

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

CASE NO: 10009/22

In the matter between :-

THE HEALTH JUSTICE INITIATIVE

Applicant

And

THE MINISTER OF HEALTH

1st Respondent


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

2nd Respondent

FILING SHEET

DOCUMENT: FIRST AND SECOND RESPONDENT'S ANSWERING AFFIDAVIT

DATED at PRETORIA this 1st day of AUGUST 2022.


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STATE ATTORNEY PRETORIA
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**TO: THE REGISTRAR OF THE HIGH COURT
GAUTENG DIVISION
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**AND
TO:**

APPLICANT'S ATTORNEYS

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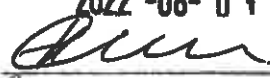
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IN THE HIGH COURT OF SOUTH AFRICA

GAUTENG DIVISION, PRETORIA

CASE NO: 10009/2022

In the matter between:

THE HEALTH JUSTICE INITIATIVE

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and

THE MINISTER OF HEALTH

First Respondent

THE INFORMATION OFFICER,

Second Respondent

NATIONAL DEPARTMENT OF HEALTH

CL NR

FIRST AND SECOND RESPONDENTS' ANSWERING AFFIDAVIT

I, the undersigned,

DR NICHOLAS GILMOUR CRISP

do hereby make oath and say that:

1. I am a Deputy Director-General of the Department of Health (NDoH). I am delegated by the Director General who is the designated Information Officer in terms of the Promotions of Access to Information Act 2000 (Act No. 2 of 2000) ("PAIA").
2. The facts contained in this affidavit fall within my personal knowledge, unless the context indicates otherwise and are, furthermore, to the best of my belief both true and correct.
3. Elsewhere in this affidavit where I rely on the information sourced from other sources, I believe the information therein to be true and correct.
4. Furthermore, elsewhere in this affidavit where I make legal submissions, I do so on the advice of the department's legal representatives. I accept such advice as



correct.

5. As delegated by the Director-General of the NDoH, who is the designed Information Officer in terms of PAIA, I have the authority to depose to this affidavit on behalf of the first respondent.
6. I have read the founding affidavit deposed to by **FATIMA HASSAN** on behalf of the applicant, and I wish to respond thereto as follows.
7. I will not answer to each, and every allegation of fact and/ or law contained in the founding affidavit. The fact that I do not answer to every allegation made in the founding affidavit should be construed as an admission of the correctness or truthfulness of such allegation.
8. Furthermore, any allegation set out in the in the founding affidavit, which is at variance with averments I make in this affidavit is denied and the applicant is put to the proof thereof.
9. The applicant in this application seeks an order setting aside and declaring as invalid the alleged failure by the respondents to provide access to the records requested in terms of Section 11 of PAIA. The applicant also seeks an order directing the first respondent (Minister of Health) to provide the records within ten (10) days of the date of the order, the copies of the following:

A handwritten signature in black ink, consisting of stylized initials or a name, located at the bottom right of the page.

[A] Copies of all Covid 19 vaccine procurement contracts, memoranda of understanding, and agreements including the following parties and/or duly authorized licensed representatives of:

- (a) Janssen Pharmaceuticals (Johnson & Johnson);**
- (b) Aspen Pharmacare;**
- (c) Pfizer;**
- (d) Serum Institute of India/Cipla;**
- (e) Sinovac/CoronaVac;**
- (f) Any other vaccine manufacturer/licensee;**
- (g) The African Union Vaccine Access Task Team (AUAVATT);**
- (h) COVAX (with the Global Vaccine Alliance: GAVI)/other; and**
- (i) The Solidarity Fund.**

[B] Copies of all Covid 19 Vaccine negotiation meeting outcomes and/or minutes; and correspondence, including with the following parties and/or duly authorised licenced representative/s of;

- (a) Janssen Pharmaceuticals (Johnson & Johnson);**
- (b) Aspen Pharmacare;**
- (c) Pfizer;**
- (d) Serum Institute of India/Cipla;**
- (e) Sinovac/CoronaVac;**
- (f) Any other vaccine manufacturer/licensee;**

- (g) *The African Union Vaccine Access Task Team (AUAVATT);*
- (h) *COVAX (with the Global Vaccine Alliance: GAVI/other; and*
- (i) *The Solidarity Fund."*

10. The applicant also seeks costs jointly and severally for opposing the application.

11. Before I deal with the grounds of opposition, I consider it is appropriate to deal with the relevant sections of the PAIA.

THE SCHEME OF PAIA

12. The PAIA permits the public or private bodies or institutions, under certain circumstances to refuse access to a record requested in terms of PAIA. In other words, the Act allows the mandatory non-disclosure under certain circumstances.

13. The Act also allows the public or private bodies the discretion non-disclosure of a record requested in terms of the PAIA.

1. Section 33(1) of the PAIA reads that: *The information officer of a public body:*

- (a) *must refuse a request for access to a record contemplated in section 34(1), 35(1), 36(1), 37(1)(a), 38(a), 39(1)(u), 40 or 43(1); or*

(b) May refuse a request for access to a record contemplated in section 37(1)(b), 38(b), 39(1)(b), 41(1)(a); or

(c) 42(1 or 3); 43(2), 44 (1 or 2); 45;

unless the provisions of section 46 apply.

"[1] Section 36(1) of the Act, provides that "Subject to subsection 2, the information officer of a public body must refuse a request for access to a record of the body, if the record contains:

(a) trade secrets of a third party;

(b) financial, commercial, scientific, or technical information, other than trade secrets, or of a third party, the disclosure of which will be likely to cause harm to the commercial or financial interests of that third party; or

(c) information supplied in confidence by a third party, the disclosure of which could reasonably be expected:

(i) to put that third party at a disadvantage in contractual or other negotiations; or

(ii) to prejudice that third party in commercial competition.

[2] A record may not be refused in terms of subsection (1) insofar as it consists of information-



- (a) already publicly available;*
- (b) about a third party who has consented in terms of Section 48 or otherwise in writing to its disclosure to the requester concerned; or*
- (c) about the results of any product or environmental testing or other investigation supplied by and earned out or on behalf of a third party and its disclosure will reveal a serious public safety or environmental risk.*

[3] For the purposes of subsection (2)(c), the results of any production or environmental testing or other investigation, do not include the results of preliminary testing or other investigation conduct for the purpose of developing methods of testing or other investigations”.

1. *Section 37(1) states: “Subject to subsection (2) the information officer of a public body-*

(a) must refuse a request for access to a record of the public body if the disclosure of the record will constitute an action for breach of duty of confidence owed to a third party in terms of an agreement; or

(b) may refuse a request for access to a record of the body if the record consists of information that was supplied in confidence by a third party-

(i) the disclosure of which could reasonably be expected to prejudice the future supply of similar information, or information from the same source; and

(ii) if it is in the public interests that similar information, or information from the same source, should continue to be supplied.

2. *A record may not be refused in terms of subsection (1) insofar as it consists of information:*

(a) already available; or

(b) about the third party concerned, that has consented in terms of Section 48 or otherwise in writing to its disclosure to the requester concerned”.

3. *Section 42 (1) reads: The information officer of a public body may refuse a request for access to a record of the public body if its disclosure would be likely to materially jeopardise the economic interests or financial welfare of the Republic or the ability of the government to manage the economy of the Republic effectively in the interests of the Republic.*

(2) The information referred to in the subsection (1) includes, without limiting the generality of that subsection, the information about-

(a) ...;

(b) ...:

(i) ...;

(ii) ...;

(iii) ...;

(iv) ...; or

(v) ...; or

(c) a contemplated –

(i) ...;

(ii) international trade agreement.

(3) Subject to subsection (5), the information officer of a public body may refuse a request for access to a record of the body if the record-

(a) contains trade secrets about the state of a public body; or

(b) contains financial, commercial, scientific, or technical information, other than trade secrets, the disclosure of which will be likely to cause harm to the commercial or financial interests of the state or the public body; or

(c) contains information, the disclosure of which could reasonably be expected:

(i) to put a public body at a disadvantage in contractual or other negotiations; or

(d) is a computer program as defined in section 1(1) of the Copyright Act of 1978 (Act No. 98 of 1978), owned by the state or public body, except insofar as it is required to give access to a record, to which access is granted in terms of this Act.

4. Section 44 reads:

[1] Subject to subsections (3) and (4) the Information Officer of a public body may refuse a request for access to the record of the body:

(a) If the record contain:

(i) an opinion, advice, report, or a recommendation obtained or prepared;

or

(ii) A consultation, discussion, or deliberation that has occurred, including, but not limited to minutes of a meeting, for the purpose of assisting to formulate a policy or make a decision in the exercise of power or the performance of duties conferred or imposed by law; or

(b) If-

(i) the disclosure of the record could reasonably be expected to frustrate the deliberative process in the public body or between public bodies by inhibiting the candid:

(aa) communication of an opinion, advice or a report, recommendation;

or

(bb) conduct of consultation, discussion, or deliberation.

5. Section 46 reads:

"Despite any other provision of this chapter, the information officer of a public body must grant a request for access to a record of the body contemplated in section 34(1), 36(1), 37(1)(a) or (b), 38(a) or (b), 39(1) (a) or (b), 40, 41(1)(a) or (b), 42(1) or 3, 43 (1) or (2), 44 (1) or (2), or 45, if-

(a) The disclosure of the record will reveal evidence of:

(i) a substantial contravention of, or failure to comply with the law; or

(ii) an imminent and serious public safety or environmental risk; and

- (b) *The public interest in the disclosure of the record clearly outweighs the harm contemplated in the provision in question”.*

6. **Section 47 reads:**

- (1) *the information officer of a public body considering a request for access to a record that might be a record contemplated in terms of Section 3(34)(1), 35(1), 36(1), 37(1), or 43(1) must take all reasonable steps to inform the third party to whom a record could relate in respect of the request.*
- (2) *the information officer must inform the third party in terms of subsection (1)-*
- (a) *as soon as reasonably possible, but in any event within (21) days after that request is received or transferred; and*
- (b) *by the fastest means possible.*
- (3) *When informing a third party in terms of subsection (1) the information officer must-*
- (a) *state that he/she is considering a request for access to a record that might be a record contemplated in sections 34(1), 35(1), 36(1), 37(1), or 43(1) as the case may be and describe the content of the record in question;*
- (b) *furnish the name of the requestor;*

- (c) *describe the provisions of sections 34(1), 35(1), 36(1), 37(1), 48(1) as the case may be.*
- (d) *in any case where the information officer believes that the provisions of section 46 might apply, describe those provisions, and specify which of the circumstances referred to in terms of section 46(u) in the opinion of the information officer might apply and state the reason why he/or she is of the opinion that section 46 might apply; and*
- (e) *state that the third party within twenty-one (21) days after the third party is informed:*
 - (i) *make written or oral representations to the information officer why the request for access should be refused; or*
 - (ii) *give written consent for disclosure of the record to the requester."*

FACTUAL BACKGROUND AND CONTEXT

14. It is axiomatic that Covid-19 pandemic is unprecedented in several ways. The extraordinary speed with which the pandemic came about and affected countries around the world. The medical research was outpaced by the rapid spread of the virus which left healthcare workers and policy makers at a

disadvantage.

- 15. The scientific community's understanding of the virus and the best manner of managing the virus changed constantly during 2020. The extraordinary efforts that have been made by the vaccine manufactures to develop a vaccine to manage the virus. The development of a vaccine normally takes more than 10 years. In respect of Covid-19 virus, vaccine development efforts had been done at an unprecedented speed.**

- 16. There was an unprecedented level of competition between countries around the world for the limited vaccine supplies that began to be made available. Because every country was desperate to protect its citizens, every country sought access to the vaccines available, and this led to a competition to secure vaccines among the countries and the largest and well-resourced countries have advantages.**

- 17. No government could afford to have a fixed or rigid strategy for procuring and distributing vaccines. What was required was a constantly evolving vaccine strategy that took account of the latest scientific developments, the latest information regarding which vaccines were effective against which variants, which vaccines were appropriate for which country's conditions and procurement procedures of the vaccines in the context of the unprecedented**

and intense competition between countries.

18. From July 2020 onwards, the NDoH and its officials engaged in discussions with various vaccine manufacturers regarding the procurement of the Covid -19 vaccines. These initial discussions were aimed at understanding whether and on what basis the manufacturers would be prepared to contract with the NDoH to supply vaccines to be distributed to the South African public.
19. These initial discussions took place before the manufacturers had completed phase 3 clinical trials and even before the appointment of the Ministerial Advisory Committee on Vaccines ("VMAC"). During the period July to December 2020, discussions were held with Pfizer, Johnson and Johnson, the Gamaleya Institute and Moderna, as well as the COVAX Facility. On 17 September 2020, the VMAC publicly issued its first advisory, dealing with the participation of South Africa in the Covid-19 Vaccines Global Access ("COVAX") facility.
20. The VMAC made several recommendations, which appear from the advisory, inter alia: that South Africa should participate in the Covax facility; South Africa should do so via the "Committed Purchase" option; the Commitment should be to purchase sufficient vaccines for 10% of its population through the Covax facility; and that South Africa should continue



with its current ongoing bilateral discussions with vaccines manufacturers. Although the VMAC is an advisory body, the NDoH had followed and effected all these recommendations.

21. By the time that the Vaccine Strategy was developed and published, only two vaccines (Pfizer and Moderna) had published stage 3 clinical trial results, both during November 2020. The NDoH had decided for very good reason and in accordance with the advice of the VMAC, to await the outcome of stage 3 trial results before concluding any agreements with the individual vaccine manufacturers.
22. There were several other vaccines at different stages of trials, including some with stage 3 results expected imminently. Some of these vaccines were anticipated to be more suitable for South African population. Some of these vaccines included AstraZeneca.
23. This means that, at the time that the Vaccine Strategy was developed and published: the NDoH had not yet concluded any direct agreement with any manufacturer for the provision of vaccines; the NDoH anticipated doing so in the near future, depending on the outcome of stage 3 trial results that were awaited; and South Africa was already part of the Covax Facility, even though it was unclear when the vaccines anticipated to be delivered via the



Covax Facility would arrive.

- 24. South Africa also boasts a number of institutions and laboratories that have for years developed and manufactured vaccines. One of these is Biovac, which the NDoH has contracted with to ensure that vaccines which arrived in the country are properly received, handled, and distributed through the provinces.**
- 25. The government allocated about R95 million towards the development of Covid-19 vaccines, treatments, therapeutics, and diagnostics by various institutions. Part this funding was allocated to ensure that South Africans participate in the clinical trials for various vaccines. This was important because it provided an opportunity to determine whether the different vaccines would have efficacy when used in South Africa given the South African conditions and circumstances.**

PURCHASE AGREEMENTS

- 26. The vaccine strategy adopted by South Africa, envisaged three ways in which South Africa could obtain vaccines after they have passed phase 3 clinical trials and certified as safe for use on people. These were through the Covax Facility; by concluding purchasing agreements with individual vaccine manufacturers; and acquisition through arrangements with the African Union. Thus, South African's procurement of vaccines must be seen**



within a greater context. There has been a struggle for African countries in procuring vaccines from manufacturers or pharmaceutical companies.

27. On the advice of the VMAC, South Africa chose to participate in the committed purchase option and did so in respect of 10% of its population (6 million people). South African made down payment of R283 million on 21 December 2020 by the Solidarity Fund to the Covax Facility. I must mention that the approach of government in line with the advice of the VMAC, was that it would not enter into any purchase agreements with the manufacturers until the phase 3 trial for the relevant vaccine had been successfully passed.

28. Even then, the mere fact that the phase 3 trial had succeeded could not mean that the government would immediately conclude an agreement with the manufacturer. Instead in determining which vaccines to contract for and in what quantities, careful consideration was given to a number of issues, inter alia: actual availability and timing of the vaccine delivery; whether regulatory approvals had been issued for the vaccine in other countries; the ease of use of schedule (whether one dose per person or two would be required; the requirements for stability during storage distribution; and cost associated with vaccine).

29. After having considered all these factors on 6 January 2021, the NDoH applied to the National Treasury for the necessary deviation to conclude

agreements with the following manufacturers: Pfizer; Moderna; AstraZeneca (via the Serum Institute of India); and Johnson and Johnson, respectively.

ASTRAZENECA (SERUM INSTITUTE OF INDIA) ("SII")

30. I must mention that the government's first engagement with Serum Institute of India, regarding the possibility of South Africa being supplied with the AstraZeneca on 14 September 2020. The NDoH was represented by Dr Anban Pillay and Ms Khadija Jamaloodien.
31. The AstraZeneca stated during the negotiations 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 thus, wanted to sub-contract the production to a range of suppliers and producers across the world. The SII was allocated to the South African market. The implication of this allocation is that instead of contracting with AstraZeneca directly, South Africa contracted with the SII for the vaccine.
32. Following the National Treasury deviation approval on 6 January 2021, extensive negotiations were entered into with SII around certain provisions of the proposed term-sheet and agreement. 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: 1 million doses would be shipped during January 2021; and 500 000

doses would be shipped during February 2021. The 1 million doses were shipped on 31 January 2021. However, the use of these doses was unfortunately, undermined by trial results.

33. After a new Covid-19 variant (501Y.V2) was detected in South Africa in December 2020 and based on the advice of VMAC it was discovered 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% against the 501Y.V2 variant.

34. This development meant that the roll-out of the vaccine which was scheduled for 15 February 2021 had to be put on hold so that other considerations could begin on what approach to take. On 15 January 2021, then Minister of Health (Dr Zweli Mkhize) in parliament announced that the AstraZeneca doses would be offered to the African Union platform for distribution to those countries who had already expressed an interest in acquiring the stock. This was to avoid wasteful and fruitless expenditure.

JOHNSON AND JOHNSON

35. The government first began engagements with Johnson and Johnson regarding the possibility of it supplying South Africa with vaccine on 4 September 2020. The government was represented by Dr Anban Pillay and

Ms Khadija Jamaloodien. Further extensive engagements followed in January 2021. On 7 January 2021, a term-sheet was signed between NDoH and Johnson and Johnson. The purchase agreement was signed on 26 February 2022. According to the agreement, South African would receive 11 million doses of the vaccine. The vaccine was being produced by Aspen in Port Elizabeth under the licence from Johnson and Johnson.

THE PFIZER

36. The government first began engaging with Pfizer regarding the possibility of it supplying South Africa with the vaccine on 24 July 2020. The people representing government in the engagements included the former Minister of Health, the Deputy Minister of Health, myself, Dr Anban Pillay and Ms Khadija Jamaloodien. In January 2021, it was decided that Pfizer was an appropriate vaccine to purchase. On 15 January 2021, a term-sheet was signed between the NDoH and Pfizer involving the supply of 20 million doses of vaccine. The purchase agreement was signed on 30 March 2022.

MODERNA

37. Following the stage 3 trial results of November 2020, the government began engaging with Moderna regarding the possibility of it supplying South Africa with the vaccine. This began on 21 December 2020 when the former Minister

met with Moderna. Moderna indicated during the engagement that the earliest date for delivery would be the third quarter of 2021. Moderna offered to deliver 20 million doses. On 24 December 2022, the term-sheet was eventually signed between the NDoH and Moderna.

CONFIDENTIALITY CLAUSE

38. I must mention that the procurement contracts, were negotiated in good faith and in the best interests of the country under the prevailing circumstances. the department had signed the agreements, which contained confidentiality clauses regarding non-disclosure of the procurement agreements. I have mentioned in the previous paragraphs that there was an intense competition between the countries to procure vaccines for their citizens.
39. The vaccine manufacturers equally have negotiated in good faith and signed a non-disclosure clause in the agreements. The agreements signed with the manufacturers mentioned in the paragraph above contained confidentiality clauses. These clauses prohibit any disclosure to the procurements without the consent of other manufacturers. Any disclosure will constitute a breach of the agreement.
40. If the NDoH provides access to these contracts, the department will be in breach of the terms of the confidentiality clauses, and the disclosure will

prejudice the respondents and the vaccine manufacturers in future engagements as contemplated in sections 36(1) (c)(i) (ii) and 37(1)(a) of the PAIA.

41. I submit with respect that there is no basis to suggest that disclosure of the agreements would reveal evidence a substantial contravention of, or failure to comply with, the law; or an imminent and serious public safety or environmental risk; and that the public interest in the disclosure of the record clearly outweighs the harm as contemplated in section 46 of PAIA.
42. The Director General received the applicant's request in terms of PAIA on 29 July 2021. After he considering the request, the Director General addressed the letter to the applicant's director (Fatima Hassan) informing her that the department has notified the vaccine manufacturers and distributors of the request by the applicant to have access to the procurement agreements and request the vaccine manufacturers to make representation regarding the disclosure of the record requested.
43. The letter is referred to is found on page 001-81 of the applicant's founding affidavit. On 11 January 2022, an email was sent to the deponent to the founding affidavit on page 109 is annexed to the applicant's founding affidavit



and is marked "HJI15". The email states-

"Kindly be informed that as per confidential agreements, the National Department of Health is not at liberty to divulge such details /information"

AD SERIATIM RESPONSE TO THE FOUNDING AFFIDAVIT

AD PARAGRAPHS 1, 2 AND 3 THEREOF

44. Save for denying that the averments in the founding affidavit are true and correct, the remainder of the allegations herein are noted.

AD PARAGRAPHS 4 TO 7 THEREOF

45. The averments herein are admitted.

AD PARAGRAPH 8 THEREOF

46. I deny that the procurement process and the parties involved have been clouded with lack of transparency. As for the manufacturers and suppliers of vaccine and distributors information, it is part of the public knowledge and is readily available from the department's website.
47. The information relating to the contracts of procurement, agreements, and negotiations are governed by different principles and cannot be made available to the members of the public, due to the ethical and legal restrictions set out in



the paragraphs supra.

AD PARAGRAPH 9 THEREOF

48. I admit that section 195(1) of the Constitution requires that public administration must be accountable and must be transparent. However, it is denied that disclosure of these records of these records is in the public interest.

49. On 21 April 2021, the former Minister of Health Dr Zweli Mkhize addressed the Portfolio Committee of Parliament on health, on the progress made on Johnson & Johnson clinical trials vaccine procurement and vaccination roll-out programme. The report of the portfolio committee is Annexed hereto and marked as "NGC1". The report also contains the cost per dose, and some of the terms and conditions of this agreement.

AD PARAGRAPH 10 THEREOF

50. I admit that the request for access to the records was made. However, deny that no meaningful response to the request or appeal was provided. I have shown in the previous paragraph that applicant was informed of the reasons for not providing it access to the contracts and agreements.

AD PARAGRAPHS 11 TO 17 THEREOF

51. The contents of these paragraphs are admitted.

AD PARAGRAPH 18 THEREOF

52. The respondents deny that they have the responsibility to join any party or parties to this application. Paragraph 21 of the applicant's affidavit states that its attorneys wrote a letter to the local representatives of the pharmaceutical companies whose vaccines have been approved for domestic use and from whom the NDoH has procured vaccines and asked them to identify the entities that have negotiated or concluded vaccine procurement agreements with the government.

AD PARAGRAPH 19 THEREOF

53. I deny the averments contained in this paragraph for the simple reason that the applicant has directed letters to the manufacturers involved in this application. The particulars of the manufactures involved are a matter of public knowledge. The information is readily available in the media statements and other electronic communications.

AD PARAGRAPH 20 THEREOF

54. I deny the contents herein. It is a matter of public knowledge that the NDoH procured vaccines from the following manufacturers: Pfizer; Astra Zeneca (via the Serum Institute of India); and Johnson & Johnson.

AD PARAGRAPHS 21 AND 22 THEREOF

Handwritten signature or initials in black ink, appearing to be 'A.P.' or similar, located in the bottom right corner of the page.

55. I take note of the contents of these paragraphs.

AD PARAGRAPHS 23 AND 24 THEREOF

56. I admit the contents of these paragraphs.

AD PARAGRAPH 25 THEREOF

57. The contents herein are denied. The government did not opt out of the African Union's Vaccine Acquisition Task Team (AUVATT) programme.

AD PARAGRAPH 26 THEREOF

58. I admit that the agreements and contracts entered with the vaccine suppliers, contain non-disclosure and confidentiality clauses, which precluded the parties to the contracts and agreements to disclose the contents to the public or other people. I, however, deny that such confidentiality clause and non-disclosure are contrary to the law or public policy.

59. The non-disclosures are protected by section 36 and 37 of the PAIA, they are therefore lawful. There is no basis to suggest that non-disclosure offends public policy and is thus unacceptable.

AD PARAGRAPH 27 THEREOF

60. I deny the averments herein.

AD PARAGRAPH 28 THEREOF

61. I deny that the allegations in the media reports are true. The non-disclosure of the agreements enjoys legal protection.

AD PARAGRAPH 29 THEREOF

62. I take note of the allegations herein. However, must point out that the allegations made herein relate to the United States and the United Kingdom. Some of the issues relating to the non-disclosure of the procurement contracts are applicable to South Africa.

AD PARAGRAPH 30 THEREOF

63. I take note of the averments herein, but state that there is no justification for the disclosure of the agreements.

AD PARAGRAPHS 31 TO 36 THEREOF

64. The contents of these paragraphs are admitted.

AD PARAGRAPH 37 THEREOF

65. I have no knowledge of the allegations in this paragraph.

AD PARAGRAPH 38 THEREOF

66. Save to deny that the clause prohibits limitation of the investment made by Johnson & Johnson, the balance of the allegations contained herein are admitted.

67. On 14 April 2021, Minister Mkhize advised the Portfolio Committee on Health about this clause. This is found on page 9 paragraph 8 of the parliamentary report referred to in the previous paragraph.

AD PARAGRAPH 39 THEREOF

68. I admit that the issues of vaccines are matters of public importance. However, deny that this is justification for the disclosure of the contracts.

AD PARAGRAPHS 40 TO 42 THEREOF

69. I admit the allegations contained in these paragraphs.

AD PARAGRAPH 43 THEREOF

70. The government entered into an agreement with Pfizer.

AD PARAGRAPH 44 THEREOF

71. The contents herein are admitted.

AD PARAGRAPH 45 THEREOF

72. I deny the allegations contained herein. In the Minister of Health's report to the portfolio committee of parliament of 14 April 2021, the price of the Astra-Zeneca Vaccine was provided. Further, millions of vaccines were procured from Pfizer. The Minister also provided a delivery schedule and some of the terms and conditions of the agreement. This information is found on page 110 paragraph 3 of the report.

AD PARAGRAPH 46 THEREOF

73. I admit the allegations contained in this paragraph.

AD PARAGRAPHS 47 AND 48 THEREOF

74. The government purchased AstraZeneca vaccine from SII. When the scientific advice indicated that AstraZeneca had reduced protection against mild to moderate Covid-19 infections from the 501Y.V2 variant, the doses that had already been received were sold to the African Union.

AD PARAGRAPH 49 THEREOF

75. Save to deny that there is no information available relating to the purchase price, the balance of the allegations herein is admitted. In the Minister of Health's report to the portfolio committee the purchase price of the vaccine is

mentioned.

AD PARAGRAPH 50 THEREOF

76. The vaccines were sold to the African Union. The spending was not wasteful and fruitless.

AD PARAGRAPH 51 THEREOF

77. I take note of the allegations contained in this paragraph.

AD PARAGRAPH 52 THEREOF

78. I deny that any agreement was conclude with Sinopharm-China National Pharmaceutical Group. There were engagements, but no agreement was reached.

AD PARAGRAPHS 53 AND 54 THEREOF

79. I take note of the allegations contained in these paragraphs.

AD PARAGRAPH 55 THEREOF

80. The contents herein are admitted.

AD PARAGRAPH 56 THEREOF

81. I take note of the allegations contained in this paragraph.



AD PARAGRAPH 57 THEREOF

82. The contents herein are admitted save to state that the amount paid to GAVI was a donation from the Solidarity Fund.

AD PARAGRAPH 58 THEREOF

83. I admit the allegations contained in this paragraph.

AD PARAGRAPH 59 THEREOF

84. I deny the allegations contained in this paragraph, save to state that NDoH purchased 1 392 300 doses of Pfizer vaccine through the Covax Facility.

AD PARAGRAPH 60 THEREOF

85. The agreements with COVAX still exist.

AD PARAGRAPHS 61 AND 62 THEREOF

86. I admit the allegations contained in these paragraphs.

AD PARAGRAPH 63 THEREOF

87. The contents herein are denied. South Africa has not opted out of the COVAX programme.

AD PARAGRAPH 64 THEREOF

88. I deny the allegations contained in this paragraph.

AD PARAGRAPHS 65 TO 71 THEREOF

89. I admit the allegations contained in these paragraphs.

AD PARAGRAPH 72 THEREOF

90. I take note of the allegations contained in this paragraph.

AD PARAGRAPHS 73 TO 76 THEREOF

91. I take note of the allegations contained in these paragraphs.

AD PARAGRAPHS 77 TO 79 THEREOF

92. I deny that the requirements of the Act were met. I have explained in the paragraph supra, the basis of the refusal. The applicant was made aware of the reasons for the refusal. There is no basis to support this conclusion.

AD PARAGRAPHS 80 THEREOF

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

AD PARAGRAPH 81 THEREOF

94. I deny the allegations contained in this paragraph.

AD PARAGRAPH 82 THEREOF



95. I take note of the argument raised herein. However, deny that the argument is legally and factually sound. The rights in the Constitution are limited by section 36 of the Constitution.

96. PAIA is a law of general application. The limitation of the rights by PAIA meets the requirements of section 36 of the Constitution. Consequently, the limitation is reasonable and justifiable in an open democratic society.

AD PARAGRAPH 83 THEREOF

97. I take note of the allegations contained in this paragraph.


CONCLUSION

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



DEPONENT

Thus, signed and sworn to, before me, at PRETORIA on this the 29th day of July 2022 by the Deponent, who has acknowledged that he knows and understands the contents of this affidavit, that he has no objection to taking the prescribed oath and that the prescribed oath is binding on his conscience.



COMMISSIONER OF OATH

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

SIGN:  DATE: 29/07/2022

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 Health 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 facts. 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 inhibited 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, or even suppress, the onset of 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. 108

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 Mathaza, 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 Mathaza, 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 Zwell Mkhfza, 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

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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 Ascus. 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 90 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 9, 10, 17 and 24 May, South Africa would receive 325 250 vaccines.
- On 31 May and 7, 14, 21 and 27 June, that amount would almost double to 636 490 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 1 837 520, and in June there would be 2 847 090 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 600 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 Buthelezzi, Director-General (DG), Department of Health, presented an update on the vaccine roll-out.

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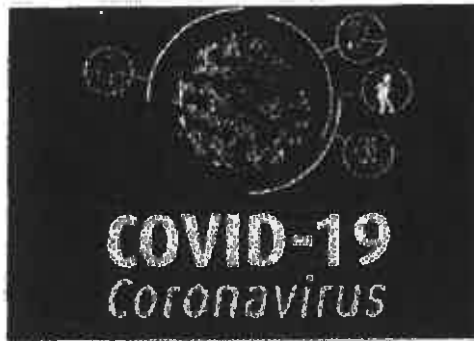
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PUBLICATIONS ADMINISTRATION

MEDIA STATEMENT: COMMITTEE ON HEALTH BRIEFED ON VACCINATION ROLL-OUT PROGRAMME

PRESS RELEASES

Parliament, Wednesday, 31 March 2021 – The Portfolio Committee on Health received an update from the Minister of Health, Dr Zweli Mkhize, and the Department of Health on the Johnson & Johnson clinical trials, vaccine procurement and progress on the vaccination roll-out programme.



DID YOU KNOW?

A joint committee of Parliament receives submissions on constitutional matters and has to review the Constitution at least once a year.

LEARN MORE (DID-YOU-KNOW)

During the meeting, Minister Mkhize said South Africa has secured 10 million Covid-19 vaccine doses from Johnson & Johnson and that the government had successfully pushed for a further 20 million doses. Government is now negotiating the terms for the additional vaccines. In total, the Minister said South Africa has 31 million doses of the Johnson & Johnson vaccine in the pipeline and an additional 20 million doses from Pfizer.

The committee was informed that advanced negotiations are taking place with other pharmaceutical manufacturers, such as Sputnik, Sinopharm and Sinovac.

The committee expressed concern about the delays in the implementation, as well as the deviation in the vaccine roll-out figures. Members of the committee said that the department had made commitments and set targets for the roll-out of the vaccines.

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but these have not been met. The committee questioned whether the revised targets will be met and what measures are in place to ensure this.

The committee also heard that to date 251 707 healthcare workers have been vaccinated under the Sisonke Protocol.

Committee Chairperson Dr Sibongiseni Dhlomo congratulated Ministerial Advisory Committee co-chair Professor Kholeka Mlisana on her appointment after the departure of Professor Salim Abdool Karim to focus on his HIV research.

ISSUED BY THE PARLIAMENTARY COMMUNICATION SERVICES ON BEHALF OF THE CHAIRPERSON OF THE PORTFOLIO COMMITTEE ON HEALTH, DR SIBONGISENI DHLOMO.

For media enquiries or interviews with the Chairperson, please contact the committee's Media Officer:

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