of record or re See next page:	elevant part of the record:	



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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))

- 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
- 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.
- 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.

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63 FORM A: REQUEST FOR ACCESS TO RECORD OF PUBLIC BODY

2. Reference	number, if available:				
3. Any furthe	r particulars of record:				
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Mark the ap	propriate box with an X.				
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64 FORM A: REQUEST FOR ACCESS TO RECORD OF PUBLIC BODY

3. If record	consists of recorded words o	r inform	nation which can be reproduced	in soun	d:		
х	listen to the soundtrack (audio cassette)		transcription of soundtrack* (written or printed document)				
4. If record	is held on computer or in an	electro	nic or machine-readable form:				
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transcription Postage is	n to be posted to you? payable.		cord (above), do you wish the co		YES X Please email	NO	
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G. Notice of	decision regarding reques	t for a	ccess				
			est has been approved / denied the necessary particulars to en				
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Signed at	ape Town		this day ^{19th} of	<i>!</i>		year .	2021
			125	Rid	te		
			SIGNATURE OF PERSON ON W		ESTER / BEHALF REQUES	ST IS MA	DE



Appendix A:
19 July 2021
To whom it may concern
Letter of Authorisation: Health Justice Initiative (HJI)
To the extent that a letter of authority is requested, this is to confirm that Dr Marlise Richter is duly authorised to submit a request in terms of the <i>Promotion of Access to Information Act of 2000</i> on behalf of the Health Justice Initiative.
Yours sincerely,
Fatima Hassan

Fatima Hassan

Director: Health Justice Initiative













Our Ref: 001/NDSAC/2021

28 July 2021

Information Officer:

Director-General: Mr Vusumusi Mkhize

Per Email: directorgeneral@dac.gov.za

Dear Mr Mkhize

Request for information pursuant to the Promotion of Access to Information Act 2000 - the Sisonke Covid-19 vaccination programme

We are writing to request specific information on government's response to the Covid-19 pandemic and the Department of Sports, Arts and Culture's ('the Department') role in it. It has come to our attention that the Department requested the prioritisation of artists, musicians, professional athletes, sports people, sport coaches, and sports administrators from different sporting codes in South Africa ahead of the general population, to be specially included in the Sisonke programme and prioritised in the national roll out.

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

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

We also request this information because due to the unique and pressing circumstances that faced the country at the time, the Sisonke programme and the national Covid-19 vaccine rollout remain deeply connected: government has and still reports the total number of people vaccinated in South Africa as the total of the Sisonke programme and the national rollout; all government dashboards and data issued shows this number as well, and under the Johnson & Johnson (Janssen) totals, while the national figures do not include the small number of people vaccinated in other clinical, placebo-controlled trials who received other active vaccines in South Africa. This underscores that the Sisonke programme was indeed different.

🚯 healthjusticeinitiative.org.za | 🦅 @HealthJusticeln | 🖂 info@healthjusticeinitiative.org.za

Reference Advisory Group: Or Francois Venter, Phumi Mtetwa, Or Francois Bonnici, Phumeza Miungwana, Or Eis Torreele, Prof Tshepo Madiingozi, Justice Kate O'Regan, Noncedo Madubedube, Dr Shuaib Manjra.

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

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

1. The scheme of PAIA is such that information must be disclosed unless it is exempt from disclosure,in circumstances where the exemptions must be narrowly construed.

2.It is indeed the holder of the information that bears the onus of establishing that a refusal of access to information is justified under PAIA.

3.A bare denial will not suffice to justify a refusal.

4. There is no discretion to withhold information that is not protected, and the unprotected material must be disclosed despite any other provision of PAIA, unless it cannot be reasonably severed from the protected portions.

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

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

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

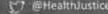
Yours sincerely,

Dr Marlise Richter

Marlise@healthjusticeinitiative.org.za

info@healthjusticeinitiative.org.za

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REPUBLIC OF SOUTH AFRICA

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

	Reference number	er:
Request received	by	(state rank
	e of information officer/deputy information officer) on	
at		(place)
Request fee (if any	y): R	
Deposit (if any):	R	
Access fee:	R	
	NFORMATION OFFICER/DEPUTY INFORMATION OFFICER	

A. Particulars of public body

The Information Officer/Deputy Information Officer

Information Officer: Director-General: Mr Vusumusi Mkhize Per Email: directorgeneral@dac.gov.za

1/2/

me

B. Particulars of person requesting access to the record

(a) The particulars of the person who requests access to the record must be given below.

(c) Proof of the capacity in which the request is made, if applicable, must be attached.

(b) The address and/or fax number in the Republic to which the information is to be sent, must be given.

Full names and surname:	Marlise Richter
Identity number:	
Postal address:	2nd Floor Community House 41 Salt River Road Salt River, Cape Town
Telephone number:	() Fax number: ()
E-mail address:	marlise@healthjusticeinitiative.org.za and info@healthjusticeinitiative.org.za
Capacity in which request is	made, when made on behalf of another person:
Dr Richter is a Senior Research Health Justice Initiative in the	ther at the Health Justice Initiative. She has been authorised to submit a request on behalf of the public interest.
C. Particulars of person on	whose behalf request is made
-	whose behalf request is made eted ONLY if a request for information is made on behalf of another person.
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Full names and surname: Identity number: D. Particulars of record (a) Provide full particulars to you, to enable the re (b) If the provided space	Not applicable of the record to which access is requested, including the reference number if that is known accord to be located. is inadequate, please continue on a separate folio and attach it to this form. The requester onal folios.
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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))

- Copies of any emails and any other written requests, motivations, and correspondence including the respective 1. 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')
- 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') and Ministerial Advisory Committee on COVID-19 vii. vaccines ('VMAC')
- 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.

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

3.

- 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.
- The provincial sites where the vaccines in 3.i. above were administered.
- The details or a list of all the art councils or bodies, sports bodies and codes that participated in 3.1 above ñi. 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.
- 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.
- 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.

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3. Any furthe	r particulars of record:					
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	consists of visual images - es photographs, slides, video	record	lings, computer-generated imag	es, sketo	ches, etc.):	
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	T							2021	
Signed at	ape lown		this day28th of	f	July		year	2021	

SIGNATURE OF REQUESTER / PERSON ON WHOSE BEHALF REQUEST IS MADE





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19 July 2021

To whom it may concern

Letter of Authorisation: Health Justice Initiative (HJI)

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

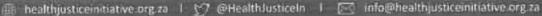
Yours sincerely,

Fatima Hassan

Fatima Hassan

Director: Health Justice Initiative













Our Ref: 001/SAMRC/2021

23 July 2021

Information Officer:

The President & Chief Executive Officer, Prof Glenda Gray

Per Email: glenda.gray@mrc.ac.za

Deputy Information Officer
Ms Nikiwe Momoti

Per Email: nikiwe.momoti@mrc.ac.za

Deputy Information Officer Dr Alfred Thutloa

Per Email: alfred.thutloa@mrc.ac.za

Dear Prof Gray, Ms Momoti and Dr Thutloa

Request for information pursuant to the Promotion of Access to Information Act 2000 - Sisonke programme

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

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

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

😥 healthjusticeinitiative.org.za | 🏹 @Healthjusticein | 🖂 info@healthjusticeinitiative.org.za

Reference Advisory Group: Dr Francois Venter, Phumi Mtetwa, Dr Francois Bonnici, Phumeza Mlungwana, Dr Els Torreele, Prof Tshepo Madlingozi, Justice Kate O'Regan, Noncedo Madubedube, Dr Shuaib Manjra.

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

We also request this information because due to the unique and pressing circumstances that faced the country at the time, the Sisonke programme and the national rollout remain deeply connected: government has and still reports the total number of people vaccinated in South Africa as the total of the Sisonke programme and the national roll out; all government dashboards and data issued shows this number as well, and under the Johnson & Johnson (Janssen) totals, while the national figures do not include the small number of people vaccinated in other clinical, placebo-controlled trials who received other active vaccines in SA. This underscores that the Sisonke programme was indeed different

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

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

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

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

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

Yours sincerely,

Dr Marlise Richter

Marlise@healthjusticeinitiative.org.za

info@healthjusticeinitiative.org.za

Richter

healthjusticeinitiative.org.za | 177 @HealthJusticeln | 1 57 info@healthjusticeinitiative.org.za





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REPUBLIC OF SOUTH AFRICA

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

FOR DEPARTMEN	NTAL USE	
	Reference numbe	r
Request received to	by	(state rank.
name and surname	e of information officer/deputy information officer) on	(date)
at		(place).
Request fee (if any	r): R	
Deposit (if any):	R	
Access fee:	R	
SIGNATURE OF I	NFORMATION OFFICER/DEPUTY INFORMATION OFFICER	

A. Particulars of public body

The Information Officer/Deputy Information Officer

Information Officer - The President & Chief Executive Officer Prof Glenda Gray
Per Email: glenda.gray@mrc.ac.za

Deputy Information Officer
Ms Nikiwe Momoti
Per Email: nikiwe.momoti@mrc.ac.za

Deputy Information Officer
Dr Alfred Thutloa
Per Email: alfred.thutloa@mrc.ac.za

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B. Particulars of person requesting access to the record

(a) The particulars of the person who requests access to the record must be given below.

(c) Proof of the capacity in which the request is made, if applicable, must be attached.

(b) The address and/or fax number in the Republic to which the information is to be sent, must be given.

Full names and surname:	Marlise Richter
Identity number:	
Postal address:	2nd Floor Community House 41 Salt River Road Salt River, Cape Town
Telephone number:	() Fax number: ()
E-mail address:	marlise@healthjusticeinitiative.org.za and info@healthjusticeinitiative.org.za
Capacity in which request is	made, when made on behalf of another person:
Dr Richter is a Senior Research Health Justice Initiative in the	her at the Health Justice Initiative. She has been authorised to submit a request on behalf of the public interest.
C. Particulars of person on	whose behalf request is made
	whose behalf request is made sted ONLY if a request for information is made on behalf of another person.
	eted ONLY if a request for information is made on behalf of another person.
This section must be comple	eted ONLY if a request for information is made on behalf of another person.
This section must be completely full names and surname: identity number:	eted ONLY if a request for information is made on behalf of another person.
This section must be completely full names and surname: identity number: D. Particulars of record	Not applicable
This section must be complete. Full names and surname: identity number: D. Particulars of record (a) Provide full particulars to you, to enable the re-	Not applicable of the record to which access is requested, including the reference number if that is known accord to be located.
This section must be complete. Full names and surname: identity number: D. Particulars of record (a) Provide full particulars to you, to enable the re-	Not applicable of the record to which access is requested, including the reference number if that is known accord to be located. is inadequate, please continue on a separate folio and attach it to this form. The requester
Full names and surname: identity number: D. Particulars of record (a) Provide full particulars to you, to enable the record (b) If the provided space in the second in in the s	Not applicable Of the record to which access is requested, including the reference number if that is known accord to be located. Is inadequate, please continue on a separate folio and attach it to this form. The requester onal folios.

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'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))

- 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.**
- 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 SAHPRAapproved protocol - including professional athletes, sports officials and government officials.
- A copy of all responses from SAHPRA related to 1.) and 2.) above and 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.
- 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.
- 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.

**https://clinicaltrials.gov/ct2/show/NCT04838795?term=VAC31518COV3012&draw=2&rank=1 and http://sisonkestudy.samrc.ac.za/#[object%200bject

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Reference	number, if available:					
3. Any furthe	er particulars of record:					
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	ord is in written or printed for copy of record*	m;	inspection of record	1		
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3. If record	consists of recorded words o	r inform	nation which can be reproduced	in soun	d:			
х	listen to the soundtrack (audio cassette)		transcription of soundtrack* (written or printed document)					
4. If record	is held on computer or in an	electro	nic or machine-readable form:					
	printed copy of record*	х	printed copy of information derived from the record*		copy in readable (stiffy or	e form*		
*If you requested a copy or transcription of a record (above), do you wish the copy or YES x NO transcription to be posted to you? Postage is payable. Note that if the record is not available in the language you prefer, access may be granted in the language in which the record is available.								
	nguage would you prefer the I	record'	English					
G. Notice of	decision regarding reques	t for a	ccess	***				
You will be manner, plo	notified in writing whether yo ease specify the manner and	ur requ provid	est has been approved / denied the necessary particulars to er	l. If you nable co	wish to be mpliance	e inform with you	ed in ano ur reques	ther t.
How would you prefer to be informed of the decision regarding your request for access to the record? Please email marlise@healthjusticeinitiative.org.za and info@healthjusticeinitiative.org.za								
Signed at	ape Town		this day23rd ofJ	uly			year	2021

SIGNATURE OF REQUESTER / PERSON ON WHOSE BEHALF REQUEST IS MADE





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19 July 2021

To whom it may concern

Letter of Authorisation: Health Justice Initiative (HJI)

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

Yours sincerely,

Fatima Hassan

Fatima Hassan

Director: Health Justice Initiative





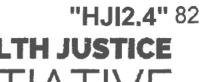


info@healthjusticeinitiative.org.za

Reference Advisory Group: Dr Francois Venter, Phumi Mtetwa, Dr Francois Bonnici, Phumeza Mlungwana, Dr Els Torreele, Prof Tshepo Madlingozi, Justice Kate O'Regan, Noncedo Madubedube, Or Shuaib Manjra.

Board: Dr Shuaib Manjra, Noncedo Madubedube, Fatima Hassan





HEALTH JUSTICE INITIATIVE

Our Ref: 001/SAHPRA/2021

23 July 2021

Information Officer:

Chief Executive Officer Dr Boitumelo Semete

Per Email: Boitumelo.Semete@sahpra.org.za

Dear Dr Semete

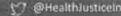
Request for Information pursuant to the Promotion of Access to Information Act 2000 -Sisonke programme

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

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

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







healthjusticeinitiative.org.za 1 57 @Healthjusticein 1 M info@healthjusticeinitiative.org.za

Reference Advisory Group: Dr François Venter, Phumi Mitetwa, Dr François Bonnici, Phumeza Milangwana, Dr Els Torreele, Prof Tshepo Madlingozi, Justice Kate O'Regan, Noncedo Madubedube, Dr Shuaib Manira.

Board: Dr Shuaib Manjra, Noncedo Madubedube, Fatima Hassan



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

We also request this information because due to the unique and pressing circumstances that faced the country at the time, the Sisonke programme and the national rollout remain deeply connected: government has and still reports the total number of people vaccinated in South Africa as the total of the Sisonke programme and the national roll out; all government dashboards and data issued shows this number as well, and under the Johnson & Johnson (Janssen) totals, while the national figures do not include the small number of people vaccinated in other clinical, placebo-controlled trials who received other active vaccines in SA. This underscores that the Sisonke programme was indeed different.

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

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

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

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

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

Yours sincerely.

Dr Marlise Richter

Marlise@healthjusticeinitiative.org.za

Hidrer

info@healthjusticeinitiative.org.za

healthjusticeinitiative org za 1 57 @HealthJusticeln 1

info@healthjusticeinitiative.org.za





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REPUBLIC OF SOUTH AFRICA

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

	Reference number	9f:
Request received	by	(state rank,
name and sumam	e of information officer/deputy information officer) on	(date)
at		(place).
Request fee (if any	y): R	
Deposit (if any):	R	
Access fee:	R	
SIGNATURE OF I	NFORMATION OFFICER/DEPUTY INFORMATION OFFICER	

A. Particulars of public body

The Information Officer/Deputy Information Officer

Information Officer - Chief Executive Office Dr Boitumelo Semete Per Email: Boitumelo.Semete@sahpra.org.za

KM

M

B. Particulars of person requesting access to the record

(a) The particulars of the person who requests access to the record must be given below.

(c) Proof of the capacity in which the request is made, if applicable, must be attached.

(b) The address and/or fax number in the Republic to which the information is to be sent, must be given.

Full names and surname:	Marlise Richter					
Identity number:						
Postal address:	2nd Floor Community House 41 Salt River Road Salt River, Cape Town					
Telephone number:	() Fax number: ()					
E-mail address:	marlise@healthjusticeinitiative.org.za and info@healthjusticeinitiative.org.za					
Capacity in which request is	s made, when made on behalf of another person:					
	Dr Richter is a Senior Researcher at the Health Justice Initiative. She has been authorised to submit a request on behalf of the Health Justice Initiative in the public interest.					
C. Particulars of person or	whose behalf request is made					
-	eted ONLY if a request for information is made on behalf of another person.					
-						
-						
This section must be compl Full names and surname:	eted ONLY if a request for information is made on behalf of another person.					
This section must be compl	eted ONLY if a request for information is made on behalf of another person.					
This section must be compl Full names and surname:	eted ONLY if a request for information is made on behalf of another person.					
Full names and surname: Identity number: D. Particulars of record (a) Provide full particulars to you, to enable the record (b) If the provided space	eted ONLY if a request for information is made on behalf of another person. Not applicable of the record to which access is requested, including the reference number if that is known ecord to be located. is inadequate, please continue on a separate folio and attach it to this form. The requester					
This section must be compl Full names and surname: Identity number: D. Particulars of record (a) Provide full particulars to you, to enable the record	eted ONLY if a request for information is made on behalf of another person. Not applicable of the record to which access is requested, including the reference number if that is known ecord to be located. is inadequate, please continue on a separate folio and attach it to this form. The requester					
This section must be complete. Full names and surname: Identity number: D. Particulars of record (a) Provide full particulars to you, to enable the record of the provided space must sign all the addit.	Not applicable Softhe record to which access is requested, including the reference number if that is known ecord to be located. Is inadequate, please continue on a separate folio and attach it to this form. The requester ional folios.					
Full names and surname: Identity number: D. Particulars of record (a) Provide full particulars to you, to enable the rought of the provided space must sign all the addit	Not applicable Softhe record to which access is requested, including the reference number if that is known ecord to be located. Is inadequate, please continue on a separate folio and attach it to this form. The requester ional folios.					

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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))

- A copy of the South African Medical Research Council ('SAMRC') or any other statutory, ethics or national or provincial government department's written request to SAHPRA to amend or waive the eligibility criteria for the Sisonke programme for the period April - June 2021.
- A copy of the submission provided to SAHPRA with the relevant ethics committee/s or other 2. regulatory or research bodies recommendations for any proposed amendments or waiver to the original trial protocol, and the ethics committee/s written and formal approval or support for any proposed amendments or waivers for the period April - June 2021.
- A copy of SAHPRA's response and written approval which also sets out the basis upon which any approval or waiver was issued in line with the provisions of the Medicines and Related Substances Act of 1965 and/or Hazardous Substances Act of 1973 and/or any other law.
- 4. Copies of relevant meeting minutes for SAHPRA's authorisation of an amendment or waiver (whichever the case may be), with 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.
- A copy of the minutes of the decisions or recommendations of any SAHPRA advisory or other internal committee that influenced the deliberations and outcomes of matters described in 1-4 above, and which informed any approval/s issued by SAHPRA.
- 6 Copies of all and any requests or correspondence with and/or from the Ministers and/or Director-Generals or Deputy Director-Generals from the National Departments of Health and/ or Arts, Culture and Sports and/or any other government department or official and any statutory body related to these requests and the response from SAHPRA.
- 7. Copies of any relevant approvals related to this matter as issued by SAHPRA.

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2. Reference	number, if available:					
3. Any furthe	er particulars of record:					

E. Fees						
proces (b) You w (c) The fe	ssed only after a request fee ill be notified of the amount re e payable for access to a re ed to search for and prepare	has be equired ecord o a reco	d to be paid as the request fee. depends on the form in which ac	cess is	required and the reasonabl	
Reason for e	exemption from payment of fe	es:				
Not applicabl	e					

····				•••••		
F. Form of a	ccess to record					
	evented by a disability to rea sability and indicate in which		or listen to the record in the form	rm of a	ccess provided for in 1 to 4	below,
Disability:	Not applicable				Form in which red is required:	cord
Mark the ap	propriate box with an X.					
		ess in	the specified form may depend	on the f	orm in which the record is	
available (b) Access i		refuse	ed in certain circumstances. In s	uch a c	ase you will be informed if	
	will be granted in another fon payable for access to the rec		any, will be determined partly by	the fon	m in which access is reques	sted.
" '	ord is in written or printed for	m:	inconstitut of accord			
2 If record	copy of record* consists of visual images -	Convenience	inspection of record		<u>. </u>	
		record	lings, computer-generated image	es, sket	ches, etc.):	
	view the images	х	copy of the images*		transcription of the images*	



3. If record	consists of recorded words o	r inform	nation which can be reproduced	in soun	d:			
х	listen to the soundtrack (audio cassette)		transcription of soundtrack* (written or printed document)					
4. If record	is held on computer or in an	electro	nic or machine-readable form:					
	printed copy of record*	х	printed copy of information derived from the record* copy in computer readable form* {stiffy or compact disc}					
transcriptio Postage is	n to be posted to you? payable.		cord (above), do you wish the co	_	YES	Х	NO	
Note that if record is a		the lan	guage you prefer, access may b	e grant	ed in the I	anguag	e in whic	h the
In which lar	nguage would you prefer the	record?	? English					
3. Notice of	decision regarding reques	t for a	ccess					***
You will be manner, pl	notified in writing whether yo ease specify the manner and	ur requ provid	est has been approved / denied e the necessary particulars to er	l. If you able co	wish to be impliance	inform with you	ed in and ur reques	ther t.
How would you prefer to be informed of the decision regarding your request for access to the record? Please email marlise@healthjusticeinitiative.org.za and info@healthjusticeinitiative.org.za								
Please email marlise@healthjusticeinitiative.org.za and info@healthjusticeinitiative.org.za Cape Town this day23rd of July year								

SIGNATURE OF REQUESTER / PERSON ON WHOSE BEHALF REQUEST IS MADE





Α		no	nd	iv	A:
м	D	ve	ПQ	ıx.	м.

19 July 2021

To whom it may concern

Letter of Authorisation: Health Justice Initiative (HJI)

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

Yours sincerely,

Fatima Hassan

Fatima Hassan

Director: Health Justice Initiative



m healthjusticeinitiative.org.za | 1 77 @HealthJusticeln |





info@healthjusticeinifiative org.za





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

STATE YOUR REFERENCE NUMBER:	003/NDoH/2021

A. Particulars of public body

The Information Officer/Deputy Information Officer:

Acting Director General: Dr Nicholas Crisp (Information Officer)

By email: dg@health.gov.za

Deputy Information Officer Justinos Motalaota

By email: justinos.motalaota@health.gov.za

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

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

Full names and surname: Identity number:	Marlise Richter
Postal address:	2nd Floor Community House, 41 Salt River Road, Salt River, Cape Town South Africa 7925
Telephone number:	(Fax number: ()
E-mail address:	marlise@healthjusticeinitiative.org.za and info@healthjusticeinitiative.org.za

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

Kn

C. Particulars of requester													
This section	This section must be completed ONLY if a third party (other than the requester) lodges the internal appeal.												
Full name	Full names and surname: N/A												
				*******			1			1	T	· · · · · · · · · · · · · · · · · · ·	T
Identity number:							<u> </u>						
D. The dec	cision against wh	ich the inter	nal appe	al is lo	odged								
Mark the o	decision against wi	hich the inter	nal appea	ai is loc	lged wi	ith an)	C in the	approp	oriate bo	ox:			
Х	Refusal of reque	st for access				·							
	Decision regarding	ng fees preso	ribed in t	erms c	of section	on 22 c	of the Ac	t					
Decision regarding the extension of the period within which the request must be dealt with in terms of section 26(1) of the Act													
	Decision in terms of section 29(3) of the Act to refuse access in the form requested by the requester												
	Decision to grant	request for	access										
E. Ground	s for appeal												
If the provi additional	ded space is inade folios.	equate, pleas	se continu	te on a	separa	ate foli	o and at	tach it	to this	form. Yo	ou mus	t sign a	I the
State the gr	rounds on which th	ne internal ap	peal is b	ased:									
On 23 July 2021, the Health Justice Initiative (HJI) submitted a request to the South African National Department of Health (NDoH) in terms of the Promotion of Access to Information Act 2 of 2000 (PAIA). The request pertained to specific information related to													
To date, the	19 pandemic and the requested informations that HJI pour local	on has not bee	n provide		e the re	levant i	ime peri	od havi	ng lapse	d. It is	on the b	asis of th	ที่ร
We await yo	deemed refusal that HJI now lodges this internal appeal. We await your urgent response to this request for information in the public interest. To the extent that no response is received, HJI will have no choice but to consider its further recourse before the appropriate forum.												
State any o	ther information th	at may be re	levant in	consid	ering th	те арр	eal:						
For ease of r	eference, a copy of t	the initial PAI	A request	is enclo	sed tog	ether w	ith this i	nternal	appeal n	narked A	Appendi	x 1.	******
						• • • • • • • • • • • • • • • • • • • •	********					*******	
*************	••••••	**********			• • • • • • • • • • • • • • • • • • • •	*******	********		* • • • • • • • • • • • • • • • • • • •				••••••



F. Notice of decision on appeal

You will be notified in working the man	writing of the decision on your internal appeal. If you wish to be info oner and provide the necessary particulars to enable compliance w	ormed in another manner, ith your request.
State the manner:	n/a	
Particulars of manner:	n/a	
Signed at CAPE TOWN	this day 8th of September	year.2021
		Midster
		SIGNATURE OF APPELLANT
		erfore from the elegation of such a history and have a residency from a resource following, provide an execution of the contract of the contra
FOR DEPARTMENTA	L USE:	
	OFFICIAL RECORD OF INTERNAL APPEAL:	
Appeal received on	(date) by	
	(state rank, name and surname of information off	icer/deputy information officer)
Appeal accompanied b	by the reasons for the information officer's/deputy information office	er's decision and, where
applicable, the particul	ars of any third party to whom or which the record relates, submitte	ed by the information
officer/deputy informati	on officer on (date) to	o the relevant authority.
OUTCOME OF APPEA	V:	
DECISION OF INFOR	MATION OFFICER/DEPUTY INFORMATION OFFICER CONFIRM	MED/NEW DECISION
NEW DECISION:		
DATE RELEVANT AU	THORITY	
RECEIVED BY THE IN	IFORMATION OFFICER/DEPUTY INFORMATION OFFICER FRO	OM THE RELEVANT
AUTHORITY ON (date):	





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

	STATE YOUR REFERENCE NUMBER: 001/NDSAC/2021
A. Particulars of public boo	dy
The Information Officer/Depo	uty Information Officer:
Director-General: Mr Vusumus Per Email: directorgeneral@da	
B. Particulars of requester	third party who lodges the internal appeal
(b) Proof of the capacity in v	rson who lodge the internal appeal must be given below. which appeal is lodged, if applicable, must be attached. d person and not the person who originally requested the information, the particulars of the C below.
Full names and surname:	Marlise Richter
Identity number: Postal address:	2nd Floor Community House, 41 Salt River Road, Salt River, Cape Town South Africa 7925
Telephone number:	(Fax number: ()

Kn



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

E-mail address:

marlise@healthjusticeinitiative.org.za and info@healthjusticeinitiative.org.za

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

Full names and surname:	n	/a	 	 	 	 	 	
								 ,
Identity number:								

D. The decision against which the internal appeal is lodged

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

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

E. Grounds for appeal

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

State the grounds on which the internal appeal is based:
Please refer to the next page
State any other information that may be relevant in considering the anneal:
State any other information that may be relevant in considering the appeal:
State any other information that may be relevant in considering the appeal: Please refer to the next page
Please refer to the next page



Grounds for appeal:

On 28 July 2021, the Health Justice Initiative (HJI) submitted a request to the Department of Sports, Arts and Culture (the Department) in terms of the Promotion of Access to Information Act 2 of 2000 (PAIA). The request followed it having come to our attention that the Department requested the prioritisation of artists, professional athletes, sports people, sports coaches and sports administrators from different sporting codes in South Africa ahead of the general population, to be specifically included in the Sisonke programme and prioritised in the national roll-out.

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

We await your urgent response to this request for information in the public interest. To the extent that no response is received, HJI will have no choice but to consider its further recourse before the appropriate forum.

Other relevant information:

For ease of reference, a copy of the initial PAIA request is enclosed together with this internal appeal marked Appendix 1.

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F. Notice of decision on appeal

	nner and provide the necessary particulars to enable compliance with your request.
State the manner:	n/a
Particulars of manner:	n/a
Signed at CAPE TOWN	this day .8th of September year .2021
	Midster
	SIGNATURE OF APPELLANT
FOR DEPARTMENTA	TELICE.
FOR DEPARTMENTA	OFFICIAL RECORD OF INTERNAL APPEAL:
	(date) by
	(state rank, name and surname of information officer/deputy information officer).
	by the reasons for the information officer's/deputy information officer's decision and, where
	ars of any third party to whom or which the record relates, submitted by the information
officer/deputy informat	ion officer on (date) to the relevant authority.
OUTCOME OF APPEA	AL:
DECISION OF INFOR SUBSTITUTED	MATION OFFICER/DEPUTY INFORMATION OFFICER CONFIRMED/NEW DECISION
NEW DECISION:	
DATE RELEVANT AU	THORITY
RECEIVED BY THE IN	FORMATION OFFICER/DEPUTY INFORMATION OFFICER FROM THE RELEVANT
AUTHORITY ON (date);



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

STATE YOUR REFERENCE NUMBER:

A. Particulars of public body

The Information Officer/Deputy Information Officer:

Prof Glenda Gray

Per Email: glenda.gray@mrc.ac.za

Deputy Information Officer

Ms Nikiwe Momoti

Per Email: nikiwe.momoti@mrc.ac.za

Deputy Information Officer Dr Alfred Thutloa Per Email: alfred.thutloa@mrc.ac.za

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

(a) The particulars of the person who lodge the internal appeal must be given below.

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

Full names and surname:	Marlise Richter							
Identity number:								
Postal address:	2nd Floor Community House, 41 Salt River Road, Salt River, Cape Town South Africa 7925							
Telephone number:	Fax number: ()							
E-mail address:	marlise@healthjusticeinitiative.org.za and info@healthjusticeinitiative.org.za							

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

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C. Particulars	of reque	ster			

								· · · · · · · · · · · · · · · · · · ·						
This sect	on must be compl	eted ON	ILY if a	a third p	party (d	other the	an the	requeste	r) lodge	es the	internal	appeal		
		/-												
	es and surname:	n/a												
Identity n	umber:													
D. The de	cision against wh	nich the	intern	nal app	eal is	lodged								
Mark the	decision against w	hich the	intern	al ann	eal is lo	ndaed w	rith en	X in the	ennron	riate h	ox.			
				и прр	00.101	ougou v		7 111 410	approp		· · ·			
х	Refusal of reque							P.45 - 2						
	Decision regardi		-									111 1 4		
	Decision regardi section 26(1) of		extensi	on of th	ne peri	od withi	n whic	the rec	luest m	ust be	dealt w	ith in te	rms of	
	Decision in term	s of sec	tion 29	(3) of t	the Act	to refus	se acc	ess in the	form r	eques	ted by th	ne requ	ester	
	Decision to gran	t reques	t for a	ccess										
	is for appeal rided space is inad folios.	lequate,	please	e contir	nue on	a sepa	rate fo	lio and al	ttach it	to this	form. Ye	ou mus	t sign a	all the
	rounds on which t	he interr	nal app	oeal is	based:									
Please refer to next page														
		•••••										• • • • • • • • • •		
								• • • • • • • • • • • • • • • • • • • •				• • • • • • • • • • • • • • • • • • • •		
State anv d	other information th	nat mav	be rele	evant ir	n consi	iderina t	he apr	neal:						
•	to next page													
							- /							
											**********			*******



Grounds for appeal:

On 23 July 2021, the Health Justice Initiative (HJI) submitted a request to the South African Medical Research Council (SAMRC) in terms of the Promotion of Access to Information Act 2 of 2000 (PAIA). The request pertained to specific information related to the COVID-19 pandemic and the Sisonke programme.

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

We await your urgent response to this request for information in the public interest. To the extent that no response is received, HJI will have no choice but to consider its further recourse before the appropriate forum.

Other relevant information:

For ease of reference, a copy of the initial PAIA request is enclosed together with this internal appeal marked Appendix 1.

Milder

F. Notice of decision on appeal

	riting of the decision on your internal appeal. If you wish to be informed in another manner, ner and provide the necessary particulars to enable compliance with your request.
State the manner:	n/a
Particulars of manner:	n/a
Signed atCAPE 1	OWNthis day8thof Septemberyear 2021
	Midde
	SIGNATURE OF APPELLANT
FOR DEPARTMENTAL	. USE:
	OFFICIAL RECORD OF INTERNAL APPEAL:
Appeal received on	(date) by
	(state rank, name and surname of information officer/deputy information officer).
	the reasons for the information officer's/deputy information officer's decision and, where
	rs of any third party to whom or which the record relates, submitted by the information
	on officer on
OUTCOME OF APPEA	
DECISION OF INFORM SUBSTITUTED	ATION OFFICER/DEPUTY INFORMATION OFFICER CONFIRMED/NEW DECISION
NEW DECISION:	
DATE RELEVANT AUT	HORITY
RECEIVED BY THE INF	FORMATION OFFICER/DEPUTY INFORMATION OFFICER FROM THE RELEVANT
AUTHORITY ON (date):	