IN THE HIGH COURT OF SOUTH AFRICA
GAUTENG DIVISION, PRETORIA

CASE NO: 10009/22

In the matter between:

THE HEALTH JUSTICE INITIATIVE	Applicant
and	
THE MINISTER OF HEALTH	First Respondent
THE INFORMATION OFFICER, NATIONAL DEPARTMENT OF HEALTH	Second Respondent

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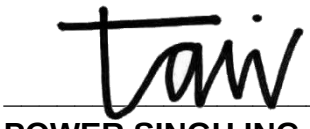
FILING SHEET

KINDLY TAKE NOTICE THAT the Applicant hereby files its replying affidavit.

DATED at **JOHANNESBURG** on **29 SEPTEMBER 2022**.



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AND TO: **STATE ATTORNEY, PRETORIA** **BY EMAIL**
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REPLYING AFFIDAVIT

I, the undersigned,

FATIMA HASSAN

do hereby make oath and state:

1. I am the Director of the Applicant – the Health Justice Initiative ("**HJI**"). I deposed to the founding affidavit in this matter.

2. I have read the answering affidavit deposed to by Dr. Nicholas Gilmour Crisp on behalf of the First and Second Respondents ("**the NDOH**"). This affidavit is made in reply to the answering affidavit.

3. The facts contained in this affidavit are true and correct, to the best of my knowledge and belief. Unless otherwise stated or indicated by context, they fall within my knowledge. Where I make submissions of law, I do so on the advice of the HJI's legal representatives.

INTRODUCTION

4. The HJI brought this application in order to procure disclosure of and access to two categories of records:

   4.1. First, all vaccine procurement contracts, memoranda of understanding, and agreements concluded with a number of identified-vaccine manufacturers and/or suppliers; and

   4.2. Second, all minutes, correspondence and negotiation meeting outcomes with those parties.

5. In its answering affidavit, the NDOH has admitted that it held a series of negotiations with various different counterparties from July 2020 until at least March 2021 (and, potentially March 2022), and that it concluded vaccine supply agreements or signed term sheets with at least 5 different entities (identified as 'SII, Johnson and Johnson, Pfizer, Moderna and COVAX). Yet, it has failed to disclose a single record of such negotiations, or a single clause of any of those agreements, or even to identify the actual entities with whom negotiations were held. Nor has it filed any confirmatory affidavits from the personnel it says were involved in the negotiations or party to the conclusion of the agreements. And it has failed to provide any evidence whatsoever that it has engaged with any of the manufacturers and/or suppliers to procure their consent to disclosure.

6. The NDOH thus asks the Court to accept its *ipse dixit* on every matter at issue, without providing any supporting evidence for its stance. Its affidavit amounts to no more than a bald assertion that it is not obliged to disclose the records sought.

7. That approach is, with respect, disdainful of this Court, and of the important rights and obligations at issue in these proceedings. It is unbecoming of an organ of state, which is duty bound to respect, protect and promote the rights in the Bill of Rights, and to safeguard and promote the proper functioning of the courts.

8. In addition, it does not make out a competent defence under the Promotion of Access to Information Act 2 of 2000 ("**PAIA**"). In this regard, I wish to address two glaring omissions by the NDOH:

   8.1. **First**, the NDOH have not raised a lawful ground of refusal for the disclosure of all Covid-19 vaccine negotiation meeting outcomes and/or minutes, and correspondence with vaccine manufacturers and/or suppliers;

   8.2. **Second**, the NDOH have failed to meet the burden of proof required by section 81(3)(a) of PAIA and have accordingly not justified their reliance on sections 36(1)(c)(i)(ii) and 37(1)(a) of PAIA.

No basis for refusing the pre-agreement records

9. As set out above, the HJI's PAIA request sought "copies of all Covid-19 vaccine negotiation meeting outcomes and/or minutes, and correspondence" with a list of specified manufacturers and/or suppliers.

10. The NDOH's answering affidavit does not deal with that request at all – and certainly does not raise a lawful ground of refusal under PAIA to justify the non-disclosure of these records.

11. The records accordingly fall to be disclosed.

No proper basis for refusing the agreements

12. In relation to the Covid-19 vaccine contracts, and associated term sheets, entered into with the 5 different vaccine manufacturers and/or suppliers, the NDOH claim they are precluded from disclosing those records, because doing so would be in breach of the confidentiality clauses contained in the agreements. They go on to allege that disclosure would prejudice them and the 'vaccine manufacturers' in future engagements as contemplated in sections 36(1)(c)(i)(ii) and 37(1)(a) of PAIA.

13. The NDOH accordingly rely on two grounds of refusal in PAIA in an attempt to justify their non-disclosure:

    13.1. Section 36(1)(c)(i) and (ii), which provides for refusal if the record contains information supplied in confidence by a third party and its disclosure "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"; and

    13.2. Section 37(1)(a) which provides for the refusal of access "if the disclosure of the record would constitute an action for breach of a duty of confidence owed to a third party in terms of an agreement."

14. The party relying on any of the grounds of refusal in PAIA to justify non-disclosure of information must substantiate such reliance. This is explicitly provided for in section 81(3) of PAIA, which places an evidentiary burden of proof on the NDOH.

15. The NDOH have not discharged this burden:

    15.1. They have adduced no evidence that proves that if they disclose the requested records, there are reasonable grounds to expect that they (or the vaccine manufacturers) will be at a disadvantage in contractual or other negotiations or be prejudiced in commercial competition.

15.2. The answering affidavit makes passing mention of the intense competition that exists between countries to procure vaccines for people in their country. However, this is the context that subsists during a global pandemic. It is unclear how this relates to the disclosure of the vaccine agreements or impacts future negotiations or competition.

15.3. In relation to the agreements concluded for the supply of Covid-19 vaccines, the NDOH claims that all the agreements include confidentiality clauses that prohibit their disclosure. However, the NDOH have not proven the existence of even one confidentiality clause included in any of the agreements. Nor have they provided any detail about any of the confidentiality clauses – each of which likely differs in terms of their nature, duration, exemptions, and penalties (and each of which is liable to challenge as being *contra bonos mores*, as set out in the founding affidavit, if it in fact enacts a complete and permanent preclusion of the disclosure of the information sought).

15.4. Even assuming that such clauses exist and are applicable, lawful and enforceable (which is not admitted), the NDOH cannot point to their mere existence to justify a blanket refusal to provide any records at all. Our courts have made it clear that parties cannot hide behind confidentiality clauses to justify the non-disclosure of information.[1] Parties are enjoined to prove, at a minimum, that such a breach would result in a successful claim against them. The NDOH have not done this.

16. The NDOH have not discharged their onus and adequately substantiated their reliance on either ground of refusal. Such an approach undermines the purpose of PAIA and negates the 'culture of justification' that permeates the Act.

[1] See for example, *Transnet Ltd & Another v SA Metal Machine Co (Pty) Ltd* [2006] 1 All SA 352 (SCA).

17. Moreover, the NDOH's own conduct undercuts their claim that there is a complete contractual ban on disclosure. On its own version (and as the sole annexure to the answering affidavit bears out), the NDOH has selectively reported on some aspects of the negotiations and/or agreements to Parliament. That it has done so suggests that disclosure is permissible and lawful

18. Finally, even if the cited grounds provided the NDOH with a basis to refuse disclosure (which is denied), disclosure is in any event lawful with the consent of the relevant manufacturer/supplier and/or in the public interest. The NDOH have provided no evidence that consent was sought, nor any of the responses given if it was, nor any evidence that the public interest override does not justify disclosure in the circumstances of this case.

SERIATIM RESPONSE

19. I now respond *seriatim* to the allegations in the NDOH's answering affidavit insofar as is necessary. I seek to avoid repeating what I have already said above. I ask that it be read as incorporated herein wherever appropriate. My failure to reply to any specific averment should not be construed as an admission thereof. The allegations in the answering affidavit are denied to the extent that they are inconsistent with anything set out in the founding affidavit or above.

Ad paragraphs 1 – 11

20. Save to deny that the facts set out in the answering affidavit are all within Dr Crisp's personal knowledge or are all true and correct, I admit these allegations.

Ad paragraphs 12 – 13

21. PAIA speaks for itself.

Ad paragraphs 14 – 17

22. The contents of these paragraphs are not in dispute.

Ad paragraphs 18 – 19

23. I note the admission that NDOH commenced discussions with several vaccine manufacturers from as early as July 2020. No reason is given for why the records of, or correspondence arising from, these discussions have not been disclosed.

Ad paragraph 20

24. The relevant advisory has not been attached to the NDOH's answering affidavit and I put them to the proof thereof.

Ad paragraphs 21 – 24

25. The NDOH have not attached any documentation to substantiate the claims made in these paragraphs. Nor has it identified who within the NDOH was responsible for the conduct described.

26. In the absence of this information, it is impossible to verify the content of these paragraphs, and I accordingly dispute them.

Ad paragraph 25

27. I note the claim that the government allocated "*about R95 million*" towards the *development* of Covid-19 vaccines, treatments, therapeutics and diagnostics – as well the NDOH's wholesale (and unjustified) failure to identify the terms on which it did so, the beneficiaries of such funding, or how much of it was allocated and/or spent on the vaccine agreements at issue.

Ad paragraphs 26 — 27

28. The "committed purchase option", and South Africa's commitments in respect of it, fall within the scope of the PAIA request. The NDOH have advanced no basis for withholding their disclosure.

Ad paragraphs 28 – 29

29. The application for deviation falls within the scope of the PAIA request. The NDOH have advanced no basis for withholding it from disclosure.

Ad paragraphs 30 – 32

30. The records of the negotiations with AstraZeneca and/or the SII, the term sheet and the purchase agreement, and the deviation approval from National Treasury all fall within the scope of the PAIA request. The NDOH have advanced no lawful basis for withholding them from disclosure.

Ad paragraphs 33 - 34

31. The HJI has sought disclosure of the records mentioned in these paragraphs in separate proceedings. I do not deal with them for present purposes.

Ad paragraphs 35 – 37

32. I assume the references to "2022" in these paragraphs are an error, and that the relevant dates were all in 2021.

33. The records of the negotiations, the term sheets and the purchase agreements concluded with the Johnson and Johnson entity, the Pfizer entity and the Moderna

entity as well as GAVI (COVAX) all fall within the scope of the PAIA request. The NDOH have advanced no lawful basis for withholding them from disclosure.

Ad paragraphs 38 – 40

34. I deny these allegations.

35. In the context of, on the one hand, the serious allegations of corruption within government around procurement during the Covid-19 pandemic, and, on the other, the credible allegations of bullying and heavy-handedness by several pharmaceutical companies and manufacturers/suppliers, the NDOH cannot expect the Court (and the HJI) simply to accept unsubstantiated claims of 'good faith' and 'acting in the public interest'. We are entitled to the documents precisely in order to test whether these standards were met. Transparency is essential to accountability in cases of this kind.

Ad paragraph 41

36. I deny the contents of this paragraph.

37. No lawful ground of refusal has been raised and substantiated that would justify the non-disclosure of the records. Nevertheless, the disclosure of the records is manifestly in the public interest and would render the disclosure of the records mandatory in terms of section 46 of PAIA.

38. The public interest in the disclosure of the records clearly outweighs any harm contemplated that might arise from it (which harm has, in any event, not been proved by the NDOH).

    38.1. The records sought are necessary to understand the basis and terms upon which the NDOH has negotiated and procured Covid-19 vaccines. Those terms may continue to bind South Africa for many years to come. And, as

set out in the founding papers, some of them (including the confidentiality clause) may be *contra bonos mores* or otherwise amenable to challenge. By shielding them from disclosure, the NDOH is effectively precluding any challenge to the terms of those agreements – which violates the right of access to court.

38.2. Moreover, reports on the conduct of pharmaceutical manufacturers elsewhere (attached to the founding papers as annexures "**HJI16 – HJI20**"), as well as the NDOH's own reports to Parliament, suggest that some or all of the vaccine manufacturers/suppliers insisted that Government provide them with far-reaching indemnities, and establish a vaccine injury fund, failing which vaccines would not be supplied. (These reports include the meeting report of the Portfolio Committee on Health dated 5 February 2021, attached as "**FH1**", and the Reports of the Portfolio Committee on Health dated 14 April 2021 (an extract of which is attached to the answering affidavit as annexure "**NGC1**")). The public is obviously entitled to know all relevant details included in the agreements related to this, what their cost to the fiscus is, and what their implications are for people who suffer vaccine injury. Government cannot lawfully bind itself secretly to commitments of this kind.

38.3. Even in the absence of such a fund, large sums of public money have been used to procure Covid-19 vaccines (via loans from the World Bank too) – in circumstances where credible allegations of corruption and misuse of public funds have been levelled around procurement during the Covid-19 pandemic generally. It is a constitutional requirement that procurement, on the one hand, and public spending and future financial commitments, on the other, be open and transparent. The need for transparency and accountability is heightened during a state of disaster, where the usual checks and balances for procurement have been relaxed.

39. Access to the information enough is accordingly crucial for promoting a transparent and accountable government and protecting the public interest.

40. In addition, the disclosure of the records may well reveal evidence of a substantial contravention of or failure to comply with the law. As alleged in my founding affidavit, media reports include several assertions that suggest that, at the very least, the NDOH did not comply with section 217 of the Constitution – to procure goods in a fair, equitable, transparent, competitive, and cost-effective way – when it procured Covid-19 vaccines. While that cannot be definitively determined without access, the potential – whether great or small – that there may be some form of contravention favours disclosure over concealment.

Ad paragraphs 42 - 43

41. I admit that the letter and emails referred to in these paragraphs were sent but otherwise deny these allegations.

42. The NDOH have never explicitly confirmed that they sought consent from the vaccine manufacturers/suppliers to disclose the records sought, and no evidence in support of that claim has been provided.

43. The letter attached at page 001 – 81, does not confirm that the NDOH had contacted the vaccine manufacturers/suppliers. Instead, it states that they had *resolved* to contact them.

44. Further, the correspondence they refer to already attached as "**HJI15**" is not proof that the NDOH notified HJI of the *reasons* for refusing the PAIA request. "**HJI15**" is the NDOH's response to the HJI's request for the particulars of the counterparties the agreements in order to *cite* them as parties in this application. The NDOH refused to provide HJI with that information, in the email already attached as "**HJI15**".

45. The NDOH's opacity concerning the views of the counterparties to the negotiations and agreements is worth noting. Without such information, it is impossible to know whether sections 36(2)(b) or 37(2)(b) may apply in response to the grounds of refusal raised by the NDOH. These sections provide that access to such records may not be refused if the third party concerned consents to their disclosure.

Ad paragraph 46

46. I deny the content of this paragraph. The procurement process and the parties involved have been shrouded in secrecy.

47. Although the corporate group/ brand name of certain (at least four that we know of) vaccine manufacturers contracted with is publicly known, such manufacturers generally have multiple subsidiary companies – often in many different countries across the world. The exact identity of the actual counterparty to each procurement agreement is unknown, and the HJI has been unable to ascertain it, despite our diligent efforts on this score. (Annexures "**HJI14**" and "**HJI15**" attached to the founding affidavit note the response of Pfizer and the NDOH that the identity of the contracting entities is confidential).

Ad paragraph 47

48. I deny the contents of this paragraph. The NDOH have not specified which ethical restrictions justify the non-disclosure of this information, and nevertheless, such considerations are irrelevant as they are not lawful grounds to refuse access to information. Further, and as explained above, the NDOH have not adequately justified their reliance on legal restrictions.

Ad paragraph 48

49. The HJI stand by our assertion that disclosure of these records is in the public interest. As discussed above, it is impossible to hold the government accountable if it operates in secret and, there is a heightened need for transparency during a pandemic.

Ad paragraph 49

50. The report attached to the answering affidavit as "**NGC1**" is dated 14 April 2021, not "21 April 2021", and only includes an extract of the meeting of the Portfolio Committee on Health. The full meeting report from the PMG is attached as annexure "**FH2**".

51. I admit that the former Minister of Health, Dr. Zweli Mkhize, shared certain information concerning the negotiations and procurement of vaccines for South Africa. In doing so, the Minister noted that although the agreements were subject to confidentiality and non-disclosure clauses, the NDOH acknowledged their "constitutional obligation to account to Parliament". It is unclear why they do not similarly accept the obligation to provide information to the public.

52. The following information was shared, as reflected in the Portfolio Committee meeting ("**FH2**"):

***Concerning the Johnson & Johnson vaccine*:**

52.1. The NDoH had "procured 31 million vaccines from J&J. The initial agreement for 11 million vaccines was signed and [...] had included an option for the Department to call for 20 million more." (Page 3, paragraph 1).

52.2. "In the second agreement, J&J approved a precondition that No Fault Compensation ("NFC") Fund regulations must be published by 30 April." (Page 3, paragraph 2).

52.3. Johnson & Johnson 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." (Page 3, paragraph 7).

52.4. "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." (Page 3, paragraph 7).

52.5. The Johnson & Johnson vaccine cost "US$10 per dose." (Page 4, paragraph 2).

52.6. The agreement had a non-refundability clause which "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." (Page 4, paragraph 3).

***Concerning the Pfizer Vaccine*:**

52.7. A pre-condition was included which required that the "No Fault Compensation ("NFC") Fund regulations must be published by 30 April." (Page 3, paragraph 2).

52.8. A pre-condition proposed by Pfizer during negotiations "stated that the manufacturers wanted to have the sole discretion to determine additional terms and guarantees for the Department to fulfil its indemnity obligations."

It was advised that this clause was not included in the final agreement. (Page 3, paragraph 9).

52.9. The Pfizer vaccine cost "US$10 per dose." (Page 4, paragraph 2).

52.10. The agreement had a non-refundability clause which "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." (Page 4, paragraph 3).

52.11. The NDOHNDOH purchased 30 million vaccines from Pfizer. (Page 4, paragraph 4).

52.12. The "current weekly delivery shipping" schedule for quarter two was provided which included dates in May and June. (Page 4, paragraph 4).

52.13. "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." (Page 4, paragraph 5).

Concerning the AstraZeneca vaccine:

52.14. The AstraZeneca vaccine cost $5.35 per dose (it was not specified whether this referred to American dollars). (Page 4, paragraph 2).

52.15. The Africa Union ("**AU**") paid the NDOH for the vaccines it sold them. The AU paid "$ 5 250 000, which was the actual cost of the vaccines, less the freight". (Page 4, paragraph 2).

52.16. "The DoH was refunded $2.675 million by the Serum Institute of India for the 500 000 doses that were not delivered." (Page 4, paragraph 2).

53. It is evident from the above, that limited information concerning inter alia the number of vaccines procured and their price at the time of negotiations was disclosed. However, the information supplied does not specify whether the amounts were used for the procurement of the vaccines in all agreements (including any subsequent agreements) or whether the prices applied when the vaccines were procured through GAVI (COVAX.). Further, the NDOH has not disclosed the price for the Moderna vaccine per the term sheet it says it has agreed to either.

54. As evidenced by the meeting report ("**FH2**"), the NDOH also disclosed information about the existence of additional clauses included in the agreements concerning the 'No Fault Compensation Fund' and non-refundability, amongst others.

55. The NDOH has disclosed some information – seemingly without falling foul of the alleged confidentiality clauses. It would appear then, that at least some of the information included in the procurement agreements is not subject to the confidentiality clauses which the Respondents say preclude disclosure. Such clauses should be disclosed, including at the very least, those relating to the number of doses, delivery schedules, price, non-refundability, breach, and the No Fault Compensation Fund.

Ad paragraph 50

56. I deny the content of this paragraph. The correspondence attached to the founding papers speaks for itself. The NDOH clearly did not provide a meaningful response to the PAIA request or the appeal, as detailed in paragraphs 66 – 76 of the founding affidavit.

Ad paragraph 52 – 54

57. This is a matter for legal argument and will be addressed at the hearing, if necessary. The HJI continue to deny that we are obliged to join the counterparties to the relevant agreements – or even that we could do so, due to our lack of knowledge of the particular entities with whom the NDOH have contracted.

Ad paragraph 57

58. The content of this paragraph is noted.

59. The records of any negotiations with, and agreements concluded with the Africa Vaccine Acquisition Trust / Task Team ("**AVATT**") fall within the scope of the PAIA request. No lawful basis for refusing their disclosure has been provided.

Ad paragraphs 58 and 59

60. I deny the contents of these paragraphs for reasons addressed above.

61. In addition to breaching the requirements of section 33 of the Constitution and PAIA, the NDOH's failure prevents the HJI from pursuing its challenge to the confidentiality terms and *contra bonos mores*. It thus also violates the HJI's right of access to court, entrenched in section 34 of the Constitution.

Ad paragraph 61

62. I deny the contents of this paragraph. The non-disclosure of the agreements does not enjoy legal protection. In any event, that is a matter for the Court to determine – not the NDOH.

Ad paragraph 62

63. I note the admission that "some of the issues relating to the non-disclosure of procurement contracts are applicable to South Africa". It is telling that the NDOH have not identified which ones.

Ad paragraph 63

64. The content of this paragraph is denied. The HJI stands by what it has said elsewhere and persists in seeking disclosure.

Ad paragraph 67

65. I do not understand the contents of this paragraph. It is not clear what is meant by the denial that "the clause prohibits limitation of the investment" and it appears that the Respondents have conflated the issue of the investment and the unfettered export rights. What the HJI hopes to understand is whether the vaccine procurement agreements, and any amendments, between the NDoH and Johnson & Johnson permits unfettered exports of locally produced vaccines to benefit Johnson and Johnson and another company in South Africa (Aspen Pharmaceuticals) and if not or no longer, when, if at all this condition was paused or substituted in any agreements with Johnson & Johnson.

Ad paragraph 68

66. I note the admission that vaccines are a matter of public importance. It follows that the disclosure of records setting out the basis and terms on which they are supplied must be in the public interest.

Ad paragraph 70

67. Pfizer is a brand name, not the name of an entity. This paragraph is consequently meaningless.

Ad paragraph 72

68. The contents of this paragraph are denied. It is not clear what report the Respondent is referring to in this paragraph. The Portfolio Committee meeting report that is attached as "**NGC1**" does not run to "page 110," only page 23.

69. Although the report attached as "**NGC1**" does include an expected delivery schedule for quarter two, it does not include all delivery schedules including for quarters three and four. Further, the information provided in the report was disclosed during a time of flux, and the final delivery schedules are accordingly unknown. In any event, the HJI's tracking of the supply of the Pfizer vaccine (and others) shows that delivery was not made in compliance with the expected delivery schedule outlined in "**NGC1**".

Ad paragraph 74

70. The records referred to in this paragraph are the subject of a separate PAIA application. I do not deal with them for current purposes.

Ad paragraph 75

71. The Parliamentary report attached to the answering affidavit as "**NGC1**" does mention that the "AstraZeneca vaccine was $5.35 per dose". However, it is not clear whether this was the price during negotiations, or the fixed price included in the contract.

72. Further, since pricing information has been disclosed in a publicly accessible portfolio committee meeting report, as included in the attached report as "**NGC1**", it

cannot be confidential. Accordingly, the clauses concerning the price in each vaccine procurement agreement fall to be disclosed.

Ad paragraph 76

73. The records regarding the on-sale to the African Union fall within the scope of the PAIA request. No lawful basis has been given for refusing their disclosure.

74. I am unable to comment on whether the spending amounted to fruitless and wasteful expenditure without access to information concerning, the original purchase price, whether the entire stock was sold, and the price per dose on re-sale.

Ad paragraph 78

75. The records of the negotiations with Sinopharm-China National Pharmaceutical Group fall within the scope of the PAIA request. No lawful basis has been given for refusing their disclosure.

Ad paragraph 82

76. The records of the negotiations and discussions between GAVI (COVAX), on the one hand, and the Solidarity Fund, on the other, regarding this payment fall within the scope of the PAIA request. No lawful basis has been given for refusing their disclosure.

Ad paragraph 85

77. The agreements with GAVI (COVAX) fall within the scope of the PAIA request. No lawful basis has been given for refusing their disclosure.

Ad paragraphs 92 – 93

78. I deny the contents of this paragraph and stand by what I have said in the founding affidavit and above.

Ad paragraphs 95 & 96

79. These are matters for legal argument and will be addressed at the hearing of the matter, if necessary. For present purposes, I deny that the NDOH's refusals are permitted under PAIA.

Ad paragraph 98

80. I deny the contents of this paragraph and submit that to the contrary, the NDOH have failed to justify the non-disclosure of the records sought. Access to the records must be granted.

81. The suggestion that the Biowatch principle does not apply to this application is unsubstantiated and entirely without merit. The application is brought by a public interest organisation acting in the public interest, to obtain the disclosure of publicly important information and to safeguard constitutional rights. It is wholly improper for the NDOH to seek costs against us – and smacks of an attempt to penalise us for holding them to account.

82. If the NDOH persists in seeking costs against the HJI, we will seek punitive costs against them.

CONDONATION

83. I am advised that following the receipt of answering papers, an Applicant has 10 days within which to file a reply. The NDOH served their answering affidavit on 29 July 2022 (without the annexure "NGC 1") and served the annexure on 4 August

2022. The replying affidavit was accordingly due on 18 August 2022. The replying affidavit has been filed on 29 September 2022 and is accordingly 30 court days late.

84. I respectfully submit that the delay is justifiable and that the interests of justice permit that it be condoned. I say so for the following three reasons:

85. First, the NDOH was itself significantly delayed in filing the answering affidavit. The founding affidavit was served on the NDOH on 21 February 2022. Their notice of intention to oppose was due on 14 March 2022, with their answering affidavit due 15 days thereafter, on 5 April 2022.

    85.1. On 3 June 2022, they sought an indulgence to file their answering affidavit by 30 June 2022, which was granted.

    85.2. On 28 June 2022, they requested a further indulgence to file by 29 July 2022. The HJI afforded them until 11 July 2022. Despite this, the NDOH filed their answering affidavit, including the annexure, on 4 August 2022; 81 court days late.

    85.3. The NDOH has not applied for condonation for the late filing.

86. Second, the HJI has a reasonable explanation for the delay. The unpredictable timing of the date upon which the NDOH would file the answering affidavit made it impossible for the HJI's legal team to prepare. The HJI's legal team were accordingly not immediately able to attend to the drafting and settling of the replying affidavit. They drafted and settled the replying affidavit as soon as they were available to do so, and it was deposed to and filed immediately thereafter.

87. Third, there is no conceivable prejudice to the NDOH.

88. In the circumstances, I respectfully submit that it would be in the interests of justice to condone the late filing of this replying affidavit.

CONCLUSION

89. For the reasons set out above, the HJI persist in seeking the relief sought in the notice of motion.

FATIMA HASSAN

I hereby certify that the deponent knows and understands the contents of this affidavit and that it is to the best of the deponent's knowledge both true and correct. This affidavit was signed and sworn to before me at Cape Town on this the 29 day of September 2022, and that the Regulations contained in Government Notice R.1258 of 21 July 1972, as amended by R1648 of 19 August 1977, and as further amended by R1428 of 11 July 1989, having been complied with.

COMMISSIONER OF OATHS

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Commissioner of Oaths

PMG PARLIAMENTARY MONITORING GROUP

"FH1"
24

Covid-19 Vaccine Rollout: with Minister & Deputy Minister of Health

Health

05 February 2021

Chairperson: Dr S Dhlomo (ANC)

Meeting Summary

Video: Portfolio Committee on Health,5 February 2021

As previous Committee sessions had not afforded sufficient opportunity for discussion, it was decided that the session would be centered primary around discussion and less on set presentations.

Members raised questions about the late procurement of vaccines, their cost, factors used in selecting suppliers, the efficacy of vaccines on the virus variant found in South Africa, and vaccine scepticism; Ivermectin and if politicians ought to receive vaccines first to dispel public fears about vaccine safety. Questions were particularly pointed about the specifics of negotiations, which the Minister said were confidential but that this did not imply a lack of transparency. He said that misinformation was stoked, at least in part, by the media peddling in "gossip" and that this could have deleterious effects on public trust.

Members asked if the rollout strategy intended the vaccination target of 40 million people to be reached by the end of 2021. They were sceptical due to a lack of healthcare workers, lack of guaranteed supply of vaccines, and almost a month had passed since the rollout plan without a single person vaccinated.

A topic prevalent in the session was the lack of access to vital information or poor timing in its release. Some members wanted the official information before its release to the public so they could field queries from their concerned constituents. Other members said that the scientific community did not support the information on the different phases of the rollout strategy. There was also a lack of clear and measurable timelines. Members requested the Finance Minister join the Health Minister to answer questions on funding, particularly for provincial rollout. They said the briefings by provinces on their rollout plans showed that the provinces were not ready to implement mass vaccinations. Members also wondered how healthcare workers who lacked internet access would register to be vaccinated. The Minister indicated that the Department would look into these "gaps" and assist provinces to prepare. He advised that many healthcare workers had already registered for Phase 1 vaccinations and their institutions would assist with digital registration.

Meeting report

The Chairperson noted the Members had received the presentation two days ago. Due to time constraints, the oral presentation should be 15 minutes to give more time for discussion. The Minister had requested to be released 15 minutes before the meeting ended.

Mr van Staden (FF+) asked if they could proceed directly to the discussion. The Committee already had the opportunity to go over the report and would rather the Minister answered all the questions that Committee members had.

The Chairperson agreed. However he would give the Minister the opportunity to make opening remarks with the Director General to provide context for the presentation and discussion. He hoped that the Committee would be able to have a second round of questions.

Mr van Staden reiterated that his concern was that if the presentation went on for too long the Committee would not have sufficient time to have their questions asked and answered.

The Chairperson told the Minister that he had been seeing media reports of PPE scandals and he hoped the Minister would see to it that this would not reoccur with the vaccine rollout.

He was grateful that the Committee had received the presentation two days prior and that therefore the Committee would proceed straight to discussion after short introductory remarks. He asked members to send through their questions so that they could be answered by the Minister.

Health Minister opening remarks

Health Minister Zweli Mkhize said he would keep his opening remarks short. Monday 1 February was an exciting day when the country had received its first consignment of vaccines. The Ministry of Health has made it clear that for this pandemic the major resource for prevention was the successful provision of vaccines to create herd immunity against the virus which wäquite virulent" in some

instances. This would alleviate pressure on the country's healthcare system.

The Minister said that it was very difficult to manage the distribution of vaccines as the global demand was similar for every country. The demand was happening at the same time for every country which created its own difficult dynamics. Nevertheless, South Africa was still on course and had not lost any time. The country could expect to receive vaccines during the next 10 to 14 days and thereafter it would proceed with its vaccination rollout programme. He reminded the Committee that not all the vaccines results were out yet. For this reason the government had to tread carefully in how they proceed with the rollout of the vaccine programme. The government was still committed to vaccinating 40 million South Africans. The government would do everything to ensure that vaccinations took place despite the difficulties inherent in global supply. Even countries who paid far more for vaccines were still waiting for them due to blockages in global supply. South Africa had seen an increase in the incidence of vaccine nationalism where countries such as the US and UK had barred the export of vaccines. Nations barring the export of vaccines was a worrying concern as they were holding onto vaccines until their populations needs were met first.

The President had constituted and inter-ministerial structure headed up by the Deputy President to oversee the vaccine rollout. This inter-ministerial structure would be constituted by various subcommittees which would be involved at various points of the process.

Linked to this inter-ministerial committee, the Director General would set up another governance structure which would bring together the private sector, civil society and labour to coordinate in assisting with the implementation of the vaccine rollout plan.

The current vaccines were stored at BioVac. The Department of Health (DoH) would identify certain centres around the country where future vaccines could be stored in the requisite cold chain storage facilities to ensure adequate preservation and security.

All provinces had produced their rollout plan ready to vaccinate people. In the course of all of this there are a number of health workers which had been trained for this purpose. They were also engaging stakeholders such as religious leaders, traditional leaders and civil society to explain to them the role which the department wished for them to play.

The Department wishes to continue to get support from the Ministerial Advisory Committee. In terms of further steps and also of any new information which might become available. The distribution plan was not going to be a smooth process and mistakes and missteps were to be expected, along with challenges and unforeseen obstacles. This should be taken in stride as they continue to implement the rollout. When DoH comes across a challenge, they were not going to announce that the plan was a failure but rather address the challenge and move on. Examples of such challenges could be observed in other countries where there were reports of breakdowns of the freezers or vehicles transporting the vaccines.

DoH was still committed to vaccinating healthcare workers in the first phase. The term 'healthcare worker' would cover everyone who deals with sick people including hospitals as well as those working in universities, research bodies, traditional healers, clinics and the like.

DoH had launched the electronic vaccination registration system which has already seen the registration of about 68 000 healthcare workers. This meant that the uptake was "quite good". He deduced that from a healthcare worker point of view, the uptake would be very successful.

The second phase included all those who were in "the front line". This group included teachers, police and all those servicing communities. This group also includes those with co-morbidities. These two phases worked out to about 16.5 million people. The first phase would take about three months and the second phase about six months. The last phase should take about three or more months depending on supply at that time.

DoH had engaged a number of platforms and manufacturers to get the vaccines and the 1.5 million vaccines that had been received from the Serum Institute of India had already been paid for.

Final agreements were in the process of being finalized with specific delivery dates and amounts per batch. In terms of the agreements there was another 9 million vaccines expected from Johnson & Johnson, 20 million from Pfizer, and 12 million expected from the COVAX facility. Altogether "no less than 26 million people's vaccines were already assured".

Over and above this, DoH had already identified a source for further vaccines which would be announced once the appropriate agreements were finalized. The presentation may have referred to a shortfall but in reality sufficient supply was dependent on the finalisation of agreements. This is in process. Thus it is not as if DoH is unaware of from where they will source further vaccines; negotiations are ongoing at present.

DoH was already in discussions with a few other suppliers including SinoVac and SinoPharm in China; they had been very supportive and wanted to offer their help. South African scientists were currently working with them, along with other potential suppliers. DoH was already engaging with Moderna and other major suppliers but have not signed any agreements with them. He reiterated that where no concrete agreements have been signed, DoH would not comment on these until the appropriate time.

DoH had been engaging with medical researchers who had the facility to store vaccines to -70 degrees. The private sector had also indicated they are interested in assisting where possible. DoH would put out an open bid which would come out either today or tomorrow for future purposes. The 1 million AstraZeneca vaccines stored by BioVac did not require such facilities. He reiterated that

DoH was still on course and the current vaccines had gone out for testing and quality control and the results should be back in the next few days.

Each province has got its own areas where they would store their vaccine supply. Maps in the presentation indicated from where they would be distributing the vaccines. These maps go right down to district hospitals and clinics. There is a lot of coordination going on in the private sector. DoH is working very well with the private sector. For the purposes of the national rollout plan government was doing central procurement and then supplying both the private and the public sector for distribution. Another form of support from the private sector was from Business South Africa as well as expertise through Nedlac.

There was a focus within the inter-ministerial committee on South Africa's capacity to manufacture vaccines locally. There are a number of countries who have indicated their willingness to work with South Africa on this.

The main focus was on the limitation of potential risks. On the procurement side, the risks were much less because only National Treasury and the Health Department would be procuring. DoH was aware that there were a number of vaccine offers but if it does not come from the original manufacturer, DoH was still willing to see what was on offer and called suppliers to come forward. DoH would then validate these supplies and verify the authenticity of what they were offering. He stressed that it was essential to ensure that the quality and safety of vaccines are not in doubt.

The Minister said the area of logistics needed attention since it is the area with the greatest risk of fraud since it involves contractual matters. DoH is also working with the Auditor-General who had provided some ideas on how to prevent such misconduct. There had been some interest from other bodies such as Corruption Watch on what was occurring and DoH was committed to a transparent process.

There was a risk assessment analysis process under the direction of the inter-ministerial committee. DoH was working with various organs of state to intervene and assist DoH should it suspect or acquire evidence of malfeasance. Theft on the ground also had to be taken into account. Since vaccines are going to be free to the recipient as medical aids and the government are paying for them, there should not be anyone selling vaccines. The fact of there being no payment for the vaccine by the recipient means the black market would be less likely to get involved. Security for the vaccine was going to be a major focus of the Department.

The Minister hoped Members would also give some ideas of what they think ought to be done. One interesting debate was whether parliamentary leaders should be vaccinated as part of the first phase. There were lots of myths and misinformation and it might be useful to boost public confidence if political leaders stepping forward to be vaccinated first thereby setting an example.

Discussion

The Chairperson thanked the Minister. Since his last update the Committee had been receiving briefings from each province on readiness to roll out the vaccine. The Committee had been briefed by Western Cape, Eastern Cape, KZN, Gauteng and Limpopo. The Northern Cape would make their presentation on 10 February. The provinces whose plans came later were stronger than those who presented their plans earlier.

Ms H Ismail (DA) asked the Minister why vaccines were procured so late. South Africa was expected to reach the third wave by June or July 2021. She asked how the country was going to reach herd immunity by then. It was sad that South Africa was going to lose more lives due to government delays in procuring vaccines. She asked for the total amount paid for the procurement of all the vaccines mentioned. She asked if South Africans from all walks of life were included in the vaccine trial programme. On what basis were the suppliers of vaccines chosen and the factors used for selecting suppliers such as price and availability.

She asked how effective the vaccines are against the variant of the virus in South Africa. She asked for a full report on the donors of the vaccines. Many South Africans were sceptical about the safety of the vaccines – how sure is the government that the vaccines were all safe? The Serum Institute of India was a private company and the government had paid more than double the price for vaccines. She asked if there was not an alternative, more cost-effective option. She asked why the vaccines could not be sourced from Aspen directly. How far was South Africa in developing its own vaccines locally? Now that SAHPRA has agreed to the controlled use of Ivermectin, where would government source the product and if there would be a single exit price for Ivermectin. She asked if DoH would consider setting a fixed price for it to prevent an influx of different prices. She asked if all vaccine sites were adequately equipped for cold storage. This was important because of the power outages prevalent in the country.

The Chairperson said Members had to be considerate of others wanting to ask questions.

Ms Ismail asked if there were to be clinical trials for the use of Ivermectin in the country. There were social media reports indicating that vaccines were not safe and had adverse effects on people living with HIV. She asked what the Minister was doing about this.

The Chairperson said he wished to have a second round of questions and therefore they needed to be considerate of others.

Mr A Shaik Emam (NFP) said as a community leader he had no problem with taking the vaccine if that would mean reducing the level of doubt about its safety. He asked if it was not more appropriate to advise the Committee on developments first before statements were released to the public. He asked why DoH was procuring vaccines from suppliers before SAHPRA had issued an authorisation for purchase. No authorisation had been granted for the purchase of any vaccines. He asked what was the rationale for purchasing from Aspen and Johnson & Johnson whose vaccines had a lower efficacy rate. Whilst the Minister was providing plans, various provinces

were still querying how the implementation would be funded. The Western Cape, for example, was looking for R1.7 billion and did not know from where it would get this. Given the agreements between government and the suppliers were confidential and the development and rollout of the vaccine was brand-new, who would be liable if something went wrong with the vaccine in terms of its safety?

On the tracking system, he asked if government would track those who had received the vaccine to monitor if they experienced major side effects. What processes were in place to ensure people could access Ivermectin which had been proved to have no side effects over the years elsewhere?

He asked if the vaccination would be an annual vaccination after everyone had received it initially, like the flu vaccine. There were reports that the AstraZeneca vaccine was not safe for use for persons older than 60 years and that countries like Germany had banned its use for senior citizens. He asked the Minister for assurances that the vaccines were effective and safe so that political leaders could go out to their communities and tell them that the vaccine was undoubtedly safe.

Mr P Van Staden (FF+) asked if there would be sufficient healthcare workers to administer vaccines and if a full report could be made available to the Committee on this including the number of healthcare workers available in each province to administer vaccines. The presentation referred to a shortfall in healthcare workers to administer vaccines and asked the Minister to explain how this would affect the rollout plan to vaccinate 40 million people by the end of year. DoH was already running behind with the 1.5 million vaccines from the Serum Institute of India which could be used to vaccinate only 750 000 people.

He asked the Minister for assurances there would be no corruption in the tender process for the distribution and administration of vaccines. He was glad to hear that the tender process would be open and hoped that it would stay that way.

He asked how government would monitor those citizens who could not register for vaccines online since most South Africans did not have access to internet. As of October 2020 only one million citizens had accessed the Covid-19 app out of 60 million citizens.

He asked if it was safe for citizens to receive different vaccine types for the first and second doses. If it is not safe how is government going to ensure that each citizen who received one vaccine from one supplier received a second vaccine from the same supplier.

Some scientists had said the vaccine would not be successful while other scientists intimated that the vaccine would be successful. He asked the Minister what his point of view was on this matter. He asked the Minister what assurances could be given that the Covid-19 vaccines were safe. If they were not efficacious, would the Minister himself approach SAHPRA to legalise the use of Ivermectin?

Mr van Staden asked again if it was reasonable for government to have a goal of vaccinating 40 million people by the end of the year given the new dates from DoH and the Presidency. The Minister had previously said 316 000 vaccinations would have to be administered daily to reach 40 million people by year-end. This target had already been missed by 29 days given current delays. He asked when exactly each province would start administering vaccinations and if they would start on the same day.

What safety precautions were being taken to prevent the theft of vaccines? If this could not be provided in this forum, then the Minister should provide a written report with specifics. 34 000 healthcare workers had already registered for the vaccine but how many healthcare workers had yet to register for Phase 1. He asked how DoH would help healthcare workers who did not have the time or internet access to register for the vaccine. He requested specific dates for the start of phases 1, 2 and 3 of the rollout plan.

The government had demonstrated time and again that it was too incompetent to manage the administration of a task of this magnitude. Government had to include the private sector in the administration of the vaccine to ensure that people do not have to wait to get vaccinated.

He asked why government would not permit provinces such as the Western Cape to procure vaccines themselves to allow people to exercise their right to be vaccinated.

Dr K Jacobs (ANC) wished to register a point of order to take exception to what Mr van Staden had just been saying about the provinces.

Mr van Staden said he was merely asking the question which was on the mind of the public given there had been rampant corruptio during the PPE procurement and other reports of corruption which were already in the media. It was important that the public should know the answer to questions such as these.

The Chairperson indicated that Members had each been asking a large number of questions. He did not want to stop Members from asking questions but wanted to afford the opportunity to others who had yet to ask their questions. If there was to be a second round, those who had already asked questions would be placed at the bottom of the list in the second round.

Ms E Wilson (DA) asked her first question [which was inaudible due to poor connectivity]. She asked for the cost per dose from AstraZeneca. Belgium, Switzerland and Norway had banned the use of AstraZeneca vaccines for a myriad of reasons.

Given the details in the presentation, the South African government would vaccinate only 36.2 million people by January 2022 which is

well below the required level for herd immunity in the country. On the current trend the country would run into a problem since the number of people to be vaccinated each month would be unacceptably low. She asked why the bulk of vaccines was coming from Pfizer which was the most expensive provider.

There seemed to be a lot of purchases from COVAX and asked which vaccines specifically would be procured from them.

The Committee had received presentations by the provinces which were wholly unprepared, especially as regards distribution, storage and data management. The government could not hope to achieve their goals when these systems were not first in place.

She had concerns that the tender processes underway would not be properly managed.

She requested that reports be made available how far government was in vaccinating the population in the same manner reports were made about infections, deaths and recovery rates.

She was concerned that the Committee had not received the data and reports which the Minister had been using in his webinars to the public. The Committee should have access to such data before such public webinars occurred. One of the reasons it is important is because the public contacts their parliamentary leaders about reports. Members are not in a position to provide answers to their constituents as they do not received the webinar documents used by the Minister.

Ms N Chirwa (EFF) said there was insufficient scientific support for the rollout strategy, especially for phases two and three of the plan. The strategy was not cognisant of the social circumstances of the country such as senior using private transport versus seniors who use public transport who are more at risk. DoH should devise a strategy which recognises these differences. The rollout strategy for people living in rural communities cannot be the same as those living in urban communities.

She said insufficient information was being communicated to the public and even Members of Parliament. Public concerns about vaccine safety are due to lack of official information. One of the pillars of DoH is to educate the public to prevent the transmission of disease. The health education of the public was not being done effectively and that this should be looked into.

The government had not taken international patents into account especially as there was discussion to localise the production of vaccines. She asked for the position of the South African government on patents. She wanted specific dates of when government planned to initiate the local production of South African-made vaccines.

She suggested that government was neglecting the public production of vaccines by instead focusing on its partnerships with the private sector. In June 2020 the Minister had said he was dedicated to helping the public sector manufacture vaccines but had since been more focused on the partnership with BioVac, a relationship which has been in operation since 2003. The government was not doing enough to ensure that state capacity was being built.

Ms S Gwarube (DA) said that while presentations and webinars were welcomed this does not replace the need for a tabled codified strategy for the vaccination rollout. DoH was obligated to provide a formal plan which indicates clear timelines, cost of vaccines, manufacturers approached, instead of "drip-feeding" the information and saying that government is unable to provide detailed information for various reasons. One reason clear and concrete information is essential is so Parliament can hold government to account. This lack of information also fuels misinformation in the public sphere.

She asked, given the second tranche of the AstraZeneca vaccine would arrive only in March 2021, if those healthcare workers who received their first dose would be able to receive the second dose within the prescribed time frame.

On the Pfizer vaccines having stringent requirements for their storage, did the provinces have adequate cold storage facilities?

The rollout of the vaccine in the first phase appears to be more manageable than it would be in the later phases. Gauteng was not ready to roll out to the general public due to challenges such as IT infrastructure and cold storage facilities. She asked if there was a risk mitigation plan in place to deal with such issues.

While DoH indicated that they were on track to meet the rollout strategy goals, a letter issued by Treasury indicated that DoH applied for the procurement of vaccines only on 6 January 2021, a process which should have started already last year. In light of this, was government still confident that it would meet its goals by the end of 2021?

Dr S Thembekwayo (EFF) said that there had been a request by the EFF Chief Whip that the Minister of Finance accompany the Minister of Health to this meeting. However, this request had not been honoured. She asked why as there were many questions on the rollout strategy costing. She asked the Minister for the estimated cost of each phase of the vaccination rollout and how each phase would be funded. If the Finance Minister had been present, he could have assisted him in answering these questions.

She asked the Minister what safety guarantees were in place for healthcare workers living with HIV. She asked what measures were in place to detect side effects and inefficacy of the vaccine.

Security measures were important. She asked what extra measures were put in place to prevent "fraudulent vaccines" from entering and leaving South Africa.

She told the Minister that while she accepted that DoH was ready for the vaccine rollout, it was nevertheless evident that individual provinces were not ready.

There were reports that South Africa was paying more than other African countries as well as European countries for vaccines. She asked why this was the case and what assurances the Minister could give that South Africa would pay less for vaccines in the future.

The Chairperson noted that he had received a letter from the EFF Chief Whip requesting that the Finance Minister be present at the next meeting.

Dr Thembekwayo interjected saying the Chairperson should inform the Committee of this later due to the limited time available for the Minister to answer questions.

The Chairperson said he just wanted to indicate that he wished to invite the Minister of Finance to appear before the Committee alone as it needed time to ask the Minister pertinent questions.

Dr K Jacobs (ANC) expressed his general satisfaction with the presentation and the work of the DoH. Most questions asked by his colleagues were answerable by referring to that presentation.

He wished to emphasise how the disposal of waste products would be undertaken in South Africa, especially used vials. Used vials were being fraudulently filled with saline and issued to unwitting members of the public in countries such as China.

Although the vaccine had arrived in South Africa, the public should still be made aware that the country is still in the midst of the second wave and that measures should be maintained to prevent the spread of the virus.

Mr M Sokatsha (ANC) asked the Minister where public representatives stood in terms of being vaccinated. He agreed with the Minister that public representatives should come forward to be vaccinated first to show the public that the vaccines are safe. He asked where South Africa was in its research capacity for the production of vaccines locally.

Ms A Gela (ANC) thanked the Minister and expressed her general satisfaction with the work of the Minister and DoH. She asked how South Africa was doing in the global competition for the procurement of vaccines given the high international demand. She acknowledged that everybody in the country should be included in the plan to be vaccinated. She did however want to confirm with the Minister whether children—especially those with co-morbidities—would be vaccinated.

Minister's response
Minister Mkhize said questions which were answered one way today could be answered another way tomorrow. This was due to the continually changing variables about the pandemic. He wanted to be upfront with Members, telling them that he did not expect the plan to run smoothly. There would always be areas where the targets needed to be revised and this is mainly for two reasons: variability in the delivery of vaccines and logistical challenges which Members had indicated had been raised by the provinces. It was a very large implementation programme and to think that every part of the plan would be followed without any challenges would be very misleading.

On how South Africa was dealing with global competition, the matter was very difficult because if no contract was signed with the manufacturers there was no guarantee that you would get a vaccine consignment even though it may have been set aside for delivery to the country initially.

On South Africa producing its own vaccines, this was going to be a long process but government was "eyeing" both Aspen (a South African company) and BioVac as partners of government. The inter-ministerial committee would look into other initiatives government will have to enter into to produce its own vaccines. South Africa has in the past been able to manufacture its own vaccines albeit not necessarily for humans but for animals. He believed that the expertise does exist in the country for local vaccine production. It was important that government focus on building this capacity. That very morning the country had been looking at offers from other countries who were looking into this. Building capacity for vaccine development would happen over a long period and if there were developments in this area, he would communicate these.

On data registration and management, there were quite a number of healthcare workers who had already submitted their registration. About 160 000 people had already registered. Obviously this was a trial run for government to have a sense of how many people wanted to get onto the system. Those who are unable to access the internet to register themselves, their institutions would be able to account for them and assist in registration.

On South Africa paying more for vaccines, many manufacturers look at different countries on the basis of whether they are low or high income countries. On this basis they determine what price to charge. The second criterion they look at is if the country was involved in the investment into the development and manufacture of vaccines early on. So the manufacturers will look at how much the country contributed to the manufacture of vaccines in the development stage. This is what has happened in the US and in Europe. Another factor is bargaining based on economies of scale. Still other countries depend on donor finance to finance the purchase of vaccines. South Africa may be able to take advantage of a pricing structure that is available through the African Union platform.

When DoH receives questions on why South Africa did not engage in bilateral negotiations, the answer is that South Africa would have paid more on this basis. Platforms are being utilised. Where South Africa can make use of bilateral arrangements, we would make use of it. The price South Africa paid for the AstraZeneca vaccine is the same price that Brazil paid. In other countries prices will vary depending on how much investment they made. In the case of Pfizer, we could enter into negotiations with them on the basis that they had undertaken research in South Africa. On this basis they had to acknowledge that South Africa had made some contribution to research and development of the vaccine. Most discussions have to be kept confidential until the arrangement has been concluded.

On the readiness of provinces, the National Department of Health would be engaging with each province to assess where the gaps are.

There is a process called the detection of adverse effects after immunization as part of the monitoring process. Everyone who has taken the vaccine can report if they are experiencing adverse effects. This would help DoH to deal with any untoward effects which arise.

On the reports supplied to the Committee, DoH takes the point and sit down and determine what additional information was required. However he would refrain from referring to these reports as "drip-feeding". One reason is that DoH comes before the Committee only upon invitation. Members of the media often pose questions to DoH. For this reason sometimes the demand for information cannot wait until DoH has already informed the Portfolio Committee. If there was a way of closing this gap, DoH would be happy to deal with it.

On the timelines for administration of vaccine doses, more doses are expected but this information cannot be made available until the agreements are finalized. He assured the Committee that the second doses will be administered within the required time. Initially the second dose had to be administered within 21 days of the first dose. Upon correspondence with UK counterparts, it has been determined through research that doses may be administered 42 days after the initial dose. In some cases they have stretched the administration of the second dose to three months after the initial dose. It is important that a person who received a vaccination from one brand receive the second vaccination from the same brand.

DoH was not worried that South Africa does not have adequate facilities to store Pfizer vaccines as it has determined there are adequate facilities and capacity. All DoH needed to do was to build its capacity as it goes along.

It was important to raise behavioral change and acceptance of the vaccines. There are cultural issues, concerns, fears, the difference between urban and rural and so on.

The question of patents was being handled at the level of the World Health Organisation. However, patents will not stop South Africa from investing in its capacity to develop vaccines locally. South Africa would work with the rest of the African continent to develop local capacity.

On the cost of the AstraZeneca vaccine, he noted the transport cost was incorporated into the price. The primary reason DoH was buying the way it was is due to availability which is the primary criterion. There will be no need to worry about the availability of vaccines in December 2021 due to the expected level of production at that point. Another 500 000 AstraZeneca vaccines arrive during February 2021. They were expecting other vaccines to arrive but he will make more information available when those agreements have been concluded. As vaccines become more available, they would not wait for three months to start the next phase but would start with the next phase concurrently. For this reason some of the phases in the plan may start earlier. The Committee needed to understand that there is no reason that government would slow the vaccination process down on its own account.

On the high cost of Pfizer vaccines, government had negotiated the price down. However, as Pfizer was offering greater availability this meant a higher price. On this basis, government had to think very clearly about what it was able to do. The question was "should we avoid getting a vaccine consignment because it is expensive when it is in fact available? This question must be asked in the context of vaccine efficacy which in the case of Pfizer is acceptable. The answer was "no".

COVAX would let DoH know which particular vaccines they have available. They were the ones who determine what is available and it is based on what they have ordered and if the countries in question would be able to manage the conditions under which the vaccines have to be stored and transported. COVAX had said to DoH that they would be able to procure about a billion vaccines. This bodes well for other countries which are more dependent on donor vaccines than South Africa. DoH has approached COVAX to find out what vaccines are available to South Africa but COVAX is also constrained by exigent factors.

On regular vaccination reports similar to the reports on statistics for Covid cases and fatalities, the Minister replied that DoH was working on such reports.

On allowing the Western Cape to go ahead and purchase its own vaccines, if this question was posed in the context of suggesting that the ANC was procuring through corrupt practices then the question was out of order. However, to address why a province might not be successful in procuring, the Minister replied that the procurement process is quite complicated such that it would be difficult for a province to procure vaccines unilaterally. If a province is asking to procure vaccines on its own, what they are inadvertently requesting is for Treasury to allocate from the budget to each province individually – this would be more conducive to corruption. Also, manufacturers would have to deal with nine separate procurement offices rather than just one central procurement office which

makes the availability of the vaccine precarious. A third problem for provincial procurement is some of the provisions required in the agreements with manufacturers are such that only the national government can assent to them. There are certain forms of authority that the Constitution does not permit provinces to exercise. A manufacturer will be reluctant to agree with a party within a country without first consulting the national government. These are the practical problems which prevent successful provincial procurement.

He told the Committee that the original dates assigned to each phase would undoubtedly change and that the Committee ought to give DoH sufficient time to get back to them once final dates have been established in accordance with changing variables.

The Minister said he will leave the questions on Ivermectin to the Deputy Director-General.

On the safety of the vaccines, the Minister said in any such situation a few things should be expected of therapeutics. Firstly they have undergone rigorous scientific analysis to establish the level of safety. In this case the scientific analysis had established safety. There would not be any procurement if safety was not established. Secondly, there is the question of efficacy which will become very important as there is a high degree of efficacy variation found in different vaccines. Even the same vaccine may show different levels of efficacy under various conditions. DoH would therefore look very closely into this.

On corruption, he invited Members to report corruption when and where they detect it.

The Minister welcomed Members' offers to come forward to take the vaccine first as an example to their constituencies.

On why one would procure a vaccine with lower efficacy rather than another, the Minister replied that as long as the efficacy is acceptable as established by the World Health Organisation, then availability should take precedence over efficacy. There is a limit to how far this can be taken.

The Minister said that confidentiality is standard in any commercial transaction. When transparency is spoken about it should not be "conflated" with non-confidentiality. Transparency means government is able to explain why it made certain decisions and under what conditions. That does not entail that government should go out in public explaining every detail of the negotiations. That is the nature of negotiations and that is why it is confidential. But there's nothing devious about confidentiality. Government may not wish to enter into an indemnity agreement, for instance, but due to the fact that every other country is doing it, not to do so would be put obstacles in obtaining the vaccine order. Lots of agreements are preceded by much negotiation which does not come out into the public. However once a decision has been settled upon, government may explain why a certain agreement was entered into.

It is important that where people die after taking the vaccine, one must take note of the tests administered to establish the cause of death. It does not entail that the vaccine was the cause. Association does not mean causation.

When power shortages occur, hospitals have generators which we expect to kick in when there is an interruption of electricity. Some of the packages for storing the vaccines have battery packs which maintain the cold chain for a particular period of time. Certain vaccines which require very low temperatures may be stored for a few days before they go bad.

On buying from Aspen directly, there is a difference between Aspen and the Serum Institute of India. AstraZeneca has given the Serum Institute of India the licence to manufacture. Aspen does not have a licence; it is a contractor to Johnson & Johnson. However DoH is still engaging with Aspen as it is happy that Aspen is building capacity inside South Africa. DoH thinks that Aspen can go further and that they can manufacture the entire value chain. As to the Johnson & Johnson vaccines which are being manufactured in South Africa, the entire continent is looking to that manufacturing to determine what proportion of that comes to the rest of Africa. You cannot buy directly from Aspen but government is dealing with Johnson &Johnson directly and in fact deals with them every second day. Procurement is based first on safety, then on efficacy, then on availability and only thereafter does cost come into consideration.

Dr Anban Pillay, DoH Deputy Director-General: Health Regulation and Compliance, replied about Ivermectin that it was important to state that SAHPRA was mandated to deal with Ivermectin. DoH does not have a specific role in the registration or evaluation of the product. He had been talking to SAHPRA and there would be licensing of good manufacturing practices (GMP) facilities to store and supply Ivermectin. There were about three suppliers who could potentially supply the drug.

On a fixed price for Ivermectin, this would be determined when they engage with suppliers after they determined who the suppliers in question were.

On vaccine efficacy, he thought it was important to appreciate that the percentage one sees for a vaccine relates to the efficacy in mild-to-moderate infection. What should be very important is if the vaccine can prevent hospitalisation and death. If you look at all the vaccines, they are more or less equally effective on that score. The goal is to prevent hospitalisation and death at the end of the day. Whether there are more or fewer symptoms is not the big issue.

The IT system put into place to track vaccines requires the batch number and other product details. These details are captured on the system. This will enable DoH to track the vaccine and ensure that a vaccine administered to a patient is one that was approved by government.

Using two different brands of vaccine on the same person would be practically difficult because the IT system would capture the details of the vaccine which was initially administered to the patient. The patient would receive a reminder to return and receive their

second dose and the correct dose would be delivered to the facility the patient attends.

On which vaccines COVAX would supply, it currently has deals with Pfizer and AstraZeneca. COVAX is also talking to Johnson & Johnson. It is anticipated that later on in the year Johnson & Johnson will also supply their vaccines through the COVAX facility.

It was important to note vaccine delivery date from commencement of vaccination date. The arrival date of the remaining 500 000 AstraZeneca vaccines from SII was anticipated in March because DoH is not too certain of the date. As the arrival date was uncertain DoH felt it prudent to allocate arrival date as March rather than February because there is no delivery date at this stage.

Further questions
Ms Wilson said there appeared to be the perception that Members were suggesting that challenges faced by DoH were by design. She wanted to assure the Minister that this was not the case.

She asked how realistic the figures were for how many vaccines DoH has already secured. She asked if these agreements were finalised or if these were still in process. She wanted clarity whether these figures were "thumb-sucked" or final.

Mr Shaik Emam asked again how DoH was able to procure vaccines without first getting authorisation from SAHPRA, according to whom there was no section 21 application even up until now.

Various organisations had indicated that they had attempted to negotiate with DoH for the sale of vaccines but had not heard back from DoH until January 2021. He asked if this was due to financial constraints or, if not, what factors were the cause of these delays.

He was not satisfied with the response about Ivermectin. There appeared to be miscommunication between SAHPRA and DoH on who was the custodian of the health of the public. He wanted clarity as to the use and registration of Ivermectin.

Mr van Staden said that according to recent reports there were about 40 000 "frozen" posts for experienced doctors and specialists due to a lack of funding and the impact of this had been seen over the past few months at state hospitals due to a lack of doctors and nurses.

In the Eastern Cape, 625 nurses are without jobs due to DoH, which does not have the money to pay for their salaries. The problems in the Eastern Cape state hospitals have been seen over the past few years. This past Wednesday doctors and other healthcare workers had been protesting in Upington in the Northern Cape due to a shortage of staff. Health care workers at this hospital were under an enormous amount of pressure. The hospital in question is a district hospital with 327 beds but it only employs 36 doctors at present. Doctors are working 40 hours a week with 20 hours overtime but are not paid if they work longer hours to fight this pandemic. There is not enough staff to assist these doctors. Hospital management must limit overtime and make use of overtime only in the event of shortage of staff. The Eastern Cape department paid tens of millions of rands for false overtime claims. How would DoH address these issues which appear to be spreading across the country. How does DoH plan to eradicate the problem of appointing interns? How does DoH plan to ensure that sufficient healthcare workers are employed across the country to help the fight the pandemic and to help the vaccine rollout? When will these appointments take place?

Minister's response:
The Minister told Mr van Staden that he had seen these numbers published and they were very high – there was no shortage of 40 000 doctors. The real issue was that there were human resources challenges. The Department had gone around to the provinces and had employed contractor doctors and nurses. Mr van Staden had referred to unemployed doctors. The Minister had asked the SA Medical Association and Health Department to look at the list of unemployed doctors. The issue of "unemployed doctors" usually manifests in different ways. A number of interns when they have not been allocated by the end of the year start tweeting that they are unemployed. When this happens the Committee start thinking that interns are not being employed; but really it is just a matter of timing.

Secondly, certain doctors employed as community service doctors start panicking at the end of their term and ask where they are going to be employed. In a number of instances this issue becomes quite emotive. The Department saw the same occur in 2020 and he called on the MECs to declare all unfilled vacancies. Thereafter he determined that the provinces were not in the same situation.

In Gauteng for example there was a call for doctors to come in for interviews. However, there were certain posts which could not be filled since doctors had not applied in large numbers. There was no "automatic translation" whereby a community service doctor would want to stay in the public service. A number of community service workers wanted to move into the private sector.

In the Northern Cape there was a different challenge, where areas were remote and away from the main cities and therefore suffered more. Doctors were unwilling to relocate to these remote areas. In smaller hospitals there tended to be fewer doctors since doctors wished to move to urban areas.

Where there are financial constraints, provinces have to pause filling posts. In the Eastern Cape for example there are very few doctor and nurse posts that are unfilled – but rather unfilled posts related to other workers such as porters and cleaners. These issues would be dealt with by formulating a "futuristic" human resource strategy. This strategy would take into account current vacancies. It would also take into account population growth and some "norms" which have been discussed.

On Ivermectin, the Minister replied the issue is there are certain divisions of responsibility. Most of the issues raised fall under the jurisdiction of the regulator who deals with registration, approval, efficacy and the analysis of available data. The regulator analyses reports to determine if the data for individual therapeutics were properly peer reviewed. SAHPRA is responsible for this and DoH cannot duplicate its work. When trials for new products happen, individual research institutions approach SAHPRA who gives them authorisation to undertake the research. The results of the trials will indicate if a particular drug is useful for a particular purpose. It is not the responsibility of any one individual researcher to go ahead and register a particular drug. The developer is the one responsible for seeking authorisation.

While there have been many questions on the Ivermectin drug, there is a need for double-blind trials. These trials have to be rigorous and scientific to prove the efficacy of Ivermectin. The results of double-blind trials for Ivermectin are not yet available. The problem with Ivermectin is that the issues surrounding the drug arose at the time when the Covid-19 surge was very high. Just because everybody was anxious about wanting a drug which could help against Covid-19 does not mean that the scientists themselves have to become emotional about the process of testing or fast-tracking the drug. It is true that scientists should fast-track the drug but only within an acceptable scientific process. The regulator has now put this process in place with doctors managing it.

On ordering vaccines before authorisation, there was a time when there was so much uncertainty DoH could not commit much. However, over time there has been much new information. Some of the vaccines have already been tried in different countries. For some of the vaccines, DoH has already started negotiating and ordering before the efficacy results have been announced. This is because there has been a short-listing of vaccines. This involved DoH having to make an "educated guess" as to what might work. DoH has been helped in this process by our scientists who have been reading a lot of relevant research papers. However, once the order has been placed, DoH has the option that if we know a given drug works, government can stand in and be the one that applies for the vaccine to be imported under the name of government. Therefore approval will be given on a conditional basis. For example, government was the one who applied for AstraZeneca to be imported. If next year, for instance, AstraZeneca wanted to import the vaccine they could apply for permission from SAPHRA to import. There was nothing wrong or untoward with the process. Some vaccines have been brought into the country under the "guise of research".

On concerns about questions raised by the media, the Minister said the media relied on "gossip". The media tries to "pitch a sale" and therefore it uses Members of Parliament to pressure DoH. Although the media will be correct in some instances, often it is mistaken, so there would be some misinformation in the public sphere. One of the problems is that the media has sources and evidence which it would not reveal, yet the story they put out will not change.

The Chairperson thanked the Minister and adjourned the meeting.

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"FH2"
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Vaccine trials, procurement & roll-out programme; with Minister & Deputy Minister

Health

14 April 2021

Chairperson: Dr S Dhlomo (ANC)

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 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 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.