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

CASE NO:

In the matter between:

THE HEALTH JUSTICE INTIATIVE	Applicant
And	
THE MINISTER OF HEALTH	First Respondent
THE INFORMATION OFFICER, NATIONAL DEPARTMENT OF HEALTH	Second Respondent
MINISTER OF COOPERATIVE GOVERNANCE AND TRADITIONAL AFFAIRS	Third Respondent

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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 the failure by the Second and/or First respondent to provide access to the information requested by the Applicant in its request attached hereto as **"A"**;

2. Directing the First Respondent to supply the Applicant, within ten (10) days of the date of order, with copies of each of the records requested in annexure **"A"**;

3. Directing the First Respondent, for as long as the Covid-19 pandemic remains a declared national disaster and/or a pandemic and/or is endemic to cause all expert advice and recommendations submitted to him by the Ministerial Advisory Committee for Covid-19 and/or the Ministerial Advisory Committee for Covid-19

Vaccines to be published on the Coronavirus website of the National Department of Health (https://www.health.gov.za/) within 72 hours of receipt by the Minister;

4. Directing that the costs of this application are to be paid jointly and severally by any Respondents who oppose it;

5. Further and/ or alternative relief.

TAKE NOTICE FURTHER that the founding affidavit of **MARLISE RICHTER** 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.

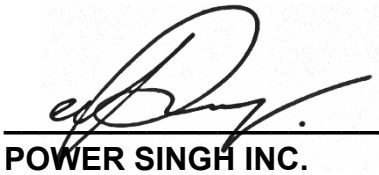
TAKE NOTICE FURTHER that if you intend opposing this application, you are required:

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**.



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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 INFORMATION OFFICER**
NATIONAL DEPARTMENT OF HEALTH
Second Respondent
Dr AB Xuma Building
1112 Voortrekker Road
Pretoria Townlands 351 -JR
PRETORIA

PRETORIA

AND TO: **MINISTER OF COOPERATIVE GOVERNANCE AND TRADITIONAL AFFAIRS**
Third Respondent
87 Hamilton Street
Arcadia
PRETORIA

HEALTH JUSTICE INITIATIVE

Our Ref: 002/NDoH/2021

20 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 - Ministerial Advisory Committee Advisories and COVID-19 vaccination prioritisation

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.

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.

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.

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

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

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

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

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

Yours sincerely,



Dr Marlise Richter

Marlise@healthjusticeinitiative.org.za

info@healthjusticeinitiative.org.za

J750

REPUBLIC OF SOUTH AFRICA

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

FOR DEPARTMENTAL USE

Reference number: .....

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

Request fee (if any): R .....

Deposit (if any): R .....

Access fee: R .....

.....

SIGNATURE OF INFORMATION OFFICER/DEPUTY INFORMATION OFFICER

A. Particulars of public body

The Information Officer/Deputy Information Officer

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

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

B. Particulars of person requesting access to the record

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

Full names and surname: Marlise Richter

Identity number: [redacted]

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

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

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

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

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

C. Particulars of person on whose behalf request is made

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

Full names and surname: Not applicable

Identity number:

D. Particulars of record

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

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

See next page:

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

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

2.i) Copies of all MAC and Ministerial Advisory Committee Covid-19 Vaccines ('VMAC') Advisories that are currently not in the public domain.
ii.) Copies of all memoranda and advisories from the MAC and VMAC that relate to options and recommendations for vaccinating all people with comorbidities.

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

B.) Prioritisation and risk framework and principles:

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

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

C.) AstraZeneca Expert Decision:

1.) Copies of all the MAC, VMAC, SAHPRA and any other expert group or individual recommendations on the use or non-use of the AstraZeneca / Covishield vaccine (from the Serum Institute of India) in South Africa for February – July 2021, for Covid-19.

2.) A copy of the scientific advice/advisories including from the MAC or VMAC or any other expert body or group of experts, that was submitted to the National Department of Health and that sets out the basis upon which the AstraZeneca vaccine should be paused for use in South Africa in 2021.

3.) Copies of the National Department of Health Memoranda, MAC and VMAC recommendations or any other expert groupings memoranda setting out the decision and rationale for pausing the use of the AstraZeneca vaccine in South Africa and the proposal and decision to donate/sell it in early 2021.

4.) A copy of the contract and details of the final sale/donation of the AstraZeneca vaccine, including all details of the cost recovery or lack thereof.

2. Reference number, if available: ……

3. Any further particulars of record:

……

……

……

……

……

E. Fees

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

Reason for exemption from payment of fees:

Not applicable

……

……

……

……

F. Form of access to record

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

Disability: Not applicable

Form in which record is required:

Mark the appropriate box with an **X**.

NOTES:
(a) Compliance with your request for access in the specified form may depend on the form in which the record is available.
(b) Access in the form requested may be refused in certain circumstances. In such a case you will be informed if access will be granted in another form.
(c) The fee payable for access to the record, if any, will be determined partly by the form in which access is requested.

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

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

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

G. Notice of decision regarding request for access

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

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

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

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

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

HEALTH JUSTICE INITIATIVE

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, Justice Kate O'Regan, Noncedo Madubedube, Dr Shuaib Manjra.

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MINISTER OF COOPERATIVE GOVERNANCE AND TRADITIONAL AFFAIRS	Third Respondent

---

FOUNDING AFFIDAVIT

I, the undersigned,

MARLISE RICHTER

do hereby make oath and state:

1. I am a Senior Researcher with the Health Justice Initiative (**"HJI"**), a registered not-for-profit organisation and the applicant in this matter. I am duly authorised to depose to this affidavit and to institute these proceedings on the HJI's behalf as appears from the resolution marked as annex **"HJI1"**.

2. Unless the context indicates otherwise, the facts set out in this affidavit are in my personal knowledge and are, to the best of my belief, true and correct. Where I make legal submissions, I do so on the advice of the HJI's legal representatives, which I accept as correct and good in law.

OVERVIEW OF APPLICATION

3. In these proceedings, the HJI seeks access to:

3.1 The names of all expert advisors to the National Department of Health ("**NDoH**") on Covid-19 (irrespective of whether they serve on any Ministerial Advisory Committee/s);

3.2 Copies of all advisories and recommendations made by the Ministerial Advisory Committee on Covid-19 ("**the MAC**") and the Ministerial Advisory Committee on Covid-19 Vaccines (**"the V-MAC"**), and/or others including those relating to options and recommendations for vaccinating people with co-morbidities (collectively, **"the MAC advisories"**);

3.3 Copies of all advisories and recommendations from the MAC and the V-MAC, regarding vaccine selection and priority group eligibility criteria from December 2020 to date (including any changes to such recommendations and advice) (**"the prioritisation advice documents"**);

3.4 The current, approved and/or draft risk and priority group framework used to make vaccine allocation and prioritisation decisions, and all submissions made in respect thereof ("**the Prioritisation Framework**");

3.5 The recommendations and advisories concerning the use or non-use of the AstraZeneca-University of Oxford / Covishield vaccine and the decision to pause its use in South Africa; (**"the AstraZeneca-University of Oxford records"**); and

3.6 A copy of the contract and details of the final sale or donation of the AstraZeneca - University of Oxford / Covishield vaccine, including all details cost recovery relating thereto (or lack thereof) (**"the AstraZeneca--University of Oxford disposal documents"**).

4. The HJI requested access to these documents in terms of the Promotion of Access to Information Act 2 of 2000 (**"PAIA"**), on 20 July 2021. A copy of the request is attached as **"HJI2"**. When the documents were not provided within the relevant time periods, it submitted an internal appeal against the deemed refusal on 9 September 2021. A copy of the internal appeal is attached as **"HJI3"**. No response was received, and the internal appeal is deemed to have been dismissed. The HJI consequently has no choice but to approach this Court for access to the documents sought.

5. In addition, the HJI contends that the Minister of Health is constitutionally obliged to make all the expert advice and recommendations that he receives from the MAC and the V-MAC (or, indeed, **any other experts**) publicly available within a reasonable period of receipt. The HJI consequently seeks mandatory relief compelling the Minister of Health to publish such expert advice as he receives in relation to the Covid-19 pandemic, within a reasonable period of receipt, for as long as the pandemic continues.

6. In the context of a global pandemic (which has also been declared a national disaster), public disclosure is essential to transparency and access to information and acts as a safeguard against misinformation. It is vital to an appropriate public health response.

THE PARTIES

The Applicant

7. The applicant is the **HEALTH JUSTICE INITIATIVE ("HJI")**, a registered not-for-profit organisation, established in July 2020, with registered offices at 41 Salt River Road, Community House, 2nd Floor, Salt River, Cape Town.

8. The HJI is a public health and law initiative dedicated to addressing the intersection between racial and gender inequality, on the one hand, and access to healthcare, on the other. The HJI's staff, board and reference advisory group

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

9. The HJI's focus areas include advocating for equitable health care, and access to affordable life-saving diagnostics and treatments, and against national profiteering – particularly in the context of Covid-19, TB, and HIV. During the Covid-19 pandemic, the HJI has engaged in ongoing advocacy and lobbying regarding the conduct of the private sector in pricing personal protective equipment ("**PPE**"), and access to vaccines in South Africa (among others).

10. The HJI brings this application:

    10.1 in its own interest as an organisation that operates within, and promotes access to, the public healthcare system; and

    10.2 in the public interest. There is an obvious public interest in ensuring that the State's response to the Covid-19 pandemic is informed by expert input and is transparent.

The Respondents

11. The First Respondent is the **MINISTER OF HEALTH** ("**Health Minister**"), who is cited in his official capacity as head of the Ministry of Health in the national government, whose address is 1112 Voortrekker Road, Pretoria Townlands 351-JR, Pretoria within the jurisdiction of this honourable Court. The Minister is the person for whom the documents requested were prepared or to whom they were submitted.

12. The Second Respondent is the **INFORMATION OFFICER OF THE NATIONAL DEPARTMENT OF HEALTH**, whose address is 1112 Voortrekker Road, Pretoria Townlands 351-JR, Pretoria (within the jurisdiction of this honourable Court). He is cited in his official capacity as the officer designated to receive, deliberate upon, and determine requests for access to information, brought in terms of PAIA.

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

FACTUAL BACKGROUND TO THE REQUESTS

The Covid-19 pandemic

14. On 30 January 2020, the World Health Organisation ("**WHO**") announced the outbreak of a novel coronavirus, Covid-19. The first official Covid-19 case was reported in South Africa on 5 March 2020. 6 days later, on 11 March 2020, the WHO declared the Covid-19 outbreak to be a pandemic.

15. On 15 March 2020, the COGTA Minister declared Covid-19 a national state of disaster in terms of section 27 of the Disaster Management Act. That declaration afforded the COGTA Minister (and, through her, the government) with extraordinary powers to address, contain and ameliorate the impact of the national disaster – including by substantially limiting constitutional rights, without first going through the ordinary legislative process.

16. Among others, section 27(2) empowers the COGTA Minister, after consultation with the responsible Cabinet member, to make recommendations or issue directions or authorise the issue of directions concerning –

> *"(a) the release of any available resources of the national government, including stores, equipment, vehicles and facilities;*
>
> *(b) the release of personnel of a national organ of state for the rendering of emergency services;*
>
> *(c) the implementation of all or any of the provisions of a national disaster management plan that are applicable in the circumstances;*
>
> *(d) the evacuation to temporary shelters of all or part of the population from the disaster-stricken or threatened area if such action is necessary for the preservation of life;*

(e) the regulation of traffic to, from or within the disaster-stricken or threatened area;

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

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

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

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

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

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

(l) emergency procurement procedures;

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

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

(o) steps to facilitate international assistance."

17. Section 6 of the Disaster Management Act requires the COGTA Minister to prescribe a national disaster management framework, which takes into account, among others, the recommendations of the Intergovernmental Committee on Disaster Management. The Health Minister is the Chairperson of that Committee. The Health Minister and the COGTA Minister also both sit on the National Coronavirus Command Council ("**NCCC**") established by the President to coordinate Government's response to the Covid-19 pandemic.

18. Since the declaration of Covid-19 as a national disaster, the COGTA Minister has issued regulations in terms of section 27(2) of the Disaster Management Act, which have been amended from time to time. They prescribe and proscribe various activities, based on the lockdown 'alert level' – which correspond to the degree of risk associated with the levels of Covid-19 infections at any given time. The Regulations associated with Alert level 5 include the most onerous

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

19. In terms of the Lockdown Regulations, as amended from time to time:

19.1 Alert level 5 was in effect from midnight 26 March to 30 April 2020.

19.2 Alert level 4 was in effect from 1 to 31 May 2020.

19.3 Alert level 3 was in effect from 1 June to 17 August 2020.

19.4 Alert level 2 was in effect from 18 August to 20 September 2020.

19.5 Alert level 1 was in effect from 21 September to 28 December 2020.

19.6 Adjusted alert level 3 was in place from 29 December 2020 until 28 February 2021.

19.7 Adjusted alert level 1 was in place from 1 March 2021 to 30 May 2021.

19.8 Adjusted alert level 2 was in place from 31 May to 15 June 2021.

19.9 Adjusted alert level 3 was in place from 16 June 2021 to 27 June 2021.

19.10 Adjusted alert level 4 was in place from 28 June to 25 July 2021.

19.11 Adjusted alert level 3 was in place from 26 July to 12 September 2021.

19.12 Adjusted alert level 2 was in place from 13 to 30 September 2021.

19.13 Adjusted alert level 1 was in effect from 1 October 2021.

19.14 The country has been on adjusted alert level 1 since 28 November 2021. The latest amendment to alert level 1 was Gazetted on 1 February 2022.

20. I emphasise that although the regulations enacted in terms of section 27(2) of the Disaster Management Act entail several serious limitations of certain constitutional rights, they have not been adopted in terms of the ordinary

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

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

The Ministerial Advisory Committees

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

Establishment of the MAC on Covid-19

23. On around 30 March 2020, the Health Minister established the Ministerial Advisory Committee on Covid-19 ("the MAC"), under the terms of reference attached as **"HJI4"** and under the Chairmanship of Professor Salim Abdool Karim, an infectious Disease Epidemiologist, and the Director of the Centre for AIDS Programme of Research in South Africa.

24. The MAC provides high-level strategic advice to the Minister of Health in the management of Covid-19. Its role is purely advisory; it has no delegated powers to act on behalf of, or to commit, the Minister to any actions. Its Terms of Reference record its purpose and scope in this way:

> *Each of these Committees will review material and evidence available locally and internationally, as well as that which is provided by technical working groups supporting the National Department of Health (NDoH) on its COVID-19 response. It will provide the Minister of Health recommendations on:*

a) Case management of individuals infected with SARS-CoV-2 at all levels of the health care system. This includes:

a. Clinical management guidelines;

b. Selection of drugs on the Essential Medicines List;

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

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

e. Emergency services and disaster management response.

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

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

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

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

25. In turn, the MAC is divided into four committees, namely (a) pathologists and laboratory; (b) clinicians; (c) public health and (d) research. Each committee has its own chair and is tasked with reviewing local and international material and evidence, as well as information provided by the technical working groups supporting the NDoH, to provide the Minister with advice and recommendations on issues related to the pandemic. On 16 February 2022, the NDoH published the names of the 21 members of the MAC on the South African Coronavirus portal (sacoronavirus.co.za). The list is attached marked "**HJI5**".

26. The MAC and its sub-committees provide input, recommendations, and advice on a number of crucial aspects of Covid-19 and its management. Their advice and views are plainly considerations that should inform Government's response

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

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

The expansion of the MAC

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

> *As we find ourselves in an extremely fortunate position of achieving effective transmission control, the true test lies in our ability to maintain low transmission rates. This requires a more wholistic approach to case management, preventative measures and public policy. It therefore became necessary to strengthen the MAC on Covid-19 so that it falls in line with its mandate to advise on effective mechanisms for the prevention of onward transmission of Covid-19.*
>
> *Recognising that the composition of the current MAC was focused on a biomedical approach, the Minister has taken a decision to augment the existing committee with various other experts from different sectors.*
>
> *In that regard, the reinforced MAC on Covid-19 consists of bio-medical practitioners; clinical experts; specialists in ethics; the nursing profession; social scientists; re-searchers; and community leaders to advise on interventions that should be considered in responding to the epidemic and to influence the behavioural change that is required to mitigate against the spread of Covid19.*

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

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

The establishment of the V-MAC

30. After vaccines were developed, it quickly became clear that vaccination is essential to an effective response and management of the Covid-19 pandemic. The procurement, and fair and equitable distribution, of vaccines thus became an issue of significant public importance.

31. On 14 September 2020, the Health Minister announced the establishment of a MAC on the Coronavirus Vaccine (that is, the V-MAC). It is chaired by Professor Barry Schoub, a virologist and vaccinologist from South Africa. The V-MAC's role is to advise the Health Minister (and, through him, government) on developments relating to Covid-19 vaccines, and on access to and procurement of vaccines. A copy of the press release announcing the establishment of the V-MAC is attached as **"HJI8"**. The HJI has been unable to locate a copy of its terms of reference.

32. The V-MAC operates in support of the MAC on Covid-19.

33. The V-MAC is an expert body constituted and tasked with advising the Health Minister on vaccines, the mainstay of the government's response to the Covid-19 pandemic. Its advice is plainly crucially relevant to any decision that the COGTA, NCCC, or Health Ministers – or government at large – makes in relation to their

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

34. We do not know the total number of advisories prepared and submitted by the V-MAC or other advisors, to date. According to our records, between 25 August 2020 and 18 August 2021, a total of 120 advisories issued by the MAC (98) or the V-MAC (21) were published on the NDoH's SA Coronavirus website (https://sacoronavirus.co.za/category/mac-advisories/). The list of published advisories is already attached as "**HJi6**".

35. We again invite the respondents to disclose in answer:

    35.1 whether the 120 published advisories constitute the full gamut of advisories received between 25 August 2020 and 18 August 2021; and

    35.2 whether they have published all advisories received to date.

Other experts

36. During mid-2021, Professor Schoub gave a television interview to eNCA, stating that there are other 'advisors' to the NDoH outside of the MAC and the V-MAC. He specifically named Florian Kramner (an affiliate to DUKE University), David Montefiori (also affiliated with DUKE University), and Barney Graham (former National Institute of Health, USA). The interview is available at: https://www.youtube.com/watch?v=BHbJ7Fy-gjk.

37. We invite the respondents to disclose whether there are additional expert advisors, besides those appointed to the MAC and the V-MAC, who have made recommendations to the Health Minister and/or the COGTA Minister on issues relating to the management of the Covid-19 pandemic.

The prioritisation advice and framework

38. One of the crucial issues on which the V-MAC (and, possibly, the MAC, the South African Health Product Regulatory Authority ("**SAHPRA**"), South African Medical Research Council ("**SAMRC**") and others) would have been called on to give advice and recommendations is in respect of the vaccine rollout strategy – including what vaccines to procure, and how to decide in what order to make them available to the public and who to prioritise for vaccination.

39. In that regard, on 15 December 2020, the V-MAC signed an advisory titled *Framework for Rational Allocation of Covid-19 vaccine in South Africa (*a copy of which is attached as ***"HJI9"*** and which was published on the NDoH website on 3 January 2021*)*. It recorded that:

> *Efficacy results from the Phase 3 Covid-19 vaccine trials are becoming available and more are expected in late 2020 / early 2021 and beyond. To date five vaccine trials have reported preliminary efficacy data ranging from 62–95%. In addition, the data suggest that these vaccines have no significant adverse events attributed to them.*
>
> *Assuming that one or more of these vaccines are approved by SAHPRA, it is unlikely that there will be sufficient vaccines available for use beyond specific high-risk groups in the country before the end of the second quarter of 2021 and even then it is likely that only limited quantities of vaccine will be available.*

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

> *Vaccine allocation will thus have to be based on a framework of prioritisation and need. The principles underpinning this Framework emphasises an evidence based approach and an ethical and moral perspective, including an African indigenous values context. The Framework will serve as a guide and will have to be adapted as new scientific information becomes available e.g.:*
>
> - *information about specific characteristics of available vaccine/s,*
> - *the benefit-risk assessment for different population sub-groups,*

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- *the amount and pace of vaccine supply,*
- *the epidemiology at the time of vaccine introduction,*
- *clinical management,*
- *public health response, and*
- *economic and social impact of the pandemic.*

41. The 'Draft Framework' was attached as 'annexure A' to the said advisory (dated 15 December 2020) and is attached as "**HJI10**". It recorded that:

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

42. The 'Draft Framework' was proposed to operate as a guide to the phased and fair allocation of vaccines domestically, taking into account available scientific information and the principle of *Ubuntu* (among others). It was also in alignment with the principles articulated by the WHO Strategic Advisory Group of Experts on Immunization (SAGE) which include 'human well-being; equal respect; global equity; national equity; reciprocity and legitimacy'. The 'Draft Framework' envisaged that prioritisation would be given to people:

    42.1 in roles considered to be essential for societal functioning;

    42.2 most at risk of infection and serious outcomes, for example, those in overcrowded living arrangements, multigenerational homes, with comorbid conditions; and

    42.3 most at risk of transmitting Covid-19 to others.

43. It proposed a three-phase approach, as follows:

43.1 *Phase 1:* to provide the vaccine to 1 250 000 front-line healthcare workers;

43.2 *Phase 2:* to provide the vaccine to a target population of:

43.2.1 2 500 000 essential workers;

43.2.2 1 100 000 persons living in congregate settings;

43.2.3 5 000 000 persons who are over the age of 65 years; and

43.2.4 8000000 persons who are over the age of 18 years and who have Covid-19 co-morbidities.

43.3 *Phase 3:* to provide the vaccine to about 22 500 000 persons who are all over the age of 18.

44. The priority groups in phase 2 were defined as follows:

> *Essential workers: Police officers, miners and workers in the security, retail food, funeral, teachers, banking and essential municipal and home affairs, border control and port health services.*
>
> *Persons in congregate settings: Persons care homes, detention centers, shelters and prisons. In addition, people working in the hospitality and tourism industry, and educational institutions are also at risk.*
>
> *Persons 60 years and older (5 000 000).*
>
> *Persons older than 18 years with co-morbidities: Persons living with uncontrolled diabetics, chronic lung disease, poorly controlled cardiovascular disease, renal disease, HIV, tuberculosis and obesity.*

45. As far as the HJI has been able to determine, the 'Draft Framework' proposed by the V-MAC was not formally adopted. We invite the Respondents to confirm this in answer.

46. The NDoH has provided some information in relation to government's vaccination strategy, in answering papers filed in the matter of *Solidarity and Another v Minister of Health and 16 Others* (case no 3623/21). According to those papers:

46.1 The V-MAC advised the NDoH to await the outcome of stage 3 clinical trial results for vaccines before it concluded any agreements with individual pharmaceutical manufacturers and recommended that "*specific high-risk groups be identified to receive the vaccine before the third quarter of 2021.*" (The relevant advisory was not disclosed in the legal papers.) I should note that by 15 December 2020, Pfizer and Moderna had published their stage 3 clinical trial results, and AstraZeneca's stage 3 results were also published the same day.

46.2 In the *Solidarity* matter, the NDoH referred to high-risk groups which, it said, had been identified based on a framework of prioritisation and need. Paragraph 61 of the answering affidavit in the *Solidarity* matter stated the following in relation to the Prioritisation Framework:

> *"This included identifying, classifying and prioritising high-risk groups, such as:*
>
> ***61.1 Health Care workers**: Health professionals, nurses, general health workers, care home workers, selected laboratory workers, and traditional healers.*
>
> ***61.2 Persons with co-morbidities and at risk for morbidity and mortality:** These include persons 60 years and older, persons living with HIV, tuberculosis, diabetics, chronic lung disease, cardiovascular disease, renal disease, obesity, etc.*
>
> ***61.3 Persons in congregate or overcrowded settings:** This group includes persons in prison, detention centres, shelters, and care homes. In addition people working in the hospitality and tourism industry, and educational institutions are also at risk.*
>
> ***61.4 Essential workers:** This group includes police officers, miners, and workers in the security, retail food, funeral, travel, banking, and essential municipal and home affairs services.*
>
> *It also emphasised that the introduction of a new vaccine into the immunisation programme provides an opportunity for health system strengthening and integration of health services. The Vaccine Strategy recorded that a National Technical Working Group for COVID-19 vaccine introduction had been established to plan and coordinate the vaccine introduction in line with the strategic objectives of the NDoH."*

47. Extracts from the relevant answering affidavit are attached as **"HJI11"**. Neither the Prioritisation Framework, nor the advice and recommendations on which it was based, have been attached to the *Solidarity* answering papers.

48. In other words, seemingly, the V-MAC advised, and the NDoH envisaged, making vaccines available based on a prioritisation framework that was needs-based, rather than only age-dependent.

49. On around 3 January 2021, the Health Minister formally announced the vaccination roll-out strategy, per the media statement attached as **"HJI12"**. It was apparently developed in close collaboration with the V-MAC. Like the V-MAC advisory and draft framework, it envisaged a 3-phase rollout of vaccines:

    - first to healthcare workers,

    - then to essential workers, people in congregate settings, people over 60, and people over 18 with co-morbidities; and

    - finally, to the rest of the 18+ population.

50. Ultimately, and for reasons I address below, the vaccination of healthcare workers began on 17 February 2021 under the auspices of a clinical trial or study programme, the 'Sisonke Study', also regarded as 'phase 1' of the national rollout.

51. On 28 March 2021, the NDoH announced that it intended to commence with a mass vaccine rollout from May to October 2021, when phase 2 got underway. At that stage, it was envisaged that phase 2 would vaccinate "*vulnerable groups, essential workers and the occupational health and safety stream*". Phase 3 would commence in November 2021 and vaccinate anyone not covered in phases 1 and 2. A copy of that announcement is **"HJI13"**.

52. Two days later, however, the Health Minister gave a slightly different report to Parliament. He said that Phase 2A (from 17 May to 31 July 2021) would target people over 60, that phase 2B (from August to 31 October 2021) would target people over the age of 40, prioritising those with co-morbidities and workers in high-risk settings, and phase 3 (from November onwards) would vaccinate the remainder. A report from the parliamentary monitoring group is **"HJI14"**.

53. The Sisonke Study (Part 1) was completed on 15 May 2021, and phase 2 of the national vaccination rollout began on 17 May 2021, commencing with adults over 60.

54. On 16 May 2021, the Health Minister announced that phase 2 would provide vaccination to 'citizens over the age of 60'. No mention was made, or explanation given, for abandoning the previous plan also to prioritise essential workers, people in congregate settings and people with co-morbidities, for vaccination.

55. The vaccine roll-out that followed proceeded on age criteria, rather than the anticipated prioritisation. Vaccines were initially made available to healthcare workers (through the Sisonke Study), then to people over the age of 60, then to people in the age group 50-59, then the cohort of 35 to 49, then to 18 to 34 year-olds and, most recently, to 12 to 17 year-olds.

56. During this time, a cohort of teachers were also identified for a special vaccination programme using additional 'donated' stock from a vaccine manufacturer, in large part due to material delays in the overall supply provision by that manufacturer (Johnson & Johnson).

57. The NDoH also issued a Special Circular in July 2021 that 'permitted' certain categories of people to apply for permission to be vaccinated outside of the prevailing age cohort roll-out, the essential public sector programme or a workplace programme – in other words, they could seek authorisation from the NDoH to 'jump the vaccine queue'. This circular was later retracted. A copy of that Special Circular is attached as **"HJI15"**.

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58. Neither the written framework underpinning the changes in the prioritisation approach, nor the advice nor recommendations on which it is based, have been made publicly available. The public is entirely in the dark as to when, why or how decisions were made on vaccine roll-out and prioritisation.

59. The public has a right to know on what basis the relevant Ministers and the government took these decisions. It is also entitled to know whether the expert advice of the MAC and the V-MAC was considered and followed and, if not, why it was departed from. Especially with new variants being detected, it is important to share information on how the country will manage vaccine supply in a timely manner.

60. Science around the pandemic is evolving at such a pace, so it is essential that government be kept abreast of, and take into account, rapidly evolving scientific knowledge. The only way that the public can be certain that government is listening to expert advice and making the appropriate decisions which are in line with the relevant and current scientific advice, is for it to share information from the experts more readily and speedily. Critically, the public has a right to know the roles of each advisor to the NDoH and their conflicts of interest (if any). That is particularly so where the decisions at issue involve vaccine selection and changes in selection, and severe restrictions on social, civil and political liberties, and where the ordinary legislative safeguards in place to protect the public, have been curtailed. The information sought is crucial to transparency and accountability and helps to mitigate confusion and hesitancy.

The Covishield vaccine roll out – and pausing it

61. On 7 January 2021, the Health Minister announced that a special order of the AstraZeneca-University of Oxford vaccine (Covishield) had been procured for healthcare workers in South Africa via the Serum Institute of India **("SII")**, and that the first batch would be delivered during the course of January 2021. A copy of that statement is **"HJI16"**

62. According to the answering affidavit filed in the *Solidarity* matter (extracts of which are attached as **"HJI17"**):

62.1 Between September and December 2020, government had negotiated with the SII – which produces the AstraZeneca-University of Oxford vaccine against Covid-19 (also called Covishield) under licence – regarding the supply to South Africa. In terms thereof, 1 million doses would be delivered in early 2021.

62.2 In December 2020, a new Covid-19 variant (501Y.V2 variant or the Beta variant) was discovered. The efficacy of the AstraZeneca-University of Oxford vaccine had not been assessed in respect of this new variant.

62.3 The V-MAC considered whether the AstraZeneca-University of Oxford vaccine should be rolled out in the fact of the 501Y.V2 variant, and apparently sought advice from overseas experts (including the WHO, and experts form the United States and the United Kingdom – whose details are not known to us). Their advice was reportedly that the vaccine was likely still to be effective against the 501Y.V2 variant. (The expert advice and the advisories in this regard have not been made public. It is not clear who exactly the international experts consulted were or what informed their assessment.)

62.4 On 22 January 2021, SAHPRA granted authorisation, in terms of section 21 of the Medicines and Related Substances and Control Act, for the domestic use of Covishield.

62.5 SII caused one million doses of Covishield to be delivered to South Africa on or around 31 January 2021.

63. On 7 February 2021, the Health Minister, together with the head of SAMRC and members of the MAC and the V-MAC, announced, at a media briefing, that a decision had been taken to pause the rollout of the AstraZeneca-University of Oxford vaccine, based on the results of a preliminary study that showed substantially reduced protection against mild to moderate infections from the 501Y.V2 variant. (The media briefing is available on Youtube at: https://www.youtube.com/watch?v=Mfu-Bk7zuPY). The Minister of Health

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

64. In March 2021, the V-MAC submitted a retrospective advisory to the Health Minister, in which it recommended that the roll-out of the AstraZeneca-University of Oxford vaccine – the Covishield vaccine – "*be suspended pending the release of data of the in-vivo efficacy against the 501Y.V2 variant*" and that, *"in the meantime, it is strongly recommended that urgent steps be taken to acquire alternate vaccines to replace the AstraZeneca vaccine"*. A copy of the retrospective advisory is attached as **"HJI19"**. The (additional) information, recommendations and advice underpinning the decision to suspend the roll-out of the AstraZeneca-University of Oxford vaccine, if any, have not been made available.

65. By the stage that the retrospective advisory was issued, government had already decided to on-sell or donate the AstraZeneca-University of Oxford vaccine supply into, as far as we know, the African Union. The retrospective advisory also recorded that:

> *"This advisory was finalised on the 7th of February, of which NDoH officials were aware of.*
>
> *It was never submitted as a formal advisory at the time as the VMAC was made aware that the AZ vaccines were to be sold to other country/ies in the African Union.*
>
> *In hindsight, to ensure that there is a proper paper trail, this advisory is retrospectively being formally submitted to regularise the information conveyed in the advisory.*
>
> *As it is only being submitted retrospectively, it was signed off on the date that the Committee recommended that it be submitted retrospectively to the NDoH, which was at the VMAC meeting on the 18th of March 2021."*

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

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

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

THE REQUESTS FOR INFORMATION

68. The appointment of the MAC and the V-MAC, their and other experts' advice and the decisions made pursuant thereto, raise issues of clear public importance.

    68.1 It is a matter of comfort to the HJI that Government was seeking expert input to inform its approach to the Covid-19 pandemic and to the rollout of a vaccination strategy. But we believe that it was and is imperative that such expert advice be made publicly available in a timely way.

    68.2 This would not only foster transparency and help to combat misinformation; it would also allow the stakeholders and the public at large (including civil society organisations such as the HJI) to interrogate the reasonableness and lawfulness of decisions taken by the Government. That is particularly important where there have been suggestions in the media that government has been disregarding the expert advice procured, for no obvious reason. I attach one example of such reports as **"HJI22"**.

    68.3 Such oversight is particularly necessary in the context of a global pandemic and a declared national disaster, where many of the checks and balances imposed by the ordinary legislative process do not apply. It is also consonant with the public's right to information (entrenched in section 32 of the Constitution) and the values of accountability and

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

69. Despite the clear public interest in the MAC and V-MAC advisories, the prioritisation advice records, the Prioritisation Framework, the AstraZeneca-University of Oxford records (Covishield) and/or the AstraZeneca-University of Oxford decision (Covishield), those records have not been made fully publicly available.

70. The HJI has repeatedly sought to obtain access to this information, as follows:

71. On 9 March 2021, the HJI emailed the NDoH requesting it to "*forward any MAC advisories published in the last two months, and that these are uploaded on the website*" HJI also enquired about how many meetings of the MAC and the V-MAC had taken place from the beginning of 2021 to date. A copy of that email is marked annexure **"HJI23"**.

72. On 10 March 2021, a representative of the NDoH responded in the email, already attached as **"HJI23"**, stating:

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

73. On 23 March 2021, HJI sent the follow-up request as included in the email correspondence attached as **"HJI23"**. The HJI again called for the publication of advisories issued since 11 January 2021 and information on how many MAC and V-MAC meetings had taken place since the beginning of the year. No response was received.

74. On 14 April 2021, the HJI wrote a formal letter to the NDoH (annexed as **"HJI24"**) recording the comments of Professor Schoub (the V-MAC Chair) in the South

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

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

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

> *In a pandemic, transparency is imperative, and it is regrettable that we have had to resort to writing repeatedly to your offices for what should be a simple disclosure on the department's part, of information that is in the public interest.*
>
> *Please note that in the interests of transparency we may publish this correspondence and any response/s received. We have also noted our correspondence with your office on the HJI's Vaccine Access Timeline that is available on our website.*

76. Further follow-up emails were sent on 20 and 30 April, and 14 May 2021, reiterating the same requests. Those emails are included in the annexure already attached as **"HJI23".**

77. During May 2021, a selection of MAC advisories was published on the NDoH website. HJI noted as much in email correspondence already attached as **"HJI23"** but noted that others had still not been published – including those relating to "*vaccine selection, the rationale for the pausing the planned AstraZeneca roll-out, the selling on of the said vaccines, and the sequence of age and co-morbidity prioritisation within the Department of Health's Electronic Vaccination Data System (EVDS)*".

78. On 22 June 2021, HJI reiterated its concerns and requests in a letter attached as **"HJI25"**. The letter noted inter alia that:

> *2. Since November 2020 we have written on numerous occasions to the National Department of Health ("Department") and other relevant*

Ministries requesting information pertaining to the COVID - 19 pandemic in order to foster transparency, disclosure and improved engagement and communication. This includes correspondence on the national vaccine programme, including on matters related to the acquisition, procurement, selection and prioritisation.

*3. Our correspondence has been copied to relevant government departments and in certain cases also addressed/copied to statutory bodies including the South African Health Products Regulatory Authority **(SAHPRA)** and also, Parliament.*

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

79. In that letter of 22 June 2021, the HJI invited the NDoH to make voluntary disclosure of the information sought in terms of section 15 of PAIA on three areas: broadly - vaccine manufacturer contracts, expert advice, and prioritisation. Copies of that letter were also sent to the Information Officer of the Presidency, the Office of the speaker of the National Assembly and the CEO and Company Secretary of SAHPRA. (Paragraphs 7.2 and 7.3 of that letter are relevant to this application. Paragraph 7.1 of that letter deals with the disclosure of relevant vaccine contracts, which is the subject of a separate PAIA application before this Court).

80. On 29 July 2021, the HJI re-sent the letter, which the NDoH then acknowledged receipt of by e-mail. On 29 July 2021 the NDoH responded in a letter, attached as **"HJI26"**. In respect of the MAC Advisories and other expert prioritisation recommendations, the letter merely stated that:

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

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

> *A.) Expert Advice and Ministerial Advisory Committees Advisories on Covid-19:*
>
> *1. A list of the names of all local and international expert advisors to the National Department of Health on Covid-19, irrespective of whether they also serve on a/ any Ministerial Advisory Committee ('MAC') for Covid-19.*
>
> *2.i) Copies of all MAC and Ministerial Advisory Committee Covid-19 Vaccines ('VMAC') Advisories that are currently not in the public domain.*
>
> *ii.) Copies of all memoranda and advisories from the MAC and VMAC that relate to options and recommendations for vaccinating all people with comorbidities.*
>
> *3) Copies of all MAC, VMAC, National Department of Health, South African Health Product Regulatory Agency (SAHPRA), and/or any other expert recommendations and expert as well as ethic bodies/other professional or expert bodies written advice including from the South African Medical Research Council (SAMRC) and the South African Medical Association (SAMA), related to the vaccine selection and priority group eligibility criteria for South Africa from December 2020 to date, and copies of any changes in the respective recommendations/advice over this time period.*
>
> *B.) Prioritisation and risk framework and principles:*
>
> *1.) A copy of the written and current approved (or in draft form) risk and priority group framework or similar, and timeline, that the National Department of Health is at present using to vaccinate people in South Africa and in turn using to make vaccine allocation and prioritisation (eligibility) decisions.*
>
> *2.) Copies of all submissions made by any other government department, trade union, political party, business body, organisations, medical schemes, statutory bodies or any other body, whether locally or internationally, on the issue of vaccine selection for South Africa; and also prioritisation of certain groups in South Africa ahead of others.*

82. On 23 July 2021, HJI received an email from the NDoH acknowledging receipt of the formal PAIA request *002/NDOH/2021* **("HJI27").** (The reply of 29 July 2021, referred to in paragraph 80 above, responded to the earlier letter of 2 July

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2021 but did not materially answer the PAIA request. It has already been attached as **HJI26**).

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

> *As you will be aware, further to our letter dated 22 June 2021, and in the absence of any timely response, the Health Justice Initiative submitted three formal requests in terms of the Promotion of Access to Information Act 2 of 2000 ("PAIA") to the National Department of Health ("NDoH") in the public interest for which we duly received relevant acknowledgements of receipt, for two of the requests.*
>
> *These three PAIA requests relate to: (1) all vaccine contracts (2) details about the Ministerial Advisory Committee/s (MAC) and its Advisories; and (3) prioritisation decisions including for the Sisonke programme.*
>
> *And:*
>
> *5.2 MAC advisories (Our PA/A Ref: 002/NDoH/2021):*
>
> *We note our appreciation for some of the MAC advisories that have been made public thus far, although this information has been difficult to navigate in the absence of a contents list. Moreover, we emphasise that this does not respond in full to our PAIA request, dated 20 July 2021.* ***For instance, we have not been provided with the relevant names relating to "all local and international expert advisors to the National Department of Health on Covid-19" as requested.*** *We trust that full disclosure will be made in accordance with our PAIA request within the 30-day prescribed period, and by no later than 19 August 2021.*

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

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The internal appeal

85. On 9 September 2021, HJI lodged an internal appeal in terms of section 75 of PAIA against the deemed refusal of its request. The appeal has already been annexed as **"HJI3".**

86. The internal appeal was lodged in compliance with the prescribed requirements – that is, it was lodged within 60 days of the deemed refusal, delivered to the Respondents, and also contained the grounds upon which the appeal was based.

87. HJI has received no response to the internal appeal, and it is deemed, under section 27 of PAIA, to have been refused.

PROVISION OF THE DOCUMENTS SOUGHT

88. The Constitution demands that transparency must be fostered by providing the public with timely, accessible, and accurate information. Access to information is fundamental to the realisation of the other rights enshrined in the Bill of Rights.

89. The purpose of PAIA is to promote a culture of transparency and accountability in public and private bodies by giving effect to the right to access of information enshrined in the Constitution which allows the public to fully exercise and protect their rights. The need for transparency and accountability in a global pandemic and also in a declared state of disaster is all the more acute.

90. The HJI has made proper requests for access to the records in question and is entitled to be provided with the documents sought. There are no grounds for access being refused – nor have any been raised by the NDoH. At no point during HJI's efforts to gain the information sought, have the respondents claimed that the information enjoys exemption from disclosure – rightfully so, because the information sought does not fall within the ambit of any of the exclusions provided for in PAIA.

91. Even if there were statutory grounds for refusing disclosure of the records sought (which is denied), the public interest would render their production mandatory under section 46 of PAIA.

92. The HJI accordingly seeks an order setting aside the refusal to provide access to the records (to the extent that is necessary) and directing the First and Second Respondents to furnish those records within 10 days of any court order.

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

93. The HJI also seeks an order directing the Health Minister, for as long as Covid-19 remains an issue of public importance (meaning, necessarily, for as long as its remains a declared national disaster and/or a pandemic and/or is endemic,) to publish advisories and/or recommendations received from the MAC, V-MAC and / or any other experts, in relation to Covid-19, on the NDoH website within 72 hours of receipt.

94. On a proper interpretation of section 12 of the National Health Act and/or section 22 of the National Disaster Management Act, those advisories and recommendations must be made publicly available to enable the public (including civil society) properly to understand and assess the basis on which the Covid-19 pandemic is being managed, and decisions (including in respect of the lockdown regulations and the vaccine roll-out) are being made, and rights and freedoms restricted.

95. In the absence of such publication, the public is unable meaningfully to interrogate the expert advice government is receiving, and the basis on which important decisions of policy and administration are being made. That is anathema to the value of transparency and accountability that govern the public administration (entrenched in section 195 of the Constitution) and does not best give effect to the right of access to information in section 32 of the Constitution. Transparency and access to information are particularly important in the context

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

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

CONCLUSION

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

M Richter

MARLISE RICHTER

I hereby certify that the deponent declares that the deponent knows and understands the contents of this affidavit and that it is to the best of the deponent's knowledge both true and correct. This affidavit was signed and sworn to before me at CAPE TOWN on this 30th day of March 2022 and that the Regulations contained in Government Notice R1258 of 21 July 1972, as amended, have been complied with.

COMMISSIONER OF OATHS

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

"HJI1"

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.

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

Dr Shuaib Manjra

Chairperson

Noncedo Madubedube

Board Member

HEALTH JUSTICE INITIATIVE

Our Ref: 002/NDoH/2021

20 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 - Ministerial Advisory Committee Advisories and COVID-19 vaccination prioritisation

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.

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.

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.

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

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

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

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

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

Yours sincerely,

Dr Marlise Richter

Marlise@healthjusticeinitiative.org.za

info@healthjusticeinitiative.org.za

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REPUBLIC OF SOUTH AFRICA

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

FOR DEPARTMENTAL USE

Reference number: .....

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

Request fee (if any): R .....

Deposit (if any): R .....

Access fee: R .....

.....

SIGNATURE OF INFORMATION OFFICER/DEPUTY INFORMATION OFFICER

A. Particulars of public body

The Information Officer/Deputy Information Officer

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

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

B. Particulars of person requesting access to the record

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

Full names and surname: Marlise Richter

Identity number: [redacted]

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

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

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

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

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

C. Particulars of person on whose behalf request is made

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

Full names and surname: Not applicable

Identity number: | | | | | | | | | | | | | |

D. Particulars of record

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

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

See next page:

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

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

2.i) Copies of all MAC and Ministerial Advisory Committee Covid-19 Vaccines ('VMAC') Advisories that are currently not in the public domain.
ii.) Copies of all memoranda and advisories from the MAC and VMAC that relate to options and recommendations for vaccinating all people with comorbidities.

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

B.) Prioritisation and risk framework and principles:

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

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

C.) AstraZeneca Expert Decision:

1.) Copies of all the MAC, VMAC, SAHPRA and any other expert group or individual recommendations on the use or non-use of the AstraZeneca / Covishield vaccine (from the Serum Institute of India) in South Africa for February – July 2021, for Covid-19.

2.) A copy of the scientific advice/advisories including from the MAC or VMAC or any other expert body or group of experts, that was submitted to the National Department of Health and that sets out the basis upon which the AstraZeneca vaccine should be paused for use in South Africa in 2021.

3.) Copies of the National Department of Health Memoranda, MAC and VMAC recommendations or any other expert groupings memoranda setting out the decision and rationale for pausing the use of the AstraZeneca vaccine in South Africa and the proposal and decision to donate/sell it in early 2021.

4.) A copy of the contract and details of the final sale/donation of the AstraZeneca vaccine, including all details of the cost recovery or lack thereof.

2. Reference number, if available: .....

3. Any further particulars of record:

.....

.....

.....

.....

.....

E. Fees

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

Reason for exemption from payment of fees:

Not applicable

.....

.....

.....

.....

F. Form of access to record

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

Disability: Not applicable

Form in which record is required:

Mark the appropriate box with an **X**.

NOTES:
(a) Compliance with your request for access in the specified form may depend on the form in which the record is available.
(b) Access in the form requested may be refused in certain circumstances. In such a case you will be informed if access will be granted in another form.
(c) The fee payable for access to the record, if any, will be determined partly by the form in which access is requested.

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

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

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

G. Notice of decision regarding request for access

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

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

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

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

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

HEALTH JUSTICE INITIATIVE

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, Justice Kate O'Regan, Noncedo Madubedube, Dr Shuaib Manjra.

Board: Dr Shuaib Manjra, Noncedo Madubedube, Fatima Hassan

REPUBLIC OF SOUTH AFRICA

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

STATE YOUR REFERENCE NUMBER: 002/NDoH/2021

A. Particulars of public body

The Information Officer/Deputy Information Officer:

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: Marlise Richter

Identity number: [redacted]

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

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

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

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

C. Particulars of requester

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

Full names and surname: N/A

Identity number:

D. The decision against which the internal appeal is lodged

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

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

E. Grounds for appeal

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

State the grounds on which the internal appeal is based:

See next page

State any other information that may be relevant in considering the appeal:

See next page

Grounds for appeal:

On 23 July 2021, the Health Justice Initiative (HJI) submitted a request to the National Department of Health (NDoH) in terms of the Promotion of Access to Information Act 2 of 2000 (PAIA).

The request pertained to specific expert advice and information related to the COVID-19 pandemic. To date, not all 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.

With specific regard to the 'MAC' and 'VMAC' Advisories, we acknowledge that some advisories have since been placed on the NDoH website. However, our analysis reveals that this does not include all the information and all the expert advice and information contemplated in our request.

The following records are incomplete or have not been provided:

- A *list of the names* of all local and international expert advisors to the National Department of Health on Covid-19, irrespective of whether they also serve on a/any Ministerial Advisory Committee ('MAC') for Covid-19.
- Copies of *all MAC and Ministerial Advisory Committee Covid-19 Vaccines ('VMAC') Advisories* and other expert advice, that are currently not in the public domain.
    - The Advisories that are available on the National Department of Health's *Corona Virus Online Portal*[1] from August 2020 to 18 August 2021 (122 MAC Advisories in total including 26 loaded since 20 July 2021 (the date of HJI's PAIA request)) are uneven, with date and thematic gaps.
- Copies of *all* memoranda and Advisories that relate to options and recommendations for vaccinating all people with comorbidities.
- Copies of all MAC, VMAC, National Department of Health, South African Health Product Regulatory Agency (SAHPRA), and/or any other expert recommendations and expert as well as ethic bodies/other professional or expert bodies written advice including from the South African Medical Research Council (SAMRC) and the South African Medical Association (SAMA), related to the *vaccine selection and priority group eligibility criteria*

[1] https://sacoronavirus.co.za/category/mac-advisories/

for South Africa from December 2020 to date, and copies of any changes in the respective recommendations/advice over this time period.

- A copy of the written and current approved (or in draft form) *risk and priority group framework* or similar, and timeline, that the National Department of Health is at present using to vaccinate people in South Africa and in turn using to make vaccine allocation and prioritisation (eligibility) decisions.
- Copies of all *submissions* made by any other government department, trade union, political party, business body, organisations, medical schemes, statutory bodies, or any other body, whether locally or internationally, on the issue of vaccine selection for South Africa; and also, prioritisation of certain groups in South Africa ahead of others.
- Copies of all the MAC, VMAC, SAHPRA and any other expert group or individual recommendations on the *use or non-use of the AstraZeneca / Covishield vaccine* (from the Serum Institute of India) in South Africa for February – July 2021, for Covid-19, over and above the 7 February 2021 Advisory (signed on 18 March 2021)[2] and 19 February 2021 Advisory[3]. And copies of the National Department of Health Memoranda, MAC and VMAC recommendations or any other expert groupings memoranda setting out the decision to donate/sell it in early 2021.

- A copy of the contract and details of the final sale/donation of the AstraZeneca vaccine, including all details of the cost recovery or lack thereof.

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 as Appendix 1 together with this internal appeal and a copy of the letter dated 29 July 2021 from the Director -General of Health marked Appendix 2.

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[2] The Advisory stated that: "A high-level consultative meeting of the technical working group of the MAC will be held on Monday, 8th February. This will consist of local and international experts in the field to develop a considered advisory on the way forward".
[3] https://sacoronavirus.b-cdn.net/wp-content/uploads/2021/07/13-ADVISORY-Vaccine-choices-for-South-Africa_19Feb21_V4.pdf

F. Notice of decision on appeal

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

State the manner: N/A

Particulars of manner: .....

Signed at Cape Town this day 9th of September year 2021

.....
SIGNATURE OF APPELLANT

FOR DEPARTMENTAL USE:

OFFICIAL RECORD OF INTERNAL APPEAL:

Appeal received on ..... (date) by .....

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

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

OUTCOME OF APPEAL: .....

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

NEW DECISION: .....

DATE RELEVANT AUTHORITY .....

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

health
Department:
Health
REPUBLIC OF SOUTH AFRICA

Ministerial Advisory Committee on COVID-19
Terms of Reference

VERSION 3.2 30 MARCH 2020

Contents

Abbreviations 2
Introduction 2
Purpose and Scope 2
Authority to act 3
Conditions of membership 4
Code of conduct 4
Remuneration 4

Abbreviations

Coronavirus Disease-2019	-	COVID-19
MAC	-	Ministerial Advisory Committee
NDoH	-	National Department of Health

Introduction

Outbreaks of emerging and re-emerging infectious diseases confer a direct threat to human health, the integrity of our health system, and the national and global economy. Like the influenza pandemics of 1918 and 2009, and epidemics of Ebola Virus Disease (2014), SARS (2002), and MERS (2012), the novel coronavirus SARS-CoV-2 now causing an epidemic of Coronavirus Disease-2019 (COVID-19) focuses our attention on the inter-sectoral, multidisciplinary response that is needed to respond within South Africa, and the critical benefit to a country that is well prepared for the next epidemic or pandemic.

South Africa has coped well with past challenges in this arena, but the rapidity and range of the response has been sub-optimal due to it being reactionary rather than proactive. The proactive, operational work that would ensure South Africa is better prepared, should be done in the inter-pandemic period, preparing the vast range of public health, clinical, research, and movement of populations interventions to 'set-piece' scenarios i.e., outbreaks, epidemics or pandemics of high consequent pathogens that are spread via respiratory, bloodborne, foodborne or other means. These same issues are critical to focus on with specific reference to COVDI-19 pandemic response.

Purpose and Scope

The Ministerial Advisory Committee (MAC) on COVID-19 is a non-statutory, advisory Committee appointed by the Minister of Health to provide high level strategic advice to the Minister of Health on the management of the COVID-19 outbreak in South Africa. The MAC on COVID-19 will provide advice but is not responsible for the delivery or coordination of services related to the COVID-19 response.

The MAC on COVID-19 will consist of four Committees:

1. Pathologists and Laboratory;
2. Clinicians;
3. Public Health; and
4. Research.

Non-members may be invited to attend meetings and provide presentations by the Chairperson of the Committee as required. Any invited guests must be approved by the Chairperson of the Committee prior to the meeting and must sign an applicable declaration of confidentiality.

Each of these Committees will review material and evidence available locally and internationally, as well as that which is provided by technical working groups supporting the National Department of Health (NDoH) on its COVID-19 response. It will provide the Minister of Health recommendations on:

a) Case management of individuals infected with SARS-CoV-2 at all levels of the health care system. This includes:
    a. Clinical management guidelines;
    b. Selection of drugs on the Essential Medicines List;
    c. Effective infection prevention and control interventions (health facilities and community level);
    d. Flow of patients into the health system, such as from port authorities and the hospitality industry; and
    e. Emergency services and disaster management response.
b) Public health interventions in the control and mitigation phases of an outbreak, such as social distancing measures, strategy for testing of case detection in communities and related isolation of cases and tracing and quarantine of their contacts, school, higher education and business closures, as well as national locked-down.
c) Communications strategies to optimize national community advocacy, awareness and education campaigns during an epidemic.
d) Research priorities into pathogenesis, clinical management (including presentation, diagnosis, and treatment modalities), disease modelling, and public health interventions. Particular emphasis on the interaction with our vulnerable HIV and NCD populations.
e) Economic impact to the health system and broader sectors within government, including issues of sector-wide procurement.

Authority to act

The MAC on COVID-19 is an advisory Committee to the Minister of Health and does not have any delegated powers to act on behalf of, or to commit, the Minister or Government to any actions.

The Minister of Health or his designated person will chair the MAC on COVID-19. The Minister will dissolve the Committee at his discretion.

Conditions of membership

Members of the MAC are participants in their individual capacity and do not represent any constituency, organization or sector. Members participate in their individual capacity. Members have a duty to act honestly and in good faith and to exercise skill, care and diligence in carrying out their duties and not make improper use of information. Members are subject to all of the applicable provisions and procedures surrounding Conflict of Interest and Confidentiality.

Members **may not** nominate representatives to attend meetings in their absence. Members may not allow non-members to listen in or attend the meetings unless approved by the Chair.

Code of conduct

Members are expected to:

- avail themselves for virtual meetings, punctually and for the whole of the scheduled meeting time;
- indicate their failure to attend any meeting in writing to the secretariat, in good time with the reason as to why they were unable to attend;
- act with the highest professional and ethical standard at all times;
- contribute to debate in an informed and rational way and take decisions solely in the interest of the public;
- regard the views expressed by individual members of the MAC on COVID-19 and recommendations as strictly confidential;
- respect and value each member's perspective and contribution;
- make decisions together and take joint responsibility for them; and
- be informed and prepared for the meeting by reading the agenda and papers.

Under no circumstances may an individual member, other than the MAC Chairperson, officially represent the views and decisions of MAC on COVID-19 with stakeholder groups.

Remuneration of Ministerial Advisory Committee members

Appointed and co-opted members of the Ministerial Advisory Committee Groups will not be remunerated for personal time spent participating in meetings and working on technical documents.

MAC on COVID-19 Members

Co-Chair	Prof	Koleka	Mlisana	Executive Manager: Academic Affairs, Research and Quality Assurance at the National Health Laboratory Service
Co-Chair	Prof	Marian	Jacobs	Emeritus Professor of Paediatrics and Child Health at the University of Cape Town
Member	Prof	Portia	Jordan	Executive Head of Department of Nursing and Midwifery at Stellenbosch University
Member	Dr	Jeremy	Nel	Head of Infectious Diseases at Helen Joseph Hospital
Member	Prof	Rudo	Mathivha	Head of Critical Care Medicine, Chris Hani Baragwanath Academic Hospital
Member	Prof	Sithembiso	Velaphi	Head of Paediatrics and Child Health, Chris Hani Baragwanath Academic Hospital
Member	Prof	Ian	Sanne	Chief Executive Officer at Right to Care and Director of Clinical HIV Research Unit at the University of the Witwatersrand
Member	Prof	Matildah	Mokgatle	Head of Health Systems Research in the School of Public Health at Sefako Makgatho Health Sciences University
Member	Prof	Juliet	Pulliam	Director of the South African Centre for Epidemiological Modelling and Analysis (SACEMA) at Stellenbosch University
Member	Dr	Jacqui	Miot	Division Director of the Health Economics and Epidemiology Research Office at the University of the Witwatersrand
Member	Prof	Helen	Rees	Chairperson of the South African Health Products Regulatory Authority and Executive Director of the Wits RHI, University of the Witwatersrand
Member	Prof	Heidi	van Rooyen	Acting Deputy CEO (Research); Group Executive: The Impact Centre, HSRC
Member	Prof	Doug	Wassenaar	Chair of the University of KwaZulu-Natal Biomedical Research Ethics Committee
Member	Dr	Thuthula	Balfour	Head of Health at Minerals Council of South Africa
Member	Prof	Sheetal	Silal	Director of the Modelling and Simulation Hub, Africa at the University of Cape Town
Member	Dr	Anam	Nyembezi	Senior Lecturer within the School of Public Health at the University of the Western Cape
Member	Dr	Allison	Glass	Clinical Virologist
Member	Prof	Tulio	de Oliveira	Head of the Network for Genomic Surveillance in South Africa
Member	Mr	Andy	Gray	Senior Lecturer in Pharmacology at the University of KwaZulu-Natal
Secretariat	Dr	Janine	Jugathpal	Deputy Director of the Essential Drugs Programme at the Affordable Medicines Directorate of the National Department of Health
Secretariat	Ms	Amanda	Brewer	Senior Manager at the USAID Global Health Supply Chain Technical Assistance Programme

NOTE: Only the MAC on COVID-19 Co-Chairpersons are authorised to speak on behalf of the MAC on COVID-19. Any public statements made by other members are made in their personal or other professional capacity. Decisions are made by consensus and not by any individual member of the MAC on COVID-19.

KW

MR

List of Published MAC Advisories

Table 1: MAC Advisories uploaded on SA Corona Virus Portal from 2020 and the comparison between date when advisory was issued vs date when advisory was uploaded to the SA Corona Virus Portal, for public access.

Available at: https://sacoronavirus.co.za/category/mac-advisories/

As of 18 March 2022

Title of Advisory	Date of Issue	Date of Upload
The MAC Covid-19 is supportive of the repatriation efforts by SAA	4/4/2020	8/26/2020
Report on SARS-COV-2 infection outbreak at St. Augustine's hospital	4/5/2020	8/26/2020
SARS-COV-2 infection outbreak at St. Augustine's hospital	4/6/2020	8/26/2020
Public use of cloth facemasks for everyone	4/9/2020	8/25/2020
Applications of drone technology in the fight against Covid-19	4/23/2020	8/25/2020
Request to review medical evacuation plan document	4/25/2020	8/26/2020
Risk factors for severe Covid-19	4/29/2020	8/25/2020
Request to provide guidance on deployment of healthcare workers at a higher risk of mortality from Covid-19	4/29/2020	8/26/2020
Request for input on guidelines for traditional health practitioners dealing with Covid-19	5/5/2020	8/25/2020
Timing of the use of invasive mechanical ventilation and the utility of CPAP (and other techniques) to avoid mechanical ventilation in the setting of Covid-19, and their relation to outcomes.	5/5/2020	8/26/2020
Request to review medical evacuation plan document - update	5/5/2020	8/26/2020
St Augustine hospital outbreak of Covid-19 – interim report	5/15/2020	8/26/2020
Switching from community screening and testing to hotspots	5/18/2020	8/25/2020
Release of modelling projections	5/19/2020	8/25/2020
Ministerial advisory committee comment on rational use of PPE poster	5/19/2020	8/26/2020
The path forward in the national covid-19 response: concurrently saving lives and livelihoods	5/19/2020	8/26/2020
Advisory on regulations related to the alert levels imposed to control Covid-19 and the implementation thereof	5/21/2020	8/26/2020
Eskom safeguard implementation	5/22/2020	8/26/2020
Advisory on disinfection tunnels for preventing SARS-COV-2 transmission	5/22/2020	8/26/2020
Getting children back to school safely	5/26/2020	8/26/2020
Impact of Covid-19 on non-covid healthcare utilisation	6/1/2020	8/26/2020
Time to peak of Covid-19 cases	6/3/2020	8/26/2020
Medical certification for death due to Covid-19	6/4/2020	8/26/2020

Advisory on the urgent need to address the current challenges in testing through prioritisation for the SARS-COV-2 daily test targets	6/4/2020	8/26/2020
Saliva as a reliable tool to detect SARS-COV-2	6/8/2020	8/26/2020
Use of Dexamethasone for the treatment of severe Covid-19	6/18/2020	8/26/2020
Mitigating legal liability of health care workers in the public and private sectors during Covid-19 pandemic in South Africa	6/18/2020	8/26/2020
Asymptomatic infections	6/18/2020	8/26/2020
Recommendations for use of antibody testing	6/24/2020	8/26/2020
Use of high-flow nasal cannula (HNFC) oxygen in the treatment of covid-19 pneumonia	6/24/2020	8/26/2020
Advisory on taxi occupancy levels to mitigate covid-19 risk	7/3/2020	8/26/2020
Decontamination – questions from national joint intelligence and operational structure (NATJOINTS)	7/6/2020	8/26/2020
Thermal screening for Covid-19	7/6/2020	8/26/2020
Updated advice on taxi occupancy levels to mitigate Covid-19 risk	7/9/2020	8/26/2020
Updated memo on interferon and artemisia use for treatment and research	7/10/2020	8/26/2020
Proposal to reduce isolation time from 14 to 8 days	7/10/2020	8/26/2020
Keeping schools safe and managing Covid-19 infections in schools	7/20/2020	8/26/2020
Enhancing uptake of prevention measures for Covid-19	7/20/2020	8/26/2020
Environmental cleaning and disinfection	7/20/2020	8/26/2020
Use of favipiravir in the management of Covid-19	7/22/2020	8/26/2020
Advisory on the NCCC questions on actions to curb the surge	7/22/2020	8/26/2020
Fitness industry reopening framework	7/23/2020	8/26/2020
Making air travel safe during Covid-19	7/27/2020	8/26/2020
Managing outbreaks in community facilities	8/7/2020	8/26/2020
Managing outbreaks in healthcare facilities	8/7/2020	8/26/2020
What should the proposed easing of restrictions be for alert level 2, and when should this be considered?	8/17/2020	8/26/2020
Guide for non-emergency surgery during the Covid-19 pandemic	8/28/2020	10/8/2020
Healthcare worker protection and support through strengthening infection prevention and control programmes	9/1/2020	12/3/2020
Minimum physical distancing to getting children back to school safely	9/3/2020	10/8/2020
SARS-COV-2 re-infection	9/7/2020	10/8/2020
Masks for children of school going age	9/10/2020	10/8/2020
Recommendations around easing restrictions	9/13/2020	10/8/2020
Parental access to hospitalised children	9/14/2020	10/8/2020
Transmission of SARS-COV-2	9/21/2020	10/8/2020
Re-opening of traditional initiation schools	9/21/2020	10/8/2020
Return to work for those with comorbidities and/or over the age of 60 years	9/21/2020	12/3/2020

Covid-19 in pregnant and lactating women	10/7/2020	12/3/2020
Coalface issues	10/9/2020	12/3/2020
Use of antigen tests at ports of entry	10/30/2020	12/3/2020
An epidemiological assessment of the likelihood of a second wave of Covid-19	11/5/2020	12/3/2020
National state of disaster extension	11/11/2020	12/3/2020
Therapeutic bronchoscopy for mucus removal in patients with Covid-19	11/12/2020	12/3/2020
Resurgence of SARS-COV-2 cases in the eastern cape	11/22/2020	12/3/2020
National ventilator project (NVP), (HFNC) and (CPAP) equipment use for Covid-19 disease and beyond the epidemic	12/2/2020	4/21/2021
Long-covid	12/2/2020	4/21/2021
Mask exemptions/use of vented masks	12/9/2020	4/21/2021
Recommendations on December period proposal	12/11/2020	4/21/2021
Covid-19 testing for aviation crew and personnel	12/14/2020	4/21/2021
Regulations from state of disaster for national health act	12/14/2020	4/21/2021
Screening process for land border crossings during the festive season	12/14/2020	4/21/2021
A framework for rational covid-19 allocation in South Africa	12/15/2020	1/25/2021
Return of all learners 2021	12/16/2020	4/21/2021
Re-invigorate implementation of the Covid-19 prevention response over the festive season	12/19/2020	4/21/2021
Mitigating the spread of SARS-COV-2, including the new coronavirus variant, and preserving	12/23/2020	4/21/2021
Screening process for land border crossings during the festive season	12/30/2020	4/21/2021
Regional and domestic airline travel risk reduction	12/30/2020	4/21/2021
COVID-19: vaccine strategy	1/3/2021	1/12/2021
Ivermectin for the treatment of Covid-19	1/7/2021	1/11/2021
Reopening of schools for the 2021 school year	1/12/2021	4/21/2021
Wrapping of corpses in plastic covering prior to burial	1/25/2021	4/21/2021
Infection prevention and control during Covid-19 vaccination	3/11/2021	4/21/2021
Updated advisory on Ivermectin	3/29/2021	6/10/2021
Preparing for a potential third wave	3/31/2021	4/21/2021
What additional measures should be put in place to mitigate the spread of SARS-COV-2 over the easter period?	4/3/2021	4/21/2021
Travel restrictions from selected countries	4/29/2021	7/23/2021
Travel restrictions from selected countries - update	5/7/2021	7/23/2021
Criteria/triggers for new Covid-19 restrictions	5/16/2021	7/23/2021
Independent electoral commission (IEC) request for inputs regarding scheduling of the municipal elections	5/17/2021	7/23/2021
Q&A: frequently asked questions of the Covid-19 vaccine rollout	6/22/2021	7/26/2021
Update: recommendations to intensify prevention measures and bolster health system capacity in the context of a resurgence of covid-19 infections "third wave"	6/10/2021	7/23/2021

Summary of update: recommendations to intensify prevention measures and bolster health system capacity in the context of a resurgence of Covid-19 infections "third wave"	6/26/2021	7/23/2021
Update: recommendations to intensify prevention measures and bolster health system capacity in the context of a resurgence of Covid-19 infections "third wave"	6/30/2021	7/23/2021
Facility readiness workstream recommendations for resurgences of the covid-19 pandemic	7/3/2021	7/23/2021
Extension of level 4 restrictions beyond 11 July 2021	7/9/2021	7/23/2021
Closure of schools	7/16/2021	8/5/2021
Extension of level 4 restrictions beyond 25 July 2021	7/22/2021	8/5/2021
Strategies to address Covid-19 vaccine hesitancy and promote acceptance in South Africa	4/12/2021	4/21/2021
Schools functioning at full capacity (daily attendance by all learners)	7/22/2021	8/5/2021
Participation of South Africa in the Covid-19 vaccines global access (COVAX) facility	9/17/2020	1/3/2021
Advisory framework for rational allocation of Covid-19 vaccine in South Africa	12/15/2020	1/3/2021
Interim advisory key considerations in the selection of Covid-19 vaccine(s)	12/15/2020	1/3/2021
Advisory Covid-19: vaccine strategy	12/15/2020	1/3/2021
Advisory delaying the administration of the second dose of Astra-Zeneca Covid-19 vaccine to healthcare workers.	1/26/2021	7/6/2021
Advisory offering vaccine to healthcare workers who have had previous Covid 19 infection	1/26/2021	7/26/2021
Advisory offering vaccine to individuals who have participated or may be participating in clinical trials of vaccines	1/26/2021	7/26/2021
Advisory impact of laboratory findings on variant 501.V2 indicating immune escape, on vaccine strategy.	1/26/2021	7/26/2021
Advisory on vaccine choices for South Africa -rolling review: 19 February 2021-	2/19/2021	7/26/2021
Advisory on concern following release of data on reduced neutralising antibody activity in sera from Pfizer vaccinees	2/28/2021	7/26/2021
Advisory on concern following release of data on reduced neutralising antibody activity in sera from Pfizer vaccinees (updated)	3/1/2021	7/26/2021
Advisory on concern following release of data on reduced neutralising antibody activity in sera from Pfizer vaccinees - 3 rd update -	3/2/2021	7/26/2021
Advisory difference between a phase 3b implementation study and a rollout of an authorised vaccine	3/10/2021	7/26/2021
Advisory phase 2 Covid-19 vaccination rollout	3/24/2021	7/6/2021
Advisory recommendations on Covid-19 vaccination in pregnancy	4/13/2021	7/26/2021

Advisory theoretical calculations to reach Covid-19 vaccine-induced herd immunity	4/19/2021	7/26/2021
Delay of second dose of Pfizer-BioNTech vaccine	4/22/2021	7/26/2021
Advisory feedback from the VMAC on Sputnik V, Gamaleya Institute	4/30/2021	7/26/2021
Second update of the advisory on recommendations on Covid-19 vaccination in pregnancy	6/11/2021	7/26/2021
Advisory implications of Delta Variant for vaccination strategy	6/28/2021	7/26/2021
Advisory developments around indications that Astra-Zeneca Covid 19 vaccine may be deficient in its protectivity against the 501y.V2 variant virus	2/7/2021	7/26/2021
Advisory recommendation for persons entering South Africa who have been vaccinated against Covid-19 outside the country	8/18/2021	11/24/2021
Extension of level 3 restrictions beyond 12 September 2021	9/6/2021	9/13/2021
Extension of level 2 restrictions beyond 26 September 2021	9/23/2021	10/6/2021
Mitigating the impact of Covid-19 during the municipal elections – update	9/23/2021	10/11/2021
Covid-19 screening requirements at borders and ports of entry (land, sea and air)	10/15/2021	12/20/2021
Response to the identification of a new variant (Omicron)	12/3/2021	1/21/2022
Quarantining and contact tracing	12/16/2021	2/7/2022
Covid-19 mitigation in institutions of learning	1/19/2022	2/7/2022
Reduction in isolation period for Covid-19 cases	12/16/2021	2/7/2022
Strategies to address Covid-19 vaccine hesitancy and promote acceptance in South Africa	12/1/2021	2/4/2022
Advisory on booster Johnson & Johnson vaccine for healthcare workers – v2	9/28/2021	11/3/2021
Advisory on booster Johnson & Johnson vaccine for healthcare workers	9/9/2021	11/3/2021
Ammendmant to advisory on booster Covid-19 Janssen vaccine (Covid-19 Janssen) for healthcare workers	10/22/2021	11/24/2021
Advisory recommendations for administering Covid-19 vaccines to people living with HIV	10/19/2021	11/24/2021
Strategies to address Covid-19 vaccine hesitancy and promote acceptance in South Africa	12/1/2021	2/4/2022
Advisory recommendations for vaccinating children 12-17 years old with Covid- 19 vaccines	9/30/2021	10/26/2021
Advisory on booster Johnson & Johnson vaccine for healthcare workers - 2 nd version -	9/28/2021	11/24/2021
Advisory on vaccination of immunocompromised individuals (other than HIV and associated infections) - version 2 -	9/16/2021	10/25/2021
Advisory on vaccination of immunocompromised individuals (other than HIV and associated infections)	9/2/2021	11/24/2021

Advisory mandatory Covid-19 vaccination in certain workspaces	8/27/2021	11/24/2021
Third update of the advisory on recommendations on Covid-19 vaccination in pregnancy	8/26/2021	11/24/2021

References:

1. MAC Advisories - COVID-19 - SA Corona Virus Online Portal. Retrieved 18 March 2022, from https://sacoronavirus.co.za/category/mac-advisories/
2. MAC Advisories - Vaccinations - SA Corona Virus Online Portal. Retrieved 18 March 2022, from https://sacoronavirus.co.za/category/mac-advisories-vaccinations/

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Media Statement

28 September 2020

As of today, the cumulative number of detected COVID-19 cases is **671 669** with 903 new cases identified since the last report.

Province	Total cases for 28 September 2020	Percentage total
Eastern Cape	88975	13,2
Free State	46349	6,9
Gauteng	219202	32,6
KwaZulu-Natal	118797	17,7
Limpopo	15309	2,3
Mpumalanga	27069	4,0
North West	29078	4,3
Northern Cape	16397	2,4
Western Cape	110493	16,5
Unknown	0	0,0
Total	**671669**	**100,0**

The cumulative number of tests conducted to date is **4 152 480** with 9 014 new tests conducted since the last report.

Sector	Total tested		New tested	
PRIVATE	2 352 986	57%	4 887	54%
PUBLIC	1 799 494	43%	4 127	46%
Total	4 152 480		9 014	

Total Deaths and Recoveries

Regrettably, we report **188** more COVID-19 related deaths: 3 from Eastern Cape 1 from KwaZulu-Natal, 2 from Gauteng, 4 from Western Cape and 178 from the Free State. This brings the total number of COVID-19 related deaths to **16 586.**

There has been a two week delay in the reporting of Free State deaths as the province collated data from the various districts and verified this against Home Affairs Data. This is part of efforts to improve the quality of data by aligning information from facilities with Home Affairs statistics. Data from postmortem swabs also had to be collated and verified. This is in line with the recommendations of the Medical Research Council. The data is now up to date.

We extend our condolences to the loved ones of the departed and thank the health-care workers that treated the deceased patients.

Our recoveries now stand at **604 478** which translates to a recovery rate of 90%

Province	Total Deaths	Total Recoveries	Active Cases
Eastern Cape	3113	84574	1288
Free State	1016	31641	13692
Gauteng	4205	195729	19268
KwaZulu-Natal	2627	109960	6210
Limpopo	386	14290	633
Mpumalanga	520	26024	525
North West	355	25870	2853
Northern Cape	197	13225	2975
Western Cape	4167	103165	3161
National	**16586**	**604478**	**50605**

Statement on Ministerial Advisory Committees (MAC's) in Health

We have now confirmed, both with the NICD and World Health Organisation Surge Team reports, that we are now past the surge and that our epidiomelogical curve has demonstrated a plateau for several weeks. Therefore, based on the conduct of the South African pandemic, we have re-evaluated our national response and identified new challenges that require new approaches. To quote from a publication in the highly respected medical journal *The Lancet*, author Richard Horton observes that *"The 'science' that has guided governments has been driven mostly by epidemic modelers and infectious disease specialists… but what we learnt so far tells us that the story of COVID-19 is not so simple… The [syndemic] nature of the threat we face means that a more nuanced approach is needed if we are to protect the health of our communities."* (Horton, *The Lancet* Vol 396 September 26 2020). Indeed these sentiments do align with with our own observations, as such we have now reevaluated the progress of the pandemic and the work of the MAC on COVID-19 and resolved that this MAC requires strengthening to ensure that it is able to address gaps and target new challenges.

We therefore wish to clarify that the MAC on COVID-19 is not disbanded- the Minister has merely strengthened the entity in line with developments of South Africa's COVID-19 pandemic.

The MAC on COVID-19 was established on 30 March 2020 with the best intentions: consisting of pathologists; laboratory practitioners; clinicians; public health practitioners and researchers.

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

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

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

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

The Minister has seen this as an opportunity to diversify the skills set in order to ensure that government is now advised on issues that not only relate to medical science but also social sciences, behaviour and psyche of the population. The MAC on COVID-19 will internally establish Technical Working Groups (TWGs) and workstreams. The scope and composition of the workstreams will be determined by the MAC members and revised based on the need for the revised scope. Additionally, the workstreams will co-opt Resource Individuals (RIs) who are not government officials but are skilled in specific disciplines. The RIs may be called upon to assist in the MAC's sub-committees and TWGs. It will be through this mechanism that entities such as the National Institute of Communicable Diseases (NICD), Medical Research Council (MRC) and National Health Laboratory Services (NHLS) will continue to interact with the MAC on COVID-19. It should be noted that such entities continue to input directly into departmental policies and annual performance plans on day to day basis working with the Director Generals.

It is important that we remain relevant as we endeavour to bring on board and educate communities on averting the risk of a second wave. This requires experts who are well versed in human behaviour. Containment measures in work and social spa-

ces has now become the key focus under the new normal. The Minister therefore requires experts who are specialized in those areas in order to advise government on the continued response.

The notion that the Minister "disbanded" the MAC because he does not want to heed its advice is furthest from the truth. The fact is that the Minister accepted and implemented almost all (more than 95%) of the advisories from the MAC on COVID-19 and, in the interest of transparency, published the advisories digitally despite there being no legal obligation to do so. Where there was divergence from the advisory, this was due to the Minister and government having to consider factors and/ or inputs from other stakeholders. Those who persist that government has not heeded the advices from the MAC on COVID-19 are dishonest and intent on misleading he public.

It is also concerning that there appears to be an expectation from some for the Minister to consult individuals when he terminates their participation. The National Health Act, 2003 provides a legislative mandate for the Minister of Health to establish Advisory and Technical Committees. The Minister is empowered to determine the composition, functions and working procedure of the Advisory and Technical Committees. Therefore, the Minister is well within his rights to exercise his discretion to reduce, increase, reconfigure, augment or even disband a MAC. He also has a responsibility to ensure that the structures that he forms remain relevant and responsive.

In his letter to MAC members, the Minister has expressed gratitude for their contribution. In Minister's view, the MAC has done an outstanding job and he believes that the newly appointed members will also add value to this great work.

During the course of the pandemic, three distinct Ministerial Advisory Committees (MACs) have been established to guide government's response to the COVID-19 pandemic : The MAC on COVID-19, the MAC for Coronavirus Vaccine and the Multisectoral MAC for Social Behavioral Change, co-chaired by the Minister of Health and the Minister of Social Development.

The MAC SBC was launched on Youth Day, June 16 2020 and its members announced on the same day. The MAC SBC focuses entirely on social mobilization and contracting not only to combat COVID-19 but also on devising a comprehensive response to the socio-economic sequelae of the pandemic. The MAC SBC is using lessons from the campaign on HIV and AIDS in which the importance of stakeholder mobilization was critical for behavioral change.

The MAC on Coronavirus Vaccine (MAC-Vacc) was announced in the 14 September Statement and the names of those members were published. This MAC focuses exclusively on the developments of the COVID-19 vaccine and ensuring we are well positioned to access adequate amounts of doses when the technology becomes available.

On behalf of the nation, Government thanks all members who have and continue to serve on all the Ministerial Advisory Committees- the captains who have steered us through the COVID storm and kept us afloat. We believe that the MACs as they stand now more accurately reflect the needs of this country's health and economic response as we look to rebuild our lives after the wreckage of the storm. These experts are fellow South Africans who stand ready to give of their expertise, commitment, and passion; turning ideas into action and innovation. For this we are truly grateful and also wish to reassure the members of our support as Ministers and as Government.

Attached is a list of all MAC Members in Ministerial Advisory Committees advising on COVID-19 (Annexure A, B, C). We also attach a list of all Ministerial Advisory Committees in the Department of Health (Annexure D)

Annexure A: Ministerial Advisory Committee on COVID-19

Infectious Disease Epidemiologist	Prof Salim Abdool Karim (Co-chair)
Public Health Medicine	Prof Marian Jacobs (Co-Chair)
Behavioural Scientist	Prof Nhlanhla Mkhize (Vice-Chair)
Virologist	Prof Barry Schoub (Vice-Chair)
Critical Care Nursing	Prof Portia Jordan (Vice-Chair)
Infectious Diseases Specialist	Prof Marc Mendelson
	Prof Nombulelo Magula
	Prof Jeremy Nel
Critical Care Specialist	Prof Rudo Mathivha
	Dr Dean Gopolan
Paediatrician	Prof Sithembiso Velaphi
Infection Control Specialist	Prof Shaheen Mehtar
Health Systems Specialist	Prof Ian Sanne
Health Promotion	Prof Matildah Mokgatle
Mathematical modeler	Dr Juliet Pulliam
Health financing specialist	Prof Jacqui Miot
Diagnostic, therapeutic and vaccine regulatory expertise	Prof Helen Rees
Psychologist (Behavioural psychology)	Dr Heidi van Rooyen
Nursing (Infectious diseases)	Ms Dikeledi Tsukudu
Ethicist	Prof Doug Wassenaar
Occupational health specialist	Dr Thuthula Balfour

Annexure B: Ministerial Advisory Committee on Coronavirus Vaccines

Chair: Professor Barry Schoub

Members:

- Dr Morena Makhoana, CEO Biovac
- Ms Glaudina Loots, Department of Science and Technology
- Dr. Boitumelo Semete-Makokotlela, CEO South African Health Products Authority
- Prof. Greg Hussey, Vaccines for Africa (UCT)
- Prof. Jeff Mphahlele, MRC, Immunologist and SAHPRA Board Member
- Prof. Helen Rees, WHO Expert Advisor
- Prof Ames Dhai, Ethicist
- Dr Mark Blecher, National Treasury

As observers in this MAC are:

- Prof. Salim Abdool Karim, Chair MAC on COVID-19
- Bishop Malusi Mpumlwana, Chair MAC Social and Behavioral Change

Annexure C: Multisectoral Ministerial Advisory Committee on Social and Behavioral Change

Name	Organisation
Ms Steve Letsike	South African National AIDS Council (SANAC)
Mr Thulani Tshefuta	NEDLAC
Dr Lydia Cairncross	People's Health Movement of SA
Mr Mluleki Zazini	NAPWA National Association of People Living with HIV and AIDS
Ms Lauren Pretorius	Health Users Sector Network Member
Mr Lucas Qhakaza	National Working Committee for the South African National Civic Organisation (SANCO)
Mr Lawrence Bale	South African National Apex Cooperative (SANACO)
Mr Dan Kekane	Disabled People South Africa (DPSA)
Mr Tebello Radebe	National Coordinator Financial Sector Campaign Coalition (NPC)
Mr Solly Nduku	National Unitary Professionals for African Tradition Health Practioners of SA
Ms Phephisile Maseko	Traditional Healers Organisation
Ms Ingrid Cupido	Age-in-Action Organisation
Ms Sasha Stevenson	Section27
Rev Bafana Khumalo	Sonke Gender Justice
Ms Jannie Oosthuizen	Public Servants Association of South Africa (PSA)
Ms Susan Ntlatleng	HOSPERSA
Mr Khaya Xaba	National Education, Health and Allied Workers' Union (NEHAWU)
Mr Cassim Lekhoathi	DENOSA
Mr Inkosi Sipho Etwell Mahlangu	National House of Traditional Leaders (NHTL)
Mr Zolani Mkiva	CONTRALESA
Pastor Ray McCauley	Rhema Family Church
Elder Ephraim Msane	The Church of Jesus Christ of Latter-Day Saints
Chief Rabbi Warren Goldstein	Jewish
Moulana Ebrahim Bham	Muslim
Pundit Ashwin Trikamjee	Hindu

Bishop Malusi Mpumlwana (Chair)	Mpumlwana Melusi Church
Apostle Collins Dhlomo	Alliance of Pentecostal and Charismatic Churches of SA
Bishop Mosa Sono	Grace Bible Church
Ms Mary Kluk	SA Jewish Board of Deputies
Ms Yamkela Makupula	Diaz Rues Africa
Ms Sulosh Pillay	Daughters of Africa
Mr Joseph Mbereni Maada	Mudzi Religious Organization
Mr Buti Joseph Tlhagale	SA Catholic Bishops
Ms Lisa Vetten	Activist - Violence against Women
Dr Nokuzola Ndende	Icamacu Institute
Mr Jacob Skosana	Older Persons Forum Chairperson
Mr Bernard Molokoane	ZCC (Engenas)
Mr Piet Lekganyane	ZCC
Ms Avhasei Mulovhedzi	SA Interfaith Council
Mr Abdul Khaliq Allie	Moslem judicial Council
Mr Vilal Vaid	Council of Muslim Theologians

Annexure D: MINISTERIAL ADVISORY OR TECHNICAL COMMITTEES

Committee Name
Advisory Committee on E-Health
Advisory Committee On The Prevention And Control of Cancer
National Advisory Group on Immunisation (NAGI)
National Committee on Confidential Enquiries into Maternal Deaths (NCCEMD).
Advisory Committee on organ Transplant
National Health Research Committee
National Essential Medicine List Committee
Ministerial Advisory Committee on Antimicrobial Resistance
Committe on Morbidity and Mortality in Children (CoMMiC)
Ministerial Advisory Committee on NHI- Legislative Processes
Ministerial Advisory Committee on NHI- Policy and Implementation
National Immunisation Safety Expert Committee
1. National Certification Committee
2. National Polio Expert Committee
3.National Authority on Containment
4. National Task Force on Poliovirus Containment
Expert Review Committees of NEMLC
The final one is the Ministerial Advisory Committee on Youth and Adolescent Health
National Forensic Pathology Services Committee (currently expired.)
Ministerial Task Team on Nursing
Ministerial Task Team for Human Resources for Health
Advisory Committee on Mental Health
Occupational Health and Safety Committee
National Perinatal Mortality Committee
Adolescent and Youth Advisory Panel
National Environmental Health Committee

The following MACs were gazetted (gazette details indicated) but not established:

Committee Name
Advisory Committee on Health Technology Assessment on NHI No. 40969 N.R 625 of 7 July 2017
Advisory Committee on Health Benefits for NHI No. 20969 of 7 July 2018
National Health Pricing Advisory Committee on NHI No. 20969 of 7 July 2018
National Advisory Committee on Consolidation of Financing Arrangements No. 20969 of 7 July 2018

Dr Zwelini Mkhize

Minister of Health

ENDS

81

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Update on Covid-19 (14th September 2020)

Sep 14th, 2020 | Press Releases and Notices

Media Statement
14 September 2020

As of today, the cumulative number of detected COVID-19 cases is 650 749 with 956 new cases identified.

Province	Total cases for 14 September 2020	Percentage total
Eastern Cape	87456	13,4
Free State	42120	6,5

Limpopo	14216	2,2
Mpumalanga	25825	4,0
North West	27262	4,2
Northern Cape	13564	2,1
Western Cape	108486	16,7
Unknown	0	0,0
Total	650749	100,0

The cumulative number of tests conducted to date is 3 928 614 with 10 136 new tests conducted since the last report.

Sector	Total tested		New tested	
PRIVATE	2 228 647	57%	6 615	65%
PUBLIC	1 699 967	43%	3 521	35%
Total	3 928 614		10 136	

Total Deaths and Recoveries

Regrettably, we report 52 more COVID-19 related deaths: 2 from KwaZulu-Natal, 3 from Gauteng, 4 from Eastern Cape, 7 from Western Cape, 15 from North West and 21 from the Free State.

This brings the total number of COVID-19 related deaths to 15 499.

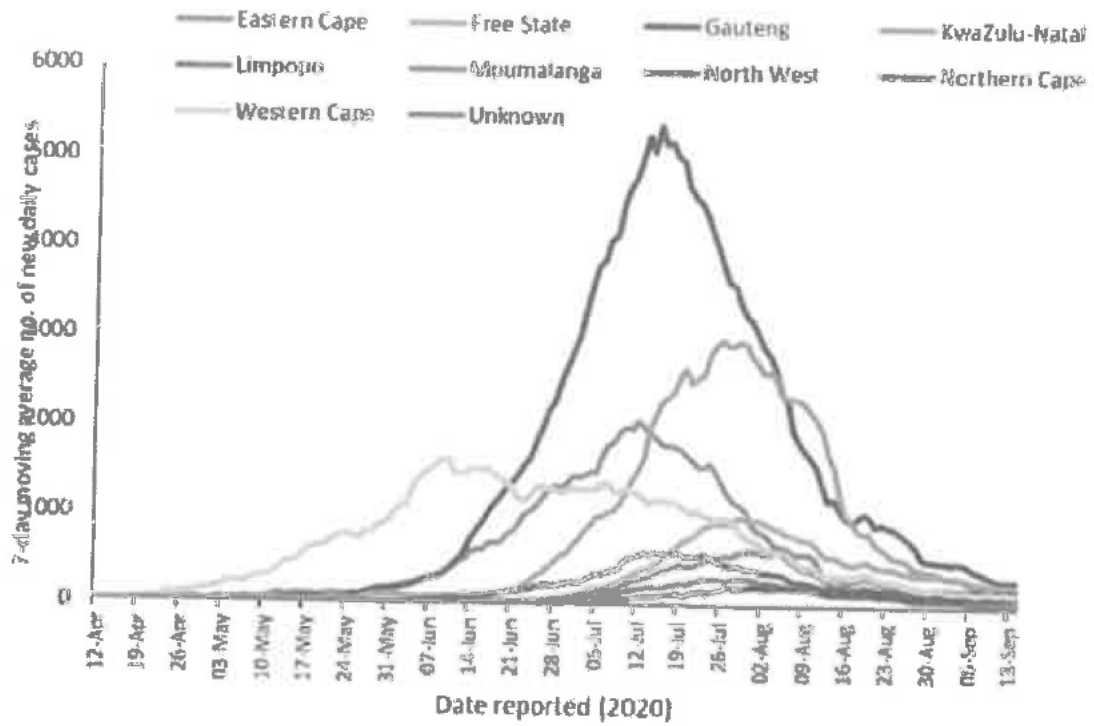
We extend our condolences to the loved ones of the departed and thank the health care workers that treated the deceased patients.

Our recoveries now stand at 579 289 which translates to a recovery rate of 88,9%

Province	Total Deaths	Total Recoveries	Active Cases
Eastern Cape	3051	82842	1563
Free State	838	27678	13604
Gauteng	3921	191198	20188
KwaZulu-Natal	2409	106540	7564

Northern Cape	165	10256	3143
Western Cape	4066	100779	3641
National	15499	579289	55961

Status of the South African COVID-19 pandemic- trends



Graph: 7 day moving average number of weekly cases

The number of detected cases countrywide continues to decline- since the 22nd of August we have reported under 3000 cases a day- at the height of the epidemic during the month of July we would report anything between 10 000 and 15 000 cases a day.

Supporting this decline is also a demonstrable decline in persons under investigation,

trough in the pandemic.

NICD analysis- Case Management

The NICD COVID Surveillance in Selected Hospitals Report of 11 September 2020 outlines analyses of data collected from 459 public and private facilities across the country.

This report shows a clear shift in the behaviour of the epidemic with downward trends in general ward and ICU admissions and deaths. In total 66 515 patients were studied with 4 314 currently admitted.

The discharge rate from hospital was 75% while the in-hospital case fatality ratio was 17,5%. The median age for admissions was between 50 and 59 and the median age for deaths was between 60 and 69.

At the height of the epidemic, these sample hospitals were reporting between 6400 and 6 800 admissions per week.

WHO analysis

South Africa has benefited significantly from the contributions of the World Health Organisation surge team that has come to reinforce our team in responding to the COVID-19 pandemic.

The WHO surge team has released a situational report on 10 September 2020 reflective of the 37th week of our epidemic, which confirms the decline as reported by NICD. This report showed a 42% decline of detected cases in the preceding two weeks and a 28,9% decline in deaths in the same period.

Admission to critical care wards increased by 13,9 percent during this epidemic week but conversely admissions into general wards decreased by 43% in the same period.

The median test positivity rate was recorded at 9,8% compared to 11,4% in the previous week.

Bed occupancy and oxygen demand is also declining.

The percentage of beds currently occupied by COVID-19 patients nationally is under 10% for non ICU beds and under 30% for ICU beds.

The benefit that we have seen during this period is that there has been an increased acquisition of ventilators with 5 444 procured or received through donations and 2 848 currently awaiting delivery.

This has assisted us to improve our facilities as ventilators were in shorty supply and there would have been a delay in providing the required health care to patients who needed it the most. It also drove us in the direction of increasing local manufacturing capacity, which resulted in South Africa manufacturing ventilators for the first time in history.

20 000 ventilators are expected to be produced through the National Ventilator Project.

We also have reports from Afrox indicating that oxygen demand has decreased nationally in the past few weeks.

Restrictions Under Review

In previous statements relating to restrictions under the National State of Disaster, we committed to reviewing these periodically as we reassess the state of the South African epidemic and this is indeed what we have done.

Having observed evidence that suggests a sustained decline in Coronavirus transmission, as the Department of Health we have considered easing restrictions in various aspects- such as the curfew, sale of alcohol, religious gatherings, and travel restrictions- for the National Coronavirus Command Council, which will make final recommendations to Cabinet.

Whatever decisions are made, it is important to emphasize that the risk of spreading and contracting COVID-19 still remains and that non-pharmaceutical interventions remain important as we learn to co-exist with the Coronavirus.

The protection of frontline workers in the health sector remains of paramount importance.

We re-iterate: no PPE no work!

We continue to track the numbers of health workers who are infected in each province. Our system now has direct linkage with the persal system so that any health worker who is diagnosed with COVID-19 is immediately identified.

As of 11 September, a cumulative total of 32 429 health care workers had been detected with Coronavirus. Sadly, 257 succumbed to COVID-19. We convey our condolences to all the loved ones of the deceased and thank the colleagues who took care of our heroes in their final hours.

PERSAL Organisation	HCW COVID19 Infected	HCW ever admitted in reporting Hospital	Total Died In Hospital	Total Discharged alive	Total Transfer to other facility
Eastern Cape Health	8 454	510	65	424	4
Free State Health	2 187	203	23	158	3
Gauteng Health	8 148	577	37	502	3
KwaZulu-Natal Health	6 062	756	69	641	2
Limpopo Health	1 096	86	7	71	
Mpumalanga Health	1 396	136	14	111	1
National Department of Health	73	6		6	
North West Health	1 602	167	10	147	5
Northern Cape Health	878	59	9	43	
Western Cape Health	2 533	246	22	212	2
Total	32 429	2 746	257	2 315	20

We are pleased that Occupational Health and Safety Committees (OHS) are now established in 3 849 public health facilities. As per the previous directive, members of Unions must be represented in all these structures. This will assist in constant monitoring of issues affecting health workers including where there is shortage of PPE.

87

We note with concern the findings of the Auditor General which include that there were deficiencies and non-compliance with PPE procurement processes, the insufficient controls to ensure receipt and payments of PPE and the level of quality of PPE, delays in the delivery of PPE as well as evidence of price gauging and failure to procure PPE at market related prices.

This cannot be accepted.

This must be condemned and, once all the investigations have been concluded, there must be consequence management for any officials that may be implicated in wrongdoing and/ or irregularity

Ministerial Advisory Committees (MAC's)

With the changing pattern of the pandemic, it has become necessary to reconfigure the Ministerial Advisory Committee on COVID-19.

The new MAC will take into account the need for the inclusion of social and behavioural scientists amongst other factors.

In addition to the Multi-sectoral MAC focussing on community mobilization, another MAC has been created to focus on Coronavirus vaccine development (MAC on Vaccine).

This MAC will advise us on all matters pertaining to the Coronavirus vaccine development and rollout- from monitoring and reporting on progress on our candidate studies, to advising on our purchasing options and our capacity to potentially manufacture vaccines in future.

This will ensure that the Department of Health and government are kept abreast on all critical developments internationally relating to the vaccine.

The Committee is chaired by Professor Barry Schoub, an expert in vaccinology and virology.

– Dr Morena Makhoana, CEO Biovac
– Ms Glaudina Loots, Department of Science and Technology
– Dr. Boitumelo Semete-Makokotlela, CEO South African Health Products Authority
– Prof. Greg Hussey, Vaccines for Africa (UCT)
– Prof. Jeff Mphahlele, MRC, Immunologist and SAHPRA Board Member
– Prof. Helen Rees, WHO Expert Advisor
– Prof Ames Dhai, Ethicist
– Dr Mark Blecher, National Treasury

As observers in this MAC are:
– Prof. Salim Abdool Karim, Chair MAC on COVID-19
– Bishop Malusi Mpumlwana, Chair MAC Social and Behavioral Change

National Seroprevalence

South Africa has seen the surge receding and thus raises the question of the level of immunity that may already be existing in society.

Initial seroprevalence studies from convenience samples have shown seroprevalence of between 29 and 40 percent. Interestingly, the revised models currently predict that there are probably about 12 million South African in total (detected and undetected) infected with Coronavirus- this translates to about 20% of the population. We are currently embarking on a national seroprevalence study which should take us closer to the actual seroprevalence of Coronavirus antibodies and will give us a more accurate indication of our status of national immunity.

Once the national study has been concluded we will communicate those results to the public

Stay Safe

Undeniably, an important contributor to the decline we are witnessing in the transmission of Coronavirus are the actions of ordinary South Africans who continue to adhere to non-pharmaceutical interventions.

continue to concentrate on the simple things that keep Coronavirus at bay- washing or sanitizing hands at every opportunity, maintaining a safe distance between each other, regular cleaning and sanitization of surfaces we come into contact with and wearing of masks whenever we are in public spaces.

The threat of a resurgence that could be more devastating than the first wave of infections remains very real. We must always remember this.

Most importantly we must encourage and remind one another that these simple interventions remain an important part of our new lives.

90

3 928 614	650 749	579 289	15 499	956
TESTS CONDUCTED	POSITIVE CASES IDENTIFIED	TOTAL RECOVERIES	TOTAL DEATHS	NEW CASES

MONDAY 14 SEPTEMBER 2020



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Enquiries: Prof B Schoub
E-mail: barry.schoub@gmail.com

INTERNAL MEMO

Date:	15 December 2020		
To:	**Minister ZL Mkhize, Honourable Minister of Health**	From:	**Prof B Schoub: Chair of the Ministerial Advisory Committee (MAC) on COVID-19 Vaccines**

ADVISORY
FRAMEWORK FOR RATIONAL ALLOCATION OF COVID-19 VACCINE IN SOUTH AFRICA

Problem Statement

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

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

Rationale

Vaccine allocation will thus have to be based on a framework of prioritisation and need. The principles underpinning this Framework emphasises an evidence based approach and an ethical and moral perspective, including an African indigenous values context.

The Framework will serve as a guide and will have to be adapted as new scientific information becomes available e.g.:

- information about specific characteristics of available vaccine/s,
- the benefit-risk assessment for different population sub-groups,
- the amount and pace of vaccine supply,
- the epidemiology at the time of vaccine introduction,
- clinical management,
- public health response, and
- economic and social impact of the pandemic.

Recommendation

The Ministerial Advisory Committee on Vaccines recommends to the honourable Minister of Health the adoption of the Framework for the Rational Allocation of Covid-19 Vaccines in South Africa.

Thank you for consideration of this request.

Kind regards,

PROFESSOR BARRY SCHOUB
CHAIRPERSON: MINISTERIAL ADVISORY COMMITTEE ON COVID-19 VACCINES
DATE: 15 December 2020

CC:

- **Dr S Buthelezi (Director-General)**
- **Dr T Pillay (Deputy Director-General: Health Regulations and Compliance Management)**

ANNEXARE A **"HJI10"**

A FRAMEWORK FOR RATIONAL COVID-19 VACCINE ALLOCATION IN SOUTH AFRICA

15 DECEMBER 2020

Introduction

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

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

The framework will serve as a guide and will have to be adapted as new scientific information becomes available e.g. information about specific characteristics of available vaccine/s, the benefit-risk assessment for different population sub-groups, the amount and pace of vaccine supply, the epidemiology at the time of vaccine introduction, clinical management, public health response, and economic and social impact of the pandemic.

African Indigenous Values and Voices in the Context of COVID-19 Vaccines

It is critical that African voices add not only to the debate but also to influencing the implementation of immunization equity. In particular, the vulnerable and disadvantaged in remote and rural areas and urban slums should not be left behind. Therefore, it is important to consider African indigenous values and draw from the principles of Ubuntu.

The importance of community is clearly indicated by Mbiti when he states "I am because we are, we are therefore i am." (Mbiti J. Introduction to African religion and philosophy. Oxford/Portsmouth: Heinemann Educational Books. 1991.) In terms of the Nguni and Sotho/Tswana sayings, *umuntu ngumuntu ngabantu* and *motho ke motho ka batho*, a human being is a human being because of other human beings. Hence, one cannot function in isolation and independently participate in a community of other people. Inter-dependence and inter-relatedness is at the heart of these values. In the context of access to COVID-19 vaccines and also addressing vaccine hesitancy, this could translate to decision-making towards the greater good for all while protecting vulnerable individuals and groups from exploitation and other forms of harms and wrongs.

Ubuntu leads to an appreciation of the survival of the community as an important ethical consideration. Therefore, the Ubuntu standard, which reflects living in solidarity with other people and humanness that is grounded in social life, comprises the fundamental basis of an African approach towards ethics. This has particular bearing *inter alia* in the vaccines discussion and decision-making.

Mutually respectful discussion and dialogue in the community as seen with the indigenous African tradition of *lekgotla* could be likened to meaningful community engagement in vaccines discussions. Members of the community are to be given a chance to voice their opinion towards reaching a consensus and the decisions generated from the process would be socially and communally negotiated.

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Framework for prioritization of fair allocation of COVID-19 vaccines

1. **Fair Allocation guided by African indigenous values**

a. Affirming the humanity of others: Allocation decisions must be for societal benefit and promote common good while respecting human dignity. Every person has equal dignity, worth, and value, hence allocation decisions must be non-discriminatory. Characteristics such as ethnicity, nationality, gender, sexual orientation, race and religion are not to play a role in allocation decisions. People are to be treated fairly and equally. Allocation decisions are to be impartial and in accordance with fair criteria.

b. Survival of the community: Allocation decisions are to be based on the best available evidence. In addition, essential service workers and those that contribute towards preventing and treating disease could be considered as essential for survival of the communities. Furthermore, those at greatest risk of severe illness and death could be included in priority groups. In this way, benefits will be maximized and the risks of severe morbidity and mortality caused by transmission due to SARS-CoV-2 reduced, and hence the community will survive.

c. Social Solidarity: Allocation decisions are to take into consideration the bonds unifying communities, interdependence, attachment to or interest in others and their concerns and the significant social, economic and personal disruptions and hardships experienced. During pandemics inequities may increase among those who are already socially vulnerable and/or new vulnerabilities may emerge for the first time among certain communities or individuals

d. Meaningful community engagement: Allocation decisions must be trusted and leaders at all levels must be at the forefront of communication to their constituencies. Community engagement allows for authenticity, trust, and ownership of the allocation decisions. Community involvement will be required for both allocation decision-making and addressing vaccine hesitancy. Faced with the challenge of maintaining public trust while simultaneously stemming the pandemic through various control measures, decision-makers need to be trustworthy by ensuring early engagement with stakeholders and that decision-making processes are ethical, transparent and actively communicated. For this, integrity, which reflects the need to act with honesty, reliability, and fairness, and a willingness to be held accountable to explain one's actions, is critical.

The framework proposed for SA is also in accordance with the principles articulated by the WHO SAGE (https://apps.who.int/iris/bitstream/handle/10665/334299/WHO-2019-nCoV-SAGE_Framework-Allocation_and_prioritization-2020.1-eng.pdf?ua=1)

- Protect and promote human well-being including health, social and economic security, human rights and civil liberties, and child development.
- Recognize and treat all human beings as having equal moral status and their interests as deserving of equal moral consideration
- Ensure equity in vaccine access and benefit within countries for groups experiencing greater burdens from the COVID-19 pandemic
- Honour obligations of reciprocity to those individuals and groups within the country who bear substantial additional risks and burdens of COVID-19 response for the benefit of society
- Make decisions about vaccine allocation and national decisions about vaccine prioritization through transparent processes that are based on shared values, best available scientific evidence, and appropriate representation and input by affected parties

2. Identification of risk groups

The allocation of vaccines to recipients will be guided by the principles outlined above and will be dependent on several factors including the efficacy of a vaccine for a specific population and on the doses available. It is unlikely that vaccines will be available to all who require them, and some sort of prioritization system will have to be applied.

Based on the principles of affirming the humanity of others, survival of the community and social solidarity and through meaningful community engagement, prioritization should be to those:

(a) in roles considered to be essential for societal functioning;
(b) most at risk of infection and serious outcomes, for example, those in overcrowded living arrangements, multigenerational homes, with comorbid conditions; and
(c) most at risk of transmitting SARS-CoV-2 to others.

Individuals in the roles considered to be essential for societal functioning include those whose absence from their societal roles or work puts others and the society at risk of loss of needed goods and services should they become infected (e.g., doctors, nurses, other health care providers, first responders, workers employed in the food supply system, transportation workers, teachers, etc.).
Those most at risk of serious outcomes and most at risk of transmitting the virus would not only benefit for themselves, but if vaccinated – would prevent the health system and other essential services from becoming overwhelmed.

A phased approach is therefore recommended when limited supplies of vaccines become available. Prioritization of groups and individual groups will be developed.

- *Health Care workers*
  Health professionals and general health workers at high risk of infection, care home workers and traditional healers

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

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

- *Essential workers*
  This group includes police officers, miners and workers in the security, retail food, funeral, banking and essential municipal and home affairs, border control and port health services.

Note that the safety and efficacy of vaccines in children and pregnant women are not known and will probably be the subject of future trials and thus the framework will be revised if necessary.

The only published peer reviewed data are from the Western Cape Province (Boulle et al; Cinical Infectious diseases 2020) <https://academic.oup.com/cid/advance-article/doi/10.1093/cid/ciaa1198/5899044>
In this population cohort of 3.5 million public sector patients in South Africa, increased COVID-19 mortality (n=625) was associated with HIV, previous and current tuberculosis as well as older age, male

sex, diabetes, hypertension and chronic kidney disease. Such data as well as other data from South Africa will be used to determine the priority groups for the country. The details of this step will be provided later with the list of groups in order of priority pending the availability of vaccine doses e.g. 3, 10 or 20% of the total SA population and at varying levels of vaccine acceptance and vaccine efficacy. In addition, the stage of the epidemic will also influence how vaccines will be prioritized e.g ongoing national community transmission, sporadic cases or clusters of cases, no cases. A draft of such a proposal for allocation is appended below.

3. Programmatic implications

Standard operating procedures are currently being developed to ensure that the vaccine rollout programme is effectively managed and implemented. These include:

a. **Development of vaccine guidelines**: This needs to be completed for each vaccine and provide guidance around eligibility, application, dosage and storage.
b. **Vaccine supply management:** This includes the ordering and distribution of and the safe storage and handling of vaccines to maintain potency.
c. **Heath care worker training**: Staff will be trained on how to counsel recipients on the benefits and risks of the vaccines and delivery of the vaccines.
d. **Adverse events following immunization surveillance:** This is a standard component of the current national Expanded programme on Immunization (EPI) and is being adapted for COVID-19 vaccine rollout as well. In addition, SAHPRA might specify certain pharmacovigilance requirements for specific vaccines.
e. **Monitoring and evaluation (M&E)**: The EPI M&E tools currently in use is being adapted for the COVID-19 vaccine rollout. This should include registration and tracing mechanisms, especially in the event of the requirement for more than one dose per person.
f. **Development of vaccination certification tools:** This should be aligned to International Health Regulations (2005) if there are any requirements. These can be paper-based or electronic.
g. **Development of a strategy to reach identified target groups:** As the target groups vary in terms of where they are located strategies on how to reach them needs to be identified.

4. Communication and social mobilisation

There is an urgent need to put in place a multi-sectoral communications strategy to support the work of government and civil society to ensure that the investment made into COVID-19 related scientific research including vaccine research and the eventual rollout is not jeopardized but protected through the provision of scientifically sound, evidence-based communications and a critical mass of community support.

The development of a Covid-19 vaccine communication strategy should be a joint effort created by government agencies and civil society and will ensure that all stakeholders have clear guidelines within which to communicate scientifically sound, evidence-based messages to the public. The strategy should take into account global research, whilst articulating where appropriate the need for South African research to explore the national context.

The issues around science denialism, anti-vax sentiments and vaccine hesitancy in South Africa should be addressed through an understanding of the main drivers of the hesitancy and the development of effective local responses.

The COVID-19 vaccine communication strategy should be informed by the communication strategies developed for other South African Health programmes (HIV, TB, Diabetes, etc), but it is of importance that the impact of the COVID-19 pandemic on the national psyche should also be taken into account. Engagement with representatives of community and professional groups affected by the COVID pandemic will be essential.

The communication strategy should include the use of online social media platforms (WhatsApp, Facebook, Twitter, etc), as well as traditional media (print, community, radio etc.) as critical platforms for engagements, and should take into account the needs of different target audiences.

Draft proposal for the distribution of vaccines to priority groups given a 3, 10 or 20% vaccine allocation based on population of 60m with a 60 or 70% vaccine coverage / acceptance rate per group.

Priority group	Number	70% accept vaccination Option A	60% accept vaccination Option B	Proportion in groups that will be covered with available doses. Option A refers to 70% vaccine acceptance and Option B refers to 60% vaccine acceptance rate						
		N	N	3% - 1.8m Option A	3% - 1.8m Option B	10% - 6m(a) Option A	10% - 6m(b) Option B	10% - 6m (a) Option A	10% - 6m (b) Option B	20% - 12m Option A or B
Health workers	1 250 000	870 000	750 000	100%	100%					
Essential workers	2 500 000	1 750 000	1 500 000	57 %	70%					
Persons in congregate settings	1 100 000	770 000	660 000							
Subtotal	*4 850 000*	*3 395 000*	*2 910 000*			100%	100%	100%	100%	
At risk population										
60 yrs and older	5 000 000	3 500 000	3 000 000			75%	100%			
Co-morbidity*	8 000 000	5 600 000	4 800 000							
Sub total	*13 000 000*	*9 100 0000*	*7 800 000*					29%	40%	
Total	17 850 000	12 495 000	10 710 000							100%**

*Co-morbidity numbers are estimate given that many in the other groups (especially the over 60 year olds) will also have co-morbidities.

** The 20% vaccine allocation option here will allow for an additional 1.3m persons to be vaccinated if vaccine coverage is only 60%

Purchase agreements

53 The Vaccine Strategy envisaged two ways in which South Africa could obtain vaccines after they passed phase 3 clinical trials and certified as safe to use on people. These were:

53.1 through the Covax facility; and

53.2 by concluding purchasing agreements with individual vaccine producers.

54 A third additional method is acquisition through arrangements with the African Union.

55 As I explain in what follows, the NDoH has adopted and implemented both of these strategies.

Regulatory approvals

56 In terms of the Medicines Act, a vaccine can only be used in South Africa once it has been approved by SAHPRA.

57 In order to ensure that those vaccines that have passed phase 3 of the clinical trial are safely and timeously approved, the Vaccine Strategy proposed that several measures be in place. These measures include:

57.1 an early engagement with the SAHPRA;

57.2 putting in place accelerated procedure for authorisation;

57.3 adopting flexibility in relation to labelling and packaging requirements.

58 All three of these measures are being implemented in respect of vaccines as necessary in order to allow a timeous roll-out once available.

Immunisation, administration and monitoring

59 The Vaccine Strategy deals with the reality that there would not be sufficient vaccines immediately in South Africa and the rest of the world for everyone who requires one.

60 On the advice of the VMAC, contained in its second advisory, the Vaccine Strategy recommended that specific high-risk groups be identified to receive the vaccine before the third quarter of 2021. In identifying the high-risk groups, the Vaccine Strategy relies on a framework of prioritisation and need.

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

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

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

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

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

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

Selection criteria for vaccines

63 The Vaccine Strategy made clear that, in order to select the best vaccines for South Africa, it was imperative that selection criteria be developed which should take into account the following aspects:

63.1 Evidence of quality, safety, and efficacy in different groups generated from clinical trials.

63.2 Review of vaccine technology and potential risks associated with different technologies e.g. established platform, new platform, viral vector, live attenuated virus, adjuvants, etc.

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South Africa's vaccine rollout strategy

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South Africa's vaccine rollout strategy

Jan 3rd, 2021 | Minister Speaks

South Africa's vaccine rollout strategy

Health Minister Dr Zweli Mkhize says government has set up structures to expedite the financing, sourcing and procurement of a vaccine for COVID-19.

During a media briefing on Sunday evening, Mkhize, along with Ministerial Advisory Committee on Vaccines chairman Professor Barry Schoub and Health Department DDG Dr Anban Pillay, presented South Africa's vaccine rollout strategy, and announcing that the country's first batch will become available soon.

made available quickly so that most of our citizens are covered by the end of the first year of rollout- this year," Mkhize said.

"We therefore want to assure the public that we are very mindful of the urgency, particularly as we feel the impact of the second wave we are currently experiencing."

Government is targeting a minimum of 67% of the population to achieve herd immunity and the approach will be a phased rollout of the vaccine, beginning with the most vulnerable in the population.

The first phase targets frontline health care workers, with a target population of about 1,250,000. Phase two will accommodate essential workers, persons in congregate settings, the elderly and those over the age of 18 who have comorbidities. The third phase will target South Africans over the age of 18.

This means that by the end of phase 3, more than 40-million citizens will have been immunized, which is equivalent to approximately 67,25% of the population.

"At this stage we have secured the doses that will be acquired through COVAX which will ensure that we immunize 10% of the population through this mechanism and we expect the processes will have delivered the vaccine by beginning of second quarter," Mkhize said.

"Having secured for 10% of the population, we have embarked on other efforts to get the rest of the 57% of the population to be targeted by the end 2021 but, more importantly we are making efforts to obtain vaccines much earlier, hopefully as early as February 2021."

Describing how the vaccines will be distributed once they arrive, Pillay said there are a number of structures which have been put in place to govern the process. This includes working closely with provincial departments, district health teams and the private health sector.

"When we supply, we need to monitor and track the stock and the vaccine u[illegible] use and coverage. Vaccine must also be monitored for perceived adverse events [illegible]e

"We're looking at three platforms to deliver the vaccines. The first is a work-based vaccine programme. This will work very well for our hospital based staff particularly public and private hospitals at district level. Second is an outreach based vaccination programme and here we will be having mobile teams moving from facility to facility. We would also be establishing vaccination centres in remote areas."

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

Health

14 April 2021

Chairperson: Dr S Dhlomo (ANC)

Documents:

PC Health - Media Statement

Minister's Statement on the FDA Temporary Suspension on J&J vaccine rollout in the United States

DOH: Update on Covid-19 Vaccine Roll-out

Meeting Summary

Audio: Vaccine trials, procurement & roll-out programme; with Minister

COVID-19 Meetings

In a virtual meeting, the Portfolio Committee (PC) on Health was given a comprehensive presentation on the current situation in South Africa with regard to the government's vaccination programme to deal with the Covid-19 pandemic, including details of the recent challenges affecting the delivery of vaccine supplies.

The Minister of Health said the decision to suspend the Johnson & Johnson (J&J) vaccine rollout had been taken as a precaution, and the government was happy that after almost 300 000 people had been vaccinated with the vaccine in South Africa, it had not received any reports of adverse events, including blood clots.

Most of the vaccination programme details had been in the public domain since the Minister's briefing to Parliament on 30 March, when it emerged that vaccinations would focus from 17 May to November on the over-60s, and then on the over-40s and workers in high-risk settings. At the meeting, the plan also defined the prioritised essential worker groups.

The Committee was briefed by the Minister and the Department of Heath delegation on the J&J clinical trials, vaccine procurement, and progress on the vaccination rollout programme. The Chairperson expressed his appreciation that 51 million vaccines had to date been secured.

In his opening remarks, the Chairperson questioned the Minister on how many vaccines have been procured from Johnson & Johnson and the cost of each vaccine, and for more information on other vaccines that were being procured and their costs. The Minister responded that both the J&J and Pfizer vaccines cost $10 per dose. The Chairperson also sought more details on the agreements that the government had entered into with the pharmaceutical companies, and if there were challenges with onerous clauses in the contracts. The Minister said the government had found itself in the precarious position of having to choose between saving citizens' lives and risking putting the country's assets into private companies' hands.

Pre-conditions by both J&J and Pfizer were that the No-Fault Compensation regulations be published by 30 April. Another pre-condition stated that the companies wanted to have sole discretion to determine additional terms and guarantees for the Department to fulfil the indemnity obligations. That condition posed a risk to South Africa's assets and to the fiscus. The Committee said it was dismayed by the terms demanded by the pharmaceutical companies, and was concerned at the financial implications if there were problems with the vaccines. It noted that the negotiations with the manufacturers had been tough, but accepted the steps taken to find suitable terms and agreements in the circumstances.

The Committee welcomed the announcement of the appointment of retired Chief Justice Sandile Ngcobo to chair the No-Fault Compensation (NFC) Fund structure. The Fund would uphold the principles of fairness, transparency and equity, and protect the constitutional rights of citizens.

Members were worried about the impact of suspending the J&J vaccine rollout because, unlike the United States -- which had initiated the suspension -- South Africa effectively did not have anything else until the Pfizer vaccine arrived. It was also suggested that given the setbacks and challenges faced by South Africa, there was little confidence that the Government would reach its vaccination targets.

The Minister, supported by officials of the Department, reassured the Committee that the vaccine roll-out would soon gather pace. The current pause was essential to ensure the community's safety was a priority. The Department's plans were to intensify the vaccination programme before the winter season in order to delay, of even suppress, the onset a third wave of Covid infections.

Meeting report

The Chairperson asked the Committee Secretary if there was a quorum, which was confirmed as being the case. While Mr P van Staden (FF+) had sent an apology, he had also sent a question to the Chairperson that he wanted to ask, and he had incorporated this into his opening remarks.

He asked for the adoption of the agenda, and if Members of the Portfolio Committee (PC) could stay on until about 12:45pm to sort out items seven and eight on the agenda.

Mr Thobani Matheza, Chief of Staff: Office of the Minister of Health, told the meeting that the Minister would be joining shortly, as he was having technical difficulties.

Department of Health delegation

Dr Sandile Buthelezi, Director-General: Department of Health (DoH), introduced the delegation from the DoH. The delegates were:

Mr Ian van der Merwe, Chief Financial Officer (CFO);
Dr Anban Pillay, Deputy Director General: Health Regulation and Compliance;
Mr Thobani Matheza, Chief of Staff: Office of the Minister of Health;
Ms Cawekazi Gcasamba, Parliamentary Liaison Officer;
Ms Ayanda Ngubo, Head of the Office of the Director General;
Dr Aquina Thulare, Technical Advisor; and
Dr Lwazi Manzi, Media Liaison Officer: Office of the Minister of Health.

Chairperson's opening remarks

The Chairperson acknowledged the presence of the Minister of Health, and said the Portfolio Committee (PC) had a legislative obligation to do oversight on the Department's work and on the Minister as an executive authority. He wanted to inform the Members that in preparation for this meeting, he had written a letter to the Minister as part of the invitation, in which he made specific requests for him to cover certain topics. One was that the Minister, in the previous meeting with the PC, when mentioning the Johnson & Johnson (J&J) vaccines, had mentioned that these were part of the clinical trial vaccine vials that were left behind. South Africa was not paying for those vials as yet, but going forward, it looked like it was going to be a different issue. The PC noted the announcement made last week, that there were 51 million vaccines that had to date been secured. The Minister would have to give the PC a bit more detail on this information, so it would be able to play its oversight role.

It was against this background that the PC would like to know how many vaccines had been procured from J&J, and the costs of each. How many vaccines were being procured from Pfizer, and at what cost? If there was any other procurement from any other source, the PC would also like to know that. The Minister would have to confirm to the Committee that the cost of the Astra Zeneca and Serum Institute of India vaccines had been taken care of in terms of a refund for the 500 000 doses that were still remaining.

South Africa had received R1 million in payment for those vaccines that went to the African Union and the PC would like to get that confirmed. It had heard that there were agreements with onerous clauses that had been entered into, and he asked that if the Minister could give the PC details of such clauses. Could he explain the extent of indemnity that was sought by the vaccine manufacturing companies? If these clauses were onerous, where they negotiated, and what was the outcome of such negotiations?

The PC had also been advised government was now required to form a no-fault compensation fund. What was the purpose of this fund? Would the manufacturers also make any contribution towards such a fund? What were the benefits and disadvantages of such a fund? The PC would also like the Minister to share with it details regarding the formation of such a fund, and when a policy governing such a fund would be made public, including how Government would ensure that this was independent, and these decisions were credible and could then stand legal scrutiny.

The Chairperson then read out Mr Van Staden's questions, which asked whether the temporary suspension of the J&J vaccine by the United States Food and Drug Administration (FDA), and the Government's subsequent announcement, would it have any impact on the vaccine rollout in the country. The Committee was aware that the scientists were meeting and preparing to advise the Minister, and perhaps the Minister knew when they would be able to advise when the suspension could be lifted.

The Chairperson hoped that these topics would be covered in the Minister's presentation, and if not, the Members would have to follow up with Parliamentary questions to the Department. That was why he had specifically written those questions down, because the PC would need to record that as Parliament, it had engaged and asked those questions of the Minister.

Minister's overview

Dr Zweli Mkhize, Minister of Health, said he would give preliminary comments in response to the Chairperson's introduction, and then the Director-General would share a presentation with the Members.

He wanted to start by acknowledging the fact that he had received the Chairperson's letter on 12 April, and he could confirm that he

received a list of questions from the Chairperson that sought details on the vaccine acquisition process. The Chairperson and Members were aware that throughout the negotiation process, the Department stated that it had entered into non-disclosure and confidentiality agreements. However, it acknowledged its constitutional obligation to account to Parliament, and to provide the responses to Members. The Minister's response contained the direct responses to the questions that had been raised in the letter by the Chairperson.
(See Minister's statement attached).

The Department of Health (DoH) had procured 31 million vaccines from J&J. The initial agreement for 11 million vaccines was signed, and the initial purchase price had been paid. This agreement had included an option for the Department to call for 20 million more vaccines, after the signing of the initial agreement. This option was immediately exercised to ensure that South Africa secured enough vaccines, so it was now procuring a total of 31 million vaccines from J&J. The conditions of the first agreements have been met.

In the second agreement, J&J approved a precondition that No Fault Compensation (NFC) Fund regulations must be published by 30 April. This condition had also been required by Pfizer. The Department was pleased that yesterday, the National Coronavirus Command Council (NCCC) had accepted the recommendation for the draft regulations to be published for public comments in relation to the No Fault Compensation Fund. This meant that South Africans would have an opportunity to make their inputs and comments on the draft regulations. This would take a period of about five days, which emphasised that the Department recognised that this period was shorter than the usual processes followed by Parliament for normal public consultation. However, the DoH believed that it gave it an opportunity to implement the Vaccine Adverse Events Compensation Scheme at the same time as it started to roll out the vaccines, which would be expected in the next few days -- the Minister estimated by next week.

It was important to Government that it would be complying not only with the terms of the agreement, but it would also be a guarantee and assurance to each and every citizen that their rights were fully protected during the process of the vaccination, and that there was sufficient recourse that indicated that measures were in place to deal with any adverse events that might occur once a person had been vaccinated. In the structure of the fund, there had not been any undertaking by any of the manufacturers to make a contribution, so the Department believed that this would be mainly a Government- funded exercise. The Department would therefore be taking into account the processing of all the public comments that it received, so that it was in a position to formally gazette the final regulations by 22 April.

As the Department had publicly announced, it intended the NFC Fund to be independent, and have the credibility and skills that were required. The DoH would now finalise the process of identifying a seasoned, retired judge to chair the scheme. Because of the urgent press briefing that the Department had the previous evening, he had had to postpone the planned meeting with the judge, as the Department was supposed to finalise a formal appointment process, and all the other administrative matters that were linked to that.

He could now formally advise the Committee that the retired Chief Justice Sandile Ngcobo had graciously agreed to assist the DoH with the mammoth task of chairing this first-of -its-kind fund. The Department believed that Mr Ngcobo's extensive experience as a jurist, including having headed the highest court in the land -- the Constitutional Court -- and his recent experience in health-related complexities, such as the health market inquiry, made him the ideal candidate to be able to oversee that all claims and processes were followed by the NFC Fund to uphold the principles of fairness, transparency, equity, and protecting the constitutional rights of South African citizens.

This therefore showed the Department's preparedness, that whilst it had fully indemnified manufacturers against any third-party claims, it would also put in place sufficient mechanisms to protect South African citizens.

After receiving the second agreement from J&J, based on the same terms as the previous agreement, and the additional precondition that had been discussed and agreed to between it and the Department, it had unfortunately now received a formal email from J&J advising that it would not sign off the 20 million doses until it received a letter from the Department of Trade Industry and Competition (DTIC) which expressed support for the local investment that J&J had made in Aspen. The Department had been taken aback by this, as there were clauses in the agreement that expressed its support and acknowledged that this production would not just be limited to South Africa and the continent, but was also targeted for the global market. Members were also aware that recently the President had led a delegation to Aspen in Gqeberha. The Department's support for this production taking place in the country was made publicly. It was of the view that the commitment had been expressed in full, as it was indicated in the signed agreement. J&J had now told the Department that if it did not give them this letter, it had not shown its political will to support J&J. The Minister mentioned this to the Chairperson, to illustrate to Members some of the difficult and sometimes unreasonable terms or preconditions that the Department had had to navigate through.

The Minister assured the Committee that "we've not been sleeping on the job." The fact that it did not previously disclose to Parliament the blow-by-blow details of the intense negotiations was because it was prioritising the closing of the agreement in order to secure the vaccines that SA required for it to reach population immunity. There had been a lot of negotiations that had had to go on without the Department being able to discuss or divulge anything to the public while it was trying to make progress in the acquisition of vaccines.

Another "classic" illustration of the terms that the Department had to deal with that were too risky, was a precondition for the supply of vaccines that it had received from Pfizer towards the end of its negotiations. This precondition stated that the manufacturers wanted to have the sole discretion to determine additional terms and guarantees for the Department to fulfil its indemnity obligations. This condition posed a potential risk to Government assets and the fiscus. The DoH had expressed this to the

manufacturers, and the Treasury had responded as the department responsible for protecting the fiscus. This had led to further delays in concluding the agreement, and meant a delay in the delivery schedule the Department was negotiating at the time. After intense negotiations by the Department's teams, Pfizer had finally considered removing this problematic term. The final agreement signed did not contain this condition, and the Department was therefore relieved. This obligation to have a determination, at the sole discretion of the manufacturer, did not bind South Africa. "As Government, we have found ourselves in the precarious position of having to choose between saving our citizens' lives and risking putting the country's assets into private companies' hands."

With all of the above negotiating complexities, the Minister wanted to say that the government's firm commitment throughout had been that it did not neglect its constitutional obligation to protect the lives and health of South Africa's people.

In response to the question asked about the different vaccines, he said the vaccine from Pfizer and J&J was US$10 per dose. The AstraZeneca vaccine was $5.35 per dose. With regard to the AstraZeneca refund, the Minister confirmed that in March the Department had already received payment for the full African Union (AU) 1 million doses which it had sold to them. The amount paid was $5 250 000, which was the actual cost of the vaccines, less the freight. Last week, the DoH was refunded $2.675 million by the Serum Institute of India for the 500 000 doses that were not delivered.. It was therefore happy that it had avoided what could have been viewed as a fruitless and wasteful expenditure.

It was also important for the Minister to mention that the J&J and Pfizer agreements had non-refundability clauses. The agreement specifically stated that down-payments that had been made in advance by the Department would not be refundable by the manufacturer to it under any circumstances. This was another onerous term that it had to settle for. However, to give Members comfort, the DoH had checked with other jurisdictions if these terms had been included in their agreements, and it appeared to be the case. The Department was aware, for example, that the agreements that had been signed with the AU platform were similar to what the Department had signed, and in its consultation with the COVID-19 Vaccines Global Access Facility (COVAX), it had found out that a number of these onerous preconditions were also experienced by the AU.

Dr Mkhize announced that the Department had received formal acceptance and confirmation from Pfizer to increase the doses being received, from 20 million to 30 million. This therefore meant that the Department could now guarantee that the number of people that would be vaccinated with a Pfizer vaccine had increased from 10 million to 15 million. He was pleased that Pfizer had also given the Department a weekly delivery schedule for quarter two. The current weekly delivery shipping for quarter two under the existing supply agreement was confirmed as follows:

On 3, 10, 17 and 24 May, South Africa would receive 325 260 vaccines.
On 31 May and 7, 14, 21 and 27 June, that amount would almost double to 636 480 doses.

The Department would get an update for the following quarters. This meant that from Pfizer, the total doses to be received in the month of May would be 1 937 520, and in June there would be 2 547 090 doses. The vaccines were already paid for. The further 10 million doses committed this week would mean that with these doses to be supplied, Pfizer was committed to supply additional amounts in quarters two and three, which was based on the Department's plea to Pfizer that it needed to increase these doses so that South Africa could get its citizens vaccinated as quickly as possible before it experienced a third wave in the country. Pfizer had, in response, committed to an additional two million doses in quarter two, on top of what he had just mentioned above, in July. This would mean that in quarter three South Africa would have a total of 16.5 million vaccines from Pfizer. Then, in quarter four it would receive the balance of 6.9 million vaccines. J&J had now formally confirmed that South Africa would receive 2.1 million doses.

He also mentioned that with the FDA, and the Department's subsequent announcement as a country to halt the J&J rollout, the determination to lift the suspension would be made jointly with J&J. Once the Department had a clear decision, it would inform the public at large. Rather than an intention to completely withdraw the rollout, the Department remained confident that as Government, it was happy that almost 300 000 people had been vaccinated in the J&J vaccine trial in South Africa. It had not received any reports of adverse events that have been caused by vaccines, including that of clots.

The halting had been a temporary arrangement, which was a precautionary measure. The Department had consulted with J&J and various other players in the world to get guidance. It had also noticed that a report from J&J was that it would temporarily halt the vaccination programme in Europe. It was trying to align with what was happening globally, and take precautions for all its people to make sure people were safe.

Dr Mkhize said that in the presentation, the DoH had looked at a few areas of review, and amongst the issues, the Members would notice that there would be an indication that the major focus of vaccinations was going to be where co-morbidities and age were a factor. Being of 40 years and upwards, were some of the factors that were important. Beyond that, the Department had asked the provinces to give it a revised schedule, so there would be some provinces that would indicate that they might spill over to the early part of next year in the vaccination programme. The Department would then say at this point that the number of vaccination sites would be shared in a list. Members just needed to be aware that it would continue to refine this list, because there were both public and private sites where it ultimately needed to agree that these were where vaccinations would be taking place.

Update on vaccine roll-out

Dr Sandile Buthelezi, Director-General (DG), Department of Health, presented an update on the vaccine roll-out.

The presentation contained the following content:

- Epidemiology and surveillance;
- Update on vaccination roll-out planning;
- Update on the establishment of the No Fault Compensation Scheme

He gave details of the seven-day moving average of new cases, sentinel hospital admissions and COVID-19 deaths up to 8 April, (shown graphically on page three of the attached presentation document). He added that the epidemic was currently at a plateau phase, and South Africa was seeing infections that would go below the plateau phase after the first wave.

The average daily tests and proportion of positive tests was shown graphically on page four.
Dr Buthelezi added that the positivity rate had dropped -- it was sitting between 3.8% and up to about 4.4%. This was what was known as the "low transmission levels" of the epidemic currently.

The confirmed number of SARS-Cov-2 cases by province were detailed (page five), and Dr Buthelezi added that there had been some cluster infections in the Northern Cape. There had been a spike earlier in March, and there were cluster infections in the Namaqua district, mainly in the schools and some mines, and also in some taverns. The Department's response teams had managed to get in there and deal with those cases. They had done contact tracing, and put people into quarantine. Now it had settled in that area.

Current COVID-19 trends considered the number of new cases per 100 000 people per day. In comparing from 15 March 2021, one could see that the Northern Cape was the only province that had more than five cases per 100 000 per day. By 22 March, this had increased to 8.1 cases per 100 000 per day. After the interventions, by 29 March, this had decreased to 5.5 cases per 100 000 per day, and then on 5 April, this had gone down to 5.4 cases per 100 000 per day. The Northern Cape was still the only province that had more than 5 cases per 100 000 per day. The other provinces were at low transmission levels. The Department was monitoring this carefully, so that it could pick up if there was a surge in new infections.

Dr Buthelezi presented the expected and actual all-cause deaths during COVID-19 (see page seven), and said deaths from the second wave were much higher, compared to the first wave. This was similar with the number of cases, but these had now gone down. The Department was "still a bit worried," because the deaths normally lagged behind in terms of responding. The number of deaths was still above the number of predicted deaths, and things would start to settle only when the red line (recorded deaths) was equal to or below the green line (predicted deaths).

Summary of key indicators as at 11 April

New cases

- There was a slight decrease in new cases, from 6 533 cases in the preceding seven days (29 March – 4 April) to 6 495 cases in the last seven days (5 – 11 April), constituting a 0.58% decrease.
- The 14-day comparisons showed that the cases decreased from 15 163 in the preceding 14 days to 14 113 cases in the last 14 days, a 7% decrease.

Deaths

- The new COVID-19 related deaths decreased by 3.4% in the last 7 days (22 – 28 March) to 335 from 324 in the preceding seven days.
- However, the 14-days' comparison showed the deaths decreased by 50.7% to 659 in the last 14 days, compared to 1 337 in the preceding 14 days.
- The cumulative case fatality ratio was 3.42% (53 322:1 558 458). The Eastern Cape (21%), Gauteng (20%), KwaZulu-Natal (19%) and Western Cape (22%) accounted for 82% of all reported deaths.

Hospitalisations

- Based on the DATCOV hospital sentinel surveillance system, 968 patients were admitted in the last seven days (5 - 11 April), constituting a 33.8% decrease from the 1 462 patients admitted in the preceding seven days.
- As of 11 April, there were 3 614 patients admitted across the country, and of these, 620 (17.16%) were in an intensive care unit (ICU) and 323 (52.1%) were on ventilation.

Health care worker infections

- There were 14 health care workers (HCWs) who had tested positive in the last seven days (5 -11 April).
- No HCW death was recorded in the last seven days.
- Cumulatively, 55 539 HCW had tested positive. Of these 14.24% (7 908) had required admission, 6 724 (85.31%) had been discharged, and 84 were currently admitted.
- Health care workers constituted 3.57% of all cases of COVID-19 reported in the country. Cumulatively, a total of 852 deaths (1.53%) had been recorded among the health care workers.

Governance structures

- Interministerial Committee (IMC) on Vaccines: Overall political oversight and governance.
- Ministerial Advisory Committee (MAC) on Vaccines: Scientific guidance.
- MAC on Social and Behaviour Change: Social and community mobilisation.
- National Vaccine Coordinating Committee: National coordination.
- Joint Working Group with Partners: Day to day granular planning.

Vaccination phases and priorities

Dr Buthelezi said there was a need for clarity on the vaccination phases. Who were we vaccinating, who goes first and when? How much vaccine do we have? Allocation of targets? When would we distribute vaccines? He said that this information had already been covered by the Minister.

Because of the difficulty of some of the logistics with the Pfizer vaccine, including the cold chain management and packaging, these would be used mostly in the metros, where it was easier to access the population. Also, the large pack size (1 170 doses) required high throughput (administered in five days) or a site would require -20 degree storage facilities for administration within 19 days. It could also be used ay work-based or mass vaccination sites.

The J&J vaccine would be used predominantly in rural districts, since it had fewer onerous requirements that needed to be met.

He told the Committee who would be vaccinated and when (see page 17), and defined the essential workers in the public sector and community, excluding HCWs. These were:

- Police
- Army
- Traffic Officers
- Correctional Officers
- Teachers, ECD
- Social workers
- Municipal workers
- Community based workers
- Home Affairs
- SASSA officials
- Faith Leaders
- Traditional leaders
- Traditional Healers

Targeted sectors in the private sector included agriculture, mining, manufacturing, utilities, construction, trade, transport, finance, community and social services, and private households (see page 19). The Department was working with the National Economic Development and Labour Council (NEDLAC) to reach people in these sectors.

Impact of age and other factors

This was work done by a team in the Western Cape. Age was the single highest predictor for morbidity and mortality. When the "hazard ratio" was used, the age bands above 60 were most at risk of getting severe COVID-19 and needing admission, but such groups were also the ones most at risk of dying from COVID-19. These groups were more at risk than those with co-morbidities such as diabetes, hypertension, hypercholesterolaemia, HIV and asthma. Vaccinating the high risk population groups before winter would result in 40 000 lives being saved, reduce hospitalisation by up to 50%, and reduce the costs that would be incurred by the healthcare system in managing infections.

Steps in the client journey

Dr Buthelezi outlined seven steps in the high level client journey. These were:

1. Social mobilisation and demand creation.
2. Enrolment on the electronic vaccination database system (EVDS).
3. Scheduling.
4. COVID-19 screening.
5. Verification of vaccinee details.
6. Vaccination.
7. Observation.

The Department had to allow for the fact that a client could exit at any point, and could enrol back into the programme. Anyone exiting should not be recorded as having received the vaccine. Paper-based forms would be used as contingency in case of load shedding, or if the EVDS was offline. Sites may allow for differentiated queuing/triaging between step 4 and 5.

Dr Buthelezi said that the Department expected the EVDS website to go live on Friday 16 April 2021. Some elderly people and those in rural areas might have problems with this. The Department had had meetings with the provinces, and the provinces would be having campaigns with community health workers, who would be going around with tablets and donated cell phones to register the elderly. It should not be a barrier if someone had not registered and got to a centre, as there would be assisted enrolment and computers at each of the sites. People would be registered in that case, although it might take a bit longer when they were there. The Department wanted to try to avoid such a situation as far as possible, because it did not want to clog the sites.

Vaccine supply chain timelines

In the case of international manufacture (Pfizer), it would take about nine days for a vaccine to be in the arm of a person. The Department was in negotiations with the National Control Laboratory to see if the testing process could be shortened.

In the case of local manufacture (J&J), it would take about five days before vaccination, and the Department had factored in the public holiday on Tuesday 27 April 2021.

Vaccination sites

There would be sequencing of the rollout across all vaccination sites, with age-based priortisation across all three settings. These settings were:

- General population vaccination sites (linked to public or private health facilities).
- Industry-facilitated vaccination sites.
- Institutions of care and support streams.

There would be small, medium/large and mass vaccination sites (see page 28), where the classification was based on throughput per day. Working with the private sector, the Department believed it would be able to do 250 000 to 300 000 vaccinations per day by September 2021.
Vaccination sites by province would be activated in an incremental manner.

Dr Buthelezi also provided details of the vaccination sites by size, as well as by local municipality.
(See pages 31 to 40)

Area based planning & reimbursement

National Treasury had allocated some money for the DoH to fund the uninsured population who would be scheduled to be vaccinated at private sites. The Department had weekly meetings with the Treasury, which would be working on gazetting the tariff. The public and private providers would play an important role in vaccinating the general population -- both those who were insured and the uninsured. The principle here was universal coverage -- the vaccine should be free at the point of care. With the general population, most of them would be covered via medical schemes (between seven and eight million people), who would mostly use private providers. There were also uninsured workers in industry, who would be taken care of by their particular sector. For example, the mining sector would put up a particular kind of insurance to take care of miners who were not insured.

The primary objective was universal coverage – to cover the entire population; with best possible access; in the quickest possible way; without proliferating the number of vaccination sites. Access to service would be based on proximity to the nearest service point. The allocation of clients on the EVDS would be in the following order of preference:

- Uninsured population – public sector site, mass vaccination site, private sector site.
- Insured population – private sector site, mass vaccination site, public sector site.
- Workers – employer-provided site, mass vaccination site, private sector site.

For the public sector in phase 1b, there would be a hub/spoke outreach for smaller facilities. All hospitals were hubs, first vaccinating HCWs in their facility, and then vaccinating HCWs in smaller facilities. The small district hospitals, community health centres (CHCs) and clinics were spokes.

In phases 2 and 3, the Department would decommission vaccination sites at higher levels of care (regional, tertiary, central), as the hospital capacity would be required should there be a third wave.
It would retain district hospitals as vaccination hubs so that it had a geographical spread, and gradually expand the number of vaccination sites.

There had been 291 244 vaccinations to date, as at 13 April.

Problematic clauses in supply agreements
The Minister had spoken about the problematic clauses in the supply agreements between the Government and vaccine manufacturers. The DoH had entered into agreements with Johnson & Johnson, Pfizer and the Serum Institute. The agreements contained broad and far-reaching clauses which required government and the DOH to do the following:

• To indemnify the manufacturers against any claims arising from the use of the vaccines.
• Manufacturers, in addition, required the Government/DOH to demonstrate that the suppliers would have adequate protection against claims by establishing a No Fault Compensation Scheme.
• There were very onerous confidentiality obligations preventing the DOH from making any disclosures, and thus from being transparent to Parliament and the public.
• Provisions indicated that the Government/DOH would not be refunded should manufacturers delay or fail to deliver.
• The agreements protected manufacturers for any delay in delivery, such as there being no penalty or consequence for any delay delivering vaccines. There was no liability for any failure to deliver doses, even where such a delay or failure was due to the gross negligence or wilful misconduct on their part.

Dr Buthelezi gave examples of provisions which had been removed through negotiation from the contracts:

• The requirement for the purchaser to provide guarantees, obligations, protections and indemnities as determined in the manufacturer's sole discretion.
• The sufficiency of such statutory or regulatory requirements or funding appropriation would be at the manufacturer's sole discretion.

No Fault Compensation (NFC) Scheme

In the process of procuring COVID-19 vaccines from suppliers as part of its COVID-19 vaccine rollout strategy, the Government was required to indemnify suppliers against adverse events resulting from the use of the vaccines. In order to ensure that any persons suffering from severe injuries as a result adverse events from the use of vaccines, suppliers required the establishment of a no fault compensation programme and a fund from which to pay compensation claims. Elements of the scheme included eligibility, process and decision making, standards of proof, elements of compensation, litigation rights, administration and funding

Dr Buthelezi added that such a scheme was a condition precedent that had been set by the vaccine manufacturers, but the Department viewed it as something that might be a good thing for the country moving forward, as the country considered how to manage medical negligence claims regarding compensation.

NFC committees and status

• National Immunisation Safety Expert Committee (already in existence), which was responsible for establishing the causal link between the vaccine and the injury.
• Adjudication panel, responsible for defining the injury and determining compensation.
• Appeals panel, which was responsible for reviewing the decision of the adjudication panel.
• Governance committee, which would be responsible for overseeing the functioning of the Scheme and providing advice to the Minister of Health. This Committee would be chaired by a retired judge.

The current status was that amendments to the Disaster Management Act (DMA) regulations to establish the Fund had been drafted, and would be published for public comment. The process of appointing the retired judge to chair the Governance Committee was under way.

Discussion

The Chairperson commented that the process of securing vaccines was not a simple one -- it required lawyers, judges and other kinds of expertise. The PC was glad that the Department was on top of it.

He read out questions from Ms M Hlengwa (IFP), who was struggling to connect to the meeting platform. Regarding the decision to expand the vaccination roll-out, when did the Minister become aware of the possible risk associated with the J&J vaccine? Why was there so little vaccination over the past weekend? Was this perhaps linked to this announcement? What measures would the Government take to ensure that those healthcare workers who had had the vaccine were monitored closely, and given priority treatment? What was the Government's plan to ensure the safety of healthcare workers through being vaccinated going forward?

Mr A Shaik Emam (NFP) noted that Mr Van Staden had sent questions.

The Chairperson replied that he had incorporated Mr Van Staden's questions into his opening remarks. He summarised that Mr van Staden had asked: Due to the temporary suspension of the J&J vaccine by the FDA, and the announcement made by the Minister last night, would this have an impact on the vaccine roll-out? How long would the Minister wait for the scientists to come back to him?

The Chairperson also read out the questions of another Member, Mr T Munyai (ANC), who was struggling to connect: How much had been allocated by the National Treasury for vaccine administration?

Mr Shaik Emam asked what the financial implications of the suspension of the J&J vaccine were, and if South Africa was, for any reason, not going to use it in the future, over and above the large quantities of vaccines that had been ordered. Clearly that would have an impact if South Africa was not going to proceed with that. He was concerned that these pharmaceutical companies were "laughing all the way to the bank," because they had caught South Africa in a very difficult situation, particularly on the issue of no-

fault compensation, over and above the fact that the companies were saying no refunds if South Africa cancelled. What would happen if South Africa had to cancel J&J, based on the challenges that it was facing, and the risks attached to that? "Why is it we don't act timeously when we establish worldwide that there are problems? Why do we wait until the eleventh hour before we take action, like in this case with Johnson & Johnson, and continue rolling it out and putting our healthcare workers at great risk."

Healthcare workers were given very few or no options. If one did not want to take the vaccine, one was not forced to take it, but one would not be protected as a healthcare worker if one got the virus. It was a "no-win" situation. He was particularly concerned about J&J, based on the fact that it had been found wanting, together with Aspen Pharmaceutical and McKinsey. Hundreds of millions of dollars had to be paid. He was very worried about this particular institution -- what impact it was having, and how it was controlling the prices.

South Africa was relying mainly on Pfizer and J&J, and he was concerned about what was going to happen going forward should it be established that there were problems with their vaccines. There was also the issue of ivermectin. It was "shocking" and "a disgrace" that the South African Health Products Regulatory Authority (SAHPRA) had not allowed it, with no further evidence, after "hundreds of people may have died and been infected in South Africa". Who would be liable? The Minister's Chief of Staff had "arrogantly" written to him and said that he would hold Mr Shaik Emam for liable for punitive costs for wanting to pursue this matter. Should it not be the CEO paying punitive costs for having taken the decision singlehandedly, without intervention from the people? It might have cost a lot of lives in South Africa.

Where was SAHPRA involved in this? The Minister had procured vaccines because he had been "in a hurry" to get them. The Minister and Department could not be blamed if something went wrong with the vaccines, because all needed to be in line to get these vaccines. SAHPRA had allowed the Department to procure vaccines without any approval, but when it came to the issue of ivermectin, there was not enough evidence. There was evidence that were challenges with the J&J vaccine, so should the PC call on the SAHPRA board to resign, particularly the CEO, who was conflicted with McKinsey, J&J, etc.? What was the Department going to do as the result of the Board's conduct, which was now costing "millions of taxpayers' money?" What was the latest on the Special Investigating Unit's (SIU's) investigation into the activities at SAHPRA involving corruption and maladministration? He had asked last time if McKinsey had paid their fine. Was there any link between what the Department had procured through Aspen and J&J, and McKinsey?

Ms S Gwarube (DA) said there had been confusion around terms such as "we have procured doses of the vaccine", or "we have secured doses here with this manufacturer", "we have reached an agreement with this manufacturer". These had often been made out to be milestones worth celebrating. What was the difference between these two? As it stood, there had been fewer than 300 000 healthcare workers vaccinated, yet the Department talked about how over 40 million people could be vaccinated due to what had been secured. What was the difference between when the Department "secures" something, and when it was in a position to be able to receive the vaccine and roll it out? Once an agreement was signed, was the next step delivery, and if the next step was delivery, was the next step then rollout?

There was a truncated delivery with Pfizer, in particular. The Department had talked about how in May, there would be different tranches of the vaccine rollout. She wanted to understand if it was because of South Africa's own storage capacity that it was only getting various doses that were limited?

She asked about vaccine rollout to healthcare workers. Members were of the understanding that the Sisonke trial was a trial phase, but it was always meant to target at least 500 000 people. The initial target was 1.2 million healthcare workers, and then that was re-adjusted to about 500 000 healthcare workers. As things stood, fewer than 300 000 healthcare workers had been vaccinated -- why was this so criminally slow? She could not understand why days went by when no health care workers were vaccinated. Over the Easter weekend, not a single South African was vaccinated. Over the past couple of days, these were marginal numbers. Why was this happening?

She asked about the Department's announcement around the FDA decision to halt the J&J rollout. The USA was in very different position than South Africa, because it had various vaccines in circulation, whereas South Africa did not. When South Africa halted the J&J rollout, it did not have anything else until Pfizer arrived. Was the decision made entirely on the basis that six people out of six million vaccinations had adverse effects? Was that a significant enough number for South Africa to halt the rollout of the vaccine? It seemed to her that the six out of six million was a very marginal figure. On what basis was this decision made?

The Department had said that J&J required a letter of support from the DTIC. What was the purpose of this letter, and when would the DTIC be able to sign it, as South Africa could not have any further delays? What must this letter say that needs to come from the DTIC?

Ms H Ismail (DA) asked if there had been any trials for the Pfizer vaccine. If yes, when could the PC expect results on Pfizer in the case of South Africa? What were the results with the South African variant with regard to Pfizer? Was this trial conducted in South Africa? What adverse side effects had been identified thus far in the South African context? There had been expectations of Pfizer, but there had been no talk on its trials. This was a bit worrisome.

Her next question was on J&J, with regard to "social media reports" on blood clotting, etc. When did the Government first know about the blood clots? Was this why the vaccinations had slowed down in South Africa? What adverse effects had been identified thus far in the South African context when it came to the J&J vaccine or trials?

Regarding the NFC Fund, she had asked questions at the previous meeting, but had not received all of her responses, so she was

happy that the Chairperson had written that letter to the Minister. What measures would be put in place to ensure that the management of this fund was transparent? What measures would be put in place to prevent theft, fraud and corruption going forward?

She was very concerned about the recent reports of blood clotting, etc. South Africa had paid for these vaccines already, and the Minister had explained that there was a clause saying that there were no refunds. Since "we don't know of Pfizer trials with the South African variant," was government sure that it was doing the right thing of paying for vaccines on which trials were not done in South Africa -- unless there were trials being done in South Africa that the PC did not know about?

She asked for a detailed distribution plan on how and which vaccines would be distributed to the various provinces, and what factors would influence these decisions. The DoH was waiting for the provinces to send it their needs, but how would the Department decide that the J&J vaccine was going to go to Gauteng, or the Pfizer vaccine was going to go to the Western Cape? What were the deciding factors on that? The Minister had specified that South Africa was receiving vaccines every week. Since the Pfizer vaccine had special requirements for storage, how was the Department going to ensure that the necessary amount of vaccinations would actually be taking place? Vaccination in this country was going very slowly. South Africa had already procured, it had already paid, and the DG had specified the delivery. She was concerned whether, on the ground, vaccinations would be done on time.

Dr K Jacobs (ANC) said that the PC noted that everything was very fluid and dynamic, and there were many changes on a daily basis. He thought that the PC must express appreciation that the Department was able to change on a daily basis and improve the terms and the negotiations for the betterment of the people of South Africa. With the intensity and difficulties of the negotiations, the PC had heard from the Department that there were great challenges, that it had been able to bridge a number of those negotiations with suitable terms and agreements with the manufacturers. The PC understood that these terms were put there by the manufacturers, and that it was the Department's job to make certain that all South Africans got the best deal out of this. However, the PC also noted the non-refundable clauses in the agreements, and it also heard from Mr Shaik Emam and Ms Ismail about their concerns with that. What happened to money that had been paid should the vaccine create challenges, such as J&J with blood clots? Could the Minister give the PC more indication and understanding of the non-refundable clauses within these agreements? The challenges must not be underestimated, as they might be huge.

The PC was happy to hear of the procurement agreement for larger amounts of the vaccine in the second, third and fourth quarters, and also of the timeframes for the receipt of the vaccines. It also noted the disclosure of the costs of the vaccines per dose, and the NFC Fund. A lot of good work had been done, and the PC should not negate that by not "giving honour where it should be given," and giving recognition where it should be given for the work that had gone into this.

One aspect of this work was the NFC Fund. The PC was pleased to see a plan which would be implementable, and that there was also some expediency appropriated to this plan. The PC also appreciated the appointment of Judge Sandile Ngcobo as the Chairperson of the Governance Committee, as one of the committees of the NFC Fund. The PC looked forward to the publication of the regulations for establishment of the fund, which the Minister said would be done in the next five days. Could the Department give an indication of the funding of this fund? Where would the funds come from, and could the Department give an indication as to the monitoring of the money of the fund once it was established?

On the confusion created by various groups, including the Western Cape Government, on the procurement and acquisition of vaccines, there seemed to be an ongoing discussion. He asked the Department to reaffirm the position on the acquisition and procurement of the vaccines at a national government level.

Ms A Gela (ANC) noted that more than 250 000 healthcare workers had been vaccinated, and the PC was looking forward to meeting the target of vaccinating all of the healthcare workers by at least mid-May, and also starting the second phase of the rollout. There was confidence that that would happen, despite the challenges coming forth, but she knew that those would be resolved. She acknowledged the vaccine rollout plan being clear in terms of vaccine procurement, the agreements in place with manufacturers, the distribution of vaccines per province, guidelines for the provinces, and vaccination sites identified. The previous Thursday, she had seen that the Department was checking the readiness and the vaccination sites in Gauteng, which was a good sign. The PC really appreciated the good work that the Department was doing throughout the country, checking the readiness and also making sure that all the sites were ready for implementation of the vaccine rollout. Who was responsible for the preparation of the vaccine sites? How would the integrity of vaccines, for example, be controlled? She reiterated her appreciation for the work that the Department was doing, and that the Minister was at the forefront.

Ms M Sukers (ACDP) said that a lot of the Members were dismayed at the terms that were being demanded. It proved the point that politics and business were a difficult combination. In reviewing the plan, she saw little provision for contingencies. The previous day, the FDA and the Centres for Disease Control and Prevention (CDC) had halted the use of the J&J vaccine, and a small study from Israel suggested that the Pfizer vaccine was not as effective against the B.1.351 variant. Further disruptions were very likely.

When she looked at the slide on the Joint Strategic Oversight Committee, she had seen a very small team working on supply, yet strategic sourcing and procurement had been the area in which South Africa had failed. How would the Minister work to strengthen the strategic sourcing capacity, and how could he be assisted to do this? It came back to the questions asked previously by her colleagues –the Department needed to make use of the collective Parliament to say, "How do we assist government to increase capacity?" She thought that one of the key failures was the fragmented approach – the failure for the DoH to effectively communicate with Parliament, and put all its cards on the table in order for Parliament to really unify around solutions. Section 32 of the Bill of

Rights stated that everyone had the right of access to any information held by the state. Members of Parliament (MPs) were representatives of the people, so it was "completely unacceptable" that MPs could not receive the information they needed to conduct oversight and hold the Executive accountable. "We cannot run away from our Constitution by simply saying, 'strict non-disclosure agreements'." This was contracting out of the Constitution, which was completely unacceptable. It was not enough to say that big business was dictating the terms to others. What steps was the Minister taking to ensure that people's constitutional rights were protected?

She commented that the Minister had mentioned the protection of the rights of South Africans in his opening. Vaccine refusal and hesitancy was increasing because of incorrect information from conspiracy theories, consultation being limited to groups government was comfortable with, and a lack of education. "We cannot think that we can order our people around, and tell them what they must think, and what is good for them." MPs needed to engage all people as key stakeholders, not just those who were in the structures that government normally engaged with. For example, government had failed to engage with religious leaders from the newer Pentecostal and charismatic churches. How was it going to ensure wide involvement, not just with this group, but with all groups that were not within the existing structures?

Dr S Thembekwayo (EFF) asked how many Chinese or Russian companies the Department had engaged on the possible supply of vaccines. Considering the rollout phases as they had been presented in relation to the available vaccines, specifically with regard to the J&J halt, and at the same time anticipating the possible adverse reactions that might be experienced by the healthcare workers, what was the DoH's contingency plan should that happen? How would the Department ensure that the healthcare providers' community was aware of the potential for adverse events? How would the Department plan for proper recognition and management due to the unique treatment required for this type of blood clot?

In Gauteng, there had recently been a warning of rising COVID-19 infections in Sedibeng, Johannesburg, Tshwane and Ekurhuleni. How did the Department approach this type of occurrence to prevent a further spread?

There was South African-born bioscientist who was behind the development of a new game-changer pill to prevent COVID-19. The vaccine, which had been tested in the form of a pill, would not have to be stored at low temperatures, according to Mr Morena Makhoana, the Biovac CEO, like the injectable vaccines. Had the Department considered having negotiations with this company and if not, why? If the Department was considering doing that, how speedily could it accommodate this company?

Mention had been made that the Department was expecting revised schedules from the provinces. This was confusing, because this provincial schedule of vaccination depended entirely on the schedule and availability of vaccines from the DoH itself. How would the Department make sure that there was less confusion and uncertainty regarding this aspect? The DG had mentioned that the Treasury had provided the Department with some money. What was the amount of money that had been provided by the Treasury, who controlled the usage, and how was it going to be used? She wanted to ask for feedback or any other information, because she usually did not get direct feedback from the Department about the questions that she posed about COVID-19.

She had a question about the Eastern Cape healthcare workers whose contract was supposed to end on 31 March. Even though the workers were told it was going to be extended, she had heard a report that the contract was extended for only three months. Why could the same not be done like in KwaZulu-Natal, and extend the contract to 12 months?

She asked for feedback on interns who were not receiving a stipend in Gauteng hospitals, while the others were receiving stipends in all the other provinces. She asked if she could get feedback saying whether interns would get stipends that would be backdated from January 2021.

Ms N Chirwa (EFF) wanted to know the reason behind deciding to centralise J&J vaccines in rural areas, and Pfizer in the metros. Her colleagues had raised this concern based on technicalities and the history in relation to reaching targets. Everything on paper looked quite convincing, despite the fact that aspirations should be much higher. How did the Department plan to reach the capacity to process 250 000 vaccines per day when it had failed with vaccinating 1.5 million healthcare workers, with the initial target at the end of April? The Department had extended the deadline and even reduced the plan for healthcare workers – it went down to 600 000, and now it was at 1.2 million, as shown in the presentation. There kept being changes, but none of the changes led the PC to believe that capacity was being increased, or that the Department would be able to get to a point where it was able to vaccinate 250 000 people per day. If one were to break it down from May to October, to reach the target that it had set, the Department would have to vaccinate 700 000 per week.

The Department was telling the PC about vaccination sites and vaccinators, who were said to be already available and already on site. Members had been told about the Department doing oversight visits to these vaccination sites, but this did not indicate that 250 000 vaccinations would be possible per day in phase two. There was a concern about that, because "it seems that we are just gearing for another failure, as we have been over the past few months and weeks of targets being changed, because capacity was proving to be a problem." There had been technical issues, vaccines not arriving, etc. Those may seem like small gaps in the presentation, and in how the Department presented this information to the PC, but as the PC, it knew better than to just take the Department's word for it, since history told it otherwise. Even if the Department were to bring a plan and say it would vaccinate 1.5 million healthcare workers, in mid-April the reality was that it was still at 250 000. That was very disappointing. It was very concerning, because then it meant that the Department would not reach the target that it had set for the second phase, of 22 million people by mid-October, based on the evidence of the work that had been done so far, and all of the targets, and the failures in the collective.

What was the update on the other vaccine manufacturers? It seemed that there was a decision that had been made already, and the PC must reach its own conclusion that as the executive, the Department had just decided on Pfizer and J&J, despite the fact that the Department had been coming in and out of the PC telling it about the other ones -- such as Sputnik -- and that it was in talks with other manufacturers. Could the Department give an update on what these talks had led to so far, especially regarding vaccines from China and Russia? It was good that the Department had decided to halt the J&J vaccination programme pending the outcome. What was being done domestically to get involved in the investigation process? Was South Africa having its own investigation, or was it just waiting for the FDA and the CDC to tell South Africa the results of an investigation? Did South Africa not have its own capacity as a country to either be involved at that level, or to have its own investigation beyond just monitoring? Part of the triggers that had been noted by the FDA was the issue of how entities had to monitor even very minor symptoms after vaccination. The Sisonke trial had said over and over again that the only symptoms it had had was nausea and muscle pain, but those were also primary symptoms that could lead to blood clots. How intricate, and how deeply involved was South Africa's monitoring system in relation to the investigation? She knew that it would last a few days, and then it may mean that the vaccination programme could continue, or be halted altogether. If the results proved that J&J should be halted indefinitely, what was the strategy?

When Members spoke of alternative vaccinations, it was because in situations where the primary vaccines that South Africa had chosen -- Pfizer did not have such a high efficacy against the variants from South Africa, and J&J was being investigated -- its hands were tied if there was not a large base of alternatives which could be made available. She wanted to know the reason why the Department was not securing other vaccines such as Sputnik.

The other issue she had raised last time with the DG was the issue of Ms Mpho Seleka, a senior medical scientist from the National Institute for Communicable Diseases (NICD), who had raised the issue of racism at the NICD, which had resulted in her being dismissed unfairly. She asked for an update, because it had been over two weeks, and she had not had an update from the DG in relation to this particular issue.

The Chairperson asked if the PC could agree that in the previous presentation, the Department had highlighted where it was with the Sputnik and Sinopharm vaccines. Could the PC have that slide retained for future presentations until the Department had made a decision, in light of whether SAHPRA had given it a green light to continue? The PC would appreciate it if that slide remained in the presentations, especially in light of how it was uncertain if South Africa was permanently tied to the two current vaccines -- it needed to know the progress.

There was the issue of vaccination sites. Two days ago, he had been phoned by a journalist who was asking if he knew about the vaccination sites. He said that PC did know about the sites, because in the previous presentation, the Department had made a presentation about vaccination sites, but it appeared that this had not been well communicated. For example, if one lived near the Tulamahase Clinic, was that site going to be available, and when would one get to know if that site would become available? Right now, as the Department was supposed to be almost rounding off giving vaccines to healthcare workers, there needed to be massive planning for the rollout all over the country.

Related to that, it had been noted that there were some glitches regarding to particular healthcare workers here and there being able to register so that they were part of this programme. Did the Department expect same for all 60-year-olds and above, whether they were in rural areas or not, to register on the system? The PC needed that information, because these older people were all over the country, and the Chairperson needs to be very clear when he provided an answer to them what would be expected of them prior to being vaccinated.

DoH's response

Dr Anban Pillay, Deputy Director-General: Health Regulation and Compliance, DoH, responded to questions.

On the adverse events relating to the J&J vaccine, South Africa had not experienced any of these events that had been reported in the USA, but they had been experienced in other countries. One should bear in mind that South Africa's rollout was close to 300 000 doses, while in the USA, for example, over six million doses had already been administered, and it had had six cases. There had not been a causal link between the vaccine and the adverse events as yet. There may be other factors involved. That was the data that the FDA would have a look at and evaluate. SAHPRA was also looking at the matter. At the same time, a number of ethics committees locally had raised the question of whether the study of these signals should proceed. Adverse events could be called "signals" that were coming out of other countries, because it did raise a concern for South Africa that these adverse events may occur in this country. It may need to take measures because of that.

Dr Pillay thought that pausing the study was an opportunity for South Africa to look at whether these adverse events were linked to the vaccine. Firstly, if the effects were linked to the vaccine, which particular groups were affected, and what was the causal relationship -- was it a particular type of age group, or were there other factors that the individual had that predisposed them to these types of clots? With those answers that colleagues in SAHPRA and the MAC would be looking for, there would potentially be some answers or approaches about how South Africa would be able to deal with the effects.

As part of the process of managing the safety of vaccines, South Africa had the Electronic Vaccine Data System (EVDS), which required that all adverse events were recorded on the system. After registration and after vaccination, there was a process of monitoring those adverse events as they occurred. The reason that Government was managing the rollout and using a single system -- the EVDS -- was so that it could get these signals of adverse events early, because if one had a single system and one noticed a particular adverse

event popping up all over, that was usually the first signal that there was something that one needed to investigate and try and understand. The EVDS would be able to pick up the other adverse events that the Department was not currently aware of, if they occurred.

The temporary suspension would hopefully be for a short time, because it would be required that the Department investigate each of these, and make a decision about how it continued with the vaccine if that was the decision.

If South Africa chose not to procure further doses of the J&J vaccine, it would still be committed for the financial implications that were in the contract currently. It would have to make sure that it engaged J&J if it went that route, and it would have to be in the same mind about that. He thought that this was very early days, because this was simply a pausing of the study – there had been no adverse events in South Africa. He thought that there were a number of other risk factors that caused adverse events, and the Department would need to establish that first.

With the Pfizer vaccine, there were challenges, but these were all challenges that had come up in Europe in particular. Those had been investigated and in each case, it was found that these adverse events were not related to the vaccine, but were instead related to co-morbidities that individuals had. In Europe, at the time when these adverse events arose, they were largely among the elderly who had a number of other co-morbidities. When an adverse event occurred and an individual was vaccinated, the cautionary approach was to say that these adverse events were related to the vaccine until an investigation was done. That was the way most regulators in countries approached this matter until a causal link was actually established.

On the matter of secured versus received vaccines, what companies required South Africa to do as soon as it agreed on the number of doses, etc, was to sign what companies called a "term sheet." That term sheet contained the doses that would be supplied, and the price at which they would be supplied, in very broad terms. That effectively secured the doses, so when the Department talked about doses being secured, it was talking about signing off on the term sheet. After the term sheet had been signed, the manufacturer would then come with a very detailed agreement, and that agreement covered a number of parameters that were not necessarily in the term sheet. The Department then had to sign off on that agreement before the manufacturer would supply the doses, even though the DoH had secured the dose and the price earlier. The manufacturer would not ship any doses to a country until those conditions were met, and there was agreement on those conditions. Some of the conditions were very onerous. Under normal circumstances, in the DoH's usual contracts with pharmaceutical companies, it would not agree to those conditions, but the Department was in a very peculiar situation where it had a great need for the vaccine, and it would then have to re-look at those conditions with that context in mind. Once the agreement was signed, as part of the agreement, the Department got information about the delivery dates of those vaccines. The delivery dates were not specific days, so manufacturers do give a specific date. The Department would get those dates only after it paid the first deposit, and following that it would get some sense of what those dates could be. However, those dates "are not firm", as the companies had indicated to the Department.

Regarding the truncated supply from Pfizer, it was important to say that Pfizer was trying to give South Africa as many doses as it could in quarter two, based on South Africa's request. These were the doses that Pfizer could release on a weekly basis. South Africa's capacity to store was much greater than that, but demand exceeded supply at the global level, so this was what it was able to provide in small quantities over the several weeks that Pfizer was able to deliver doses to South Africa. It was happy to receive them because it helped, particularly in quarter two, where the Department was looking at trying to vaccinate as many of the high-risk groups during that time as possible.

It was important to note that the Sisonke study was regulated by SAHPRA in terms of the number of sites it had, and the way it conducted its study. As a consequence, there were very few sites that had actually been activated for vaccination, because the regulations were in place for researchers to do the vaccinations. It would be very slow, because there were only 40-odd sites that were doing vaccination. When South Africa moved to mass vaccination, there would be thousands of sites. The pace at which it would be going would be much higher, as it did not necessarily have to comply with all of the study requirements that Sisonke had to comply with. There would be a massive change. The provinces would be in full control of the process. All of their clinics could start vaccinating, and in private sector hospitals, a similar situation would exist. The Department's count was that it would have over 6 000 vaccinators available. The pace at which the country would be vaccinating would be much faster at that point.

From the J&J side, the incidence of one adverse event in one million was low, but it was important for the DOH to be cautious about these adverse events, so that it understands them, and it classifies them as adverse events that were rare, and related to particular risk groups. Maybe the Department would decide not to offer that vaccine to that risk group, for example. It could not simply say that it was continuing with vaccination without having an appreciation of what the causal relationship was.

Dr Pillay said the Pfizer vaccine was trialled in South Africa, and the trial results had been published and were available globally. The effect of the Pfizer vaccine on the variant had been available as well. The effect of the variant was not in a clinical trial, because when the vaccine was trialled in South Africa, the 501.V2 variant was not dominant, so researchers did not have results of that in their trial. Thereafter, what the researchers did was an "in-vitro assessment" -- a challenge test of the vaccine against the variant. Researchers found that that the Pfizer vaccine continued to be effective against the variant, even in the challenge test. The MAC had looked at this data, and so had other scientists, and these parties were convinced that the Pfizer vaccine would be effective against South Africa's variant.

On the blood clots and when the Department knew about them, he said there was a scientific paper that had been published a few years ago that identified a number of the viral vectors that were used by most of the vaccines that were available now that had the

propensity for potential clotting factors, the extent of which was fairly limited. However, the Department was seeing this issue rearing its head with the J&J vaccine. It had seen a bit of that with the Astra Zeneca vaccine, so it needed to better understand that. Dr Pillay thought that the scientists needed to do a lot more work on trying to understand what the pathways were for this to happen, what could be done to prevent it, and which groups should maybe get a different vaccine, because such groups may have a greater propensity for these types of clots.

On the No-Fault Compensation (NFC) fund, when the regulations come out, there would clearly be the principles relating to transparency and accountability, etc, as all funds of this nature were required to comply with the Public Finance Management Act (PFMA). There were a number of measures in the regulations that outlined what the accountability measures would be.

On the detailed distribution plan for the vaccines, as the Minister had indicated, the DoH would prefer that the Pfizer vaccine was used predominantly in metro areas, and J&J in the rural areas, for a few reasons. One was that the Pfizer vaccine came in much larger dose quantities per pack. For example, one could have 1 100 doses in one package, and one would need to open the whole package. Once one opened it, one had to use that package. If one did not, one may then have wastage. The second reason was that the Pfizer vaccine required specialised refrigeration, which was available in much larger quantities in close proximity within the metro areas than in the rural areas. Thirdly, the Pfizer vaccine was a two-dose vaccine. With a two-dose vaccine, one wanted the person to come back to get the second dose. The Department knew from its experience with other vaccines, and across the world, that a two-dose vaccine worked better in areas where people were in particular confined areas, such as a workplace, or within an institution, where one could go back to them there and give them the second dose. If one gave the Pfizer vaccine in a community setting, the likelihood of the person remembering to come back, and of finding them, was usually a huge challenge, and that was what most countries had experienced. This created a situation where many people were vaccinated with only one dose instead of two, which was a real challenge.

On the contingency plans, the Department had the Pfizer vaccine as its contingency -- the Minister had shared that information already.

With regard to strategic sourcing, there were a very limited number of vaccine suppliers, and the Department had been engaging with all of them. The team that was involved was supported where necessary in pursuing the strategic sourcing. There were just a handful of suppliers -- large companies that were responsible for the production of these vaccines -- and the Department had been engaging with all of them. The difficulty all of these suppliers had was that the vaccines that they had were not in the quantities that were required globally, so demand exceeded supply. In South Africa's particular situation, the Department needed to understand whether the vaccine was effective against the variant, and many of these vaccines had not been assessed against South Africa's variant itself to understand that. Dr Pillay thought that that was a particular challenge for a number of the vaccines.

On the non-disclosure agreements (NDAs), the Department had approached the companies going forward to say that it had a constitutional obligation to share information with Parliament and with many other bodies regarding its accountability. Many of the clauses in such agreements made it very difficult to share this information, and the Department would like to be released from those NDAs for the purposed of sharing information. It would be awaiting the companies' response on how they saw that, because the way the NDAs were currently crafted, they did not allow the Department to share a lot of the information that it would certainly want to.

The Department was still engaging on the Sputnik, Sinopharm and Sinovac vaccines. With the Sputnik vaccine, there were a number of suppliers in South Africa, but the suppliers in South Africa did not have a lot of the clinical and technical information relating to this vaccine. The MAC had had to engage directly with the Gamelaya Institute, which it had done. There were a number of areas where further information was requested, which the Gamelaya Institute did not have at the time. Once that information became available to the Institute, the MAC could finalise its view on this. SAHPRA was independently engaging with these suppliers, and it had also requested information relating to various aspects of the vaccine.

In the case of the Sinopharm vaccine, the Department had signed an NDA with the supplier as Sinopharm had requested, which was very similar to the other manufacturers. It was hoping that the Sinopharm manufacturers would provide it with information. It had indicated that it was caught up with its suppliers in other countries, and it was not able to provide the Department with all the information that was required by the MAC, as well as by SAHPRA. Sinopharm manufacturers had attempted to register their product with the World Health Organisation (WHO), and if the product achieved a WHO pre-qualification approval, that may make it easier for SAHPRA to consider the product, because that information could be shared with SAHPRA for the purpose of registration. The Department was hoping that there would be some success on that front.

In the case of Sinovac, it had one supplier in South Africa, and the supplier had met with the MAC, and had shared information. There was additional information that the MAC would require from that supplier, and that had been communicated. Additionally, SAHPRA had been meeting with Sinovac's representative here as well to receive that information so that it could finalise its decision on it.

With the increase in the cases in Gauteng, the signal suggested that these were upticks which were small increases. These usually developed into upswings, but at this stage they remained upticks. The DoH kept watching the upticks. It had a dashboard which was publically available on the National Institute for Communicable Diseases (NICD) website, that identified each district, what its number of cases were, which direction it was moving in, and which ones appeared to be riskier than others. This was where the Department would engage with its provincial colleagues, and ask them to put in more effort to reduce the transmission in those areas.

The Department had been talking to Biovac, and Biovac was part of the MAC as well. At this stage, the company that was responsible

for the vaccine was still in the developmental phase, so it would take a while before the company was in the clinical trials phase. The Department would need to await that information, so that it could make some decision relating to that.

On the question relating to revised schedules from the provinces, the Department had shared the vaccine supply volumes to the provinces, and it met with the provinces almost every other day. The provinces had that information. Many provinces had provided the Department with a plan, but there were some outstanding provinces that needed to give the DoH their plan relating to the volumes that would be allocated to those provinces.

National Treasury funding had seen it giving provinces about R1.5 billion to support the vaccination programme. The DoH had also been in discussion with the Treasury about receiving approximately R900 million to support provinces on administration, where the Department could potentially augment provinces' vaccination capacity by contracting in private providers, for example, in order to increase the platform for the provinces to be able to deal speedily with their vaccines.

Dr Pillay explained how the Department would get to 250 000 vaccinations per day. It would proceed from the current rate, which was limited by the Sisonke study and what SAHPRA required, to a point where it would then be able to open all of its public private sector sites, and it would have vaccinators at each site. The pace would thus be much faster than what the Department was currently at.

Regarding the J&J vaccine investigation, the question was whether the Department was waiting only what the USA would be doing. Its colleagues at SAHPRA would be doing an investigation. In addition, the MAC was going to be meeting that day, and would also be providing its views on this matter.

The glitches in the EVDS were linked largely to the Sisonke study, because the Department needed to add into the EVDS something that it had not planned for. It had not planned to be doing the Sisonke study as part of the EVDS initially. That was informed consent in the context of a study, which had required additional programming, and that programming had led to some glitches because it was done at the last minute in order to make sure that the Sisonke study was rolled out. Those glitches had been fixed. However, when the Department went to the EVDS as it had planned prior to the Sisonke study, it did not anticipate any glitches. There had been a lot of stress-testing on the EVDS system, and all of the reports that the DoH had seen thus far suggested that the system would be able to tolerate the number of applications for vaccination and the vaccination process itself.

With people over 60, many may not be able to use the information technology (IT) system required for the EVDS. What the Department had made provision for was that in addition to the IT system, where a family member could do the registration for their relative, a person could arrive at the vaccination site, and the registration could be done at the vaccination site. The Department was also planning a call centre, where the registration could be done over the telephone. Dr Pillay said he understood that a number of provinces were planning to do community-based registrations on the EVDS. The importance of the registration was that it allowed the facility to plan and schedule people so it did not necessarily have to have long queues in the facility, and people would know exactly when to go and at what time. The Department did not anticipate long waiting times in that context, which would then also address the issues of social distancing.

Many provinces had identified vaccination sites, but some would not be there all of the time, because once that community had been vaccinated, the vaccinators would want to move on. The Department would be communicating all the sites. Once an individual was registered on the EVDS, the scheduling system would send a message informing an individual that they would be going to site X on this day and time, which would provide the individual with the specific site where they needed to be vaccinated.

Dr Buthelezi said that he would address some of the remaining questions.

One question was on the issue of Ms Mpho Seleka. The Department had asked for more information on the matter. Dr Seleka was dismissed on 16 March 2021, but the matter was not closed because she had appealed. The internal process of her dismissal was not yet finalised, so the Department would get that information from the chief executive officer (CEO) of the National Health Laboratory Services. It would officially respond in writing to the Member who asked the question. The Department had recently received a letter from the CEO, so it did have some details. With the appeal process, the matter could go to the Commission for Conciliation, Mediation and Arbitration (CCMA). If there was still an issue at the CCMA, it could go to the Labour Court. The Department would update the Members when it was briefed on the outcome of the appeal. It was an internal matter that was still ongoing, and the Department would await the outcome of the final internal processes.

Dr Buthelezi said that Dr Thembekwayo had been correct regarding the interns in the Eastern Cape – the Department had extended the contracts for three months. This was based on discussions with the Eastern Cape's provincial treasury and the availability of funding. He was aware that there were still discussions with the treasury, and he had had a discussion with the Head of Department (HOD) of the Eastern Cape DoH to see what the possibilities were to go beyond the three months that it had extended. Everyone had taken a knock in terms of budget cuts, so the Department would update the Members on that issue.

Regarding the interns in Gauteng, who were mainly in the medical field, the DG had said something officially to the HOD, and he would follow up that day and would respond through the Department's Parliamentary Liaison Officer (PLO) to the Member who had asked the question. He did have specific names, some of which had been shared with him by the Deputy Minister. The DG would follow up with the HOD in Gauteng, to check what the situation was.

The Minister asked if the Deputy Minister would like to come in.

Dr Joe Phaahla, Deputy Minister (DM) of Health, acknowledged that several Members had emphasised their scepticism, based on the number of healthcare workers vaccinated thus far. He urged the PC not to be too sceptical, because Members knew that the background to this was the fact that were already a million doses of Astra Zeneca vaccines due to be delivered in a few weeks' time. There was the fact that the rollout of that vaccine had been discontinued because of the report from the trials done in South Africa, which showed limited efficacy. That had clearly set South Africa backwards. The Sisonke phase 3b trial, which was being used to vaccinate the healthcare workers, had come in as a rescue plan, to make sure that in the absence of the 1.5 million doses secured of the Astra Zeneca vaccine which could not be used, the Department could then go to the Sisonke trial.

In light of what the Minister and other colleagues had said about the vaccines secured thus far, he urged the PC to have faith in the DoH, that pending clearing up the current difficulty with J&J -- which the Department hoped would be limited -- and the delivery of doses happened as committed by the manufacturers, all the vaccination sites which had already been prepared would be rolled out, and the numbers would be ramped up. The DM thought that it was "unfair" for Members to judge the Department on the basis of a setback to what had already been planned.

South Africa as a country and several other countries in the world were in a difficult situation because of the fact that the pandemic was wreaking havoc, and causing death and the destruction of normal life and economies. All of these countries were under pressure to find solutions. With Astra Zeneca, the Department had taken a precaution, but some members of society and leaders had already criticised the Department by saying that it should have gone ahead. If the Department had gone ahead and disregarded the scientific report, it "would have been hammered."

At the same there were the onerous conditions which the manufacturers were imposing, and also the risks, and despite all of South Africa's regulators and various authorities (including the WHO) helping to make sure that there was risk mitigation in the interest of safety, the reality was that all of this was being done in a fast-tracked fashion. Normally, vaccines and new medications were tested over a long period, and tested again, until they could be rolled out on a mass basis. However, because of the pressure of this pandemic, many of these things had had to be compressed and fast-tracked, and therefore in the process of implementing all over the world, there would be some challenges here and there. It was a question of balance, as one would hear various scientists saying. There was always going to be a balance between how many lives could be saved while at the same time knowing that because those things that usually take a long time have been compressed into a short time period, there would be some risks. However, the Department's aim would be to balance those factors and reduce the risk as much as possible.

Minister Mkhize said that the Department had noted Members' concerns, and it would try to give as many answers as it could. He wanted to clarify a few more issues.

He responded to why few people were vaccinated over the last weekend, and whether it was linked to the FDA issue. The delay had been because of the slow delivery of the vaccines, and did not have anything to do with the Department's concerns about the adverse reactions that had been reported. While there had been adverse reactions reported before, which had been part of the literature, there had not been much found in real life situations. The Department became aware of these issues as they were arising mainly in the USA only in the past few days, and therefore the Department's decision to suspend had been largely based on the consultations with South African scientists and experts, the ethics committees that were consulted, the head of the MAC, and the head of the South African Medical Research Council (SAMRC). All had agreed that there was a need to take this seriously, and to halt the J&J rollout temporarily. The Department also noted that with the J&J vaccine, it had suggested that the same thing -- temporary suspension -- should be done in Europe. The Department thought that it was important to be aligned in this case. At the moment, the Department did not think there would be a serious impact on the rollout, because it had had very few people vaccinated, and there were only 200 000 to go, which would be concluded in this week. This could be expedited without any problem if the Department resumed. It was not yet considering the termination of the contract.

Mr Munyai had asked how much had been allocated by National Treasury for vaccine administration. The Treasury had allocated over R10 billion to deal with the procurement of the vaccine. The rest of the administrative costs that were related to the accessories, staff, etc, would be carried by the departments at the provincial and national level on the basis of existing allocations. There was no specific allocation from Treasury for that.

Another Member had raised the issue of what would happen if the Department did not use the J&J vaccine. The Minister wanted to suggest that at this point, "we must consider this to be a precautionary halting of the programme," and that the Department would have enough information to guide it in this regard. In this process, the Department was in consultation with the Africa Centres for Disease Control and Prevention (ACDC), as well as the WHO. It would also look at what was going on in other countries, and would therefore be able to proceed from that point of view.

The manufacturers had put stringent conditions, particularly on the issue of the No-Fault Compensation Fund. However, the Department had accepted that this was a good proposal. The only thing it could not agree on was that the manufacturers could have discretion of deciding what to do with South African assets. The compensation fund was important, and it was agreed that it needed to be extended to deal with cover for protecting people against any medical injuries that arose in the course of normal healthcare.

The Department had acted timeously in the case of J&J. This matter had arisen only in the past few days, and from that point of view, the Department felt that it had acted adequately. There were people who had asked why it even wanted to take that precaution, but it believed that it was correct that it had dealt with it that way. Healthcare workers had been given access to J&J, and those who had

come to be vaccinated had done so willingly, and with a lot of enthusiasm, knowing what the vaccine situation was about. Workers had signed consent forms, so they were not being put in a situation with no choices. Those who might have wanted a different option would have access to the Pfizer vaccine later on, in the course of May.

There was an issue that was difficult for the Department to respond to. It was related to J&J as a company involved in the payment of hundreds of dollars, and how it controlled drug prices, etc. The Department was not part of that discussion, and so it was difficult for it to respond to all of these issues. Whatever the Department was dealing with, it would respond to it.

On the challenges Pfizer might have had with adverse effects, the whole world was going through those lessons at this point to find out what was significant, what the vaccination had reacted against, and what it was that warranted sending a warning to recipients.

The Minister would follow up on the investigation at SAHPRA. He did not have that information on hand, and would follow it up.

Regarding Ivermectin, a Member had referred to SAHPRA as having sort of allowed lives to be lost, and he thought that was "an incorrect point to make." SAHPRA analysed what had been submitted for its own approval, so it could not be held responsible for issues that took place outside that setting. The Minister did not agree with putting punitive costs at that level. The issue of SAHPRA, as far as the Department was concerned, was that there had not been a change from the original position -- that the evidence still quite weak and it did not confirm that Ivermectin could be used without any form of oversight. That was the understanding. In fact, the MAC had reviewed this issue three times, and had come to the same conclusion. A number of bodies, such as the CDC, the FDA and the WHO, were aligned to the same thinking, that the evidence was weak. The evidence also showed that there were minimal benefits in taking it, and the studies done were very small. There was a need to do a much bigger study. There was a need to understand what the basis of the decision that SAHPRA had taken was. Doctors could continue to order the drug on the basis of a Section 21 arrangement wherein they had to take responsibility for the outcomes of particular patients.

Ms Gwarube raised the issue of confusing terms. Where the Department was now, it was saying that its orders were confirmed on these particular vaccines, then it was expecting that there should be delivery on those, give or take some of the logistical issues that came in, and some of the issues that might need to be cleaned up in the communication between the DoH and the manufacturing companies. The 300 000 people that had been vaccinated had come through the J&J Sisonke protocol. Because of the Department's disappointment with the Astra Zeneca results, it had then felt that it needed to bridge that gap, but it was aware that there would be delays in the way that this had been done, and that this was a problem for the DoH, in the sense that the numbers showed that it was not vaccinating at full steam. Nevertheless, it understood that it could not blame anybody for that.

On the weekly breakdown of the vaccines, Pfizer had indicated to the Department that it was much easier for them for vaccines to come in on a regular basis, based on its ability to satisfy various players. To that extent, it wants to use a system which would enable it to get goods to South Africa as soon as it needed them, so that it did not end up having to store millions of vaccines that could have been used somewhere else. That had become one of the rate-determining steps in the speed of the rollout of the vaccine. The slowness of the roll-out had been related to the fact that South Africa had vaccines ready, but it could not go ahead. To say it was criminally slow was "not an appropriate term to use." The numbers that had been vaccinated would be increasing in the next few weeks when all the vaccines landedin the country.

[Ms Ismail wrote in the chat box:https://www.businessinsider.com/pfizer-vaccine-may-be-less-effective-uk-south-africa-variants-2021-4

[Ms Sukers wrote in the chat box: Please note the updated info on vaccine efficacy as per latest trials!]

[Dr Pillay wrote in the chat box: Please note the following in the above report: "The study suggests that the Pfizer vaccine provides less protection against the South African variant than the original coronavirus, but it is not able to actually conclude that because it is focused on those who have already tested positive for the virus, not total infection rates." Less protection does not imply no protection. The key outcome is reduced hospitalization and mortality. Higher levels of mild symptoms is a secondary outcome.]

[Mr Shaik Emam wrote in the chat box: Chair, I have a follow-up (question).]

[Ms Sukers wrote in the chat box: Please explain the meaning of "eight times more prevalent among the vaccinated study participants" in terms of breakthrough infections. "Our study indicates that vaccine effectiveness is lower against the SA variant" - as per Adi Stern, the study author and prof at Tel Aviv university.]

Dr Mkhize said there had been an interesting issue raised by Members. The question essentially was whether there would be a drug that had no side effects. The answer was no. The question was whether one had a cost-benefit analysis -- if the benefits of use exceeded the risk of the use of the medication. In this case, the figure of six adverse effects out of six million was not a huge number to halt the entire programme. It was an important issue for the Department to take into account. It needed an analysis on that to be able to know what was causing that effect so it could see how to limit the impact of those side effects. For example, was there a causal link between the vaccine and the effect that had been observed? Were there other conditions that were associated with it? Did it have to do with the vaccine, or the reaction to the vaccine? Were there conditions of age, of gender, the use of contraceptives, or other medication, co-morbidities, any familial factors, any cardiovascular or other allergic or connective tissue disorders? These were the factors that the answers must give the Department now. The DoH knew that the answers it would get now were not going to be accurate, and that it would take the Department a while before it could get adequate information from the scientific research. In terms of size, the numbers involved were not significant enough to pose a huge risk to the entire population. Nevertheless, it needed

to be investigated, and it should not come in as an opinion -- it should come in as the considered view of experts. That was why the Department had taken the approach that it had taken.

On the letter from the DTIC, the Minister was sitting in the meeting, and he was specifically asking, "What are the terms and conditions?" The Department had satisfied all of them. The issue was that this letter was from a different minister and a different department, but the DoH had already complied with all the regulations. All that the Department was trying to demonstrate was that these conditions sometimes kept evolving as time went on. The Department would deal with this issue in the way that it needed to be dealt with. At this point, it was trying to explain the conditions which were involved in the negotiations, and how the situation kept evolving. When the Department explained the difficulties, it was just trying to ensure that the PC appreciated what went into the negotiations, and what went into the terms and conditions that the Department had been asked to talk about.

The upcoming regulations on the vaccine compensation scheme could be commented upon, to include any additional requirements for transparency and fighting against corruption. The public was free to do that. It would be an independent body that would be presided over by a Chief Justice. This was to make sure that the scheme was transparent, and that it could deal with issues of corruption.

The Department was convinced that even though there had been reports that the Pfizer vaccine had shown a dilution in terms of the neutralising effect on the 501.V2 variant, South Africa actually had an effective vaccine against that variant. There was some work that had been done in a laboratory that indicated that there was still quite a lot of a neutralising effect, so the Department would use it. The Department had indicated that it would show the distribution per province, and to the public and private sectors. When that was ready, the Department would make it available.

Looking at the numbers that the Department had reported, it expected that those numbers would guide the rate at which South Africa vaccinated its people. That was why the Department was transparent about it, so that the Members "must not be so pessimistic" about the fact that this process was actually gaining momentum, and was going to be effectively rolled out in the next few weeks.

Dr Jacobs had indicated an appreciation of the immensity of the work. Part of that was how South Africa had assisted the African Union (AU) to use it as a framework to negotiate terms that were not worse than what South Africa had achieved. The Department thought that its team had done its best to deal with this issue.

The NFC fund regulations would be released, and when these were published, the Department would need comments. The Department had been pleased to see that former Chief Justice Ngcobo was prepared to lead, as he had adequate experience to deal with it. The funds that were involved in the NFC would come from the National Treasury. A Member had asked if the manufacturers were going to make a contribution, but there was no provision for them to do so. The Department thought that it needed to do everything to protect its people, and therefore the fiscus would deal with that issue.

Dr Jacobs had raised the issue of the confusion about the Western Cape procuring its own vaccine. The Minister did not understand why the Western Cape would have made such a statement when it knew that all the vaccines were procured by national government, both for the public sector and the private sector. All had worked together. It was the quickest way of limiting corruption, and also ensuring that there could be a fair distribution in the country. National Treasury had had to make certain special provisions to allow the country to be able to procure the vaccines in a manner that was not necessarily in keeping with South Africa's normal supply chain provisions, which no province would be allowed to do. The procurement had been done on behalf of all the provinces. A province could not on its own give all the indemnities, guarantees and immunity to these obligations, to any manufacturing company unless national government had done so. It was not possible for a province to procure any of these vaccines for itself. However, the Department had vaccines available for all of the provinces, so there would be equity in their distribution.

Ms Gela had asked how the Department would ensure the integrity of the vaccines. There was very sophisticated software that followed up on the vaccine storage, so that it could always see if there had been any breach in the vaccine cold chain storage conditions. It could be picked up, and that would therefore always be audited. If one looked at every batch, there was also an indication as to whether there had been tampering with any vaccine. The Department would be able to deal with that, and when the vaccines landed in the country, they would go through a quality control analysis that made sure that the quality of the vaccine was there. As the Department took the vaccines to the various provinces, it checked that the storage was going to be adequate, and that there was adequate training for the various vaccinators, so that everything was done in such a way that there was minimal wastage and loss of integrity of the vaccines.

The Department would have to publish the list of vaccination sites. The challenges with the vaccination sites was that it had given the numbers, but there were still a number of sites where the Department was trying to refine and agree on whether a location was in the right place or not. As soon as that had been done between the Department, the provinces and the private sector, it would be made available.

Ms Sukers had raised the issue of dismay about the terms demanded of government. The Minister was glad that Members appreciated what had cost all of this time, namely the delays in the negotiations because of the onerous nature of the terms and conditions. All of that was behind the Department at this point.

There was the issue of the Pfizer report from Israel. It was not different to the reports that the Department had got. This basically

refers to the dilution, but it did not mean that Pfizer was not effective against the 501.V2 variant.

On strategic procurement, this had largely been concluded, so the Minister did not think that the Department needed assistance there. Where the Department would need a lot of assistance was in procuring capacity at the vaccination level, and the distribution of the vaccine at the vaccination points. If there was any need for the Department to make a call, it would come back to Parliament on that.

A Member had raised an important point about the rising level of vaccine refusal and hesitancy. The Department would engage with the relevant sectors, particularly the Pentecostal and charismatic churches. There was work being done in various church formations to help the Department to reach out to people so that there was no fear of the vaccines.

Dr Thembekwayo had raised the issue of the Chinese and Russian vaccines. South Africa was still pursuing the procurement of some of the vaccines from these two countries. The Department had said that experts must try and expedite this discussion. The Minister had been in contact with a number of these companies personally, as had departmental teams as well. The DoH was aware that the process of registration of the Sputnik and Sinovac vaccines was on course, but Sinopharm was still a bit behind. The Department had not given up on these particular vaccines -- it believed that there was still a need for it to approach those companies.

At this point, the Department was not particularly worried that there was an immediate threat of a third wave, but it would watch that space.

There had been a discussion with Mr Patrick Soon-Shiong from Port Elizabeth, who had indicated that he wanted to go to the next generation of vaccine, and that he was working with a number of companies and research institutions in South Africa. The Department was very keen on that work, and so it had had a meeting with him and the Minister of Science and Innovation. That process indicated to the Department that there was a hope that South Africa could reach second generation vaccines, but also that it could end up playing a role in producing vaccines, and become successful.

Provincial vaccine schedules were dependent on the national vaccine delivery. The Department would align all of it so that there would be no problem with any particular province regarding vaccination availability.

Ms Chirwa had asked why Johnson & Johnson was going to be used in the rural areas, and Pfizer in the cities. It was a matter of convenience. There would be areas where the Department found that there was easy storage capacity and high population numbers that would use Pfizer, because it would like to find people who were available within a very short distance from the vaccination centre. The Department also wanted to make sure that in the rural areas, the storage demands did not compromise the quality of the vaccines. A once-off dose made it easy for people where there were transport challenges, and so on. The Department was quite confident on the efficacy of Johnson & Johnson, so it was not seen in any way as an inferior vaccine. Both the President and the Minister had actually taken that vaccine. At this point, the Department was quite happy that the J&J vaccine was suitable for use, and therefore it would be a case of just managing the logistics, as well as creating ease of administration, and that was what it was looking at. It was looking at it from that point of view, although there would be some people, particularly in the urban areas, who would maybe also be using Johnson & Johnson, particularly in areas where there were migrant communities which were moving and not easy to find at the same pace again.

Dr Mkhize noted Members' concerns about the capacity in the Department. It was building it up, and as the Deputy Minister indicated, it was going to be looking at that and giving a positive experience, rather than the sense of desperation that had been expressed. It had given an update on the Sputnik and Sinovac vaccines. The Department had said in the past that it was working with Cuba, but that was still at an early stage of development.

Between the Brazil, Russia, India, China and South Africa (BRICS) partners, there had been a decision to work together to build a vaccine institute. The Department hoped that South Africa would work together with those partners to build that capacity. South Africa had its own experts who had the capacity to investigate and analyse all the literature, and therefore they would be giving guidance in terms of what had happened to the Johnson & Johnson vaccine.

South Africa was not going to rely only on the FDA, as Members would have seen in the past when the Department dealt with Astra Zeneca, where it had used its own experts to give it a sense as to what was useful for South Africa. Even though Astra Zeneca was successful in the UK, Brazil and other parts of the world, South Africa had to take its own decisions. The Minister reassured Members that South Africa's own scientists and experts were good enough for the DoH to take guidance from those experts. It did not get guided only by what happened in other countries. However, South Africa knew what went on there, and it took into account its own situation.

The Department would by May have Pfizer as well, which meant that if there were any delays with Johnson & Johnson, the vaccination programme would not be delayed -- it would still continue. The Department had indicated that it would continue to follow up with Sputnik and Sinovac, and hopefully at some point, their vaccines would also be available. Bearing in mind this was new territory, and therefore there may well be unexpected issues that would arise, but the Department thought that the scientific findings up to now had guided it to be where it was, and that it was important to continue with that guidance, knowing that surprises would arise, or knowing that there would be areas where it would need to intervene in a particular way. All of that was part of a very complex process which no one in the world had experienced, and therefore countries kept learning from one another and also from the countries' own experience.

The list of vaccination sites was very long. The Department would, at some point, make it public, but in the process, there was quite a lot of cleaning up that it had to do. It was in disagreement in some areas, and was refining other areas. A very important point about the electronic vaccination data system was that not everyone could use the technology required. It had made provision for that – people could do it electronically themselves, but if they were not able to do so, there was a proposal for community health workers to assist. Nevertheless, when the Department called for vaccination of the elderly, it would invite them to the sites and they would register on the EVDS site. The prior registration helped the Department to plan, but effectively it needed a record of who had been vaccinated. It would do the vaccination, and it would also register people on the spot. It would make sure that no one was disadvantaged by a lack of access to technology. The Department would then be looking out for any form of confusion that needed to be cleared up in communicating to the elderly, with regard to the times at which they would to come for vaccination. With all of this, the Department would be doing regular updates, as the PC had requested.

There was quite a lot of discussion and work that went on behind the scenes with various departments, various committees, and various work streams. The Department was very confident at this point that everything was on course for it to be able to get the vaccination process moving. There were those who had felt that the slow vaccination rates of the past few weeks might be a matter of concern – and everyone was concerned about it – but nevertheless, that concern would be resolved with the number of vaccines that had been announced. In the past, the Department had not announced that it would have as many of these vaccines, and when it did have some challenges with the delivery, it had explained them. However, in the future it expected that it would be guided by all of the vaccines that should be coming through. It was looking forward to working together with all the communities, all the leaders in society and all the sectors of society, so that it delivered a very successful vaccination programme that would ensure that all South Africans were protected from COVID-19, and that South Africa would continue with its non-pharmaceutical interventions, such as the use of a mask, the use of social distancing, hand sanitisers, hand washing and encouraging people to be in well-ventilated areas.

The Department had had discussions with modellers over when South Africa was likely to have a resurgence, and there was general consensus that this would be determined largely by human behaviour. Minister Mkhize therefore wanted to encourage all South Africans to continue with the way they had managed so far, so that South Africa could stay on this plateau for much longer, and it would help if the Department could vaccinate as many people as possible whilst South Africa was on this plateau. The Department had seen in other countries that the fact that the vaccination had started, with millions of people having been vaccinated, they were still experiencing a resurgence. However, in South Africa's case without the vaccine being widespread, it had seen that it was able to reduce a resurgence so that it was now at a plateau. If it could continue to maintain this situation, it would then be in a position to delay the next resurgence, so that more South African's lives were saved. Of course, South Africa wanted to make sure that the vaccines were successful in preventing any further severity of infections, as well as hospitalisation and deaths.

Further discussion

The Chairperson said that a few Members wanted to make one follow-up question each.

[Ms Ismail wrote in the chat box: https://www.iol.co.za/news/politics/healthcare-workers-could-require-j-and-j-booster-shot-78f8393c-f45b-4226-9e3c-3d3e66888af7]

Ms Ismail said that the J&J trials had been evaluated for a period of efficacy for only around 60 to 70 days, and with the Pfizer vaccine, the trials were done for around six months. There had now been a social media report stating that healthcare workers should possibly get a second J&J booster shot. Did this mean that the original J&J one boost was not effective? In the same media statement, it was stated that J&J would do a two-day schedule to determine whether there was a longer-lasting protection with two doses. Had the Department received any feedback on this, and could it please give clarity and feedback on this matter?

Ms Sukers wanted to raise the concern that had been brought to the PC's attention where health care workers were concerned. She had heard the Minister speak about the tracking of adverse reactions to the vaccine. She had heard reports from healthcare workers, firstly, that there was a low buy-in from healthcare workers around the vaccines, and she thought that the PC had established some of the concerns as well, or had raised them. The second was that where there were adverse reactions, the staff had been asked to not speak about it. That was a concern, and she had raised it in terms of the NDAs and the need for transparency. This fed into more concerns for MPs, and also because it reflected the concerns of constituents who were saying that the healthcare workers were muzzled when they showed any kind of adverse effects.

Mr Shaik Emam said he was not satisfied with the explanation that the Minister had given regarding Ivermectin. In the Minister's explanation, he had conceded that the evidence was weak. He said it was not true that one now needed a section 21 application to roll out Ivermectin. In terms of the settlement agreement, Ivermectin could be used without any such section 21 application any more. The FDA, the World Health Organisation and other institutions agreed – as did he – that there might not be enough evidence yet that Ivermectin worked for COVID-19, but that was as a result of the limited tests and trials. However, the limited tests and trials that had been done had "proven without any doubt" great efficacy in fighting COVID-19. What was the reason that SAHPRA and the Department had not done anything, but had now agreed to roll it out? Was it because now the vaccines were procured, and the pharmaceutical industry was protected, and their interests had been seen to? Now the Department wanted to roll out Ivermectin. There was no change in the evidence, and yet it had changed its decision -- R2 million later, many lives lost later. He wanted the Department to give an explanation of why it had changed its attitude and decision when there was no new evidence.

DoH's responses

Minister Mkhize said he had read the latest report from the WHO on Ivermectin, and that was where the Department stood. There were issues that were still going on regarding the court matter, which as far as SAHPRA had reported to the Minister, SAHPRA was appealing clauses 1 and 2, which had not been discussed. The judge had stated that he had heard the counsel for the applicant, and it was a lengthy matter that was being dealt with. There was that issue in court. The Department would still insist that the position of the WHO was that the current evidence on the use of Ivermectin to treat COVID-19 patients was inconclusive. Whatever else the Department did, the PC needed to understand that that was where it was coming from. The Department was not involved in taking care of the interests of pharmaceutical companies. As a regulator, SAHRA had to focus on available evidence and findings from the studies that had been done, so that was really what guided the Department in terms of how it dealt with these particular issues. He did not believe that there was much more the Department could do. The point at the end of the day was that if the evidence remained inconclusive, the matter would remain on the table for debate until the Department had conclusive evidence.

The Department had said that with Ivermectin, the doctors who dealt with it must take responsibility. It was on that basis that one was allowed the limited use of the medication. If one did not have full evidence, then one could allow whoever was taking charge of it to collect basic information about the safety of the patient, so that that person must take responsibility for whatever outcome resulted. If a doctor said, "I think this will help", then the doctor became the ultimate person that would then utilise that particular drug, and on that basis, the doctor could be allowed to use it. If that doctor used it and anything untoward happened, one could not say that the regulator had said it was safe. The regulator was here to protect South Africans. SAHPRA was not about protecting the interests of pharmaceutical companies-- it was about protecting the public. SAHPRA had to ensure that it analysed all the research findings around the development of a particular product, until it was satisfied that there was nothing unsafe about that product, in order to protect South Africans. That was what SAHPRA was all about and therefore, if it was not sure that this would actually protect South Africans, it would say so. However, if there was an insistence from a particular doctor that she/he would like to use this particular medication on the basis of X and Y that they had seen, then of course there was leeway to get the doctor to help the patient on the basis that the doctor had to take responsibility.

The next question was from Ms Ismail, talking about the second booster from Johnson & Johnson. The current approach to the J&J vaccine was not to use a booster. There had been discussions with various other manufacturers who had suggested that they could combine the technology, and therefore maybe also use a booster. For example, when the Department raised the issue of Astra Zeneca, there were some scientists who were speculating that maybe in future South Africa might end up using AstraZeneca, and then when the J&J vaccine came, it could be used as a booster. It was in the context of that debate, but not because that was what the protocol was on the use of the J&J vaccine. The Department had not received any further feedback from J&J about the two-jab schedule that Ms Ismail was talking about. It had had only one approach, and that was that the J&J vaccines would be administered to an individual, and it was expected that in 14 days there should be the development of immunity, and that there would not be a need for a second booster as one moved into the future. The trials done were based on this approach. The Department had therefore felt that there was no need to consider combining the J&J vaccine with something else. What was stated on social media was not necessarily a matter of authority. The Minister had not seen such reports himself. What the Department says about Johnson & Johnson was what it knew, and that was what it was going to implement as a country. There could well be a debate going on with views, with suggestions, with hearsay, with everything that came through social media, but it was difficult to say that a report from social media would actually make the Department change something in the management of this vaccine. At this point, the Department would continue with it in the way that had been described – that was that only a once-off dose was needed, and the Department had described how it wanted to use it in the country.

Ms Ismail clarified that the report was not actually just on social media -- it was the fact that a professor had put on to a media statement. He had been interviewed, so it was not just a social media statement. It was from a professor that she knew the Minister and the MAC spoke to.

The Minister replied that the Department could follow up on the statement that came from the professor. He was not aware of it, but when the Department knew about it, it could talk about it. However, right now the Department was not getting any advice from Johnson & Johnson that there should be any booster provided for the doses that the Department was dealing with. It would refer what the professor had said to the MAC so that it could be debated.

The other issue was related to tracking adverse reactions to vaccines. All those who had gone through the vaccines had been advised to report if there were any adverse reactions, and the Department had not yet received a report of anyone who had been found to have suffered the kind of adverse reaction that had been reported in the USA. It had also not had any serious reports that were suggesting it was picking up adverse effects from the J&J vaccines. Fortunately, all those who were in this particular cohort had actually been recorded as part of a study, so there was an obligation to report if there was any particular challenge that was coming from the vaccinations.

It was as serious allegation that a Member was making, that healthcare workers had been muzzled, and that they had been told not to speak about adverse reactions. The Minister requested that the Member should please write to him and give him the specifics, so the Department could find out what had actually happened. There was no way that one could muzzle a healthcare worker. In the first instance, the bulk of workers tended to understand the issues of drug reactions and adverse effects of any medical product that was administered. Such workers would know that they needed to seek assistance. He did not believe that it was accurate information that had been conveyed to these particular health workers, as there was no requirement for anyone to hide any side effects or any symptoms. If there was such an incident, the Department would have to deal with it, and it had not been brought to its attention. Now that a Member was bringing it to the Department's attention, it would like to get more details and it would follow it up, but when

Members came across healthcare workers in their capacity as a public representative, they must indicate to workers that they actually had an obligation to report the side effects, or any adverse effects.

During this Sisonke protocol it was even more so, but even afterwards, when Government did the normal vaccination rollout programme, every person who had any symptoms or any side effects needed to report them, and it was important for the DoH to send out that message. That was the basis on which the Department was now setting up the NFC Fund, so that people would not feel that they could suffer harm, and not be able to get the matter addressed. The Department needed to make sure that this was made very well known, and no one could be silenced when it came to any possible side effects they might be suffering. Let them be examined so that the Department knew what exactly the cause of the problem was. It would then establish whether there was a causal link between the vaccine and the symptom that the individual was experiencing. There should not be any doubt amongst the Members of this particular Committee that the Department would not accept any muzzling. It would always make sure that all of its members of staff sent the same and correct message that if a person had any symptoms that were uncomfortable, they should just come back and report so that the Department could record them. It was to the Department's benefit to know what was going on.

If there were any issues to be concerned with, the Department would monitor them. That was why it was doing the Sisonke protocol. It would do a similar kind of post-market surveillance with Pfizer as well, just to make sure that in a larger cohort of vaccinees, it picked up anything that was worth focusing on as a matter of concern. The Department would make sure that when it got the details of the issue raised, it would investigate the matter, and take it forward. In this current Sisonke protocol, ethics committees obviously had to oversee any possibility of an infringement of the human rights of any individual participating. As the Department moved into the future, the same principles would apply to all those who would receive the vaccine -- that one could not hide the adverse effects of any drug. When the next opportunity arose, the Department would come to share the progress that it had been able to register at that point.

[Ms Sukers wrote in the chat box: So, we are still sourcing for other vaccines but we are not in need of assistance with strategic sourcing? It is not just social media unfortunately.]

The Chairperson requested that as there was going to be another public update, which the Department normally did in a webinar, could the team of the Minister's office please inform the PC on time? Some Members wanted to join in and listen. Sometimes the PC got those invitations late.

He thanked the Department for the presentation and also the engagement. It would probably be in a fortnight's time that the PC had another interaction with the Department. The work that the DoH was doing, and the flexibility it showed as a leader, was appreciated. There was a moving target, which was moving quite fast, and the PC really hoped that the Department was going to have a very short pause with the J&J vaccine. Of course, the issue was that it was just six patients out of six million, but the Department was taking precautions. The PC was looking forward to receiving an update on this matter.

The Minister thanked the Chairperson, and said that the Department would make sure that it informed the PC on time.

Adoption of Committee Programme

The Chairperson presented a draft Committee programme for consideration by the Members prior to submitting it to the House Chair for approval.

He said Parliament reopened on 4 May, and that week there was an expectation from all committees to process annual reports of entities and departments that they were associated with for the purpose of preparing for mini plenaries.

On 4 May, it was suggested that Members have a meeting with the Auditor- General (AG), who could point out issues they should look out for, prior to listening to the Minister and the entities. Following that, the PC needed to get the Financial and Fiscal Commission to come in and raise their issues. On the same day, it would have to receive the annual presentation of the South African Medical Research Council (SAMRC) -- three presentations on one day.

The next day, the PC had a briefing by the medical schemes and a briefing by SAHPRA. All of those entities were also coming in with their annual performance plans, but he was aware that Members also wanted to ask some of the questions relevant to the things that they were dealing with, and the Chairperson would not stop Members from doing that.

[Ms E Wilson (DA) wrote in the chat box: Time was indeed limited Chair, but we must be mindful of constituency duties.]

On May 6, the Chairperson did not know whether there would political party caucuses. Hence, it had been requested that the briefing from the Compensation Commissioner for Occupational Diseases be done at 08h00, so that in the event that there were caucuses, the PC could break at 10h00 and reconvene at 13h00 to take the Office of Health Standards Compliance (OHSC) and the briefing by the National Health Laboratory Service (NHLS),

The PC had to continue on Friday, 7 May, to get a briefing from the Department of Health from 09h00. This meant that the Committee Secretary would have to compile a report after the briefing by the Minister over the weekend, and on Monday, the PC would consider and then give its views on the report. That was critical, because all committees had to complete their work by 12 May.

The budget vote for the DoH was starting on 13 May, and therefore it was coming in much earlier than usual. That part was a Parliamentary obligation that the PC could not change. It had to be approved.

The Chairperson said Members would recall that the Committee had been inundated with work carried over from the previous administration. Now, not through its own fault, the National Health Insurance Bill (NHI) had been sitting with the PC for longer than one would expect because of COVID-19 and other challenges. He requested that during the period from 13 to 26 May, after the debates on the budget of the DoH, the PC consider doing public hearings, which would involve listening to 121 organisations that were coming in. It would come as a separate application for submission that the PC consider 18, 19 and 20 May, sitting in virtually to listen to those public hearings. Thereafter, it could visit vaccination sites and perhaps see one or two hospitals. There were challenges out there that the PC was not aware of. A separate submission would be made for the Committee to conduct an oversight visit to the Northern Cape from May 20 to 22. The following week, it would conduct oversight in the Western Cape.

Ms Gela fully supported the programme of action. She hoped the PC would have the site visits in order to check the vaccination sites. She moved for approval of the programme.

Ms Gwarube said Members should appreciate that this was a massive balancing act for everyone, and that there was a lot going on. She was in full support of the programme. The parliamentary programme was one that could not be changed. She supported the suggestion to conduct oversight in the various provinces and to listen to the submissions by organisations. The only thing that she saw as a problem was the proposal for the constituency period in August. If things went according to what the Independent Electoral Commission (IEC) had said, then South Africa would be approaching an election in less than eight weeks, so there was bound to be too much pressure at that time to really be on the ground. The Committee could look at using the first week after Parliament rises. She did not foresee the PC being able to use a chunk of its constituency period so close to an election.

Dr Jacobs said that the PC should be mindful of what had been raised by Ms Gwarube. The Committee had to approve today the first part of the programme, up to the Minister's budget vote on 13 May. He seconded Ms Gela's proposal to approve it, and that the PC approve the second part, considering what had been raised by Ms Gwarube, that as the PC moves forward, it might have to make a few changes here and there.

The Chairperson responded that the PC might then not go right up to August. Using just one week might not be a problem. It would be up to the Committee to decide such things as using the time up to the middle of July, and nothing more than that. They could agree to approve the first part of the programme, which was non-negotiable. He would bring the other part back, and the PC may have to make some adjustments.

The PC was now in a constituency week. There were certain Members that were on the ground working, but he doubted whether they had as heavy a schedule as those present. It might mean working over some weekends, but he was glad that Members were agreeing that even if there was constituency work, the PC would continue on the Thursday, Friday and Saturday, and do these visits in the provinces. Its visibility in provinces was very limited, and it should not be like that.

Adoption of Minutes

Dr Jacobs moved the adoption of the minutes of 24 March 2021, and Ms Gela seconded.

In the statement that the PC would release today, among other things, it would wish Mr M Sokatsha (ANC) a speedy recovery while he was still in hospital, and also wish Mr T Munyai (ANC) a speedy recovery after his accident.

There was some confusion at the end of the meeting as to what was going on. Members were not sure if the meeting was adjourned. Mr Shaik Emam said the Chairperson had said that Members were released.

Ms Sukers said that she still wanted to inform the Chairperson about an oversight visit to Helderberg, and wanted to hear if any of the PC Members would like to join her.

At that point, the Chairperson had already left the meeting.

Ms Gwarube suggested calling the Chairperson on the side, and that the Members could discuss the visit on the PC's WhatsApp group.

Dr Jacobs said that he would like to support Ms Sukers.

The meeting was adjourned.The Chairperson asked the Committee Secretary if there was a quorum, which was confirmed as being the case. While Mr P van Staden (FF+) had sent an apology, he had also sent a question to the Chairperson that he wanted to ask, and he had incorporated this into his opening remarks.

He asked for the adoption of the agenda, and if Members of the Portfolio Committee (PC) could stay on until about 12:45pm to sort out items seven and eight on the agenda.

Mr Thobani Matheza, Chief of Staff: Office of the Minister of Health, told the meeting that the Minister would be joining shortly, as he was having technical difficulties.

Department of Health delegation

Dr Sandile Buthelezi, Director-General: Department of Health (DoH), introduced the delegation from the DoH. The delegates were:

Mr Ian van der Merwe, Chief Financial Officer (CFO);
Dr Anban Pillay, Deputy Director General: Health Regulation and Compliance;
Mr Thobani Matheza, Chief of Staff: Office of the Minister of Health;
Ms Cawekazi Gcasamba, Parliamentary Liaison Officer;
Ms Ayanda Ngubo, Head of the Office of the Director General;
Dr Aquina Thulare, Technical Advisor; and
Dr Lwazi Manzi, Media Liaison Officer: Office of the Minister of Health.

Chairperson's opening remarks

The Chairperson acknowledged the presence of the Minister of Health, and said the Portfolio Committee (PC) had a legislative obligation to do oversight on the Department's work and on the Minister as an executive authority. He wanted to inform the Members that in preparation for this meeting, he had written a letter to the Minister as part of the invitation, in which he made specific requests for him to cover certain topics. One was that the Minister, in the previous meeting with the PC, when mentioning the Johnson & Johnson (J&J) vaccines, had mentioned that these were part of the clinical trial vaccine vials that were left behind. South Africa was not paying for those vials as yet, but going forward, it looked like it was going to be a different issue. The PC noted the announcement made last week, that there were 51 million vaccines that had to date been secured. The Minister would have to give the PC a bit more detail on this information, so it would be able to play its oversight role.

It was against this background that the PC would like to know how many vaccines had been procured from J&J, and the costs of each. How many vaccines were being procured from Pfizer, and at what cost? If there was any other procurement from any other source, the PC would also like to know that. The Minister would have to confirm to the Committee that the cost of the Astra Zeneca and Serum Institute of India vaccines had been taken care of in terms of a refund for the 500 000 doses that were still remaining.

South Africa had received R1 million in payment for those vaccines that went to the African Union and the PC would like to get that confirmed. It had heard that there were agreements with onerous clauses that had been entered into, and he asked that if the Minister could give the PC details of such clauses. Could he explain the extent of indemnity that was sought by the vaccine manufacturing companies? If these clauses were onerous, where they negotiated, and what was the outcome of such negotiations?

The PC had also been advised government was now required to form a no-fault compensation fund. What was the purpose of this fund? Would the manufacturers also make any contribution towards such a fund? What were the benefits and disadvantages of such a fund? The PC would also like the Minister to share with it details regarding the formation of such a fund, and when a policy governing such a fund would be made public, including how Government would ensure that this was independent, and these decisions were credible and could then stand legal scrutiny.

The Chairperson then read out Mr Van Staden's questions, which asked whether the temporary suspension of the J&J vaccine by the United States Food and Drug Administration (FDA), and the Government's subsequent announcement, would it have any impact on the vaccine rollout in the country. The Committee was aware that the scientists were meeting and preparing to advise the Minister, and perhaps the Minister knew when they would be able to advise when the suspension could be lifted.

The Chairperson hoped that these topics would be covered in the Minister's presentation, and if not, the Members would have to follow up with Parliamentary questions to the Department. That was why he had specifically written those questions down, because the PC would need to record that as Parliament, it had engaged and asked those questions of the Minister.

Minister's overview

Dr Zweli Mkhize, Minister of Health, said he would give preliminary comments in response to the Chairperson's introduction, and then the Director-General would share a presentation with the Members.

He wanted to start by acknowledging the fact that he had received the Chairperson's letter on 12 April, and he could confirm that he received a list of questions from the Chairperson that sought details on the vaccine acquisition process. The Chairperson and Members were aware that throughout the negotiation process, the Department stated that it had entered into non-disclosure and confidentiality agreements. However, it acknowledged its constitutional obligation to account to Parliament, and to provide the responses to Members. The Minister's response contained the direct responses to the questions that had been raised in the letter by the Chairperson.
(See Minister's statement attached).

The Department of Health (DoH) had procured 31 million vaccines from J&J. The initial agreement for 11 million vaccines was signed, and the initial purchase price had been paid. This agreement had included an option for the Department to call for 20 million more vaccines, after the signing of the initial agreement. This option was immediately exercised to ensure that South Africa secured enough vaccines, so it was now procuring a total of 31 million vaccines from J&J. The conditions of the first agreements have been met.

In the second agreement, J&J approved a precondition that No Fault Compensation (NFC) Fund regulations must be published by 30 April. This condition had also been required by Pfizer. The Department was pleased that yesterday, the National Coronavirus Command Council (NCCC) had accepted the recommendation for the draft regulations to be published for public comments in relation to the No Fault Compensation Fund. This meant that South Africans would have an opportunity to make their inputs and comments on the draft regulations. This would take a period of about five days, which emphasised that the Department recognised that this period was shorter than the usual processes followed by Parliament for normal public consultation. However, the DoH believed that it gave it an opportunity to implement the Vaccine Adverse Events Compensation Scheme at the same time as it started to roll out the vaccines, which would be expected in the next few days -- the Minister estimated by next week.

It was important to Government that it would be complying not only with the terms of the agreement, but it would also be a guarantee and assurance to each and every citizen that their rights were fully protected during the process of the vaccination, and that there was sufficient recourse that indicated that measures were in place to deal with any adverse events that might occur once a person had been vaccinated. In the structure of the fund, there had not been any undertaking by any of the manufacturers to make a contribution, so the Department believed that this would be mainly a Government- funded exercise. The Department would therefore be taking into account the processing of all the public comments that it received, so that it was in a position to formally gazette the final regulations by 22 April.

As the Department had publicly announced, it intended the NFC Fund to be independent, and have the credibility and skills that were required. The DoH would now finalise the process of identifying a seasoned, retired judge to chair the scheme. Because of the urgent press briefing that the Department had the previous evening, he had had to postpone the planned meeting with the judge, as the Department was supposed to finalise a formal appointment process, and all the other administrative matters that were linked to that.

He could now formally advise the Committee that the retired Chief Justice Sandile Ngcobo had graciously agreed to assist the DoH with the mammoth task of chairing this first-of-its-kind fund. The Department believed that Mr Ngcobo's extensive experience as a jurist, including having headed the highest court in the land -- the Constitutional Court -- and his recent experience in health-related complexities, such as the health market inquiry, made him the ideal candidate to be able to oversee that all claims and processes were followed by the NFC Fund to uphold the principles of fairness, transparency, equity, and protecting the constitutional rights of South African citizens.

This therefore showed the Department's preparedness, that whilst it had fully indemnified manufacturers against any third-party claims, it would also put in place sufficient mechanisms to protect South African citizens.

After receiving the second agreement from J&J, based on the same terms as the previous agreement, and the additional precondition that had been discussed and agreed to between it and the Department, it had unfortunately now received a formal email from J&J advising that it would not sign off the 20 million doses until it received a letter from the Department of Trade Industry and Competition (DTIC) which expressed support for the local investment that J&J had made in Aspen. The Department had been taken aback by this, as there were clauses in the agreement that expressed its support and acknowledged that this production would not just be limited to South Africa and the continent, but was also targeted for the global market. Members were also aware that recently the President had led a delegation to Aspen in Gqeberha. The Department's support for this production taking place in the country was made publicly. It was of the view that the commitment had been expressed in full, as it was indicated in the signed agreement. J&J had now told the Department that if it did not give them this letter, it had not shown its political will to support J&J. The Minister mentioned this to the Chairperson, to illustrate to Members some of the difficult and sometimes unreasonable terms or preconditions that the Department had had to navigate through.

The Minister assured the Committee that "we've not been sleeping on the job." The fact that it did not previously disclose to Parliament the blow-by-blow details of the intense negotiations was because it was prioritising the closing of the agreement in order to secure the vaccines that SA required for it to reach population immunity. There had been a lot of negotiations that had had to go on without the Department being able to discuss or divulge anything to the public while it was trying to make progress in the acquisition of vaccines.

Another "classic" illustration of the terms that the Department had to deal with that were too risky, was a precondition for the supply of vaccines that it had received from Pfizer towards the end of its negotiations. This precondition stated that the manufacturers wanted to have the sole discretion to determine additional terms and guarantees for the Department to fulfil its indemnity obligations. This condition posed a potential risk to Government assets and the fiscus. The DoH had expressed this to the manufacturers, and the Treasury had responded as the department responsible for protecting the fiscus. This had led to further delays in concluding the agreement, and meant a delay in the delivery schedule the Department was negotiating at the time. After intense negotiations by the Department's teams, Pfizer had finally considered removing this problematic term. The final agreement signed did not contain this condition, and the Department was therefore relieved. This obligation to have a determination, at the sole discretion of the manufacturer, did not bind South Africa. "As Government, we have found ourselves in the precarious position of having to choose between saving our citizens' lives and risking putting the country's assets into private companies' hands."

With all of the above negotiating complexities, the Minister wanted to say that the government's firm commitment throughout had been that it did not neglect its constitutional obligation to protect the lives and health of South Africa's people.

In response to the question asked about the different vaccines, he said the vaccine from Pfizer and J&J was US$10 per dose. The

AstraZeneca vaccine was $5.35 per dose. With regard to the AstraZeneca refund, the Minister confirmed that in March the Department had already received payment for the full African Union (AU) 1 million doses which it had sold to them. The amount paid was $5 250 000, which was the actual cost of the vaccines, less the freight. Last week, the DoH was refunded $2.675 million by the Serum Institute of India for the 500 000 doses that were not delivered.. It was therefore happy that it had avoided what could have been viewed as a fruitless and wasteful expenditure.

It was also important for the Minister to mention that the J&J and Pfizer agreements had non-refundability clauses. The agreement specifically stated that down-payments that had been made in advance by the Department would not be refundable by the manufacturer to it under any circumstances. This was another onerous term that it had to settle for. However, to give Members comfort, the DoH had checked with other jurisdictions if these terms had been included in their agreements, and it appeared to be the case. The Department was aware, for example, that the agreements that had been signed with the AU platform were similar to what the Department had signed, and in its consultation with the COVID-19 Vaccines Global Access Facility (COVAX), it had found out that a number of these onerous preconditions were also experienced by the AU.

Dr Mkhize announced that the Department had received formal acceptance and confirmation from Pfizer to increase the doses being received, from 20 million to 30 million. This therefore meant that the Department could now guarantee that the number of people that would be vaccinated with a Pfizer vaccine had increased from 10 million to 15 million. He was pleased that Pfizer had also given the Department a weekly delivery schedule for quarter two. The current weekly delivery shipping for quarter two under the existing supply agreement was confirmed as follows:

On 3, 10, 17 and 24 May, South Africa would receive 325 260 vaccines.
On 31 May and 7, 14, 21 and 27 June, that amount would almost double to 636 480 doses.

The Department would get an update for the following quarters. This meant that from Pfizer, the total doses to be received in the month of May would be 1 937 520, and in June there would be 2 547 090 doses. The vaccines were already paid for. The further 10 million doses committed this week would mean that with these doses to be supplied, Pfizer was committed to supply additional amounts in quarters two and three, which was based on the Department's plea to Pfizer that it needed to increase these doses so that South Africa could get its citizens vaccinated as quickly as possible before it experienced a third wave in the country. Pfizer had, in response, committed to an additional two million doses in quarter two, on top of what he had just mentioned above, in July. This would mean that in quarter three South Africa would have a total of 16.5 million vaccines from Pfizer. Then, in quarter four it would receive the balance of 6.9 million vaccines. J&J had now formally confirmed that South Africa would receive 2.1 million doses.

He also mentioned that with the FDA, and the Department's subsequent announcement as a country to halt the J&J rollout, the determination to lift the suspension would be made jointly with J&J. Once the Department had a clear decision, it would inform the public at large. Rather than an intention to completely withdraw the rollout, the Department remained confident that as Government, it was happy that almost 300 000 people had been vaccinated in the J&J vaccine trial in South Africa. It had not received any reports of adverse events that have been caused by vaccines, including that of clots.

The halting had been a temporary arrangement, which was a precautionary measure. The Department had consulted with J&J and various other players in the world to get guidance. It had also noticed that a report from J&J was that it would temporarily halt the vaccination programme in Europe. It was trying to align with what was happening globally, and take precautions for all its people to make sure people were safe.

Dr Mkhize said that in the presentation, the DoH had looked at a few areas of review, and amongst the issues, the Members would notice that there would be an indication that the major focus of vaccinations was going to be where co-morbidities and age were a factor. Being of 40 years and upwards, were some of the factors that were important. Beyond that, the Department had asked the provinces to give it a revised schedule, so there would be some provinces that would indicate that they might spill over to the early part of next year in the vaccination programme. The Department would then say at this point that the number of vaccination sites would be shared in a list. Members just needed to be aware that it would continue to refine this list, because there were both public and private sites where it ultimately needed to agree that these were where vaccinations would be taking place.

Update on vaccine roll-out

Dr Sandile Buthelezi, Director-General (DG), Department of Health, presented an update on the vaccine roll-out.

The presentation contained the following content:

- Epidemiology and surveillance;
- Update on vaccination roll-out planning;
- Update on the establishment of the No Fault Compensation Scheme

He gave details of the seven-day moving average of new cases, sentinel hospital admissions and COVID-19 deaths up to 8 April, (shown graphically on page three of the attached presentation document). He added that the epidemic was currently at a plateau phase, and South Africa was seeing infections that would go below the plateau phase after the first wave.

The average daily tests and proportion of positive tests was shown graphically on page four.

Dr Buthelezi added that the positivity rate had dropped -- it was sitting between 3.8% and up to about 4.4%. This was what was known as the "low transmission levels" of the epidemic currently.

The confirmed number of SARS-Cov-2 cases by province were detailed (page five), and Dr Buthelezi added that there had been some cluster infections in the Northern Cape. There had been a spike earlier in March, and there were cluster infections in the Namaqua district, mainly in the schools and some mines, and also in some taverns. The Department's response teams had managed to get in there and deal with those cases. They had done contact tracing, and put people into quarantine. Now it had settled in that area.

Current COVID-19 trends considered the number of new cases per 100 000 people per day. In comparing from 15 March 2021, one could see that the Northern Cape was the only province that had more than five cases per 100 000 per day. By 22 March, this had increased to 8.1 cases per 100 000 per day. After the interventions, by 29 March, this had decreased to 5.5 cases per 100 000 per day, and then on 5 April, this had gone down to 5.4 cases per 100 000 per day. The Northern Cape was still the only province that had more than 5 cases per 100 000 per day. The other provinces were at low transmission levels. The Department was monitoring this carefully, so that it could pick up if there was a surge in new infections.

Dr Buthelezi presented the expected and actual all-cause deaths during COVID-19 (see page seven), and said deaths from the second wave were much higher, compared to the first wave. This was similar with the number of cases, but these had now gone down. The Department was "still a bit worried," because the deaths normally lagged behind in terms of responding. The number of deaths was still above the number of predicted deaths, and things would start to settle only when the red line (recorded deaths) was equal to or below the green line (predicted deaths).

Summary of key indicators as at 11 April

New cases

- There was a slight decrease in new cases, from 6 533 cases in the preceding seven days (29 March – 4 April) to 6 495 cases in the last seven days (5 – 11 April), constituting a 0.58% decrease.
- The 14-day comparisons showed that the cases decreased from 15 163 in the preceding 14 days to 14 113 cases in the last 14 days, a 7% decrease.

Deaths

- The new COVID-19 related deaths decreased by 3.4% in the last 7 days (22 – 28 March) to 335 from 324 in the preceding seven days.
- However, the 14-days' comparison showed the deaths decreased by 50.7% to 659 in the last 14 days, compared to 1 337 in the preceding 14 days.
- The cumulative case fatality ratio was 3.42% (53 322:1 558 458). The Eastern Cape (21%), Gauteng (20%), KwaZulu-Natal (19%) and Western Cape (22%) accounted for 82% of all reported deaths.

Hospitalisations

- Based on the DATCOV hospital sentinel surveillance system, 968 patients were admitted in the last seven days (5 - 11 April), constituting a 33.8% decrease from the 1 462 patients admitted in the preceding seven days.
- As of 11 April, there were 3 614 patients admitted across the country, and of these, 620 (17.16%) were in an intensive care unit (ICU) and 323 (52.1%) were on ventilation.

Health care worker infections

- There were 14 health care workers (HCWs) who had tested positive in the last seven days (5 -11 April).
- No HCW death was recorded in the last seven days.
- Cumulatively, 55 539 HCW had tested positive. Of these 14.24% (7 908) had required admission, 6 724 (85.31%) had been discharged, and 84 were currently admitted.
- Health care workers constituted 3.57% of all cases of COVID-19 reported in the country. Cumulatively, a total of 852 deaths (1.53%) had been recorded among the health care workers.

Governance structures

- Interministerial Committee (IMC) on Vaccines: Overall political oversight and governance.
- Ministerial Advisory Committee (MAC) on Vaccines: Scientific guidance.
- MAC on Social and Behaviour Change: Social and community mobilisation.
- National Vaccine Coordinating Committee: National coordination.
- Joint Working Group with Partners: Day to day granular planning.

Vaccination phases and priorities

Dr Buthelezi said there was a need for clarity on the vaccination phases. Who were we vaccinating, who goes first and when? How much vaccine do we have? Allocation of targets? When would we distribute vaccines? He said that this information had already been

covered by the Minister.

Because of the difficulty of some of the logistics with the Pfizer vaccine, including the cold chain management and packaging, these would be used mostly in the metros, where it was easier to access the population. Also, the large pack size (1 170 doses) required high throughput (administered in five days) or a site would require -20 degree storage facilities for administration within 19 days. It could also be used ay work-based or mass vaccination sites.

The J&J vaccine would be used predominantly in rural districts, since it had fewer onerous requirements that needed to be met.

He told the Committee who would be vaccinated and when (see page 17), and defined the essential workers in the public sector and community, excluding HCWs. These were:

- Police
- Army
- Traffic Officers
- Correctional Officers
- Teachers, ECD
- Social workers
- Municipal workers
- Community based workers
- Home Affairs
- SASSA officials
- Faith Leaders
- Traditional leaders
- Traditional Healers

Targeted sectors in the private sector included agriculture, mining, manufacturing, utilities, construction, trade, transport, finance, community and social services, and private households (see page 19). The Department was working with the National Economic Development and Labour Council (NEDLAC) to reach people in these sectors.

Impact of age and other factors

This was work done by a team in the Western Cape. Age was the single highest predictor for morbidity and mortality. When the "hazard ratio" was used, the age bands above 60 were most at risk of getting severe COVID-19 and needing admission, but such groups were also the ones most at risk of dying from COVID-19. These groups were more at risk than those with co-morbidities such as diabetes, hypertension, hypercholesterolaemia, HIV and asthma. Vaccinating the high risk population groups before winter would result in 40 000 lives being saved, reduce hospitalisation by up to 50%, and reduce the costs that would be incurred by the healthcare system in managing infections.

Steps in the client journey

Dr Buthelezi outlined seven steps in the high level client journey. These were:

1. Social mobilisation and demand creation.
2. Enrolment on the electronic vaccination database system (EVDS).
3. Scheduling.
4. COVID-19 screening.
5. Verification of vaccinee details.
6. Vaccination.
7. Observation.

The Department had to allow for the fact that a client could exit at any point, and could enrol back into the programme. Anyone exiting should not be recorded as having received the vaccine. Paper-based forms would be used as contingency in case of load shedding, or if the EVDS was offline. Sites may allow for differentiated queuing/triaging between step 4 and 5.

Dr Buthelezi said that the Department expected the EVDS website to go live on Friday 16 April 2021. Some elderly people and those in rural areas might have problems with this. The Department had had meetings with the provinces, and the provinces would be having campaigns with community health workers, who would be going around with tablets and donated cell phones to register the elderly. It should not be a barrier if someone had not registered and got to a centre, as there would be assisted enrolment and computers at each of the sites. People would be registered in that case, although it might take a bit longer when they were there. The Department wanted to try to avoid such a situation as far as possible, because it did not want to clog the sites.

Vaccine supply chain timelines

In the case of international manufacture (Pfizer), it would take about nine days for a vaccine to be in the arm of a person. The Department was in negotiations with the National Control Laboratory to see if the testing process could be shortened.

In the case of local manufacture (J&J), it would take about five days before vaccination, and the Department had factored in the public holiday on Tuesday 27 April 2021.

Vaccination sites

There would be sequencing of the rollout across all vaccination sites, with age-based priortisation across all three settings. These settings were:

- General population vaccination sites (linked to public or private health facilities).
- Industry-facilitated vaccination sites.
- Institutions of care and support streams.

There would be small, medium/large and mass vaccination sites (see page 28), where the classification was based on throughput per day. Working with the private sector, the Department believed it would be able to do 250 000 to 300 000 vaccinations per day by September 2021.
Vaccination sites by province would be activated in an incremental manner.

Dr Buthelezi also provided details of the vaccination sites by size, as well as by local municipality.
(See pages 31 to 40)

Area based planning & reimbursement

National Treasury had allocated some money for the DoH to fund the uninsured population who would be scheduled to be vaccinated at private sites. The Department had weekly meetings with the Treasury, which would be working on gazetting the tariff. The public and private providers would play an important role in vaccinating the general population – both those who were insured and the uninsured. The principle here was universal coverage -- the vaccine should be free at the point of care. With the general population, most of them would be covered via medical schemes (between seven and eight million people), who would mostly use private providers. There were also uninsured workers in industry, who would be taken care of by their particular sector. For example, the mining sector would put up a particular kind of insurance to take care of miners who were not insured.

The primary objective was universal coverage – to cover the entire population; with best possible access; in the quickest possible way; without proliferating the number of vaccination sites. Access to service would be based on proximity to the nearest service point. The allocation of clients on the EVDS would be in the following order of preference:

- Uninsured population – public sector site, mass vaccination site, private sector site.
- Insured population – private sector site, mass vaccination site, public sector site.
- Workers – employer-provided site, mass vaccination site, private sector site.

For the public sector in phase 1b, there would be a hub/spoke outreach for smaller facilities. All hospitals were hubs, first vaccinating HCWs in their facility, and then vaccinating HCWs in smaller facilities. The small district hospitals, community health centres (CHCs) and clinics were spokes.

In phases 2 and 3, the Department would decommission vaccination sites at higher levels of care (regional, tertiary, central), as the hospital capacity would be required should there be a third wave.
It would retain district hospitals as vaccination hubs so that it had a geographical spread, and gradually expand the number of vaccination sites.

There had been 291 244 vaccinations to date, as at 13 April.

Problematic clauses in supply agreements
The Minister had spoken about the problematic clauses in the supply agreements between the Government and vaccine manufacturers. The DoH had entered into agreements with Johnson & Johnson, Pfizer and the Serum Institute. The agreements contained broad and far-reaching clauses which required government and the DOH to do the following:

- To indemnify the manufacturers against any claims arising from the use of the vaccines.
- Manufacturers, in addition, required the Government/DOH to demonstrate that the suppliers would have adequate protection against claims by establishing a No Fault Compensation Scheme.
- There were very onerous confidentiality obligations preventing the DOH from making any disclosures, and thus from being transparent to Parliament and the public.
- Provisions indicated that the Government/DOH would not be refunded should manufacturers delay or fail to deliver.
- The agreements protected manufacturers for any delay in delivery, such as there being no penalty or consequence for any delay in delivering vaccines. There was no liability for any failure to deliver doses, even where such a delay or failure was due to the gross negligence or wilful misconduct on their part.

Dr Buthelezi gave examples of provisions which had been removed through negotiation from the contracts:

• The requirement for the purchaser to provide guarantees, obligations, protections and indemnities as determined in the manufacturer's sole discretion.
• The sufficiency of such statutory or regulatory requirements or funding appropriation would be at the manufacturer's sole discretion.

No Fault Compensation (NFC) Scheme

In the process of procuring COVID-19 vaccines from suppliers as part of its COVID-19 vaccine rollout strategy, the Government was required to indemnify suppliers against adverse events resulting from the use of the vaccines. In order to ensure that any persons suffering from severe injuries as a result adverse events from the use of vaccines, suppliers required the establishment of a no fault compensation programme and a fund from which to pay compensation claims. Elements of the scheme included eligibility, process and decision making, standards of proof, elements of compensation, litigation rights, administration and funding

Dr Buthelezi added that such a scheme was a condition precedent that had been set by the vaccine manufacturers, but the Department viewed it as something that might be a good thing for the country moving forward, as the country considered how to manage medical negligence claims regarding compensation.

NFC committees and status

• National Immunisation Safety Expert Committee (already in existence), which was responsible for establishing the causal link between the vaccine and the injury.
• Adjudication panel, responsible for defining the injury and determining compensation.
• Appeals panel, which was responsible for reviewing the decision of the adjudication panel.
• Governance committee, which would be responsible for overseeing the functioning of the Scheme and providing advice to the Minister of Health. This Committee would be chaired by a retired judge.

The current status was that amendments to the Disaster Management Act (DMA) regulations to establish the Fund had been drafted, and would be published for public comment. The process of appointing the retired judge to chair the Governance Committee was under way.

Discussion

The Chairperson commented that the process of securing vaccines was not a simple one – it required lawyers, judges and other kinds of expertise. The PC was glad that the Department was on top of it.

He read out questions from Ms M Hlengwa (IFP), who was struggling to connect to the meeting platform. Regarding the decision to expand the vaccination roll-out, when did the Minister become aware of the possible risk associated with the J&J vaccine? Why was there so little vaccination over the past weekend? Was this perhaps linked to this announcement? What measures would the Government take to ensure that those healthcare workers who had had the vaccine were monitored closely, and given priority treatment? What was the Government's plan to ensure the safety of healthcare workers through being vaccinated going forward?

Mr A Shaik Emam (NFP) noted that Mr Van Staden had sent questions.

The Chairperson replied that he had incorporated Mr Van Staden's questions into his opening remarks. He summarised that Mr van Staden had asked: Due to the temporary suspension of the J&J vaccine by the FDA, and the announcement made by the Minister last night, would this have an impact on the vaccine roll-out? How long would the Minister wait for the scientists to come back to him?

The Chairperson also read out the questions of another Member, Mr T Munyai (ANC), who was struggling to connect: How much had been allocated by the National Treasury for vaccine administration?

Mr Shaik Emam asked what the financial implications of the suspension of the J&J vaccine were, and if South Africa was, for any reason, not going to use it in the future, over and above the large quantities of vaccines that had been ordered. Clearly that would have an impact if South Africa was not going to proceed with that. He was concerned that these pharmaceutical companies were "laughing all the way to the bank," because they had caught South Africa in a very difficult situation, particularly on the issue of no-fault compensation, over and above the fact that the companies were saying no refunds if South Africa cancelled. What would happen if South Africa had to cancel J&J, based on the challenges that it was facing, and the risks attached to that? "Why is it we don't act timeously when we establish worldwide that there are problems? Why do we wait until the eleventh hour before we take action, like in this case with Johnson & Johnson, and continue rolling it out and putting our healthcare workers at great risk."

Healthcare workers were given very few or no options. If one did not want to take the vaccine, one was not forced to take it, but one would not be protected as a healthcare worker if one got the virus. It was a "no-win" situation. He was particularly concerned about J&J, based on the fact that it had been found wanting, together with Aspen Pharmaceutical and McKinsey. Hundreds of millions of dollars had to be paid. He was very worried about this particular institution -- what impact it was having, and how it was controlling the prices.

South Africa was relying mainly on Pfizer and J&J, and he was concerned about what was going to happen going forward should it be established that there were problems with their vaccines. There was also the issue of Ivermectin. It was "shocking" and "a disgrace" that the South African Health Products Regulatory Authority (SAHPRA) had not allowed it, with no further evidence, after "hundreds of people may have died and been infected in South Africa". Who would be liable? The Minister's Chief of Staff had "arrogantly" written to him and said that he would hold Mr Shaik Emam for liable for punitive costs for wanting to pursue this matter. Should it not be the CEO paying punitive costs for having taken the decision singlehandedly, without intervention from the people? It might have cost a lot of lives in South Africa.

Where was SAHPRA involved in this? The Minister had procured vaccines because he had been "in a hurry" to get them. The Minister and Department could not be blamed if something went wrong with the vaccines, because all needed to be in line to get these vaccines. SAHPRA had allowed the Department to procure vaccines without any approval, but when it came to the issue of Ivermectin, there was not enough evidence. There was evidence that were challenges with the J&J vaccine, so should the PC call on the SAHPRA board to resign, particularly the CEO, who was conflicted with McKinsey, J&J, etc.? What was the Department going to do as the result of the Board's conduct, which was now costing "millions of taxpayers' money?" What was the latest on the Special Investigating Unit's (SIU's) investigation into the activities at SAHPRA involving corruption and maladministration? He had asked last time if McKinsey had paid their fine. Was there any link between what the Department had procured through Aspen and J&J, and McKinsey?

Ms S Gwarube (DA) said there had been confusion around terms such as "we have procured doses of the vaccine", or "we have secured doses here with this manufacturer", "we have reached an agreement with this manufacturer". These had often been made out to be milestones worth celebrating. What was the difference between these two? As it stood, there had been fewer than 300 000 healthcare workers vaccinated, yet the Department talked about how over 40 million people could be vaccinated due to what had been secured. What was the difference between when the Department "secures" something, and when it was in a position to be able to receive the vaccine and roll it out? Once an agreement was signed, was the next step delivery, and if the next step was delivery, was the next step then rollout?

There was a truncated delivery with Pfizer, in particular. The Department had talked about how in May, there would be different tranches of the vaccine rollout. She wanted to understand if it was because of South Africa's own storage capacity that it was only getting various doses that were limited?

She asked about vaccine rollout to healthcare workers. Members were of the understanding that the Sisonke trial was a trial phase, but it was always meant to target at least 500 000 people. The initial target was 1.2 million healthcare workers, and then that was re-adjusted to about 500 000 healthcare workers. As things stood, fewer than 300 000 healthcare workers had been vaccinated -- why was this so criminally slow? She could not understand why days went by when no health care workers were vaccinated. Over the Easter weekend, not a single South African was vaccinated. Over the past couple of days, these were marginal numbers. Why was this happening?

She asked about the Department's announcement around the FDA decision to halt the J&J rollout. The USA was in very different position than South Africa, because it had various vaccines in circulation, whereas South Africa did not. When South Africa halted the J&J rollout, it did not have anything else until Pfizer arrived. Was the decision made entirely on the basis that six people out of six million vaccinations had adverse effects? Was that a significant enough number for South Africa to halt the rollout of the vaccine? It seemed to her that the six out of six million was a very marginal figure. On what basis was this decision made?

The Department had said that J&J required a letter of support from the DTIC. What was the purpose of this letter, and when would the DTIC be able to sign it, as South Africa could not have any further delays? What must this letter say that needs to come from the DTIC?

Ms H Ismail (DA) asked if there had been any trials for the Pfizer vaccine. If yes, when could the PC expect results on Pfizer in the case of South Africa? What were the results with the South African variant with regard to Pfizer? Was this trial conducted in South Africa? What adverse side effects had been identified thus far in the South African context? There had been expectations of Pfizer, but there had been no talk on its trials. This was a bit worrisome.

Her next question was on J&J, with regard to "social media reports" on blood clotting, etc. When did the Government first know about the blood clots? Was this why the vaccinations had slowed down in South Africa? What adverse effects had been identified thus far in the South African context when it came to the J&J vaccine or trials?

Regarding the NFC Fund, she had asked questions at the previous meeting, but had not received all of her responses, so she was happy that the Chairperson had written that letter to the Minister. What measures would be put in place to ensure that the management of this fund was transparent? What measures would be put in place to prevent theft, fraud and corruption going forward?

She was very concerned about the recent reports of blood clotting, etc. South Africa had paid for these vaccines already, and the Minister had explained that there was a clause saying that there were no refunds. Since "we don't know of Pfizer trials with the South African variant," was government sure that it was doing the right thing of paying for vaccines on which trials were not done in South Africa -- unless there were trials being done in South Africa that the PC did not know about?

She asked for a detailed distribution plan on how and which vaccines would be distributed to the various provinces, and what factors would influence these decisions. The DoH was waiting for the provinces to send it their needs, but how would the Department decide

that the J&J vaccine was going to go to Gauteng, or the Pfizer vaccine was going to go to the Western Cape? What were the deciding factors on that? The Minister had specified that South Africa was receiving vaccines every week. Since the Pfizer vaccine had special requirements for storage, how was the Department going to ensure that the necessary amount of vaccinations would actually be taking place? Vaccination in this country was going very slowly. South Africa had already procured, it had already paid, and the DG had specified the delivery. She was concerned whether, on the ground, vaccinations would be done on time.

Dr K Jacobs (ANC) said that the PC noted that everything was very fluid and dynamic, and there were many changes on a daily basis. He thought that the PC must express appreciation that the Department was able to change on a daily basis and improve the terms and the negotiations for the betterment of the people of South Africa. With the intensity and difficulties of the negotiations, the PC had heard from the Department that there were great challenges, that it had been able to bridge a number of those negotiations with suitable terms and agreements with the manufacturers. The PC understood that these terms were put there by the manufacturers, and that it was the Department's job to make certain that all South Africans got the best deal out of this. However, the PC also noted the non-refundable clauses in the agreements, and it also heard from Mr Shaik Emam and Ms Ismail about their concerns with that. What happened to money that had been paid should the vaccine create challenges, such as J&J with blood clots? Could the Minister give the PC more indication and understanding of the non-refundable clauses within these agreements? The challenges must not be underestimated, as they might be huge.

The PC was happy to hear of the procurement agreement for larger amounts of the vaccine in the second, third and fourth quarters, and also of the timeframes for the receipt of the vaccines. It also noted the disclosure of the costs of the vaccines per dose, and the NFC Fund. A lot of good work had been done, and the PC should not negate that by not "giving honour where it should be given," and giving recognition where it should be given for the work that had gone into this.

One aspect of this work was the NFC Fund. The PC was pleased to see a plan which would be implementable, and that there was also some expediency appropriated to this plan. The PC also appreciated the appointment of Judge Sandile Ngcobo as the Chairperson of the Governance Committee, as one of the committees of the NFC Fund. The PC looked forward to the publication of the regulations for establishment of the fund, which the Minister said would be done in the next five days. Could the Department give an indication of the funding of this fund? Where would the funds come from, and could the Department give an indication as to the monitoring of the money of the fund once it was established?

On the confusion created by various groups, including the Western Cape Government, on the procurement and acquisition of vaccines, there seemed to be an ongoing discussion. He asked the Department to reaffirm the position on the acquisition and procurement of the vaccines at a national government level.

Ms A Gela (ANC) noted that more than 250 000 healthcare workers had been vaccinated, and the PC was looking forward to meeting the target of vaccinating all of the healthcare workers by at least mid-May, and also starting the second phase of the rollout. There was confidence that that would happen, despite the challenges coming forth, but she knew that those would be resolved. She acknowledged the vaccine rollout plan being clear in terms of vaccine procurement, the agreements in place with manufacturers, the distribution of vaccines per province, guidelines for the provinces, and vaccination sites identified. The previous Thursday, she had seen that the Department was checking the readiness and the vaccination sites in Gauteng, which was a good sign. The PC really appreciated the good work that the Department was doing throughout the country, checking the readiness and also making sure that all the sites were ready for implementation of the vaccine rollout. Who was responsible for the preparation of the vaccine sites? How would the integrity of vaccines, for example, be controlled? She reiterated her appreciation for the work that the Department was doing, and that the Minister was at the forefront.

Ms M Sukers (ACDP) said that a lot of the Members were dismayed at the terms that were being demanded. It proved the point that politics and business were a difficult combination. In reviewing the plan, she saw little provision for contingencies. The previous day, the FDA and the Centres for Disease Control and Prevention (CDC) had halted the use of the J&J vaccine, and a small study from Israel suggested that the Pfizer vaccine was not as effective against the B.1.351 variant. Further disruptions were very likely.

When she looked at the slide on the Joint Strategic Oversight Committee, she had seen a very small team working on supply, yet strategic sourcing and procurement had been the area in which South Africa had failed. How would the Minister work to strengthen the strategic sourcing capacity, and how could he be assisted to do this? It came back to the questions asked previously by her colleagues --the Department needed to make use of the collective Parliament to say, "How do we assist government to increase capacity?" She thought that one of the key failures was the fragmented approach -- the failure for the DoH to effectively communicate with Parliament, and put all its cards on the table in order for Parliament to really unify around solutions. Section 32 of the Bill of Rights stated that everyone had the right of access to any information held by the state. Members of Parliament (MPs) were representatives of the people, so it was "completely unacceptable" that MPs could not receive the information they needed to conduct oversight and hold the Executive accountable. "We cannot run away from our Constitution by simply saying, 'strict non-disclosure agreements'." This was contracting out of the Constitution, which was completely unacceptable. It was not enough to say that big business was dictating the terms to others. What steps was the Minister taking to ensure that people's constitutional rights were protected?

She commented that the Minister had mentioned the protection of the rights of South Africans in his opening. Vaccine refusal and hesitancy was increasing because of incorrect information from conspiracy theories, consultation being limited to groups government was comfortable with, and a lack of education. "We cannot think that we can order our people around, and tell them what they must think, and what is good for them." MPs needed to engage all people as key stakeholders, not just those who were in the structures

that government normally engaged with. For example, government had failed to engage with religious leaders from the newer Pentecostal and charismatic churches. How was it going to ensure wide involvement, not just with this group, but with all gaps that were not within the existing structures?

Dr S Thembekwayo (EFF) asked how many Chinese or Russian companies the Department had engaged on the possible supply of vaccines. Considering the rollout phases as they had been presented in relation to the available vaccines, specifically with regard to the J&J halt, and at the same time anticipating the possible adverse reactions that might be experienced by the healthcare workers, what was the DoH's contingency plan should that happen? How would the Department ensure that the healthcare providers' community was aware of the potential for adverse events? How would the Department plan for proper recognition and management due to the unique treatment required for this type of blood clot?

In Gauteng, there had recently been a warning of rising COVID-19 infections in Sedibeng, Johannesburg, Tshwane and Ekurhuleni. How did the Department approach this type of occurrence to prevent a further spread?

There was South African-born bioscientist who was behind the development of a new game-changer pill to prevent COVID-19. The vaccine, which had been tested in the form of a pill, would not have to be stored at low temperatures, according to Mr Morena Makhoana, the Biovac CEO, like the injectable vaccines. Had the Department considered having negotiations with this company and if not, why? If the Department was considering doing that, how speedily could it accommodate this company?

Mention had been made that the Department was expecting revised schedules from the provinces. This was confusing, because this provincial schedule of vaccination depended entirely on the schedule and availability of vaccines from the DoH itself. How would the Department make sure that there was less confusion and uncertainty regarding this aspect? The DG had mentioned that the Treasury had provided the Department with some money. What was the amount of money that had been provided by the Treasury, who controlled the usage, and how was it going to be used? She wanted to ask for feedback or any other information, because she usually did not get direct feedback from the Department about the questions that she posed about COVID-19.

She had a question about the Eastern Cape healthcare workers whose contract was supposed to end on 31 March. Even though the workers were told it was going to be extended, she had heard a report that the contract was extended for only three months. Why could the same not be done like in KwaZulu-Natal, and extend the contract to 12 months?

She asked for feedback on interns who were not receiving a stipend in Gauteng hospitals, while the others were receiving stipends in all the other provinces. She asked if she could get feedback saying whether interns would get stipends that would be backdated from January 2021.

Ms N Chirwa (EFF) wanted to know the reason behind deciding to centralise J&J vaccines in rural areas, and Pfizer in the metros. Her colleagues had raised this concern based on technicalities and the history in relation to reaching targets. Everything on paper looked quite convincing, despite the fact that aspirations should be much higher. How did the Department plan to reach the capacity to process 250 000 vaccines per day when it had failed with vaccinating 1.5 million healthcare workers, with the initial target at the end of April? The Department had extended the deadline and even reduced the plan for healthcare workers – it went down to 600 000, and now it was at 1.2 million, as shown in the presentation. There kept being changes, but none of the changes led the PC to believe that capacity was being increased, or that the Department would be able to get to a point where it was able to vaccinate 250 000 people per day. If one were to break it down from May to October, to reach the target that it had set, the Department would have to vaccinate 700 000 per week.

The Department was telling the PC about vaccination sites and vaccinators, who were said to be already available and already on site. Members had been told about the Department doing oversight visits to these vaccination sites, but this did not indicate that 250 000 vaccinations would be possible per day in phase two. There was a concern about that, because "it seems that we are just gearing for another failure, as we have been over the past few months and weeks of targets being changed, because capacity was proving to be a problem." There had been technical issues, vaccines not arriving, etc. Those may seem like small gaps in the presentation, and in how the Department presented this information to the PC, but as the PC, it knew better than to just take the Department's word for it, since history told it otherwise. Even if the Department were to bring a plan and say it would vaccinate 1.5 million healthcare workers, in mid-April the reality was that it was still at 250 000. That was very disappointing. It was very concerning, because then it meant that the Department would not reach the target that it had set for the second phase, of 22 million people by mid-October, based on the evidence of the work that had been done so far, and all of the targets, and the failures in the collective.

What was the update on the other vaccine manufacturers? It seemed that there was a decision that had been made already, and the PC must reach its own conclusion that as the executive, the Department had just decided on Pfizer and J&J, despite the fact that the Department had been coming in and out of the PC telling it about the other ones – such as Sputnik – and that it was in talks with other manufacturers. Could the Department give an update on what these talks had led to so far, especially regarding vaccines from China and Russia? It was good that the Department had decided to halt the J&J vaccination programme pending the outcome. What was being done domestically to get involved in the investigation process? Was South Africa having its own investigation, or was it just waiting for the FDA and the CDC to tell South Africa the results of an investigation? Did South Africa not have its own capacity as a country to either be involved at that level, or to have its own investigation beyond just monitoring? Part of the triggers that had been noted by the FDA was the issue of how entities had to monitor even very minor symptoms after vaccination. The Sisonke trial had said over and over again that the only symptoms it had had was nausea and muscle pain, but those were also primary symptoms that could lead to blood clots. How intricate, and how deeply involved was South Africa's monitoring system in relation to the investigation?

She knew that it would last a few days, and then it may mean that the vaccination programme could continue, or be halted altogether. If the results proved that J&J should be halted indefinitely, what was the strategy?

When Members spoke of alternative vaccinations, it was because in situations where the primary vaccines that South Africa had chosen -- Pfizer did not have such a high efficacy against the variants from South Africa, and J&J was being investigated – its hands were tied if there was not a large base of alternatives which could be made available. She wanted to know the reason why the Department was not securing other vaccines such as Sputnik.

The other issue she had raised last time with the DG was the issue of Ms Mpho Seleka, a senior medical scientist from the National Institute for Communicable Diseases (NICD), who had raised the issue of racism at the NICD, which had resulted in her being dismissed unfairly. She asked for an update, because it had been over two weeks, and she had not had an update from the DG in relation to this particular issue.

The Chairperson asked if the PC could agree that in the previous presentation, the Department had highlighted where it was with the Sputnik and Sinopharm vaccines. Could the PC have that slide retained for future presentations until the Department had made a decision, in light of whether SAHPRA had given it a green light to continue? The PC would appreciate it if that slide remained in the presentations, especially in light of how it was uncertain if South Africa was permanently tied to the two current vaccines – it needed to know the progress.

There was the issue of vaccination sites. Two days ago, he had been phoned by a journalist who was asking if he knew about the vaccination sites. He said that PC did know about the sites, because in the previous presentation, the Department had made a presentation about vaccination sites, but it appeared that this had not been well communicated. For example, if one lived near the Tulamahase Clinic, was that site going to be available, and when would one get to know if that site would become available? Right now, as the Department was supposed to be almost rounding off giving vaccines to healthcare workers, there needed to be massive planning for the rollout all over the country.

Related to that, it had been noted that there were some glitches regarding to particular healthcare workers here and there being able to register so that they were part of this programme. Did the Department expect same for all 60-year-olds and above, whether they were in rural areas or not, to register on the system? The PC needed that information, because these older people were all over the country, and the Chairperson needs to be very clear when he provided an answer to them what would be expected of them prior to being vaccinated.

DoH's response

Dr Anban Pillay, Deputy Director-General: Health Regulation and Compliance, DoH, responded to questions.

On the adverse events relating to the J&J vaccine, South Africa had not experienced any of these events that had been reported in the USA, but they had been experienced in other countries. One should bear in mind that South Africa's rollout was close to 300 000 doses, while in the USA, for example, over six million doses had already been administered, and it had had six cases. There had not been a causal link between the vaccine and the adverse events as yet. There may be other factors involved. That was the data that the FDA would have a look at and evaluate. SAHPRA was also looking at the matter. At the same time, a number of ethics committees locally had raised the question of whether the study of these signals should proceed. Adverse events could be called "signals" that were coming out of other countries, because it did raise a concern for South Africa that these adverse events may occur in this country. It may need to take measures because of that.

Dr Pillay thought that pausing the study was an opportunity for South Africa to look at whether these adverse events were linked to the vaccine. Firstly, if the effects were linked to the vaccine, which particular groups were affected, and what was the causal relationship – was it a particular type of age group, or were there other factors that the individual had that predisposed them to these types of clots? With those answers that colleagues in SAHPRA and the MAC would be looking for, there would potentially be some answers or approaches about how South Africa would be able to deal with the effects.

As part of the process of managing the safety of vaccines, South Africa had the Electronic Vaccine Data System (EVDS), which required that all adverse events were recorded on the system. After registration and after vaccination, there was a process of monitoring those adverse events as they occurred. The reason that Government was managing the rollout and using a single system -- the EVDS -- was so that it could get these signals of adverse events early, because if one had a single system and one noticed a particular adverse event popping up all over, that was usually the first signal that there was something that one needed to investigate and try and understand. The EVDS would be able to pick up the other adverse events that the Department was not currently aware of, if they occurred.

The temporary suspension would hopefully be for a short time, because it would be required that the Department investigate each of these, and make a decision about how it continued with the vaccine if that was the decision.

If South Africa chose not to procure further doses of the J&J vaccine, it would still be committed for the financial implications that were in the contract currently. It would have to make sure that it engaged J&J if it went that route, and it would have to be in the same mind about that. He thought that this was very early days, because this was simply a pausing of the study -- there had been no adverse events in South Africa. He thought that there were a number of other risk factors that caused adverse events, and the Department

would need to establish that first.

With the Pfizer vaccine, there were challenges, but these were all challenges that had come up in Europe in particular. Those had been investigated and in each case, it was found that these adverse events were not related to the vaccine, but were instead related to co-morbidities that individuals had. In Europe, at the time when these adverse events arose, they were largely among the elderly who had a number of other co-morbidities. When an adverse event occurred and an individual was vaccinated, the cautionary approach was to say that these adverse events were related to the vaccine until an investigation was done. That was the way most regulators in countries approached this matter until a causal link was actually established.

On the matter of secured versus received vaccines, what companies required South Africa to do as soon as it agreed on the number of doses, etc, was to sign what companies called a "term sheet." That term sheet contained the doses that would be supplied, and the price at which they would be supplied, in very broad terms. That effectively secured the doses, so when the Department talked about doses being secured, it was talking about signing off on the term sheet. After the term sheet had been signed, the manufacturer would then come with a very detailed agreement, and that agreement covered a number of parameters that were not necessarily in the term sheet. The Department then had to sign off on that agreement before the manufacturer would supply the doses, even though the DoH had secured the dose and the price earlier. The manufacturer would not ship any doses to a country until those conditions were met, and there was agreement on those conditions. Some of the conditions were very onerous. Under normal circumstances, in the DoH's usual contracts with pharmaceutical companies, it would not agree to those conditions, but the Department was in a very peculiar situation where it had a great need for the vaccine, and it would then have to re-look at those conditions with that context in mind. Once the agreement was signed, as part of the agreement, the Department got information about the delivery dates of those vaccines. The delivery dates were not specific days, so manufacturers do give a specific date. The Department would get those dates only after it paid the first deposit, and following that it would get some sense of what those dates could be. However, those dates "are not firm", as the companies had indicated to the Department.

Regarding the truncated supply from Pfizer, it was important to say that Pfizer was trying to give South Africa as many doses as it could in quarter two, based on South Africa's request. These were the doses that Pfizer could release on a weekly basis. South Africa's capacity to store was much greater than that, but demand exceeded supply at the global level, so this was what it was able to provide in small quantities over the several weeks that Pfizer was able to deliver doses to South Africa. It was happy to receive them because it helped, particularly in quarter two, where the Department was looking at trying to vaccinate as many of the high-risk groups during that time as possible.

It was important to note that the Sisonke study was regulated by SAHPRA in terms of the number of sites it had, and the way it conducted its study. As a consequence, there were very few sites that had actually been activated for vaccination, because the regulations were in place for researchers to do the vaccinations. It would be very slow, because there were only 40-odd sites that were doing vaccination. When South Africa moved to mass vaccination, there would be thousands of sites. The pace at which it would be going would be much higher, as it did not necessarily have to comply with all of the study requirements that Sisonke had to comply with. There would be a massive change. The provinces would be in full control of the process. All of their clinics could start vaccinating, and in private sector hospitals, a similar situation would exist. The Department's count was that it would have over 6 000 vaccinators available. The pace at which the country would be vaccinating would be much faster at that point.

From the J&J side, the incidence of one adverse event in one million was low, but it was important for the DOH to be cautious about these adverse events, so that it understands them, and it classifies them as adverse events that were rare, and related to particular risk groups. Maybe the Department would decide not to offer that vaccine to that risk group, for example. It could not simply say that it was continuing with vaccination without having an appreciation of what the causal relationship was.

Dr Pillay said the Pfizer vaccine was trialled in South Africa, and the trial results had been published and were available globally. The effect of the Pfizer vaccine on the variant had been available as well. The effect of the variant was not in a clinical trial, because when the vaccine was trialled in South Africa, the 501.V2 variant was not dominant, so researchers did not have results of that in their trial. Thereafter, what the researchers did was an "in-vitro assessment" – a challenge test of the vaccine against the variant. Researchers found that that the Pfizer vaccine continued to be effective against the variant, even in the challenge test. The MAC had looked at this data, and so had other scientists, and these parties were convinced that the Pfizer vaccine would be effective against South Africa's variant.

On the blood clots and when the Department knew about them, he said there was a scientific paper that had been published a few years ago that identified a number of the viral vectors that were used by most of the vaccines that were available now that had the propensity for potential clotting factors, the extent of which was fairly limited. However, the Department was seeing this issue rearing its head with the J&J vaccine. It had seen a bit of that with the Astra Zeneca vaccine, so it needed to better understand that. Dr Pillay thought that the scientists needed to do a lot more work on trying to understand what the pathways were for this to happen, what could be done to prevent it, and which groups should maybe get a different vaccine, because such groups may have a greater propensity for these types of clots.

On the No-Fault Compensation (NFC) fund, when the regulations come out, there would clearly be the principles relating to transparency and accountability, etc, as all funds of this nature were required to comply with the Public Finance Management Act (PFMA). There were a number of measures in the regulations that outlined what the accountability measures would be.

On the detailed distribution plan for the vaccines, as the Minister had indicated, the DoH would prefer that the Pfizer vaccine was

used predominantly in metro areas, and J&J in the rural areas, for a few reasons. One was that the Pfizer vaccine came in much larger dose quantities per pack. For example, one could have 1 100 doses in one package, and one would need to open the whole package. Once one opened it, one had to use that package. If one did not, one may then have wastage. The second reason was that the Pfizer vaccine required specialised refrigeration, which was available in much larger quantities in close proximity within the metro areas than in the rural areas. Thirdly, the Pfizer vaccine was a two-dose vaccine. With a two-dose vaccine, one wanted the person to come back to get the second dose. The Department knew from its experience with other vaccines, and across the world, that a two-dose vaccine worked better in areas where people were in particular confined areas, such as a workplace, or within an institution, where one could go back to them there and give them the second dose. If one gave the Pfizer vaccine in a community setting, the likelihood of the person remembering to come back, and of finding them, was usually a huge challenge, and that was what most countries had experienced. This created a situation where many people were vaccinated with only one dose instead of two, which was a real challenge.

On the contingency plans, the Department had the Pfizer vaccine as its contingency -- the Minister had shared that information already.

With regard to strategic sourcing, there were a very limited number of vaccine suppliers, and the Department had been engaging with all of them. The team that was involved was supported where necessary in pursuing the strategic sourcing. There were just a handful of suppliers -- large companies that were responsible for the production of these vaccines -- and the Department had been engaging with all of them. The difficulty all of these suppliers had was that the vaccines that they had were not in the quantities that were required globally, so demand exceeded supply. In South Africa's particular situation, the Department needed to understand whether the vaccine was effective against the variant, and many of these vaccines had not been assessed against South Africa's variant itself to understand that. Dr Pillay thought that that was a particular challenge for a number of the vaccines.

On the non-disclosure agreements (NDAs), the Department had approached the companies going forward to say that it had a constitutional obligation to share information with Parliament and with many other bodies regarding its accountability. Many of the clauses in such agreements made it very difficult to share this information, and the Department would like to be released from those NDAs for the purposed of sharing information. It would be awaiting the companies' response on how they saw that, because the way the NDAs were currently crafted, they did not allow the Department to share a lot of the information that it would certainly want to.

The Department was still engaging on the Sputnik, Sinopharm and Sinovac vaccines. With the Sputnik vaccine, there were a number of suppliers in South Africa, but the suppliers in South Africa did not have a lot of the clinical and technical information relating to this vaccine. The MAC had had to engage directly with the Gamelaya Institute, which it had done. There were a number of areas where further information was requested, which the Gamelaya Institute did not have at the time. Once that information became available to the Institute, the MAC could finalise its view on this. SAHPRA was independently engaging with these suppliers, and it had also requested information relating to various aspects of the vaccine.

In the case of the Sinopharm vaccine, the Department had signed an NDA with the supplier as Sinopharm had requested, which was very similar to the other manufacturers. It was hoping that the Sinopharm manufacturers would provide it with information. It had indicated that it was caught up with its suppliers in other countries, and it was not able to provide the Department with all the information that was required by the MAC, as well as by SAHPRA. Sinopharm manufacturers had attempted to register their product with the World Health Organisation (WHO), and if the product achieved a WHO pre-qualification approval, that may make it easier for SAHPRA to consider the product, because that information could be shared with SAHPRA for the purpose of registration. The Department was hoping that there would be some success on that front.

In the case of Sinovac, it had one supplier in South Africa, and the supplier had met with the MAC, and had shared information. There was additional information that the MAC would require from that supplier, and that had been communicated. Additionally, SAHPRA had been meeting with Sinovac's representative here as well to receive that information so that it could finalise its decision on it.

With the increase in the cases in Gauteng, the signal suggested that these were upticks which were small increases. These usually developed into upswings, but at this stage they remained upticks. The DoH kept watching the upticks. It had a dashboard which was publically available on the National Institute for Communicable Diseases (NICD) website, that identified each district, what its number of cases were, which direction it was moving in, and which ones appeared to be riskier than others. This was where the Department would engage with its provincial colleagues, and ask them to put in more effort to reduce the transmission in those areas.

The Department had been talking to Biovac, and Biovac was part of the MAC as well. At this stage, the company that was responsible for the vaccine was still in the developmental phase, so it would take a while before the company was in the clinical trials phase. The Department would need to await that information, so that it could make some decision relating to that.

On the question relating to revised schedules from the provinces, the Department had shared the vaccine supply volumes to the provinces, and it met with the provinces almost every other day. The provinces had that information. Many provinces had provided the Department with a plan, but there were some outstanding provinces that needed to give the DoH their plan relating to the volumes that would be allocated to those provinces.

National Treasury funding had seen it giving provinces about R1.5 billion to support the vaccination programme. The DoH had also been in discussion with the Treasury about receiving approximately R900 million to support provinces on administration, where the Department could potentially augment provinces' vaccination capacity by contracting in private providers, for example, in order to

increase the platform for the provinces to be able to deal speedily with their vaccines.

Dr Pillay explained how the Department would get to 250 000 vaccinations per day. It would proceed from the current rate, which was limited by the Sisonke study and what SAHPRA required, to a point where it would then be able to open all of its public private sector sites, and it would have vaccinators at each site. The pace would thus be much faster than what the Department was currently at.

Regarding the J&J vaccine investigation, the question was whether the Department was waiting only what the USA would be doing. Its colleagues at SAHPRA would be doing an investigation. In addition, the MAC was going to be meeting that day, and would also be providing its views on this matter.

The glitches in the EVDS were linked largely to the Sisonke study, because the Department needed to add into the EVDS something that it had not planned for. It had not planned to be doing the Sisonke study as part of the EVDS initially. That was informed consent in the context of a study, which had required additional programming, and that programming had led to some glitches because it was done at the last minute in order to make sure that the Sisonke study was rolled out. Those glitches had been fixed. However, when the Department went to the EVDS as it had planned prior to the Sisonke study, it did not anticipate any glitches. There had been a lot of stress-testing on the EVDS system, and all of the reports that the DoH had seen thus far suggested that the system would be able to tolerate the number of applications for vaccination and the vaccination process itself.

With people over 60, many may not be able to use the information technology (IT) system required for the EVDS. What the Department had made provision for was that in addition to the IT system, where a family member could do the registration for their relative, a person could arrive at the vaccination site, and the registration could be done at the vaccination site. The Department was also planning a call centre, where the registration could be done over the telephone. Dr Pillay said he understood that a number of provinces were planning to do community-based registrations on the EVDS. The importance of the registration was that it allowed the facility to plan and schedule people so it did not necessarily have to have long queues in the facility, and people would know exactly when to go and at what time. The Department did not anticipate long waiting times in that context, which would then also address the issues of social distancing.

Many provinces had identified vaccination sites, but some would not be there all of the time, because once that community had been vaccinated, the vaccinators would want to move on. The Department would be communicating all the sites. Once an individual was registered on the EVDS, the scheduling system would send a message informing an individual that they would be going to site X on this day and time, which would provide the individual with the specific site where they needed to be vaccinated.

Dr Buthelezi said that he would address some of the remaining questions.

One question was on the issue of Ms Mpho Seleka. The Department had asked for more information on the matter. Dr Seleka was dismissed on 16 March 2021, but the matter was not closed because she had appealed. The internal process of her dismissal was not yet finalised, so the Department would get that information from the chief executive officer (CEO) of the National Health Laboratory Services. It would officially respond in writing to the Member who asked the question. The Department had recently received a letter from the CEO, so it did have some details. With the appeal process, the matter could go to the Commission for Conciliation, Mediation and Arbitration (CCMA). If there was still an issue at the CCMA, it could go to the Labour Court. The Department would update the Members when it was briefed on the outcome of the appeal. It was an internal matter that was still ongoing, and the Department would await the outcome of the final internal processes.

Dr Buthelezi said that Dr Thembekwayo had been correct regarding the interns in the Eastern Cape -- the Department had extended the contracts for three months. This was based on discussions with the Eastern Cape's provincial treasury and the availability of funding. He was aware that there were still discussions with the treasury, and he had had a discussion with the Head of Department (HOD) of the Eastern Cape DoH to see what the possibilities were to go beyond the three months that it had extended. Everyone had taken a knock in terms of budget cuts, so the Department would update the Members on that issue.

Regarding the interns in Gauteng, who were mainly in the medical field, the DG had said something officially to the HOD, and he would follow up that day and would respond through the Department's Parliamentary Liaison Officer (PLO) to the Member who had asked the question. He did have specific names, some of which had been shared with him by the Deputy Minister. The DG would follow up with the HOD in Gauteng, to check what the situation was.

The Minister asked if the Deputy Minister would like to come in.

Dr Joe Phaahla, Deputy Minister (DM) of Health, acknowledged that several Members had emphasised their scepticism, based on the number of healthcare workers vaccinated thus far. He urged the PC not to be too sceptical, because Members knew that the background to this was the fact that were already a million doses of Astra Zeneca vaccines due to be delivered in a few weeks' time. There was the fact that the rollout of that vaccine had been discontinued because of the report from the trials done in South Africa, which showed limited efficacy. That had clearly set South Africa backwards. The Sisonke phase 3b trial, which was being used to vaccinate the healthcare workers, had come in as a rescue plan, to make sure that in the absence of the 1.5 million doses secured of the Astra Zeneca vaccine which could not be used, the Department could then go to the Sisonke trial.

In light of what the Minister and other colleagues had said about the vaccines secured thus far, he urged the PC to have faith in the DoH, that pending clearing up the current difficulty with J&J -- which the Department hoped would be limited -- and the delivery of

doses happened as committed by the manufacturers, all the vaccination sites which had already been prepared would be rolled out, and the numbers would be ramped up. The DM thought that it was "unfair" for Members to judge the Department on the basis of a setback to what had already been planned.

South Africa as a country and several other countries in the world were in a difficult situation because of the fact that the pandemic was wreaking havoc, and causing death and the destruction of normal life and economies. All of these countries were under pressure to find solutions. With Astra Zeneca, the Department had taken a precaution, but some members of society and leaders had already criticised the Department by saying that it should have gone ahead. If the Department had gone ahead and disregarded the scientific report, it "would have been hammered."

At the same there were the onerous conditions which the manufacturers were imposing, and also the risks, and despite all of South Africa's regulators and various authorities (including the WHO) helping to make sure that there was risk mitigation in the interest of safety, the reality was that all of this was being done in a fast-tracked fashion. Normally, vaccines and new medications were tested over a long period, and tested again, until they could be rolled out on a mass basis. However, because of the pressure of this pandemic, many of these things had had to be compressed and fast-tracked, and therefore in the process of implementing all over the world, there would be some challenges here and there. It was a question of balance, as one would hear various scientists saying. There was always going to be a balance between how many lives could be saved while at the same time knowing that because those things that usually take a long time have been compressed into a short time period, there would be some risks. However, the Department's aim would be to balance those factors and reduce the risk as much as possible.

Minister Mkhize said that the Department had noted Members' concerns, and it would try to give as many answers as it could. He wanted to clarify a few more issues.

He responded to why few people were vaccinated over the last weekend, and whether it was linked to the FDA issue. The delay had been because of the slow delivery of the vaccines, and did not have anything to do with the Department's concerns about the adverse reactions that had been reported. While there had been adverse reactions reported before, which had been part of the literature, there had not been much found in real life situations. The Department became aware of these issues as they were arising mainly in the USA only in the past few days, and therefore the Department's decision to suspend had been largely based on the consultations with South African scientists and experts, the ethics committees that were consulted, the head of the MAC, and the head of the South African Medical Research Council (SAMRC). All had agreed that there was a need to take this seriously, and to halt the J&J rollout temporarily. The Department also noted that with the J&J vaccine, it had suggested that the same thing -- temporary suspension -- should be done in Europe. The Department thought that it was important to be aligned in this case. At the moment, the Department did not think there would be a serious impact on the rollout, because it had had very few people vaccinated, and there were only 200 000 to go, which would be concluded in this week. This could be expedited without any problem if the Department resumed. It was not yet considering the termination of the contract.

Mr Munyai had asked how much had been allocated by National Treasury for vaccine administration. The Treasury had allocated over R10 billion to deal with the procurement of the vaccine. The rest of the administrative costs that were related to the accessories, staff, etc, would be carried by the departments at the provincial and national level on the basis of existing allocations. There was no specific allocation from Treasury for that.

Another Member had raised the issue of what would happen if the Department did not use the J&J vaccine. The Minister wanted to suggest that at this point, "we must consider this to be a precautionary halting of the programme," and that the Department would have enough information to guide it in this regard. In this process, the Department was in consultation with the Africa Centres for Disease Control and Prevention (ACDC), as well as the WHO. It would also look at what was going on in other countries, and would therefore be able to proceed from that point of view.

The manufacturers had put stringent conditions, particularly on the issue of the No-Fault Compensation Fund. However, the Department had accepted that this was a good proposal. The only thing it could not agree on was that the manufacturers could have discretion of deciding what to do with South African assets. The compensation fund was important, and it was agreed that it needed to be extended to deal with cover for protecting people against any medical injuries that arose in the course of normal healthcare.

The Department had acted timeously in the case of J&J. This matter had arisen only in the past few days, and from that point of view, the Department felt that it had acted adequately. There were people who had asked why it even wanted to take that precaution, but it believed that it was correct that it had dealt with it that way. Healthcare workers had been given access to J&J, and those who had come to be vaccinated had done so willingly, and with a lot of enthusiasm, knowing what the vaccine situation was about. Workers had signed consent forms, so they were not being put in a situation with no choices. Those who might have wanted a different option would have access to the Pfizer vaccine later on, in the course of May.

There was an issue that was difficult for the Department to respond to. It was related to J&J as a company involved in the payment of hundreds of dollars, and how it controlled drug prices, etc. The Department was not part of that discussion, and so it was difficult for it to respond to all of these issues. Whatever the Department was dealing with, it would respond to it.

On the challenges Pfizer might have had with adverse effects, the whole world was going through those lessons at this point to find out what was significant, what the vaccination had reacted against, and what it was that warranted sending a warning to recipients.

The Minister would follow up on the investigation at SAHPRA. He did not have that information on hand, and would follow it up.

Regarding Ivermectin, a Member had referred to SAHPRA as having sort of allowed lives to be lost, and he thought that was "an incorrect point to make." SAHPRA analysed what had been submitted for its own approval, so it could not be held responsible for issues that took place outside that setting. The Minister did not agree with putting punitive costs at that level. The issue of SAHPRA, as far as the Department was concerned, was that there had not been a change from the original position -- that the evidence still quite weak and it did not confirm that Ivermectin could be used without any form of oversight. That was the understanding. In fact, the MAC had reviewed this issue three times, and had come to the same conclusion. A number of bodies, such as the CDC, the FDA and the WHO, were aligned to the same thinking, that the evidence was weak. The evidence also showed that there were minimal benefits in taking it, and the studies done were very small. There was a need to do a much bigger study. There was a need to understand what the basis of the decision that SAHPRA had taken was. Doctors could continue to order the drug on the basis of a Section 21 arrangement wherein they had to take responsibility for the outcomes of particular patients.

Ms Gwarube raised the issue of confusing terms. Where the Department was now, it was saying that its orders were confirmed on these particular vaccines, then it was expecting that there should be delivery on those, give or take some of the logistical issues that came in, and some of the issues that might need to be cleaned up in the communication between the DoH and the manufacturing companies. The 300 000 people that had been vaccinated had come through the J&J Sisonke protocol. Because of the Department's disappointment with the Astra Zeneca results, it had then felt that it needed to bridge that gap, but it was aware that there would be delays in the way that this had been done, and that this was a problem for the DoH, in the sense that the numbers showed that it was not vaccinating at full steam. Nevertheless, it understood that it could not blame anybody for that.

On the weekly breakdown of the vaccines, Pfizer had indicated to the Department that it was much easier for them for vaccines to come in on a regular basis, based on its ability to satisfy various players. To that extent, it wants to use a system which would enable it to get goods to South Africa as soon as it needed them, so that it did not end up having to store millions of vaccines that could have been used somewhere else. That had become one of the rate-determining steps in the speed of the rollout of the vaccine. The slowness of the roll-out had been related to the fact that South Africa had vaccines ready, but it could not go ahead. To say it was criminally slow was "not an appropriate term to use." The numbers that had been vaccinated would be increasing in the next few weeks when all the vaccines landedin the country.

[Ms Ismail wrote in the chat boxhttps://www.businessinsider.com/pfizer-vaccine-may-be-less-effective-uk-south-africa-variants-2021]4

[Ms Sukers wrote in the chat box: Please note the updated info on vaccine efficacy as per latest trials!]

[Dr Pillay wrote in the chat box: Please note the following in the above report: "The study suggests that the Pfizer vaccine provides less protection against the South African variant than the original coronavirus, but it is not able to actually conclude that because it is focused on those who have already tested positive for the virus, not total infection rates." Less protection does not imply no protection. The key outcome is reduced hospitalization and mortality. Higher levels of mild symptoms is a secondary outcome.]

[Mr Shaik Emam wrote in the chat box: Chair, I have a follow-up (question).]

[Ms Sukers wrote in the chat box: Please explain the meaning of "eight times more prevalent among the vaccinated study participants" in terms of breakthrough infections. "Our study indicates that vaccine effectiveness is lower against the SA variant" - as per Adi Stern, the study author and prof at Tel Aviv university.]

Dr Mkhize said there had been an interesting issue raised by Members. The question essentially was whether there would be a drug that had no side effects. The answer was no. The question was whether one had a cost-benefit analysis -- if the benefits of use exceeded the risk of the use of the medication. In this case, the figure of six adverse effects out of six million was not a huge number to halt the entire programme. It was an important issue for the Department to take into account. It needed an analysis on that to be able to know what was causing that effect so it could see how to limit the impact of those side effects. For example, was there a causal link between the vaccine and the effect that had been observed? Were there other conditions that were associated with it? Did it have to do with the vaccine, or the reaction to the vaccine? Were there conditions of age, of gender, the use of contraceptives, or other medication, co-morbidities, any familial factors, any cardiovascular or other allergic or connective tissue disorders? These were the factors that the answers must give the Department now. The DoH knew that the answers it would get now were not going to be accurate, and that it would take the Department a while before it could get adequate information from the scientific research. In terms of size, the numbers involved were not significant enough to pose a huge risk to the entire population. Nevertheless, it needed to be investigated, and it should not come in as an opinion -- it should come in as the considered view of experts. That was why the Department had taken the approach that it had taken.

On the letter from the DTIC, the Minister was sitting in the meeting, and he was specifically asking, "What are the terms and conditions?" The Department had satisfied all of them. The issue was that this letter was from a different minister and a different department, but the DoH had already complied with all the regulations. All that the Department was trying to demonstrate was that these conditions sometimes kept evolving as time went on. The Department would deal with this issue in the way that it needed to be dealt with. At this point, it was trying to explain the conditions which were involved in the negotiations, and how the situation kept evolving. When the Department explained the difficulties, it was just trying to ensure that the PC appreciated what went into the negotiations, and what went into the terms and conditions that the Department had been asked to talk about.

The upcoming regulations on the vaccine compensation scheme could be commented upon, to include any additional requirements for transparency and fighting against corruption. The public was free to do that. It would be an independent body that would be presided over by a Chief Justice. This was to make sure that the scheme was transparent, and that it could deal with issues of corruption.

The Department was convinced that even though there had been reports that the Pfizer vaccine had shown a dilution in terms of the neutralising effect on the 501.V2 variant, South Africa actually had an effective vaccine against that variant. There was some work that had been done in a laboratory that indicated that there was still quite a lot of a neutralising effect, so the Department would use it. The Department had indicated that it would show the distribution per province, and to the public and private sectors. When that was ready, the Department would make it available.

Looking at the numbers that the Department had reported, it expected that those numbers would guide the rate at which South Africa vaccinated its people. That was why the Department was transparent about it, so that the Members "must not be so pessimistic" about the fact that this process was actually gaining momentum, and was going to be effectively rolled out in the next few weeks.

Dr Jacobs had indicated an appreciation of the immensity of the work. Part of that was how South Africa had assisted the African Union (AU) to use it as a framework to negotiate terms that were not worse than what South Africa had achieved. The Department thought that its team had done its best to deal with this issue.

The NFC fund regulations would be released, and when these were published, the Department would need comments. The Department had been pleased to see that former Chief Justice Ngcobo was prepared to lead, as he had adequate experience to deal with it. The funds that were involved in the NFC would come from the National Treasury. A Member had asked if the manufacturers were going to make a contribution, but there was no provision for them to do so. The Department thought that it needed to do everything to protect its people, and therefore the fiscus would deal with that issue.

Dr Jacobs had raised the issue of the confusion about the Western Cape procuring its own vaccine. The Minister did not understand why the Western Cape would have made such a statement when it knew that all the vaccines were procured by national government, both for the public sector and the private sector. All had worked together. It was the quickest way of limiting corruption, and also ensuring that there could be a fair distribution in the country. National Treasury had had to make certain special provisions to allow the country to be able to procure the vaccines in a manner that was not necessarily in keeping with South Africa's normal supply chain provisions, which no province would be allowed to do. The procurement had been done on behalf of all the provinces. A province could not on its own give all the indemnities, guarantees and immunity to these obligations, to any manufacturing company unless national government had done so. It was not possible for a province to procure any of these vaccines for itself. However, the Department had vaccines available for all of the provinces, so there would be equity in their distribution.

Ms Gela had asked how the Department would ensure the integrity of the vaccines. There was very sophisticated software that followed up on the vaccine storage, so that it could always see if there had been any breach in the vaccine cold chain storage conditions. It could be picked up, and that would therefore always be audited. If one looked at every batch, there was also an indication as to whether there had been tampering with any vaccine. The Department would be able to deal with that, and when the vaccines landed in the country, they would go through a quality control analysis that made sure that the quality of the vaccine was there. As the Department took the vaccines to the various provinces, it checked that the storage was going to be adequate, and that there was adequate training for the various vaccinators, so that everything was done in such a way that there was minimal wastage and loss of integrity of the vaccines.

The Department would have to publish the list of vaccination sites. The challenges with the vaccination sites was that it had given the numbers, but there were still a number of sites where the Department was trying to refine and agree on whether a location was in the right place or not. As soon as that had been done between the Department, the provinces and the private sector, it would be made available.

Ms Sukers had raised the issue of dismay about the terms demanded of government. The Minister was glad that Members appreciated what had cost all of this time, namely the delays in the negotiations because of the onerous nature of the terms and conditions. All of that was behind the Department at this point.

There was the issue of the Pfizer report from Israel. It was not different to the reports that the Department had got. This basically refers to the dilution, but it did not mean that Pfizer was not effective against the 501.V2 variant.

On strategic procurement, this had largely been concluded, so the Minister did not think that the Department needed assistance there. Where the Department would need a lot of assistance was in procuring capacity at the vaccination level, and the distribution of the vaccine at the vaccination points. If there was any need for the Department to make a call, it would come back to Parliament on that.

A Member had raised an important point about the rising level of vaccine refusal and hesitancy. The Department would engage with the relevant sectors, particularly the Pentecostal and charismatic churches. There was work being done in various church formations to help the Department to reach out to people so that there was no fear of the vaccines.

Dr Thembekwayo had raised the issue of the Chinese and Russian vaccines. South Africa was still pursuing the procurement of some of the vaccines from these two countries. The Department had said that experts must try and expedite this discussion. The Minister had been in contact with a number of these companies personally, as had departmental teams as well. The DoH was aware that the process of registration of the Sputnik and Sinovac vaccines was on course, but Sinopharm was still a bit behind. The Department had not given up on these particular vaccines -- it believed that there was still a need for it to approach those companies.

At this point, the Department was not particularly worried that there was an immediate threat of a third wave, but it would watch that space.

There had been a discussion with Mr Patrick Soon-Shiong from Port Elizabeth, who had indicated that he wanted to go to the next generation of vaccine, and that he was working with a number of companies and research institutions in South Africa. The Department was very keen on that work, and so it had had a meeting with him and the Minister of Science and Innovation. That process indicated to the Department that there was a hope that South Africa could reach second generation vaccines, but also that it could end up playing a role in producing vaccines, and become successful.

Provincial vaccine schedules were dependent on the national vaccine delivery. The Department would align all of it so that there would be no problem with any particular province regarding vaccination availability.

Ms Chirwa had asked why Johnson & Johnson was going to be used in the rural areas, and Pfizer in the cities. It was a matter of convenience. There would be areas where the Department found that there was easy storage capacity and high population numbers that would use Pfizer, because it would like to find people who were available within a very short distance from the vaccination centre. The Department also wanted to make sure that in the rural areas, the storage demands did not compromise the quality of the vaccines. A once-off dose made it easy for people where there were transport challenges, and so on. The Department was quite confident on the efficacy of Johnson & Johnson, so it was not seen in any way as an inferior vaccine. Both the President and the Minister had actually taken that vaccine. At this point, the Department was quite happy that the J&J vaccine was suitable for use, and therefore it would be a case of just managing the logistics, as well as creating ease of administration, and that was what it was looking at. It was looking at it from that point of view, although there would be some people, particularly in the urban areas, who would maybe also be using Johnson & Johnson, particularly in areas where there were migrant communities which were moving and not easy to find at the same pace again.

Dr Mkhize noted Members' concerns about the capacity in the Department. It was building it up, and as the Deputy Minister indicated, it was going to be looking at that and giving a positive experience, rather than the sense of desperation that had been expressed. It had given an update on the Sputnik and Sinovac vaccines. The Department had said in the past that it was working with Cuba, but that was still at an early stage of development.

Between the Brazil, Russia, India, China and South Africa (BRICS) partners, there had been a decision to work together to build a vaccine institute. The Department hoped that South Africa would work together with those partners to build that capacity. South Africa had its own experts who had the capacity to investigate and analyse all the literature, and therefore they would be giving guidance in terms of what had happened to the Johnson & Johnson vaccine.

South Africa was not going to rely only on the FDA, as Members would have seen in the past when the Department dealt with Astra Zeneca, where it had used its own experts to give it a sense as to what was useful for South Africa. Even though Astra Zeneca was successful in the UK, Brazil and other parts of the world, South Africa had to take its own decisions. The Minister reassured Members that South Africa's own scientists and experts were good enough for the DoH to take guidance from those experts. It did not get guided only by what happened in other countries. However, South Africa knew what went on there, and it took into account its own situation.

The Department would by May have Pfizer as well, which meant that if there were any delays with Johnson & Johnson, the vaccination programme would not be delayed -- it would still continue. The Department had indicated that it would continue to follow up with Sputnik and Sinovac, and hopefully at some point, their vaccines would also be available. Bearing in mind this was new territory, and therefore there may well be unexpected issues that would arise, but the Department thought that the scientific findings up to now had guided it to be where it was, and that it was important to continue with that guidance, knowing that surprises would arise, or knowing that there would be areas where it would need to intervene in a particular way. All of that was part of a very complex process which no one in the world had experienced, and therefore countries kept learning from one another and also from the countries' own experience.

The list of vaccination sites was very long. The Department would, at some point, make it public, but in the process, there was quite a lot of cleaning up that it had to do. It was in disagreement in some areas, and was refining other areas. A very important point about the electronic vaccination data system was that not everyone could use the technology required. It had made provision for that -- people could do it electronically themselves, but if they were not able to do so, there was a proposal for community health workers to assist. Nevertheless, when the Department called for vaccination of the elderly, it would invite them to the sites and they would register on the EVDS site. The prior registration helped the Department to plan, but effectively it needed a record of who had been vaccinated. It would do the vaccination, and it would also register people on the spot. It would make sure that no one was disadvantaged by a lack of access to technology. The Department would then be looking out for any form of confusion that needed to be cleared up in communicating to the elderly, with regard to the times at which they would to come for vaccination. With all of this, the Department would be doing regular updates, as the PC had requested.

There was quite a lot of discussion and work that went on behind the scenes with various departments, various committees, and various work streams. The Department was very confident at this point that everything was on course for it to be able to get the vaccination process moving. There were those who had felt that the slow vaccination rates of the past few weeks might be a matter of concern -- and everyone was concerned about it -- but nevertheless, that concern would be resolved with the number of vaccines that had been announced. In the past, the Department had not announced that it would have as many of these vaccines, and when it did have some challenges with the delivery, it had explained them. However, in the future it expected that it would be guided by all of the vaccines that should be coming through. It was looking forward to working together with all the communities, all the leaders in society and all the sectors of society, so that it delivered a very successful vaccination programme that would ensure that all South Africans were protected from COVID-19, and that South Africa would continue with its non-pharmaceutical interventions, such as the use of a mask, the use of social distancing, hand sanitisers, hand washing and encouraging people to be in well-ventilated areas.

The Department had had discussions with modellers over when South Africa was likely to have a resurgence, and there was general consensus that this would be determined largely by human behaviour. Minister Mkhize therefore wanted to encourage all South Africans to continue with the way they had managed so far, so that South Africa could stay on this plateau for much longer, and it would help if the Department could vaccinate as many people as possible whilst South Africa was on this plateau. The Department had seen in other countries that the fact that the vaccination had started, with millions of people having been vaccinated, they were still experiencing a resurgence. However, in South Africa's case without the vaccine being widespread, it had seen that it was able to reduce a resurgence so that it was now at a plateau. If it could continue to maintain this situation, it would then be in a position to delay the next resurgence, so that more South African's lives were saved. Of course, South Africa wanted to make sure that the vaccines were successful in preventing any further severity of infections, as well as hospitalisation and deaths.

Further discussion

The Chairperson said that a few Members wanted to make one follow-up question each.

[Ms Ismail wrote in the chat box: https://www.iol.co.za/news/politics/healthcare-workers-could-require-j-and-j-booster-shot-78f8393c-f45b-4226-9e3c-3d3e66888af7]

Ms Ismail said that the J&J trials had been evaluated for a period of efficacy for only around 60 to 70 days, and with the Pfizer vaccine, the trials were done for around six months. There had now been a social media report stating that healthcare workers should possibly get a second J&J booster shot. Did this mean that the original J&J one boost was not effective? In the same media statement, it was stated that J&J would do a two-day schedule to determine whether there was a longer-lasting protection with two doses. Had the Department received any feedback on this, and could it please give clarity and feedback on this matter?

Ms Sukers wanted to raise the concern that had been brought to the PC's attention where health care workers were concerned. She had heard the Minister speak about the tracking of adverse reactions to the vaccine. She had heard reports from healthcare workers, firstly, that there was a low buy-in from healthcare workers around the vaccines, and she thought that the PC had established some of the concerns as well, or had raised them. The second was that where there were adverse reactions, the staff had been asked to not speak about it. That was a concern, and she had raised it in terms of the NDAs and the need for transparency. This fed into more concerns for MPs, and also because it reflected the concerns of constituents who were saying that the healthcare workers were muzzled when they showed any kind of adverse effects.

Mr Shaik Emam said he was not satisfied with the explanation that the Minister had given regarding Ivermectin. In the Minister's explanation, he had conceded that the evidence was weak. He said it was not true that one now needed a section 21 application to roll out Ivermectin. In terms of the settlement agreement, Ivermectin could be used without any such section 21 application any more. The FDA, the World Health Organisation and other institutions agreed -- as did he -- that there might not be enough evidence yet that Ivermectin worked for COVID-19, but that was as a result of the limited tests and trials. However, the limited tests and trials that had been done had "proven without any doubt" great efficacy in fighting COVID-19. What was the reason that SAHPRA and the Department had not done anything, but had now agreed to roll it out? Was it because now the vaccines were procured, and the pharmaceutical industry was protected, and their interests had been seen to? Now the Department wanted to roll out Ivermectin. There was no change in the evidence, and yet it had changed its decision -- R2 million later, many lives lost later. He wanted the Department to give an explanation of why it had changed its attitude and decision when there was no new evidence.

DoH's responses

Minister Mkhize said he had read the latest report from the WHO on Ivermectin, and that was where the Department stood. There were issues that were still going on regarding the court matter, which as far as SAHPRA had reported to the Minister, SAHPRA was appealing clauses 1 and 2, which had not been discussed. The judge had stated that he had heard the counsel for the applicant, and it was a lengthy matter that was being dealt with. There was that issue in court. The Department would still insist that the position of the WHO was that the current evidence on the use of ivermectin to treat COVID-19 patients was inconclusive. Whatever else the Department did, the PC needed to understand that that was where it was coming from. The Department was not involved in taking care of the interests of pharmaceutical companies. As a regulator, SAHRA had to focus on available evidence and findings from the studies that had been done, so that was really what guided the Department in terms of how it dealt with these particular issues. He did not believe that there was much more the Department could do. The point at the end of the day was that if the evidence remained inconclusive, the matter would remain on the table for debate until the Department had conclusive evidence.

The Department had said that with Ivermectin, the doctors who dealt with it must take responsibility. It was on that basis that one was allowed the limited use of the medication. If one did not have full evidence, then one could allow whoever was taking charge of it to collect basic information about the safety of the patient, so that that person must take responsibility for whatever outcome resulted. If a doctor said, "I think this will help", then the doctor became the ultimate person that would then utilise that particular drug, and on that basis, the doctor could be allowed to use it. If that doctor used it and anything untoward happened, one could not say that the regulator had said it was safe. The regulator was here to protect South Africans. SAHPRA was not about protecting the interests of pharmaceutical companies-- it was about protecting the public. SAHPRA had to ensure that it analysed all the research findings around the development of a particular product, until it was satisfied that there was nothing unsafe about that product, in order to protect South Africans. That was what SAHPRA was all about and therefore, if it was not sure that this would actually protect South Africans, it would say so. However, if there was an insistence from a particular doctor that she/he would like to use this particular medication on the basis of X and Y that they had seen, then of course there was leeway to get the doctor to help the patient on the basis that the doctor had to take responsibility.

The next question was from Ms Ismail, talking about the second booster from Johnson & Johnson. The current approach to the J&J vaccine was not to use a booster. There had been discussions with various other manufacturers who had suggested that they could combine the technology, and therefore maybe also use a booster. For example, when the Department raised the issue of Astra Zeneca, there were some scientists who were speculating that maybe in future South Africa might end up using AstraZeneca, and then when the J&J vaccine came, it could be used as a booster. It was in the context of that debate, but not because that was what the protocol was on the use of the J&J vaccine. The Department had not received any further feedback from J&J about the two-jab schedule that Ms Ismail was talking about. It had had only one approach, and that was that the J&J vaccines would be administered to an individual, and it was expected that in 14 days there should be the development of immunity, and that there would not be a need for a second booster as one moved into the future. The trials done were based on this approach. The Department had therefore felt that there was no need to consider combining the J&J vaccine with something else. What was stated on social media was not necessarily a matter of authority. The Minister had not seen such reports himself. What the Department says about Johnson & Johnson was what it knew, and that was what it was going to implement as a country. There could well be a debate going on with views, with suggestions, with hearsay, with everything that came through social media, but it was difficult to say that a report from social media would actually make the Department change something in the management of this vaccine. At this point, the Department would continue with it in the way that had been described -- that was that only a once-off dose was needed, and the Department had described how it wanted to use it in the country.

Ms Ismail clarified that the report was not actually just on social media -- it was the fact that a professor had put on to a media statement. He had been interviewed, so it was not just a social media statement. It was from a professor that she knew the Minister and the MAC spoke to.

The Minister replied that the Department could follow up on the statement that came from the professor. He was not aware of it, but when the Department knew about it, it could talk about it. However, right now the Department was not getting any advice from Johnson & Johnson that there should be any booster provided for the doses that the Department was dealing with. It would refer what the professor had said to the MAC so that it could be debated.

The other issue was related to tracking adverse reactions to vaccines. All those who had gone through the vaccines had been advised to report if there were any adverse reactions, and the Department had not yet received a report of anyone who had been found to have suffered the kind of adverse reaction that had been reported in the USA. It had also not had any serious reports that were suggesting it was picking up adverse effects from the J&J vaccines. Fortunately, all those who were in this particular cohort had actually been recorded as part of a study, so there was an obligation to report if there was any particular challenge that was coming from the vaccinations.

It was as serious allegation that a Member was making, that healthcare workers had been muzzled, and that they had been told not to speak about adverse reactions. The Minister requested that the Member should please write to him and give him the specifics, so the Department could find out what had actually happened. There was no way that one could muzzle a healthcare worker. In the first instance, the bulk of workers tended to understand the issues of drug reactions and adverse effects of any medical product that was administered. Such workers would know that they needed to seek assistance. He did not believe that it was accurate information that had been conveyed to these particular health workers, as there was no requirement for anyone to hide any side effects or any symptoms. If there was such an incident, the Department would have to deal with it, and it had not been brought to its attention. Now that a Member was bringing it to the Department's attention, it would like to get more details and it would follow it up, but when Members came across healthcare workers in their capacity as a public representative, they must indicate to workers that they actually had an obligation to report the side effects, or any adverse effects.

During this Sisonke protocol it was even more so, but even afterwards, when Government did the normal vaccination rollout programme, every person who had any symptoms or any side effects needed to report them, and it was important for the DoH to send out that message. That was the basis on which the Department was now setting up the NFC Fund, so that people would not feel that they could suffer harm, and not be able to get the matter addressed. The Department needed to make sure that this was made very well known, and no one could be silenced when it came to any possible side effects they might be suffering. Let them be examined so that the Department knew what exactly the cause of the problem was. It would then establish whether there was a causal link between the vaccine and the symptom that the individual was experiencing. There should not be any doubt amongst the Members of this particular Committee that the Department would not accept any muzzling. It would always make sure that all of its

members of staff sent the same and correct message that if a person had any symptoms that were uncomfortable, they should just come back and report so that the Department could record them. It was to the Department's benefit to know what was going on.

If there were any issues to be concerned with, the Department would monitor them. That was why it was doing the Sisonke protocol. It would do a similar kind of post-market surveillance with Pfizer as well, just to make sure that in a larger cohort of vaccinees, it picked up anything that was worth focusing on as a matter of concern. The Department would make sure that when it got the details of the issue raised, it would investigate the matter, and take it forward. In this current Sisonke protocol, ethics committees obviously had to oversee any possibility of an infringement of the human rights of any individual participating. As the Department moved into the future, the same principles would apply to all those who would receive the vaccine -- that one could not hide the adverse effects of any drug. When the next opportunity arose, the Department would come to share the progress that it had been able to register at that point.

[Ms Sukers wrote in the chat box: So, we are still sourcing for other vaccines but we are not in need of assistance with strategic sourcing? It is not just social media unfortunately.]

The Chairperson requested that as there was going to be another public update, which the Department normally did in a webinar, could the team of the Minister's office please inform the PC on time? Some Members wanted to join in and listen. Sometimes the PC got those invitations late.

He thanked the Department for the presentation and also the engagement. It would probably be in a fortnight's time that the PC had another interaction with the Department. The work that the DoH was doing, and the flexibility it showed as a leader, was appreciated. There was a moving target, which was moving quite fast, and the PC really hoped that the Department was going to have a very short pause with the J&J vaccine. Of course, the issue was that it was just six patients out of six million, but the Department was taking precautions. The PC was looking forward to receiving an update on this matter.

The Minister thanked the Chairperson, and said that the Department would make sure that it informed the PC on time.

Adoption of Committee Programme

The Chairperson presented a draft Committee programme for consideration by the Members prior to submitting it to the House Chair for approval.

He said Parliament reopened on 4 May, and that week there was an expectation from all committees to process annual reports of entities and departments that they were associated with for the purpose of preparing for mini plenaries.

On 4 May, it was suggested that Members have a meeting with the Auditor- General (AG), who could point out issues they should look out for, prior to listening to the Minister and the entities. Following that, the PC needed to get the Financial and Fiscal Commission to come in and raise their issues. On the same day, it would have to receive the annual presentation of the South African Medical Research Council (SAMRC) -- three presentations on one day.

The next day, the PC had a briefing by the medical schemes and a briefing by SAHPRA. All of those entities were also coming in with their annual performance plans, but he was aware that Members also wanted to ask some of the questions relevant to the things that they were dealing with, and the Chairperson would not stop Members from doing that.

[Ms E Wilson (DA) wrote in the chat box: Time was indeed limited Chair, but we must be mindful of constituency duties.]

On May 6, the Chairperson did not know whether there would political party caucuses. Hence, it had been requested that the briefing from the Compensation Commissioner for Occupational Diseases be done at 08h00, so that in the event that there were caucuses, the PC could break at 10h00 and reconvene at 13h00 to take the Office of Health Standards Compliance (OHSC) and the briefing by the National Health Laboratory Service (NHLS),

The PC had to continue on Friday, 7 May, to get a briefing from the Department of Health from 09h00. This meant that the Committee Secretary would have to compile a report after the briefing by the Minister over the weekend, and on Monday, the PC would consider and then give its views on the report. That was critical, because all committees had to complete their work by 12 May.

The budget vote for the DoH was starting on 13 May, and therefore it was coming in much earlier than usual. That part was a Parliamentary obligation that the PC could not change. It had to be approved.

The Chairperson said Members would recall that the Committee had been inundated with work carried over from the previous administration. Now, not through its own fault, the National Health Insurance Bill (NHI) had been sitting with the PC for longer than one would expect because of COVID-19 and other challenges. He requested that during the period from 13 to 26 May, after the debates on the budget of the DoH, the PC consider doing public hearings, which would involve listening to 121 organisations that were coming in. It would come as a separate application for submission that the PC consider 18, 19 and 20 May, sitting in virtually to listen to those public hearings. Thereafter, it could visit vaccination sites and perhaps see one or two hospitals. There were challenges out there that the PC was not aware of. A separate submission would be made for the Committee to conduct an oversight visit to the Northern Cape from May 20 to 22. The following week, it would conduct oversight in the Western Cape.

Ms Gela fully supported the programme of action. She hoped the PC would have the site visits in order to check the vaccination sites. She moved for approval of the programme.

Ms Gwarube said Members should appreciate that this was a massive balancing act for everyone, and that there was a lot going on. She was in full support of the programme. The parliamentary programme was one that could not be changed. She supported the suggestion to conduct oversight in the various provinces and to listen to the submissions by organisations. The only thing that she saw as a problem was the proposal for the constituency period in August. If things went according to what the Independent Electoral Commission (IEC) had said, then South Africa would be approaching an election in less than eight weeks, so there was bound to be too much pressure at that time to really be on the ground. The Committee could look at using the first week after Parliament rises. She did not foresee the PC being able to use a chunk of its constituency period so close to an election.

Dr Jacobs said that the PC should be mindful of what had been raised by Ms Gwarube. The Committee had to approve today the first part of the programme, up to the Minister's budget vote on 13 May. He seconded Ms Gela's proposal to approve it, and that the PC approve the second part, considering what had been raised by Ms Gwarube, that as the PC moves forward, it might have to make a few changes here and there.

The Chairperson responded that the PC might then not go right up to August. Using just one week might not be a problem. It would be up to the Committee to decide such things as using the time up to the middle of July, and nothing more than that. They could agree to approve the first part of the programme, which was non-negotiable. He would bring the other part back, and the PC may have to make some adjustments.

The PC was now in a constituency week. There were certain Members that were on the ground working, but he doubted whether they had as heavy a schedule as those present. It might mean working over some weekends, but he was glad that Members were agreeing that even if there was constituency work, the PC would continue on the Thursday, Friday and Saturday, and do these visits in the provinces. Its visibility in provinces was very limited, and it should not be like that.

Adoption of Minutes

Dr Jacobs moved the adoption of the minutes of 24 March 2021, and Ms Gela seconded.

In the statement that the PC would release today, among other things, it would wish Mr M Sokatsha (ANC) a speedy recovery while he was still in hospital, and also wish Mr T Munyai (ANC) a speedy recovery after his accident.

There was some confusion at the end of the meeting as to what was going on. Members were not sure if the meeting was adjourned. Mr Shaik Emam said the Chairperson had said that Members were released.

Ms Sukers said that she still wanted to inform the Chairperson about an oversight visit to Helderberg, and wanted to hear if any of the PC Members would like to join her.

At that point, the Chairperson had already left the meeting.

Ms Gwarube suggested calling the Chairperson on the side, and that the Members could discuss the visit on the PC's WhatsApp group.

Dr Jacobs said that he would like to support Ms Sukers.

The meeting was adjourned.

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INSTRUCTIONS ON PROCESS FOR VACCINATION OF SPECIAL GROUPS AND INDIVIDUALS AGAINST COVID-19

1. The Department of Health receives requests to arrange vaccination against Covid-19 for special groups and individuals who are not currently eligible to be vaccinated under the national vaccine roll-out.

2. The purpose of providing a process for special cases of groups or individuals to be vaccinated outside of the prevailing age cohort roll-out, the essential public sector programme, or a workplace programme, is to accommodate people who need to travel abroad for the purposes listed in this document and who require proof of vaccination to do so.

3. Exemption will be considered for Individuals who need to travel outside of South Africa, specifically for the following reasons:

    a. business or work-related travel abroad
    b. study at an accredited educational institution abroad
    c. sportsmen/women who need to travel outside of South Africa to represent the country
    d. accessing medical care abroad

    Individuals who have received one dose of Pfizer vaccine outside of South Africa more than 42 days ago will be eligible to receive a second dose of the vaccine in the country and for this will require an EVDS generated code.

4. For each individual requesting accelerated vaccination to facilitate travel the accompanying form should be submitted by email to vaccine.admin@health.gov.za. Submission of documents supporting an individual's application for vaccination may be requested and must be submitted before the application will be approved. This documentation may include (but is not limited to): visa, work or study permit for country to which individual is travelling, letter from employer, institution of study or sports federation, affidavit signed by commissioner of oaths.

5. Once available, the EVDS vaccination code will be sent to the individual's cell phone number. No scheduling of vaccinations will be done by the department. Individuals will be responsible for arranging vaccination at a local vaccination site.

ENDS

health
Department:
Health
REPUBLIC OF SOUTH AFRICA

2030 NDP

REQUEST FOR VACCINATION FOR SPECIAL CIRCUMSTANCES

1. This form should be completed by individuals requesting to be vaccinated due to special circumstances.

2. The completed form as well as a letter of request (which outlines the special circumstances) and documents supporting the request must be submitted to vaccine.admin@health.gov.za.

3. Individuals will be notified as to whether or not their request has been approved. Following approval, the individual will be provided with an EVDS vaccination code. This will allow the individual to present at a vaccination site for vaccination.

4. Please provide the information below:

NAME:	
SURNAME:	
SA ID NUMBER:	
PASSPORT NUMBER (if no SA ID):	
COUNTRY OF ISSUE:	
DATE OF BIRTH:	
RESIDENTIAL ADDRESS:	
MOBILE NUMBER:	
EMAIL ADDRESS:	
NAME OF MEDICAL SCHEME (IF APPLICABLE)	
PRIMARY MEMBER NUMBER	

REASON FOR TRAVEL	Mark with a 'X'
Business or work-related travel abroad	
Study at an accredited educational institution abroad	
Sportsman/woman representing the country	
Accessing medical care abroad	

I, _____ hereby verify that the above information is correct and give consent for the information to be uploaded onto the Electronic Vaccine Data System (EVDS).

_____ Signed

_____ Date

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SAcoronavirus.co.za

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

Jan 7th, 2021 | In The Media

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

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

155

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COVID-19 Public Hotline: 0800 029 999
WhatsApp Support Line: 0600-123456
info@vaccinesupport.org.za

120 A copy of the deviation request is attached marked **Annexure SB11.** It was approved by National Treasury on the same day. A copy of the approval letter is attached marked **Annexure SB12.** The NDoH was also granted authorisation to engage other manufacturers and, as stock became available, to secure the vaccines.

121 Against this backdrop, I turn to deal with the various vaccines that South Africa has considered procuring the latest position in respect of each. I must emphasise, however, that this is a fluid and constantly moving situation.

The AstraZeneca vaccine

122 The AstraZeneca vaccine requires two doses, that are 12 weeks apart, and needs to be stored in a refrigerator for a period of up to six months.

123 The AstraZeneca vaccine's phase 3 trial results were released on 8 December 2020. They indicated a success rate of 70.4%.

124 The AstraZeneca vaccine was first given emergency authorisation in the United Kingdom and Argentina on 30 December 2020. It was approved in India (as Covishield) on 3 January 2020. On 22 January 2021, the SAHPRA granted a section 21 authorisation in terms of the Medicines Act for the AstraZeneca vaccine to be used against Covid-19. A copy is attached marked **Annexure SB12A.**

125 The Government first engaged with the Serum Institute of India ("**SII**") regarding the possibility of South Africa being supplied with the AstraZeneca vaccine on 14

September 2020. The people representing Government in the subsequent engagements were Dr Anban Pillay and Ms Khadija Jamaloodien.

126 The role of the SII requires brief explanation. AstraZeneca stated that it wanted to enable broad and equitable access to its vaccine and that it does not have capacity to supply all countries with the vaccine. It therefore sub-contracted the production to a range of suppliers and producers across the world, and then allocated these producers to particular markets. The SII was allocated to the South African market. The implication of this allocation was that instead of contracting with AstraZeneca directly, South Africa contracted with the SII for the vaccine.

127 Following the release of the Phase 3 trial results in December 2020 and the Treasury deviation approval on 6 January 2021, extensive negotiations were entered into with SII around certain provisions of the proposed term sheet and agreement. These included, in particular, certain requirements that South Africa indemnify SII in respect of future claims. A copy of a fact sheet issued by National Treasury on this score is attached marked **Annexure SB13.**

128 On 7 January 2021, the term-sheet between the NDoH and SII was signed. This was followed by the purchase agreement, which was signed on 18 January 2021. It provided that:

128.1 One million doses would be shipped during January 2021; and

128.2 500 000 doses would be shipped during February 2021.

129 The one million doses were duly shipped on 31 January 2021 and arrived on 1 February 2021.

130 However, regrettably, our ability to make use of these doses has been undermined by disappointing trial results.

130.1 The NDoH had relied on the stage 3 trial results of AstraZeneca to conclude the agreement. These had a 70.4% success rate.

130.2 But in December 2020, it was announced that a new Covid-19 variant (501Y.V2) was detected in South Africa, and that it was rapidly spreading in three provinces: the Eastern Cape, Western Cape, and KwaZulu-Natal. The genomic data highlighted that the 501Y.V2 variant quickly displaced other lineages circulating in South Africa.

130.3 This was not mainly the variant that the AstraZeneca stage three trials had involved. Accordingly, a concern was expressed as to whether the AstraZeneca vaccine would still be effective in South Africa.

130.4 The VMAC considered the issue and sought advice from overseas experts. These included the WHO and other experts from United Kingdom and the United States. Their advice was that the vaccine was likely to still be effective against the 501.YV2 variant. Given this and given the urgent need for vaccines, the agreement was concluded and the first million doses duly arrived.

130.5 However, on 7 February 2021, Dr Madhi announced the results of a study that he had been performing on the effectiveness of the

AstraZeneca vaccine, which included the 501Y.V2 variant. It concluded that the AstraZeneca vaccine provides reduced protection against mild to moderate Covid-19 infections from the 501Y.V2 variant. While the vaccine maintained its high efficacy against the original virus, it had an efficacy of 22% as against the 501Y.V2 variant.

130.6 This study is not the final word on the issue. It was a relatively small study and questions remain about whether the AstraZeneca vaccine might still provide effective protection against more severe Covid-19 infections in relation to the 501Y.V2 variant.

130.7 But this development meant that the roll-out of the AstraZeneca vaccine (which was due to happen on 15 February 2020) had to be put on hold so that further consideration can be begin on what approach to take. This is because the 22% efficacy results would not justify a roll-out of this vaccine.

131 In light of this, it was announced by Minister Mkhize in Parliament on 15 February 2021 that the AstraZeneca doses concerned will be offered to the African Union platform, for distribution to those countries who have already expressed an interest in acquiring the stock. This will also avoid any wasteful and fruitless expenditure.

<u>The Johnson & Johnson vaccine</u>

132 The Johnson & Johnson vaccine is a single vaccine dose. It also can remain stable in a refrigerator (at 2 to 8°C) for three months. It thus has very substantial

160
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Minister Zweli Mkhize briefs parliament on suspension and distribution of Astrazeneca vaccine

11 Feb 2021

Committee on Health hears from Minister Mkhize about suspension of distribution of Astrazeneca Vaccine

The Chairperson of the Portfolio Committee on Health, Dr Sibongiseni Dhlomo, told Members of his committee today that since the news broke on the lack of the desired efficacy of AstraZeneca's vaccine against the 501Y. V2 variant dominant in South Africa, there has been a lot of confusion and indiscriminate panic about the universal safety and efficacy of Covid-19 vaccines.

He said yesterday's briefing meeting by Minister Dr Zweli Mkhize was convened against that background to afford Members of the committee first-hand information from the Department of Health on the matter. As such, he said: "It is ideal that we afford the department an opportunity to update us on the new development related to the efficacy of AstraZeneca, what will be done with it, what interventions the department will implement to mitigate any adverse effects, public panic or growing mistrust of all vaccines?"

Briefing the committee, Dr Zweli Mkhize said concerns about the efficacy of AstraZeneca have scuppered the rollout plans of the department. He reiterated to the committee that yes, the news about the efficacy of AstraZeneca affected the rollout plans. "And as government we are

disappointed by these developments. But we have new rollout plans in place to ensure that vaccines are dispensed to save lives," he said.

To allay people's fears, Dr Mkhize reassured the committee that the research results that have been reported in the media do not mean that AstraZeneca is dangerous, but it is just that it is not responsive to our variant. "Before the emergence of our variant, AstraZeneca had around 75% to 77% efficacy rate," he added.

He further stated that the South African results of the efficacy of AstraZeneca were still outstanding when the results of its efficacy to South African variant emerged in the media. "Our scientists have done their research studies and were ready to disclose them, but were still tied up by research protocol involved to ensure that their findings were peer reviewed before they could make them public," he said.

The committee wanted to know how this happened. Dr Mkhize replied: "When we procured AstraZeneca, we procured it on the basis of the universal variant that was in place at the time. And it showed positive results, hence other countries have ordered it for use. Our variant emerged thereafter, at the time the manufacturing of the vaccine was designed accordingly and procurement thereof was done before the variant emerged."

On what will be done with AstraZeneca, he responded: "Our scientists will do their own study to determine how we will deal with it. But we have officially suspended the distribution of this vaccine for now until a scientific determination is made."

Members wanted to know, given the recent revelations, what is the department's intervention? The Minister replied: "We have spoken to Johnson & Johnson, whose vaccine has a 57% efficacy rate to our variant, to afford us a bridging stock that was part of their research trials in order for us to be able to dispense doses to the frontline staff."

He added: "Johnson & Johnson has assured us that they will afford us those supplies on top of the orders we have placed with them. And we will adjust our rollout plans on receipt of these doses. We will be able to announce the new vaccine rollout plans when we have secured our supplies," said the Minister.

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Issued by: Parliament of South Africa
More on: CoronavirusHealth

health
Department:
Health
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Enquiries: Prof B Schoub
E-mail: barry.schoub@gmail.com

INTERNAL MEMO

Date:	7th February 2021		
To:	**Minister ZL Mkhize, Honourable Minister of Health**	From:	**Ministerial Advisory Committee (MAC) on COVID-19 Vaccines**

ADVISORY
DEVELOPMENTS AROUND INDICATIONS THAT ASTRA-ZENECA COVID 19 VACCINE MAY BE DEFICIENT IN ITS PROTECTIVITY AGAINST THE 501Y.V2 VARIANT VIRUS

Problem Statement

Background

- In vitro laboratory studies carried out using both a pseudo-virus assay as well as a live virus assay have worryingly demonstrated total abrogation of neutralisation by first wave post-infection and post-vaccination antibodies against the 501Y.v2 variant.
- In 50% of the sera, neutralising activity was absent, and in the remaining 50%, neutralising activity was seriously reduced against the 501Y.v2 variant.
- To date, some 4000 cases of second infections between the first and second waves have been collected and work is ongoing to establish whether the second wave breakthroughs were due to the 501Y.v2 variant.

Points considered

- In vitro studies in the USA using a construct with the three relevant receptor binding domain mutations, have demonstrated that post-vaccination sera from the two mRNA vaccines retain reduced but significant neutralising activity against the 501Y.v2 variant.
- There is no data on in-vivo efficacy against 501Y.v2 variant with the two mRNA vaccines, as they have not featured in rollouts with these vaccines.
- In-vivo vaccine efficacy against the 501Y.v2 variant with the Novovax vaccine trial showed a marked reduction to less than 50%, and with the Johnson & Johnson vaccine, efficacy with a single dose regimen was 57%.
- Data on in-vivo efficacy against the 501Y.v2 variant is due to be released on Monday 8th February.
- A high-level consultative meeting of the technical working group of the MAC will be held on Monday, 8th February. This will consist of local and international experts in the field to develop a considered advisory on the way forward
- There is insufficient data to assess the efficacy of any of the vaccines with regard to protection against serious infection and hospitalization with the 501Y.v2 variant.

Recommendations

- In view of the uncertainty regarding the efficacy of the AstraZeneca vaccine, it is recommended that the roll-out of this vaccine be suspended pending the release of data of the in-vivo efficacy against the 501.v2 variant. The high-level working group will discuss in depth implications of the data and information with respect to the advisability of rolling out at AstraZeneca vaccine will be forthcoming

- In the meantime, it is strongly recommended that urgent steps be taken to acquire alternate vaccines to replace the AstraZeneca vaccine, should the decision be taken to not use it for the vaccine rollout.

Thank you for consideration of this request.

Kind regards,

PROFESSOR BARRY SCHOUB
CHAIRPERSON: MINISTERIAL ADVISORY COMMITTEE ON COVID-19 VACCINES
DATE: 18 March 2021

CC:
» **Dr S Buthelezi (Director-General)**
» **Dr T Pillay (Deputy Director-General: Health Regulations and Compliance Management)**

Notes on the reasons for retrospective submission of this advisory:
- This advisory was finalised on the 7th of February, of which NDoH officials were aware of.
- It was never submitted as a formal advisory at the time as the VMAC was made aware that the AZ vaccines were to be sold to other country/ies in the African Union.
- In hindsight, to ensure that there is a proper paper trail, this advisory is retrospectively being formally submitted to regularise the information conveyed in the advisory.
- As it is only being submitted retrospectively, it was signed off on the date that the Committee recommended that it be submitted retrospectively to the NDoH, which was at the VMAC meeting on the 18th of March 2021.

164
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Media Statement

21 March 2021

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

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

Issued by the Ministry of Health

Further queries:

Dr. Lwazi Manzi

MLO Ministry of Health

0826788979



75,000 Doses Of AstraZeneca Vaccine Arrived Yesterday

CORONAVIRUS APRIL 9, 2021 **WRITTEN BY:** AINSWORTH MORRIS



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166

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

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

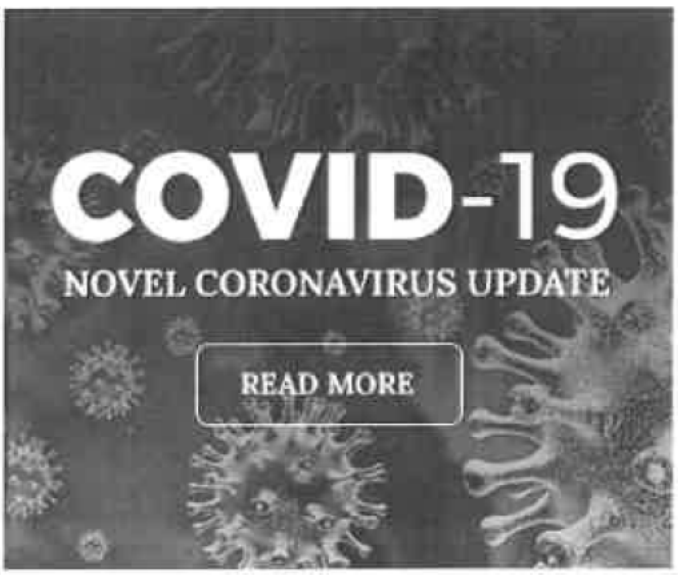
The first shipment was donated by the Indian Government and the second shipment came through the COVAX Facility, organised by the World Health Organization/Pan American Health Organization (WHO/PAHO) for member countries that have made a collective purchase.

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

"This shipment is going to be used for our [vaccination] blitz exercise, starting this weekend. As early as tomorrow, we're going to be dispatching. The intention is to inoculate as many persons as possible, hopefully well over 50,000. We are doing 60 years and over, and we are including now our teachers and we are also including our hotel workers," Minister Tufton said.

"We have another shipment coming in this month from COVAX. Approximately 50,000 doses should come in about the third week of April, and possibly another shipment for 20,000," he said.

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NATIONAL / HEALTH

167
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SCIENTIFIC ADVISERS

Evidence piles up that Covid advice was ignored

Government has overridden advice from the ministerial advisory committee on Covid-19

25 MARCH 2022 - 05:40 *by* TAMAR KAHN



The government has proposed wide-ranging regulations dealing with the size of gatherings, social distancing, quarantine and isolation, funerals, travel in and out of SA, and the handling of corpses. Picture: GETTY IMAGES/KB MPOFU

Fresh evidence has emerged of how the government ignored the counsel of experts appointed to advise it on managing the coronavirus pandemic.

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Earlier this week, Business Day reported that the government had overridden advice from the ministerial advisory committee on Covid-19 to scrap all testing for travellers to SA and to ditch rules on social distancing.

It now transpires that a technical working group supporting the ministerial advisory committee warned the government six weeks ago that its plan to replace the coronavirus regulations brought into effect in terms of the Disaster Management Act with regulations to the National Health Act risked legal challenge because they would potentially undermine constitutionally enshrined rights.

But the government, under growing pressure to end the national state of disaster — which was brought into effect two years ago to manage Covid-19 — has pressed ahead with its plan to use National Health Act regulations to deal with Covid-19 and any future health threats.

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The government has proposed wide-ranging regulations dealing with the size of gatherings, social distancing, quarantine and isolation, funerals, travel in and out of SA, and the handling of corpses.

They are contained in amendments to three sets of regulations to the National Health Act and amendments to regulations to the International Health Regulations Act, published in the Government Gazette on March 15.

The working group's advice is contained in a position paper dated February 8, released on the government's coronavirus website on Wednesday night.

Ministerial advisory committee co-chair Koleka Mlisana said the group provided evidence-based scientific advice, but could not force the government to follow it.

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"They decide whether to take our advice, tweak it, or not take it. Difficult as it is, it is something we have learnt to live with."

Mlisana said the ministerial advisory committee had insisted its advisories were dated and urged the government to publish them timeously so the public could see the counsel that had been provided. It is up to the government to explain why it deviated from the advice.

Ministerial advisory committee advisories are typically published on the government's coronavirus site weeks, and sometimes months, after they are submitted to health minister Joe Phaahla. These advisories inform the input he provides to the national coronavirus command council and the cabinet.

The working group advised the government to scrap an array of measures it said are ineffective at containing the spread of the virus, including temperature screening, hand sanitising and decontamination of premises. These measures are still required by law.

It also advocated dropping outdoor mask mandates and ending PCR testing for international travellers, measures that were partially scrapped this week. Masks outdoors are no longer required, but only vaccinated travellers to SA are exempt from PCR tests, according to the latest iteration of the government's coronavirus regulations, which came into effect on Wednesday.

The working group recommended moving from a containment to a mitigation strategy, saying it is clear the virus will not be eliminated.

"As Covid-19 continues to pose a health risk into 2022 and beyond, there is a need to consider responses that are integrated into the health system, that are not detrimental to other health needs, and which aim to minimise the extraordinary cost to the macroeconomy," it said.

While the lockdown imposed shortly after SA's first cases were identified in March 2020 was justified, the economic damage and large-scale job losses that ensued cannot be ignored, it said.

At this stage, the threat of a Covid-19 surge overwhelming the health service has been substantially reduced by access to vaccines, which protect against severe illness and death, and extensive prior infection.

A study led by Wits dean of health sciences Prof Shabir Madhi found more than 70% of Gauteng's population had antibodies to SARS-CoV-2 before the onset of the fourth wave, which peaked in December.

kahnt@businesslive.co.za

From: Marlise Richter <Marlise@healthjusticeinitiative.org.za>
Sent: Wednesday, 2 June 2021, 08:20
To: 'Lwazi Manzi'; 'Popo Maja'; 'Nombulelo Leburu'
Cc: 'Janine Jugathpal'; marjan.jacobs@uct.ac.za; 'Koleka Mlisana'; barry.schoub@gmail.com; Fatima Hassan
Subject: Follow-up: Request for publication of missing MAC advisories

Dear Mr Maja and Dr Manzi

I hope you are keeping well?

Our correspondence dated 14, 20 and 30 April and 14 May refers.

We note that the latest MAC advisory published is dated 12 April 2021 and concerns "Strategies to address COVID-19 Vaccine Hesitancy and Promote Acceptance in South Africa".

We believe that a number of MAC Advisories exist related to COVID-19 Vaccines and related issues, but that these have not been published on the Department of Health website. These include vaccine selection, the rationale for the pausing of the planned AstraZeneca roll-out, the selling on of the said vaccines, and the sequence of age and co-morbidity prioritisation within the Department of Health's Electronic Vaccination Data System (EVDS).

This information should be in the public domain and it is deeply regrettable that more than 105 days since the start of the Sisonke study (17 Feb) and 16 days since the official start of South African vaccine roll-out (17 May) this information is still not available.

Please could you forward these by close of business on 4 June 2021 or unfortunately we will have no choice but to submit a formal request in terms of the Promotion of Access to Information Act? We believe the MAC Advisories are of public importance in a pandemic.

Yours sincerely

Marlise Richter

From: Marlise Richter
Sent: Friday, May 14, 2021 10:59 AM
To: 'Lwazi Manzi' <lwazimanzi@gmail.com>; **'Popo Maja'** <popo.maja@health.gov.za>; **'Nombulelo Leburu'** <Nombulelo.leburu@health.gov.za>

Cc: 'Janine Jugathpal' <janine.jugathpal@health.gov.za>; marian.jacobs@uct.ac.za; **'Koleka Mlisana'** <koleka.mlisana@nhls.ac.za>; barry.schoub@gmail.com; 'Fatima Hassan' <Fatima@healthjusticeinitiative.org.za>
Subject: Follow-up: Request for publication of missing MAC advisories on AstraZeneca and selection
Importance: High

Dear Mr Maja and Dr Manzi

I hope you are keeping well?

Our correspondence dated 14, 20 and 30 April refers.

Could you please advise when the MAC advisories that relate to the pausing of the planned AstraZeneca roll-out, the selling on of the said vaccines and any additional advisories on current or future vaccine selection will be published?

We look forward to your response.

Yours sincerely

Marlise Richter

From: Marlise Richter
Sent: Friday, April 30, 2021 9:59 AM
To: 'Lwazi Manzi' <lwazimanzi@gmail.com>; **'Popo Maja'** <popo.maja@health.gov.za>; **'Nombulelo** Leburu' <Nombulelo.leburu@health.gov.za>
Cc: 'Janine Jugathpal' <janine.jugathpal@health.gov.za>; 'marian.jacobs@uct.ac.za' <marian.jacobs@uct.ac.za>; 'Koleka Mlisana' <koleka.mlisana@nhls.ac.za>; 'barry.schoub@gmail.com' <barry.schoub@gmail.com>; 'Fatima Hassan' <Fatima@healthjusticeinitiative.org.za>
Subject: Follow-up: Request for publication of missing MAC advisories on AstraZeneca and selection
Importance: High

Dear Mr Maja and Dr Manzi

I hope you are keeping well?

Our correspondence dated 14 and 20 April refers.

Thank you for the publication of 7 additional MAC advisories that we now note on the website.

There are however some key documents missing. We cannot find the advisories that relate to the pausing of the planned AstraZeneca roll-out, the selling on of the said vaccines and any additional advisories on current or future selection.

Could you please assist?

Yours sincerely

Marlise Richter

From: Marlise Richter
Sent: Tuesday, April 20, 2021 5:25 PM
To: Lwazi Manzi <lwazimanzi@gmail.com>; Popo Maja <popo.maja@health.gov.za>; Nombulelo Leburu <Nombulelo.leburu@health.gov.za>
Cc: Janine Jugathpal <janine.jugathpal@health.gov.za>; marian.jacobs@uct.ac.za; Koleka Mlisana <koleka.mlisana@nhls.ac.za>; barry.schoub@gmail.com; Fatima Hassan <Fatima@healthjusticeinitiative.org.za>
Subject: Follow-up: Request for publication of MAC advisories since 11 January 2021
Importance: High

Dear Mr Maja and Dr Manzi

Our correspondence dated 14 April and subsequently re-directed to your offices has reference. It is also attached for your convenience.

Could you kindly advise when the MAC advisories will be published and and/or provide us with written reasons why they are not yet publicly released?

We look forward to your response.

Yours sincerely

Marlise Richter

HEALTH JUSTICE INITIATIVE

Marlise Richter, PhD
Senior Researcher

From: Jane J. Riddin <Jane.Riddin@health.gov.za>
Sent: Wednesday, April 14, 2021 9:35 AM
To: Lwazi Manzi <lwazimanzi@gmail.com>; Popo Maja <popo.maja@health.gov.za>; Nombulelo Leburu <Nombulelo.leburu@health.gov.za>
Cc: Marlise Richter <Marlise@healthjusticeinitiative.org.za>; Janine Jugathpal <janine.jugathpal@health.gov.za>
Subject: Fw: Request for publication of MAC advisories since mid-January 2021
Importance: High

WHC CAUTION: Don't click on links or open attachments unless you know that the content is safe. Check with IT if unsure.

Dear Mr Maja and Dr Manzi,

Kindly see attached letter from Marlise Richter, Health Justice Initiative; requesting the publication of MAC advisories.

Can you please assist.

Kind regards

Jane Riddin

Essential Drugs Programme

Tel: 084 825 7052

From: Marlise Richter <Marlise@healthjusticeinitiative.org.za>
Sent: 14 April 2021 09:21
To: Jane J. Riddin <Jane.Riddin@health.gov.za>
Cc: marian.jacobs@uct.ac.za <marian.jacobs@uct.ac.za>; Koleka Mlisana <koleka.mlisana@nhls.ac.za>; barry.schoub@gmail.com <barry.schoub@gmail.com>; Fatima Hassan <Fatima@healthjusticeinitiative.org.za>; Georgina Sylvester <Georgina.Sylvester@health.gov.za>; Janine Jugathpal <janine.jugathpal@health.gov.za>; amanda.brewer@za-scta.com <amanda.brewer@za-scta.com>
Subject: Request for publication of MAC advisories since mid-January 2021

Dear Ms Riddin

Please find a letter attached, which has been copied below for your ease of reference.

Yours sincerely

Marlise Richter

HEALTH JUSTICE INITIATIVE

Marlise Richter, PhD
Senior Researcher

+27 82 855 9927
marlise@healthjusticeinitiative.org.za
www.healthjusticeinitiative.org.za
@HealthJusticeIn

14 April 2021

Ms Jane Riddin

Essential Drugs Programme

National Department of Health

By email: jane.riddin@health.gov.za

Dear Ms Rudin

Re: Request for publication of MAC advisories since mid-January 2021

We refer to our correspondence dated 9 and 23 March 2021.

Our correspondence of 9 March 2021 was forwarded to Professors Schoub and Abdool-Karim on the same day and is attached for ease of reference below.

On 10 March 2021 you indicated that the MAC Advisories are subject to "internal processes" and that you are "working with [your] media liaison to see about what can be loaded to the website". Since then, we have not had a further response from your offices, nor have they been made public.

Yet, in a South African Medical Journal (SAMJ) article published on 9 April 2021, Professor Schoub wrote:

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

Given the above, kindly publish the said advisories, and/or please provide us with written reasons why they are not yet publicly released.

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

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

We look forward to hearing from you shortly.

Yours sincerely,

Dr Marlise Richter

Senior Researcher – HJI

marlise@healthjusticeinitiative.org.za

Copies to:

1. Professor Marian Jacobs: marian.jacobs@uct.ac.za

Co-chair: COVID-19 Ministerial Advisory Committee (MAC)

2. Professor Koleka Mlisana: koleka.mlisana@nhls.ac.za

Co-chair: COVID-19 Ministerial Advisory Committee (MAC)

3. Professor Barry Schoub: barry.schoub@gmail.com

Chairperson: Ministerial Advisory Committee (MAC) on COVID-19 Vaccines

Attachment –previous correspondence

From: Marlise Richter
Sent: Tuesday, March 23, 2021 5:09 PM
To: Jane J. Riddin Jane.Riddin@health.gov.za
Cc: Georgina Sylvester Georgina.Sylvester@health.gov.za; **Fatima Hassan** Fatima@healthjusticeinitiative.org.za; Janine Jugathpal janine.jugathpal@health.gov.za; amanda.brewer@za-scta.com
Subject: RE: Request for MAC advisories - follow-up

Dear Ms Riddin

I hope you are keeping well and that you had a good long weekend?

Thank you for the feedback below.

I am writing to request an update on the publication of the MAC advisories. The last MAC advisory on the website is dated 11 January.

Also, could you please provide information on how many VMAC and MAC meetings have taken place since the beginning of the year?

Thank you in advance.

Yours sincerely

Marlise Richter

From: Jane J. Riddin <Jane.Riddin@health.gov.za>
Sent: Wednesday, March 10, 2021 8:52 AM
To: Marlise Richter <Marlise@healthjusticeinitiative.org.za>
Cc: Georgina Sylvester <Georgina.Sylvester@health.gov.za>; Fatima Hassan <Fatima@healthjusticeinitiative.org.za>; Janine Jugathpal <janine.jugathpal@health.gov.za>; amanda.brewer@za-scta.com
Subject: Re: Request for MAC advisories

Good day Marlise,

Thank you for the request.

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

I will be in touch soon.

Kind regards

Jane Riddin

Essential Drugs Programme

Tel: 084 825 7052

From: Marlise Richter <Marlise@healthjusticeinitiative.org.za>
Sent: 09 March 2021 11:51
To: Jane J. Riddin <Jane.Riddin@health.gov.za>
Cc: Georgina Sylvester <Georgina.Sylvester@health.gov.za>; **Fatima Hassan** <Fatima@healthjusticeinitiative.org.za>
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Dear Ms Riddin

I hope you are keeping well?

I am a researcher at the Health Justice Initiative – an NGO that works on access to life saving diagnostics, treatment and vaccines for COVID-19, TB and HIV and health equity.

We have been following the decisions of the Ministerial Advisory Committee on COVID-19 (the 'MAC') and the Vaccines Ministerial Advisory Committee (the 'VMAC') closely. The MAC advisories available on the internet are very useful and thank you for the useful webpage: https://sacoronavirus.co.za/category/mac-advisories/

I have noticed that there haven't been any MAC Advisories published in the last two months. This is at a time of key developments on the vaccine roll-out and decisions about what vaccines to use.

Could I request that you forward any MAC advisories in the last two months, and that these are uploaded to the website?

Can I also enquire how many meetings of the MAC and the VMAC took place in from the beginning of 2021 to date?

Thank you.

Kind regards

HEALTH JUSTICE INITIATIVE

14 April 2021

Ms Jane Riddin

Essential Drugs Programme

National Department of Health

By email: jane.riddin@health.gov.za

Dear Ms Rudin

Re: Request for publication of MAC advisories since mid-January 2021

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

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We look forward to hearing from you shortly.

Yours sincerely,

Dr Marlise Richter

Senior Researcher – HJI

marlise@healthjusticeinitiative.org.za

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1. Professor Marian Jacobs: marian.jacobs@uct.ac.za
   Co-chair: COVID-19 Ministerial Advisory Committee (MAC)
2. Professor Koleka Mlisana: koleka.mlisana@nhls.ac.za
   Co-chair: COVID-19 Ministerial Advisory Committee (MAC)
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Essential Drugs Programme

Tel: 084 825 7052

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Thank you.

Kind regards

Marlise

HEALTH JUSTICE INITIATIVE

22 June 2021

National Department of Health
Acting Minister Mmamoloko Kubayi-Ngubane
Director General Dr Sandile Buthelezi (Information Officer)

Copies to:

The Presidency
Information Officer

National Assembly
The Office of the Speaker

SAHPRA
The CEO
Company Secretary

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

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

1. The Health Justice Initiative (**HJI**) is a dedicated public health and law initiative addressing the intersection between racial and gender inequality with a special focus on access to life-saving diagnostics, treatment and vaccines for COVID-19, TB and HIV.

2. Since November 2020 we have written on numerous occasions to the National Department of Health ("Department") and other relevant Ministries requesting information pertaining to the COVID-19 pandemic in order to foster transparency, disclosure and improved engagement and communication. This includes correspondence on the national vaccine programme, including on matters related to the acquisition, procurement, selection and prioritisation.

3. Our correspondence has been copied to relevant government departments and in certain cases also addressed/copied to statutory bodies including the South African Health Products Regulatory Authority (**SAHPRA**) and also, Parliament.

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.

Board: Dr Shuaib Manjra, Noncedo Madubedube, Fatima Hassan

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

Open procurement and voluntary disclosure of information

5. As you are aware, section 217(1) Constitution requires that when an organ of state contracts for goods and services, it must do so in accordance with a system which is "**fair, equitable, transparent, competitive and cost-effective**". In addition, section 15 of the Promotion of Access to Information Act 2 of 2000 (**PAIA**) enables the voluntary disclosure and automatic availability of records, *without* a person having to request access in terms of PAIA and without a fee.

6. Due to the ongoing public health crisis occasioned by the Covid-19 pandemic and also allegations of corruption in the health care sector, there is an urgent need for the voluntary disclosure and automatic availability of any and all information pertaining to the government's Covid-19 response, particularly as it relates to the national vaccine programme. This is squarely a matter of public interest, which warrants openness and accountability from the government and a state-led approach to information-sharing.

Information that should be voluntarily disclosed and automatically accessible

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

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

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

7.1.6. The African Union Vaccine Access Task Team (AU AVATT).

7.1.7. 'COVAX' (with the Global Vaccine Alliance – GAVI /Other).

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

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

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

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

7.2.1. the decision and / or other advice on vaccine selection and specifically, pausing the use of the AstraZeneca (AZ) vaccine in South Africa and to donate and / or sell it;

7.2.2. the prioritisation of people over 60 years old and / or those with comorbidities;

7.2.3. the prioritisation of 'elite' athletes and sport officials, South African government officials and diplomats / others;

7.2.4. the prioritisation of teachers and school support staff / others.

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

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

other at-risk populations, for vaccine administration.
We note that our correspondence in this regard has also remained unanswered.

8. We request that the voluntary disclosures are made, or reasons for non-disclosure are given, by no later than **2 July 2021**, failing which we will formally submit relevant Promotion of Access to Information Act (PAIA) requests, if applicable, and/or pursue any other recourse that may be available to us. We hope that this will not have to be the case.

9. We sincerely hope that this letter and the request for the voluntary disclosures lead to meaningful and transparent engagements with the state and that the relevant stakeholders open channels for co-operation on these issues, which are far-reaching and will remain in the public interest for the foreseeable future.

We look forward to hearing from you.

Sincerely,



Fatima Hassan (Director)

DIRECTOR GENERAL
HEALTH
REPUBLIC OF SOUTH AFRICA

PRETORIA
Private Bag X828, PRETORIA, 0001, 27th Floor, Civitas Building, Cnr Thabo Sehume and Struben Street, PRETORIA 0002 Tel (012) 395 8402 Fax (012) 395 8422
CAPE TOWN
P.O. Box 3675, CAPE TOWN, 8000, 103 Parliament Towers, Room 615, 120 Plein Street, CAPE TOWN, 8000 Tel (021) 461 2040 Fax (021) 461 6864

Attention: Ms Fatima Hassan
Director of Health Justice Initiative

E-mail: Althea@healthjusticeinitiative.org.za

Dear Ms Hassan

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

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

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

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

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

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

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

Kind Regards

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

From: Marlise Richter <Marlise@healthjusticeinitiative.org.za>
Sent: Friday, 23 July 2021 10:38
To: Justinos Motalaota <justinos.motalaota@health.gov.za>
Cc: Valerie Rennie <valerie.rennie@health.gov.za>; Kgorohlo Moabelo <Kgorohlo.Moabelo@health.gov.za>; Info HJI <info@healthjusticeinitiative.org.za>
Subject: RE: Request for information pursuant to the Promotion of Access to Information Act 2000 - Ministerial Advisory Committee Advisories and COVID-19 vaccination prioritisation

Dear Justinos

Thank you for the acknowledgement of our previous correspondence (our ref numbers 001/NDoH/2021 and 002/NDoH/2021)

We look forward to your response.

Yours sincerely

Marlise

From: Justinos Motalaota <justinos.motalaota@health.gov.za>
Sent: Friday, July 23, 2021 10:34 AM
To: Marlise Richter <Marlise@healthjusticeinitiative.org.za>
Cc: Valerie Rennie <valerie.rennie@health.gov.za>; Kgorohlo Moabelo <Kgorohlo.Moabelo@health.gov.za>
Subject: Re: Request for information pursuant to the Promotion of Access to Information Act 2000 - Ministerial Advisory Committee Advisories and COVID-19 vaccination prioritisation

Dear Marlise,

The above matter refers.

This serve to acknowledge your request and further be informed that we will revert to you with response.

Regards,
Justinos

From: Marlise Richter <Marlise@healthjusticeinitiative.org.za>
Sent: Tuesday, 20 July 2021 13:36
To: DG <dg@Health.gov.za>; Justinos Motalaota <justinos.motalaota@health.gov.za>
Cc: Nokwethemba Mchiza <Nokwethemba.Mchiza@health.gov.za>; Ayanda Ngubo <ayanda.ngubo@health.gov.za>; Info HJI <info@healthjusticeinitiative.org.za>
Subject: Request for information pursuant to the Promotion of Access to Information Act 2000 - Ministerial Advisory Committee Advisories and COVID-19 vaccination prioritisation

Dear Dr Buthelezi and Mr Motalaota

In addition to our request dated 19 July 2021 (with our reference number: 001/NDoH/2021), please find a request for information pursuant to the Promotion of Access to Information Act 2000 attached.

Our reference number for this Request is 002/NDoH/2021.

We look forward to your response.

Yours sincerely

Marlise Richter

MARLISE RICHTER, PHD
Senior Researcher
+27 82 858 9927
marlise@healthjusticeinitiative.org.za

HEALTH JUSTICE INITIATIVE

YN MR

HEALTH JUSTICE INITIATIVE

6 August 2021

To:

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

Copy to:

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

Dear Dr Buthelezi

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

1. Please convey our congratulations to the newly appointed Minister of Health, Dr Joe Phaahla.

2. We acknowledge receipt of your letter dated 29 July 2021.

3. As you will be aware, further to our letter dated 22 June 2021, and in the absence of any timely response, the Health Justice Initiative submitted three formal requests in terms of the Promotion of Access to Information Act 2 of 2000 ("PAIA") to the National Department of Health ("NDoH") in the public interest for which we duly received relevant acknowledgements of receipt, for two of the requests.

4. These three PAIA requests relate to: (1) all vaccine contracts (2) details about the Ministerial Advisory Committee/s (MAC) and its Advisories; and (3) prioritisation decisions including for the Sisonke programme.

5. Accordingly, we draw your attention to the following:

   5.1 ***Vaccine Contracts (Our PAIA Ref: 001/NDoH/2021):*** With regard to the vaccine contracts, we have noted your intention to consult with the vaccine manufacturers and distributors. We note further that, in terms of section 26 of PAIA, there is no basis to extend the time period for a PAIA request in order to consult with private bodies. However, we are amenable to granting you a one-

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.
Board: Dr Shuaib Manjra, Noncedo Madubedube, Fatima Hassan

KW MJZ

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

5.2 ***MAC advisories (Our PAIA Ref: 002/NDoH/2021):*** We note our appreciation for some of the MAC advisories that have been made public thus far, although this information has been difficult to navigate in the absence of a contents list. Moreover, we emphasise that this does not respond in full to our PAIA request, dated 20 July 2021. For instance, we have not been provided with the relevant names relating to "all local and international expert advisors to the National Department of Health on Covid-19" as requested. We trust that full disclosure will be made in accordance with our PAIA request within the 30-day prescribed period, and by no later than ***19 August 2021***.

5.3 ***Sisonke programme (Our PAIA Ref: 003/NDoH/2021):*** Your letter of 29 July 2021 does not address our PAIA request for information related to the Sisonke programme, dated 23 July 2021 (this request has not yet been formally acknowledged). We trust that full disclosure will be made in accordance with our PAIA request within the 30-day prescribed period, and by no later than ***22 August 2021***.

6. Given the inherent urgency and public interest in these requests for information – as well as the constitutional rights and values of access to information, openness, transparency, and accountability – it is imperative that this information be made available without delay. We highlight that these requests are made in the context of the ongoing pandemic and a vaccine supply chain that is not always reliable. We are therefore not amenable to granting any further extensions in order to respond to our respective PAIA requests.

7. We trust that we will receive a response in accordance with the time periods set out above, if not, kindly note that we will have no option but to consider our further legal options in order to compel disclosure of this information in the public interest.

We await to hear from you.

Yours sincerely,

Fatima Hassan

Director – Health Justice Initiative