IN THE HIGH COURT OF SOUTH AFRICA
WESTERN CAPE DIVISION, CAPE TOWN

CASE: 1943/2021

In the matter between:

DEMOCRATIC ALLIANCE	Applicant
and	
THE PRESIDENT OF THE REPUBLIC OF SOUTH AFRICA	First Respondent
THE MINISTER OF HEALTH	Second Respondent
THE MINISTER OF CO-OPERATIVE GOVERNANCE AND TRADITIONAL AFFAIRS	Third Respondent
THE MINISTER OF FINANCE	Fourth Respondent
THE CHAIRPERSON OF THE INTER-MINISTERIAL COMMITTEE ON VACCINATION	Fifth Respondent
THE GOVERNMENT OF THE REPUBLIC OF SOUTH AFRICA	Sixth Respondent
THE PREMIER OF THE EASTERN CAPE	Seventh Respondent
THE PREMIER OF THE FREE STATE	Eighth Respondent
THE PREMIER OF GAUTENG	Ninth Respondent
THE PREMIER OF KWAZULU NATAL	Tenth Respondent
THE PREMIER OF LIMPOPO	Eleventh Respondent
THE PREMIER OF MPUMALANGA	Twelfth Respondent
THE PREMIER OF THE NORTHERN CAPE	Thirteenth Respondent

THE PREMIER OF THE NORTH WEST	Fourteenth Respondent
THE PREMIER OF THE WESTERN CAPE	Fifteenth Respondent
THE MEMBER OF THE EXECUTIVE COUNCIL OF THE EASTERN CAPE FOR HEALTH	Sixteenth Respondent
THE MEMBER OF THE EXECUTIVE COUNCIL OF THE FREE STATE FOR HEALTH	Seventeenth Respondent
THE MEMBER OF THE EXECUTIVE COUNCIL OF GAUTENG FOR HEALTH	Eighteenth Respondent
THE MEMBER OF THE EXECUTIVE COUNCIL OF KWAZULU-NATAL FOR HEALTH	Nineteenth Respondent
THE MEMBER OF THE EXECUTIVE COUNCIL OF LIMPOPO FOR HEALTH	Twentieth Respondent
THE MEMBER OF THE EXECUTIVE COUNCIL OF MPUMALANGA FOR HEALTH	Twenty-first Respondent
THE MEMBER OF THE EXECUTIVE COUNCIL OF THE NORTHERN CAPE FOR HEALTH	Twenty-second Respondent
THE MEMBER OF THE EXECUTIVE COUNCIL OF NORTH WEST FOR HEALTH	Twenty-third Respondent
THE MEMBER OF THE EXECUTIVE COUNCIL OF THE WESTERN CAPE FOR HEALTH	Twenty-fourth Respondent

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I, the undersigned,

SABELO SIYABONGA SANDILE BUTHELEZI

make oath and state as follows:

1 I am the Director-General of the National Department of Health ("**NDoH**").

2 I am authorised to depose to this affidavit on behalf of the first to sixth respondents. These respondents are referred to as the National Government in the founding affidavit. In this affidavit, I shall either refer to them as the National Government, or simply the government. Confirmatory affidavits from the relevant respondents confirming my authority to depose to this affidavit on their behalf will be filed as soon as possible and in any event prior to the hearing of this matter.

3 The facts set out in this affidavit draw on the information available to me in my capacity as Director-General. Save where the context indicates to the contrary, or where it is otherwise stated, I accordingly have the necessary personal knowledge to depose to the facts concerned. I believe the facts set out to be both true and correct. Confirmatory affidavits from the departmental officials mentioned in this affidavit and from Professor Barry Schoub will be filed as soon as possible and in any event prior to the hearing of this matter.

4 Where I make legal submissions, I do so on the advice of the first to the sixth respondents' legal representatives. I accept such advice as correct.

5 I have read the founding affidavit deposed to by **John Henry Steenhuisen** on behalf of the applicant ("**DA**") and respond to it in what follows.

5.1 I deny that all of allegations contained in DA's affidavit are true and correct. Where those allegations are inconsistent with any part of this affidavit they must be taken to be denied by the National Government.

5.2 Moreover, I note that the DA's affidavit is replete with allegations are plainly not in Mr Steenhuisen's personal knowledge. Much of it consisting of sweeping factual allegations about what persons and institutions within South Africa do or do not know without any explanation as to how Mr Steenhuisen can have the requisite personal knowledge. Much of it amounts to sheer speculation.

5.3 I do not accept that this information is properly before the Court and specifically reserve the right of the Government to contend that such allegations fall to be disregarded on a range of grounds.

5.4 I emphasise that the mere fact that I have responded to some such allegations as best I am able (in the time available and having regard to the pressures on me and other government officials) does not mean that I accept that such allegations are properly before the Court. The contrary is true.

INTRODUCTION

6 In its application before Court, the DA seeks three substantive orders:

6.1 In prayer 2 of its Notice of Motion, it seeks an order declaring that the government's conduct in "procuring and obtaining" the Covid-19 vaccines is irrational and unconstitutional.

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6.2 In prayer 3 of its Notice of Motion, it seeks an order declaring that the government's conduct in "preparing and implementing its programme to administer" Covid-19 vaccines is irrational and unconstitutional.

6.3 In prayer 4 of its Notice of Motion, it seeks an order directing the government to develop a comprehensive and co-ordinated plan for procuring, obtaining and administering the vaccines.

7 As will be demonstrated in this affidavit and in legal argument, the DA's case is wholly misconceived, both in fact and in law.

8 The DA rests its case on four main lines of attack.

9 The DA's first main line of attack is an allegation is that, despite its expert advice to the contrary, the National Government has failed to timeously procure and roll-out vaccines. It alleges, in the main, that the NDoH did little or nothing to procure vaccines until 6 January 2021 when it submitted an application for a procurement deviation to National Treasury.

9.1 This answering affidavit demonstrates that this contention is simply wrong on the facts.

9.2 The government took numerous steps throughout the second half of 2020 to ensure that vaccines were procured as speedily as possible and was, at all times, guided by the expert advice it received. The steps included formally entering into the Covax vaccine programme which I

describe below and engaging in a discussions with a range of vaccine manufacturers, beginning as early as 24 July 2020.

9.3 The government was faced with extremely difficult and unprecedented questions of precisely when to conclude agreements with which vaccine channels and manufacturers. Its decisions in this regard were very carefully considered and always relied on expert advice. The decisions were always made with the aim of ensuring an expeditious, effective and sustainable vaccine programme.

9.4 The DA now says, with the benefit of hindsight, that things should or could have been done differently. For a start, it is wrong on the facts. But even if it were right on the facts, this does not demonstrate that the government's conduct was irrational or unconstitutional.

10 The DA's second main line of attack, in an attempt to bolster the first, attempts to compare South Africa to other purportedly similarly placed countries which are ahead of South Africa in relation to the procurement and roll-out of the vaccines. This affidavit demonstrates that this point is without any merit. As I demonstrate, the DA has engaged in what is regrettably a glib attempt to draw comparisons with other countries which are inappropriate, unhelpful and unjustified.

11 The DA's third main line of attack is an attempt to contend that the conduct of the National Government in preparing and implementing its programme to administer Covid-19 vaccines is irrational and unconstitutional.

11.1 I submit that this leg of the DA's challenge is entirely unfounded and does not get out of the starting blocks.

11.2 It appears that the DA may contend that the Government has no plan for administering the Covid-19 vaccines. If that is the DA's case, then this affidavit demonstrates that it is plainly unsustainable. There is plainly such a plan.

11.3 If that is not the DA's case, then its case must be that there is a plan, but that it is somehow inadequate in its "prepar[ation] and implement[tation]". I am advised and submit that this is premature and, in any event, legally unsustainable. The DA cannot point to any evidence that the administering of the vaccines has been flawed or delayed. At the time of the launch of the application, there were no vaccines yet to administer as none had yet arrived – for the reasons I have spelt out in considerable detail in what follows.

11.4 In any event, the DA's criticisms of the implementation programe are without merit.

12 The DA's fourth main line of attack is an allegation that government has not been sufficiently transparent in its vaccine plans.

12.1 This affidavit again demonstrates that this is incorrect.

12.2 The President, the Minister of Health and numerous public officials have had repeatedly and extensively provided information to the public via a variety of forums, including formal speeches, briefings to the

media, interviews and a slew of documents placed on the Government's website. There is a portal on the Government's website that is dedicated to information relating to Covid-19.

12.3 Having regard to the constantly and rapidly changing nature of developments around Covid-19 vaccines, the criticism levelled is without any merit – even if it could theoretically justify the relief (which it cannot).

13 In what follows, I deal with the following issues in turn:

13.1 South Africa's vaccine strategy;

13.2 The three channels being used by South Africa to procure the vaccines;

13.3 The DA's attempt to rely on vaccine rollouts in other countries;

13.4 The plans to administer the vaccines; and

13.5 The complaint about transparency.

SOUTH AFRICA'S VACCINE STRATEGY

14 The Covid-19 pandemic is unprecedented in a number of ways, at least in our lifetime.

14.1 First, there is the extraordinary speed with which the pandemic came about and affected countries around the world. This speed has meant that for much of 2020, medical research was outpaced by the rapid spread of the virus which left health workers and policy makers at a

disadvantage. Our understanding of the virus and the best manner of dealing with it changed constantly during 2020 and continues to do so, as the results of additional scientific studies and investigations become available. This is demonstrated, for example, by the identification of new variants of the virus in late 2020 and the outcome of recent studies on the effect of AstraZeneca on one of those variants.

14.2 Second, there are the extraordinary efforts that have been made by a wide range of vaccine manufacturers to develop a vaccine to deal with the Covid-19 pandemic. The development of a vaccine normally takes in excess of ten years and normally involves a very high failure rate – sometimes estimated upwards of 90%. In respect of Covid-19, vaccine development efforts have taken place at an unprecedented pace and on an unprecedented scale, despite the inherent uncertainties in such efforts. Some vaccines have already been abandoned after testing. Many others remain in the development or testing stages. A very small handful have reached the end of the development and testing stages and have recently been given final approval for various countries. Only one has been approved thus far for non-trial use in South Africa.

14.3 Third, there has been an unprecedented level of competition between countries around the world for the limited vaccine supplies that have begun to be made available over the past few months. Because every country is desperate to protect its citizens, every country is seeking access to the vaccines available – despite the very limited supply of vaccines that is presently available. This has led to intense competition

in what may fairly be termed a "sellers' market" and where the largest and most well-resourced countries have massive and obvious advantages.

15 In this context, no country can afford to have a fixed or rigid strategy for procuring and distributing vaccines. To do so would be utterly counter-productive and irresponsible. Instead, what is required is a constantly evolving vaccine strategy that takes account of the latest scientific developments, the latest information regarding which vaccines are effective against which variants, the question of which vaccines are appropriate for which country conditions and the actual availability of the given vaccines in the context of the unprecedented competition between countries for access to them.

16 That is precisely the approach that the NDoH has adopted. This is made clear by considering Government's vaccine strategy as it has been developed over the last few months.

17 The DA appears to fail to understand this, despite the wealth of information that the NDoH and other role players in Government have made available in the public domain.

The initial discussions with vaccine manufacturers

18 The DA appears to contend that Government took no steps to engage with vaccine manufacturers until after 6 January 2021. This is not true.

19 As the President and other members of government and the NDoH have repeatedly made clear in the public domain, discussions with various vaccine manufacturers did not only begin in January 2021.

20 Instead, and as I explain in more detail below, discussions with these vaccine manufacturers took place throughout the second half of 2020, beginning as early as 24 July 2020.

21 These were initial discussions aimed at understanding whether and on what basis the manufacturers would be prepared to contract with the NDoH directly to supply vaccines to South Africa.

22 These initial discussions took place before the manufacturers had completed phase 3 clinical trials and even before the appointment of the Ministerial Advisory Committee on Vaccines ("**VMAC**"). During the period July to December 2020 discussions were held with Pfizer, Johnson and Johnson, Gamaleya Institute, Serum Institute, Covax and Moderna.

The appointment of the VMAC

23 On 14 September 2020, the Minister of Health ("**Minister**") announced through the media the establishment of the Ministerial Advisory Committee on Vaccines ("**VMAC**"), a multi-disciplinary collective of experts that was tasked to develop the national Covid-19 vaccine strategy for the acquisition of vaccines as soon as they become available.

24 The VMAC also advises the government on all issues pertaining to Covid-19 vaccines. These include the development and rollout, guidelines on purchasing and critical international developments.

25 The VMAC is chaired by Professor Barry Schoub. I pause to mention that Professor Schoub is an expert the field. He is widely regarded as one of South Africa's leading virologist and vaccinologists. A copy of his curriculum vitae is attached marked **Annexure SB1**.

26 The other members of the VMAC are:

26.1 Dr Anban Pillay, the Deputy Director-General of the NDOH;

26.2 Dr Morena Makhoana, the CEO of Biovac;

26.3 Ms Glaudina Loots, of the Department of Science and Innovation;

26.4 Dr Boitumelo Semete-Makokotlela, the CEO of SAHPRA;

26.5 Prof Greg Hussey, of Vaccines for Africa;

26.6 Prof Jeff Mphahlele, an immunologist of the Medical Research Council and the board of SAHPRA;

26.7 Prof Helen Rees, an expert adviser to the WHO; Gavi the Vaccine Alliance and the Coalition for Epidemic Preparedness Innovations;

26.8 Prof Ames Dhai, an ethicist;

26.9 Dr Mark Blecher, of National Treasury.

27 There are four observers who also sit on the VMAC:

27.1 Prof Salim Abdool Karim, the Chairperson of the MAC on Covid-19;

27.2 Bishop Malusi Mpumlwana, the Chairperson: Multi-Sectoral MAC on Social Behaviour;

27.3 Dr Angelique Coetzee, the Chairperson of the South African Medical Association; and

27.4 Dr Owen Kaluwa, the World Health Organisation's South African representative.

The first VMAC advisory – on COVAX

28 On 17 September 2020, the VMAC publicly issued its first advisory, dealing with the participation of South Africa in the Covid-19 Vaccines Global Access (COVAX) facility. A copy is attached as **Annexure SB2.** The VMAC made a series of recommendations, which appear from the advisory. These included that:

28.1 South Africa should participate in the COVAX facility;

28.2 South Africa should do so via the "Committed Purchase" option;

28.3 The commitment made by South Africa in this regard should be to purchase sufficient vaccines for 10% of its population though the COVAX facility; and

28.4 South Africa should continue with its current ongoing bilateral discussions with vaccine manufacturers.

29 Though the VMAC is, as its name suggests, an advisory body, the NDoH has followed and effected all of these recommendations. I deal with the steps taken in this regard and the likely delivery date of vaccines under the auspices of COVAX below.

30 For now it suffices to say that, in accordance with the VMAC's advice, on 10 December 2020, South Africa formally registered that as part of the Covax facility for purposes of obtaining vaccines sufficient to cover 10% of the South African population – that is approximately 6 million people. As I explain below, the requisite deposit was paid shortly thereafter.

The Vaccine Strategy

31 On 15 December 2020, the NDoH publicly issued a policy document entitled "COVID-19: Vaccine Strategy". A copy is attached as **Annexure SB3.** I refer to it as the Vaccine Strategy.

32 In developing the Vaccine Strategy, the NDoH was alive to the devastating effects that Covid-19 has had and continues to have on both the economy and human life, as well as the intersection between the two, and the need for vaccines to be used in combatting this.

33 By December 2020, when the Vaccine Strategy was finalised, about 58 out of about 260 vaccines against Covid-19 in development were in the clinical evaluation phase.

34 The Vaccine Strategy recorded that four vaccine trials had reported preliminary efficacy data ranging from 62-95%.

34.1 However, as I explain below, the NDoH had decided, for very good reason and in accordance with the advice of the VMAC, to await the outcome of stage 3 trial results before concluding any agreements with individual manufacturers.

34.2 But by the time that the Vaccine Strategy was developed and published only two vaccines (Pfizer and Moderna) had published stage 3 trial results, both during November 2020.

34.3 There were several other vaccines at different stages of trials, including some with stage 3 trial results expected imminently. Some of these vaccines were anticipated to be more suitable for South Africa. They included AstraZeneca. (The AstraZeneca stage 3 trial results were in fact published on the same day as the Vaccine Strategy).

34.4 This meant that, at the time that the Vaccine Strategy was developed and published:

34.4.1 The NDoH had not yet concluded any direct agreements with manufacturers for the provisions of vaccines;

34.4.2 The NDoH anticipated doing so in the near future, depending on the stage three trial results that were awaited; and

34.4.3 South Africa was already part of the COVAX programme, but there was not yet clarity on precisely when the vaccines

anticipated to be delivered via the COVAX programme would arrive.

35 In this context, the Vaccine Strategy was developed and adopted in order for South Africa to be able to secure access to and delivery of, safe and effective Covid-19 vaccines as soon as they became available.

36 To that end, the Vaccine Strategy listed five objectives. These were:

36.1 sufficient supply and adequate access to a safe and effective vaccine to achieve population immunity to Covid-19;

36.2 protection of vulnerable population groups from acquiring Covid-19;

36.3 contribution to South Africa's social and economic recovery following the negative impact of Covid-19;

36.4 enhancement of South Africa's preparedness for response to future disease outbreaks; and

36.5 development of a comprehensive communication programme developed with civil society and the media, to address vaccine hesitancy and increase vaccine confidence.

37 The Vaccine Strategy compromised six elements:

37.1 research and development;

37.2 purchase agreements;

37.3 support for local manufacturing;

37.4 regulatory approvals;

37.5 immunisation administration and monitoring;

37.6 selection criteria for vaccines.

Research and Development

38 With regard to the first element, research and development, the Vaccine Strategy notes South Africa's "*world-class clinical, sociological, epidemiological, and laboratory research expertise*" as the basis for "*the development of a wide-ranging research agenda for Covid-19 including vaccine development.*" In other words, South Africa boasts a number of institutions and laboratories that have for years developed and manufactured vaccines. (I explain below that one of these is Biovac, which the NDoH has contracted with in order to ensure that vaccines which arrive in the country are properly received, handled and distributed throughout the provinces.)

39 Because South Africa has these capabilities, the government allocated about R95 million towards the development of Covid-19 "*vaccines, treatments, therapeutics, and diagnostics*" by the various institutions. The South African Medical Research Council is managing the funding in relation to:

> "*research activities targeting the clinical evaluation of potential treatments and vaccines against Covid-19; development of antiviral therapies for Covid-19; and the improvement of the health system's response to Covid-19 and future pandemics.*"

40 This means that some of the funding was allocated to ensure that South Africans participates in clinical trials for the various vaccines. Doing this was important because it provided an opportunity to determine whether the different vaccines would have efficacy in South Africa, and that they would be appropriate for the South African context and circumstances. For example, South Africa has a high percentage of the population living with HIV.

Purchase agreements

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

41.1 through the Covax facility; and

41.2 by concluding purchasing agreements with individual vaccine producers.

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

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

Regulatory approvals

44 In terms of the Medicines and Related Substances Act 101 of 1965 ("**Medicines Act**"), a vaccine can only be used in South Africa once it has been approved by the South African Health Products Regulatory Authority ("**SAHPRA**").

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

45.1 an early engagement with the SAHPRA;

45.2 putting in place accelerated procedure for authorisation;

45.3 adopting flexibility in relation to labelling and packaging requirements.

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

Immunisation administration and monitoring

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

48 On the advice of the VMAC, contained in its second advisory, the Vaccine Strategy recommended that specific high-risk groups be identified to receive the

vaccine before the third quarter of 2021. In identifying the high-risk groups, the Vaccine Strategy relies on a framework of prioritisation and need.

49 This included identifying, classifying and prioritizing high- risk groups, such as:

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

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

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

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

50 It also emphasised that the introduction of a new vaccine into the immunisation programme provides an opportunity for health system strengthening and integration of health services. The Vaccine Strategy recorded that a National Technical Working Group for COVID-19 vaccine introduction had been

established to plan and coordinate the vaccine introduction in line with the strategic objectives of the NDoH.

Selection criteria for vaccines

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

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

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

51.3 Epidemiology at the time of vaccine introduction i.e. no cases, clusters of cases, community transmission.

51.4 The ability to secure vaccine in 2021 and possible amounts of a vaccine available over time.

51.5 Cost of the vaccine, the amount of financing requested, the schedule, and conditions of the related payments.

51.6 Liability attached to specific vaccines.

51.7 Capacity to supply through the development of production capacity.

51.8 Vaccine presentation and suitability for the South African market.

51.9 Local registration is a requirement.

51.10 Ease of introduction into programmes including cold chain requirements, single or multidose vials, risk of wastage, storage space requirements, etc.

The second and third VMAC advisories

52 On 15 December 2020, the VMAC issued two further advisories. These were:

52.1 An advisory on key considerations in the selection of Covid-19 vaccines, a copy of which is attached as **Annexure SB4**; and

52.2 An advisory on the framework for rational allocation of Covid-19 vaccines, a copy of which is attached as **Annexure SB5**.

53 I do not deal with the details of the advisories at this stage. Suffice it to say that both were accepted by the NDoH and fed into the Rollout Strategy which I set out below.

The Rollout Strategy

54 On 3 January 2021, the NDoH published its "Covid-19 Vaccine Rollout Strategy". A copy is attached as **Annexure SB6.** I refer to it as "the Rollout Strategy".

55 The Rollout Strategy was developed in close collaboration with the VMAC.

Leadership and co-ordination

56 The Rollout Strategy sets out details of how the vaccine rollout will be lead and co-ordinated.

57 It explains that the vaccine rollout will be lead nationally and in close coordination with provincial health departments and the private healthcare sector.

58 Coordination of the roll-out through the different phases will be facilitated by the national vaccine coordinating committee, which was established by the NDoH and chaired by Dr Bamford. It comprises representatives from different clusters as follows:

58.1 Expanded Programme for Immunisation (**EPI**);

58.2 Communicable Disease Cluster (**CDC**);

58.3 Medicines, Supply Chain Management (**SCM**);

58.4 Information Systems, Human Resources for Health (**HRH**);

58.5 Primary Health Care (**PHC**);

58.6 Monitoring and evaluation;

58.7 The chair of the provincial co-ordinating committees;

58.8 The chair of the national private sector, co-ordinating committee; and

58.9 The World Health Organisation.

59 At the provincial level, coordination will be through committees that are appointed by the Heads of Departments in the different provinces, and with representation from:

59.1 EPI;

59.2 CDC;

59.3 SCM;

59.4 HRH;

59.5 PHC;

59.6 Monitoring and evaluation; and

59.7 the provincial private sector co-ordinating committee.

60 The Rollout Strategy also requires provinces to establish structures at the district level in order to manage the mass vaccine roll-outs.

61 The Strategy contemplates the participation of the private health sector through a co-ordinating committee, that will include medical schemes, private hospital associations, pharmacies groups, general practitioners and specialist associations, nursing associations, allied health professions associations, logistics providers, pharmaceutical manufacturers, employers, labour unions, and business associations.

A phased approach and the identification of priority groups

62 The Rollout Strategy explains the phased approach that will be used in the roll-out strategy and how groups are to be prioritised in this regard.

63 It provides for the three phases of vaccine rollout. These are:

63.1 *Phase 1:* to provide the vaccine to 1 250 000 front line health care workers;

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

63.2.1 2 500 000 essential workers;

63.2.2 1 100 000 persons living in congregate settings;

63.2.3 5 000 000 persons who are over the age of 65 years; and

63.2.4 8,000,000 persons who are over the age of 18 years and who have Covid-19 co-morbidities.

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

64 The strategy contemplates that the supply of vaccines may improve with the time. In that case, the distribution of vaccines will be adjusted in correlation with the increased supply. This translates to more people being given access to the vaccine more quickly.

The plan for administering the vaccines

65 The Rollout Strategy also dealt with how the vaccines would be roll-out and administered. I return to this issue below.

THE THREE CHANNELS BEING USED TO PROCURE THE VACCINES

66 South Africa's procurement of vaccines must be seen within a greater context. There has been a struggle for African countries (especially) in procuring vaccines from manufacturers or otherwise pharmaceutical companies. President Ramaphosa has continuously highlighted this in his capacity as the co-chair of the Access to COVID-19 Tools Accelerator (Act-A) ("**ACT-A**"). In his statement to ACT-A, he emphasised that:

> "We cannot achieve universal health coverage when the COVID-19 vaccine is available only to countries that are well resourced in terms of research, manufacturing, distribution and service."

67 A copy of the President's statement is attached as **Annexure SB7**.

68 Indeed because of the unprecedented competition for vaccines, there have been disputes even between developed countries on this issue, even where developed countries had advance purchase orders prior to stage 3 trial results being released.. For example, it has been widely reported that the European Union has threatened to take Pfizer to court for at least two reasons. The first is that Pfizer promised to deliver a particular number of doses but was not able run up their capacity to meet that commitment, and the second relates to a complaint that

too many vaccines were given to the United Kingdom, despite the fact that the EU had procured these vaccines in advance.

69 Against this backdrop and, as was publicly announced by the President in early January 2021, the Government is using three channels to procure vaccines. I deal with each in turn.

The first procurement channel – obtaining vaccines via the COVAX facility

70 The first way in which the NDoH is proceeding to obtain the vaccines is via the Covax facility.

71 The Covax facility is part of a global collaboration which aims to accelerate the development and manufacture of Covid-19 vaccines, as well as to guarantee fair and equitable access for every country in the world. It was launched in April 2020.

72 It is part of the Act-A partnership launched by the World Health Organization ("**WHO**") and partners. I have noted above that the ACT-A partnership is co-chaired by the President of South Africa. He has been very active in that capacity, because he represents both South Africa and the African Union ("**AU**") in this regard. President Ramaphosa oversees the AU strategy for vaccine procurement and deployment in relation to Covid-19.

73 The Covax facility was created to establish a pooled procurement mechanism to secure adequate and equitable supplies of vaccines at competitive prices for countries throughout the world, irrespective of their wealth status. In other words,

it works by pooling vaccine volumes and funds from numerous countries and then seeking to contract with vaccine manufacturers, leveraging off economies of scale. This seeks to avoid the risk that smaller and less wealthy countries (including countries like South Africa) will not have the leverage and resources to engage in negotiations and agreements with vaccine manufacturers as effectively as wealthier countries.

74 While the DA's approach effectively appears to write off the Covax facility in favour of exclusively direct contracting with manufacturers, this approach is not sustainable. The Covax facility is critical for ensuring equitable access to Covid-19 vaccines for countries around the world. This in turn is essential as a method of combatting Covid-19, which is a global pandemic – rather than a local or national epidemic.

75 Under the Covax facility, and as was explained in the first VMAC advisory referred to earlier, self-financing countries (including South Africa) can procure vaccines through one of two avenues.

75.1 The first is by means of a committed purchase. This options requires participating countries to make an upfront payment of about 10%, and then to make a firm offer and guarantees to procure doses of vaccines from the Covax facility without an option to opt out of specific vaccine candidates.

75.2 The second option is the optional purchase, in terms of which participating countries make a larger upfront payment, but can opt-out

of vaccine allocations while they still reserve the option for later vaccines.

76 On the advice of the VMAC, South Africa chose to participate in the committed purchase option and did so in respect of 10% of its population (6 million people).

76.1 The preference for the committed purchases option was because the down payment for the opt-out option was quite large. South Africa thus elected to go with the committed purchase option.

76.2 Once that decision was made, the next question was how many vaccines to commit to from the Covax facility. The figure of 10% was considered appropriate because it was (a) relatively affordable; (b) would ensure that South Africa had catered for especially high-risk groups; and (c) South Africa did not want to be too over committed because it was already having bilateral negotiations with the manufacturers themselves.

77 Accordingly, on 10 December 2020, South Africa formally registered to participate via the Covax facility and to obtain vaccines sufficient to cover 10% of the South African population – that is approximately 6 million people.

78 South Africa was then required to make a down payment to participate in the facility.

78.1 This down payment of $19.2 million (R283 million) was paid on 21 December 2020 by the Solidarity Fund; a fund that was created as South Africa's rapid response vehicle in the fight against Covid-19.

78.2 The payment was made by the Solidarity Fund at the request of the National Government, as this would avoid delays that could have resulted from National Government itself making the payment.

78.3 I emphasise that by at the time the Solidarity Fund made the payment, the Government had already committed that it would cover the remainder of the costs of the vaccine doses concerned, when these came due.

78.4 In this regard, I attach as **Annexure SB8** the decision of National Treasury approving the necessary procurement deviation for the purchase through the Covax facility.

79 The concerns in the media that the delivery the vaccines from Covax would be delayed because Government had "missed" the deadline for paying the deposit, were regrettably not correct.

79.1 It is quite clear that South Africa will be receiving vaccines via the Covax facility as part of the first batch of COVID-vaccine distributions. This appears, for example, from **Annexure SB9**, a copy of the "*Covax Facility: Interim Distribution Forecast*" (dated 3 February 2021).

79.2 As part of the first batches of Covax vaccine doses, South Africa is due to receive 117,000 of the Pfizer vaccine at the end of February 2021 and 2,976,000 doses of AstraZeneca in March/April 2021.

79.3 (The question of whether South Africa should proceed with the AstraZeneca doses or seek to make an alternative arrangement will have to be given careful consideration in the near future as I explain below.)

The second procurement channel – obtaining vaccines via the African Union

80 The second way in which the NDoH is seeking to obtain vaccines is via the African Union (AU).

81 The African Union is in the process of concluding agreements with certain manufacturers whereby vaccine doses will be allocated to the AU for distribution between its member states. The AU vaccine acquisition task team has managed to procure 270 million vaccine doses, which are likely to be made available during the second half of 2021.

82 There is not yet finality around the AU process or how doses between the various countries will be divided. Discussions and arrangments regarding the distribution of doses have not been concluded within the AU process. However if, for example, the vaccines were to be distributed in accordance with the relative population size of each country in the AU this would mean that South Africa would be entitled to contract for 4.7% of the doses – approximately 12 million doses.

The third procurement channel – obtaining vaccines via direct agreements with manufacturers

83 The third way in which the NDoH is obtaining vaccines is via direct agreements with vaccine manufacturers.

84 As I have explained, discussions with these manufacturers began as long ago as July 2020, well before phase 3 trials had been concluded and phase 3 trial results published.

85 However, in accordance with the advice of the VMAC, the NDoH did not conclude agreements with any manufacturer until after that manufacturer had successfully completed a stage 3 trial for the vaccine concerned. The reasons for this approach require brief explanation.

86 Vaccine development is a lengthy, difficult and uncertain process. The development of a vaccine normally takes in excess of ten years and normally involves a very high failure rate – sometimes estimated upwards of 90%. In other words, there is less than 10% chance of a given vaccine succeeding and only a very small number of proposed vaccines ultimately end up succeeding.

87 Vaccines must generally go through three stages of trials successfully before they can be registered and used for the public. Broadly speaking the stages are as follows:

87.1 During stage 1 trials, the vaccines are tested in a small group of healthy adults (which could be from 20 – 80 people). This is done to evaluate safety ad measure the immune response received.

87.2 During stage 2 trials, the vaccines are tested in a broader group of healthy persons (hundreds of people) to provide additional safety information on common short-term side effects and risks, to examine the relationship between the dose administered and the immune response, and to provide initial information regarding the effectiveness of the vaccine in its ability to generate an immune response.

87.3 During stage 3 trials, a significantly larger group of vaccine subjects (thousands of people) is used. The stage 3 trials aim to establish the safety and efficacy of the vaccine – in other words that it is safe to be used and effective in combatting the disease concerned.

88 Some countries, especially developed countries, opted to place advance purchase orders with vaccine manufacturers even before the vaccines concerned had passed stage 3 trials.

88.1 This involved them paying very substantial sums of money – literally billions of dollars – at that stage.

88.2 The advantage for them of this approach was that, if the vaccine concerned passed stage 3 trials (and if it was authorised for use by the relevant regulatory bodies), then these countries would be at the front of the queue for purposes of receiving doses of that vaccine.

88.3 However, the disadvantage and risk of this approach was that if the vaccine did not pass stage 3 trials or was not authorised for use by the relevant regulatory authorities or proved less effective than hoped, the money paid would be forfeited and little or no benefit would be obtained.

89 For developed countries with substantial resources available, the approach of these advance purchase orders made sense. They could take the risk of a "bet" on a particular vaccine or vaccines because, in the event that the vaccine failed, they could afford to absorb the substantial wasted sums.

90 However, South Africa is not such a country.

90.1 South Africa intends to pay very substantial sums to procure vaccines and intends to do so – in January 2021 Government estimated a total cost in excess of R20 billion for just 67% of the population. But this does not accounted for wasted funds on unsuccessful "bets".

90.2 After consulting the VMAC, the Government took the stance (which it maintains) that South Africa could not and cannot afford to risk wasting such substantial money by purchasing and paying for vaccines that had not yet passed stage 3 approvals.

90.3 On the contrary, given the need for massive and rapid expenditure on the procurement of vaccines and the roll-out of those vaccines, it was and is imperative that South Africa maintained all of its available

resources to procure and distribute vaccines that had been shown via stage 3 trials to be effective.

91 The rationality and reasonableness of this approach is especially clear when one considers the startling number of vaccines being developed and the unpredictability of which vaccines will succeed first.

91.1 There are presently at least 295 Covid-19 vaccine candidates which are undergoing or have undergone some form of assessment. 72 of these are in clinical testing.

91.2 Only a very small number have now successfully passed stage 3 trials – all within the last three months, the earliest being Pfizer on 9 November 2020.

91.3 It was impossible at the time to say in advance, within any degree of confidence or certainty, which particular vaccines would likely get past phase 3 trials and which would do so first.

91.4 For example, on 10 December 2020, it was reported that an Australian vaccine had encountered problems in clinical trials. By then the Australian government had already purchased 50 million doses of that vaccine.

91.5 On the next day, 11 December 2020, it was reported that two of the largest drug manufacturers in the world – Sanofi and GlaxoSmithKline Plc – announced that they had delayed advanced trials of their vaccine after it failed to produce a strong enough immune response in older

people, pushing its earliest potential availability to the 2022. This followed the public announcement in July 2020 that the United States government would provide up to $2.1 billion to fund the development of the vaccine and including delivery of an initial 100 million doses.

91.6 Nor are these the only vaccine giants that have run into difficulties. The company Merck is rightly described as a "vaccine titan" given that it has been in the vaccine business for many years and has developed some of the world's most well-known vaccines for other diseases.

91.6.1 As the New York Times explained in an article on 10 February 2021 (attached as **Annexure SB10**):

> *"[W]hen the company announced last May that it was a late entrant in the race to develop a Covid-19 vaccine, Merck was a popular pick to win. Even if the company wasn't first, proponents argued, its expertise as the world's second-largest vaccine maker gave it a good shot at developing the best product — and manufacturing it quickly."*

91.6.2 However, contrary to these expectations, in January 2021, Merck then exited the Covid-19 vaccine race when its two vaccines did not do well in clinical trials.

91.7 The point I make is clear: it is impossible to predict, in advance, which vaccines are most likely to succeed and when.

91.8 It is for this reason that developed countries which have opted for these advance purchase agreements have had to place advance purchase

orders with a series of different manufacturers – to spread their bets in the hope that some come off.

91.9 For example, it is reported that Canada, which has a population of 38 million, has contracts for 234 million doses across at least seven different companies – without even including the vaccines it agreed to buy through the Covax consortium.

91.10 A country like South Africa simply cannot afford to adopt this approach.

92 The approach of the Government, in line with the advice of the VMAC, was therefore that it would not enter into any purchase agreements with manufacturers until the phase 3 trials for the relevant vaccine had been successfully passed.

93 Even then, the mere fact that the phase 3 trial for a given vaccine had succeeded could not mean that the government would immediately conclude an agreement with the manufacturer. Instead in determining which vaccines to contract for and in what quantities, careful consideration had to be given to a range of issues, including:

93.1 The actual availability and timing of the vaccine delivery – having regard to factors such as how willing the manufacturer was to supply South Africa, how many pre-purchase orders had been made, the remaining capacity of the supplier and so on;

93.2 Whether regulatory approvals had been issued for the vaccine in other jurisdictions – which would assist with fast-tracking the regulatory approval process required in South Africa via SAHPRA;

93.3 The ease of use and schedule – in particular whether one dose per person or two would be required;

93.4 The requirements for stability during storage distribution – for example some vaccines such as Pfizer require storage at minus 70 degrees Celsius; and

93.5 Cost associated with the vaccine.

94 In order to best utilise these factors to ensure that the vaccines selected were most suitable for South Africa it was obviously preferable not merely to contract for whichever vaccine first happened to pass stage three trials but to seek to survey the broader vaccine options.

95 Having done so over the last few months of 2020, it was on 6 January 2021 that NDoH applied to the National Treasury for the necessary deviation to conclude agreements with vaccine manufacturers. It referred to four vaccine manufacturers:

95.1 Pfizer;

95.2 Moderna;

95.3 AstraZeneca (via the Serum Institute of India); and

95.4 Johnson & Johnson.

96 A copy of the deviation request is attached marked **Annexure SB11**. It was approved by National Treasury on the same day. A copy of the approval letter is attached marked **Annexure SB12.** The NDoH was also granted authorization to engage other manufacturers and, as stock became available, to secure the vaccines.

97 Against this backdrop, I turn to deal with the various vaccines that South Africa has considered procuring the latest position in respect of each. I must emphasise, however, that this is a fluid and constantly moving situation.

The AstraZeneca vaccine

98 The AstraZeneca vaccine requires two doses, that are 12 weeks apart, and needs to be stored in a refrigerator for a period of up to six months.

99 The AstraZeneca vaccine's phase three trial results were released on 8 December 2020. They indicated a success rate of 70.4%.

100 The AstraZeneca vaccine was first given emergency authorization in the United Kingdom and Argentina on 30 December 2020. It was approved in India (as Covishield) on 3 January 2020. On 22 January 2021, the SAHPRA granted a section 21 authorisation in terms of the Medicines Act for the AstraZeneca vaccine to be used against Covid-19.

101 The Government first engaged with the Serum Institute of India ("**SII**") regarding the possibility of South Africa being supplied with the AstraZeneca vaccine on 14

September 2020. The people representing Government in the subsequent engagements were Dr Anban Pillay and Ms Khadija Jamaloodien.

102 The role of the SII requires brief explanation. AstraZeneca stated that it wanted to enable broad and equitable access to its vaccine and that it does not have capacity to supply all countries with the vaccine. It therefore sub-contracted the production to a range of suppliers and producers across the world, and then allocated these producers to particular markets. The SII was allocated to the South African market. The implication of this allocation was that instead of contracting with AstraZeneca directly, South Africa contracted with the SII for the vaccine.

103 Following the release of the Phase 3 trial results in December 2020 and the Treasury deviation approval on 6 January 2021, extensive negotiations were entered into with SII around certain provisions of the proposed term sheet and agreement. These included, in particular, certain requirements that South Africa indemnify SII in respect of future claims. A copy of a fact sheet issued by National Treasury on this score is attached marked **Annexure SB13.**

104 On 7 January 2021, the term-sheet between the NDoH and SII was signed. This was followed by the purchase agreement, which was signed on 18 January 2021. It provided that:

104.1 One million doses would be shipped during January 2021; and

104.2 500 000 doses would be shipped during February 2021.

105 The one million doses were duly shipped on 31 January 2021 and arrived on 1 February 2021.

106 However, regrettably, our ability to make use of these doses has been undermined by disappointing trial results.

106.1 The NDoH had relied on the stage 3 trial results of AstraZeneca to conclude the agreement. These had a 70.4% success rate.

106.2 But in December 2020, it was announced that a new Covid-19 variant (501Y.V2) was detected in South Africa, and that it was rapidly spreading in three provinces: the Eastern Cape, Western Cape, and KwaZulu-Natal. The genomic data highlighted that the 501Y.V2 variant quickly displaced other lineages circulating in South Africa.

106.3 This was not mainly the variant that the AstraZeneca stage three trials had involved. Accordingly, a concern was expressed as to whether the AstraZeneca vaccine would still be effective in South Africa.

106.4 The VMAC considered the issue and sought advice from overseas experts. These included the WHO and other experts from United Kingdom and the United States. Their advice was that the vaccine was likely to still be effective against the 501.YV2 variant. Given this and given the urgent need for vaccines, the agreement was concluded and the first million doses duly arrived.

106.5 However, on 7 February 2021, Dr Madhi announced the results of a study that he had been performing on the effectiveness of the

AstraZeneca vaccine, which included the 501Y.V2 variant. It concluded that the AstraZeneca vaccine provides reduced protection against mild to moderate Covid-19 infections from the 501Y.V2 variant. While the vaccine maintained its high efficacy against the original virus, it had an efficacy of 22% as against the 501Y.V2 variant.

106.6 This study is not the final word on the issue. It was a relatively small study and questions remain about whether the AstraZeneca vaccine might still provide effective protection against more severe Covid-19 infections in relation to the 501Y.V2 variant.

106.7 But this development meant that the roll-out of the AstraZeneca vaccine (which was due to happen on 15 February 2020) had to be put on hold so that further consideration can be begin on what approach to take. This is because the 22% efficacy results would not justify a roll-out of this vaccine.

107 In light of this, it was announced by Minister Mkhize in Parliament on 15 February 2021 that the AstraZeneca doses concerned will be offered to the African Union platform, for distribution to those countries who have already expressed an interest in acquiring the stock. This will also avoid any wasteful and fruitless expenditure.

<u>The Johnson & Johnson vaccine</u>

108 The Johnson & Johnson vaccine is a single vaccine dose. It also can remain stable in a refrigerator (at 2 to 8°C) for three months. It thus has very substantial

advantages over two of the other vaccines I mention in this section, namely the Pfizer vaccine and the Moderna vaccine.

109 However, the phase 3 Johnson & Johnson trial results came out much later than the other three vaccines I mention in this section. These results were only released as recently as 29 January 2021. There was an efficacy rate of 72% in United States, 66% in Latin America and 57% in South Africa for its vaccine.

110 Given the lateness of these trial results, the Johnson & Johnson vaccine has not yet been approved for use in foreign jurisdictions or South Africa. On 4 February 2021, Johnson & Johnson submitted an application to the Food and Drug Administration in the United States for emergency use authorization. Johnson & Johnson has submitted an application for registration to SAHPRA, which is still under review.

111 The Government first began engaging with Johnson & Johnson regarding the possibility of it supplying South Africa with the vaccine on 4 September 2020. The people representing government in these engagements were Dr Anban Pillay and Ms K Jamaloodien. Further extensive engagements followed in January 2021, even before the stage three trial results came out.

112 On 7 January 2021, a term sheet was signed between NDOH and Johnson & Johnson. The purchase agreement is being finalised and, in terms thereof, South Africa will receive 9 million doses of the vaccine. The Johnson & Johnson vaccine is being produced by Aspen in Port Elizabeth under licence from Johnson & Johnson.

113 In addition, given the disappointing results of the AstraZeneca study, the consequent pause in the distribution of the AstraZeneca vaccine and the urgent need to vaccinate healthcare workers, in particular, as soon as possible, the NDOH has now rapidly shifted strategy to make use of the Johnson & Johnson vaccine.

113.1 As indicated, on 7 February 2021, the disappointing results of the AstraZeneca study were announced. The NDoH and VMAC immediately considered those results and determined that in light thereof, the roll-out of the AstraZeneca vaccines purchased from the SII needed to be paused.

113.2 In an effort to minimise the delay caused to the vaccine programme and keep it on track, the NDoH engaged in urgent discussions with Johnson & Johnson.

113.3 Johnson & Johnson recognised the dilemma and stepped in at the NDoH's request to assist; it has agreed to provide 80 000 doses of the Johnson & Johnson vaccine every 14 days beginning almost immediately.

113.4 These vaccine doses are excess stock that had originally been produced for the Johnson & Johnson phase 3 trial. They are, from a scientific perspective, identical to the 9 million Johnson & Johnson vaccine dosages that will be purchased and rolled out in due course as referred to above.

113.5 Because of the very recent Johnson & Johnson phase 3 trial results (released on 29 January 2021), the Johnson & Johnson vaccine has not yet obtained formal approval from relevant regulators in other countries or SAHPRA.

113.6 However, at the request of the NDoH, on 12 February 2021, SAHPRA provided urgent approval that these Johnson & Johnson vaccines could be distributed via limited number of research sites, in conjunction with the Medical Research Council, as part of a phase 3B clinical trial.

113.7 The practical effect is that this will allow the Johnson & Johnson vaccines to be administered to health care workers.

113.8 The speed with which the NDoH, SAHPRA and other entities have managed to find a solution to the unanticipated news of the AstraZeneca results demonstrates the seriousness and urgency with which the Government is dealing with the vaccine issue.

The Pfizer vaccine

114 The Pfizer vaccine requires two doses, three weeks apart. It needs to be stored at –70°C at all times.

115 The Pfizer vaccine's phase three trial results were released on 9 November 2020. They indicated a success rate of 90% in preventing Covid-19 in participants without evidence of prior SARS-CoV-2 infection in the first interim efficacy analysis.

116 On 8 December 2020, the Food and Drug Administration ("**FDA**") in the United States released its independent analysis of the clinical trials, that determined the Pfizer vaccine's efficacy to be 95%. It was registered in the United Kingdom for emergencies only on 2 December 2020, and in the United States (also for emergencies only) on 11 December 2020. Pfizer has submitted an application for registration to SAHPRA, which is still under review.

117 The government first began engaging with Pfizer regarding the possibility of it supplying South Africa with the vaccine on 24 July 2020. The people representing government in these engagements included the Minister of Health, the Deputy Minister of Health, myself, Dr Anban Pillay and Ms Khadija Jamaloodien.

118 While the Pfizer stage 3 trial results were very positive, the vaccine suffers from certain disadvantages.

118.1 First, though I am not permitted to disclose precise prices, it is more than double the price of certain of the other vaccines.

118.2 Second, the Pfizer vaccine requires to be stored at -70 degrees. Given the equipment needed for this, this makes it more difficult to use the vaccine for mass vaccination than would be the case with certain of the other vaccines.

118.3 Third, the Pfizer vaccine needs to be diluted, which causes a reasonable proportion of wastage if not appropriately managed and reconstituted.

118.4 Fourth, the Pfizer vaccine uses a slightly different syringe; it uses a 0.3ml syringe which is not as easily available as a 0.5ml syringe in South Africa.

119 Given these drawbacks and after talking advice from the VMAC, the NDoH did not wish to rush into a mass purchase of the Pfizer vaccine after its phase 3 trial results were released in November 2020 and after its registration in December 2020.

120 Ultimately, however, having fully considered the options available, it was determined in January 2021 that Pfizer was an appropriate vaccine to purchase as a part of the vaccines to be distributed.

121 Accordingly, on 15 January 2021 a term sheet was signed between the NDOH and Pfizer involving the supply of 20 million doses of the vaccine. The purchase agreement is being finalised. South Africa is not confined to only 20 million vaccines, it can order more. Careful consideration will have to be given to whether to do so, given the challenges in storing the vaccine and the limitations of South Africa's storage capacity in this regard.

122 The formal delivery schedule has not been finalised and provided by Pfizer yet, but in terms of a verbal commitment, the vaccines will start arriving in May 2021, likely as follows:

122.1 2 million doses in May;

122.2 1.5 million doses in June;

122.3 1.5 million doses in July;

122.4 1.5 million in August;

122.5 1.5 million doses in September;

122.6 2.5 million doses in October;

122.7 2.5 million doses in November;

122.8 3.5 million doses in December;

122.9 3.5 million doses in January 2022.

123 That would bring the total vaccine doses procured directly from Pfizer to 20 million. South Africa is also due to receive 117 000 Pfizer vaccines through the Covax facility. These are expected to arrive in February.

The Moderna vaccine

124 The Moderna vaccine is administered in two doses, four weeks apart. It can be refrigerated for up to 30 days, or up to six months frozen at - 30°C.

125 On 16 November 2020, Moderna announced its stage three trial results, which produced 94.5% efficacy.

126 On 18 December 2020, the Food and Drug Administration in the United States authorized the Moderna vaccine for emergency use, followed by Canada on 23

December 2020, and Israel on 4 January 2021. Moderna has not yet filed any dossier with SAHPRA for its registration.

127 Following the stage 3 trial results of 16 November 2020, the government began engaging with Moderna regarding the possibility of it supplying South Africa with the vaccine. This began on 21 December 2020 when Minister Mkhize met with Moderna.

128 During the engagements, in which Dr Pillay also participated after that initial meeting, Moderna indicated that the earliest they could supply the vaccine would be the third quarter of 2021. However, the DOH continued to negotiate for an earlier delivery date. At this stage, the latest offer from Moderna is that 20 million doses would be made available – predominantly in quarter three; but 300 000 in quarter two. The negotiations continue.

129 I emphasise that South Africa is hardly alone in having to deal with these relatively long lead-times from Moderna. It has been widely reported that even substantially more resourced countries – such as the United Kingdom – are unlikely to obtain doses of Moderna until the second quarter of 2021 because the company has prioritised its commitments to the United States.

The way forward

130 I have set out the status of orders and negotiations with the four manufacturers identified.

131 However, it is important to emphasise that the NDoH is not limiting itself to these manufacturers. On the contrary, the NDoH continues to engage in negotiations with other vaccine manufacturers, including those in Russia and China to seek to ensure that vaccinations are provided as expeditiously as possible.

131.1 The NDoH has been engaging with Russia from the time that they developed their vaccine (Sputnik V). At that time (around October 2020), Russia had not done stage 3 clinical trials so the engagements could not proceed further. Russia's stage 3 clinical test results came out in the first week of February 2021. Now that these results are out and in light of the fact that the manufacturers have recently applied to SAPHRA for registration, the NDoH is giving serious consideration to whether the vaccine (given the manner in which it operates) is suitable for the South African context.

131.2 The NDoH has also had multiple discussions with the Chinese vaccine manufacturers (Sinovac and Sinopharm), which were facilitated via the Chinese embassy here.

131.3 The NDoH will do the same with any new manufacturers whose vaccines appears likely to assist. For example, the NDoH has been engaging with an Indian producer, Bharat Biotech which is manufacturing a vaccine. Though there are no phase 3 clinical studies yet (they are due in March 2021), the NDoH has decided to engage with such manufacturers now, in the hopes of being able to move speedily following phase 3 clinical trials that would justify procurement of the vaccines concerned.

132 Moreover, the NDoH is continuing to monitor developments elsewhere in the world and in South Africa to determine what additional orders to place with relevant manufacturers to fulfil the remainder of the vaccine doses required to reach herd immunity.

132.1 The recent developments regarding the 501Y.V2 variant and the AstraZeneca vaccine make plain that it would not be wise to, in advance, place even greater orders for vaccines immediately.

132.2 Rather, it is far better to ensure that the necessary flexibility and agility is maintained to obtain the most suitable and effective vaccines as quickly as possible as lessons are learned from the roll-out of vaccines here and across the world.

132.3 This is especially so given that, as I have explained, there are numerous other vaccines presently being developed beyond those already mentioned which could be suitable and expeditiously available.

THE DA'S ATTEMPT TO RELY ON VACCINE ROLLOUTS IN OTHER COUNTRIES

133 It is clear from what I have set out above that Government did not remain supine in relation to the vaccine issue. On the contrary, it was proactive and put in place clear vaccine strategies, including procurement strategies.

134 It is easy, with the benefit of hindsight, to say that if this or that step had been taken, it might have been possible to obtain vaccines somewhat sooner (though the DA has not remotely established this). But this is not the test for lawfulness,

rationality or unconstitutionality. It is clear from what I have stated above that the decisions and approach of Government have been careful and considered responses to difficult and unprecedented issue and have always been based on expert advice. The DA's case is therefore without merit.

135 Presumably in an effort to avoid these problems or to create atmosphere, the DA resorts to seeking to rely on how far other countries, are in rolling out vaccines. This is an inappropriate and untenable approach. Even if it were the case that a truly comparable country were further along than South Africa, this would not render the government's conduct irrational or unreasonable.

136 But in fact the DA's argument is entirely contrived. As I demonstrate in what follows, its comparisons are hollow because of the differences between South Africa and the countries it cites or because it omits critical facts which explain the differences.

137 The DA's founding affidavit begins by making reference to the five countries that had each administered two million doses or more of Covid-19 vaccines at the time that the application was launched.

137.1 It offers no explanation <u>at all</u> as to what it says these countries have done right as opposed to South Africa, beyond the bald (and quite incorrect) contention that South Africa waited until 6 January 2021 to engage in discussions with vaccine manufacturers.

137.2 This makes it almost impossible to respond meaningfully to the DA's case, save to say the following.

137.3 It appears clear that the United States, the United Kingdom and Israel all engaged in pre-orders with vaccine manufacturers. I have already explained why South Africa did not do so. Suffice it to say that South Africa does not have the luxury of the resources to do so, compared to these countries. (The resources of the United States and United Kingdom speak for themselves. Israel has a GDP per capita in excess of $40 000 – almost seven times the South African GDP per capita.)

137.4 In addition, Israel employs a mandatory public health digital network in terms of which health maintenance organisations keep digital records of all patients' medical data since birth; including details of past hospitalisations, prescribed medications and vaccinations. It appears that Israel leveraged its digitised system to secure additional doses from Pfizer by undertaking to provide Pfizer with its vast collection of vaccine data to enable the manufacturer to monitor the ongoing effects of the disease and the vaccine on citizens.

137.5 China is an equally bad comparator. It is a very large vaccine manufacturer and is using Chinese vaccines for its vaccine programme.

137.6 The reason India has been able to proceed so quickly, relatively speaking, is that the SII (the entity with which South Africa contracted for the AstraZeneca vaccine) is located in India and has serviced the Indian government prior to other countries. This is quite apart from the fact that its population size makes India one of the very largest vaccine purchasers in the world, giving it obvious advantages in negotiation.

137.7 These five countries are therefore patently bad comparisons.

138 The DA then tries to point to other countries that have administered vaccine dosages – even where some have done relatively small numbers of vaccine dosages – in an effort to criticize Government.

138.1 Again, the DA offers no explanation at all as to what it says these countries have done right as opposed to South Africa, beyond the bald (and quite incorrect) contention that South Africa waited until 6 January 2021 to engage in discussions with vaccine manufacturers.

138.2 Again, this makes it almost impossible to respond meaningfully to the DA's case, save to say the following.

138.3 The vast bulk of the countries concerned fall within the EU. The EU is one of the largest and most powerful and well-resourced economic entities in the world. Much of the vaccine procurement for the EU has been procured via the EU bloc. The EU used these advantages to engaged in pre-orders with vaccine manufacturers, with all the risks these entail.

138.4 The three Latin American countries referred appear to have benefitted primarily from a bulk purchase order agreement signed with AstraZeneca for various Latin American countries for 150 million dosages. This was facilitated and in part funded by Carlos Slim, Latin America's richest man who is himself worth in excess of $40 billion and included the right for Mexico and Argentina to manufacture vaccine doses to supply themselves and other Latin American countries.

138.5 Of the countries referred to by the DA, that leaves only Oman and the Seychelles.

138.5.1 Oman's GDP/capita is more than twice that of South Africa. In any event, it had administered 34 000 doses at the time that the application was launched, which has now grown to a total of 46 000 doses. This is less than South Africa plans to be administering every two weeks under the recent Johnson & Johnson arrangement which is about to begin bearing fruit.

138.5.2 The Seychelles had administered 20 000 doses at the time that the application was launched, which has now grown to a total of 50 000 doses. Again this is less than South Africa plans to be administering very shortly every two weeks under the recent Johnson & Johnson agreement. But what the DA ignores is that these doses have been donated to it by third parties. In December 2020, the United Arab Emirates donated 50,000 doses of the Sinopharm vaccine to the Seychelles and a further 50,000 doses of the AstraZeneca vaccine were donated to it by India.

138.5.3 The reliance that the DA seeks to place on the example of the Seychelles, is thus entirely misplaced.

139 In the circumstances, even if it were theoretically possible to evaluate the lawfulness of the Government's performance by comparing it to other countries (which it is not), the DA's arguments are entirely unsustainable.

THE PLAN TO ADMINISTER THE VACCINES

140 The second leg of the DA's case is its contention that the conduct of the National Government in preparing and implementing its programme to administer Covid-19 vaccines is irrational and unconstitutional.

141 I submit that this leg of the DA's challenge is entirely unfounded and does not get out of the starting blocks.

141.1 It appears that the DA may contend that the Government has no plan for administering the Covid-19 vaccines. If that is the DA's case, then this affidavit demonstrates that it is plainly unsustainable. There is plainly such a plan.

141.2 If that is not the DA's case, then the DA's case must be that the plan is somehow inadequate in its "prepar[ation] and implement[tation]". I am advised and submit that this is premature and, in any event, legally unsustainable. The DA cannot point to any suggestion that the administering of the vaccines is flawed or delayed. At the time of the launch of the application, there were no vaccines yet to administer as none had yet arrived – for the reasons I have spelt out in considerable detail.

141.3 So the DA effectively asks this Court to second-guess and declare invalid Government's plans for administering the vaccines where:

141.3.1 It can point to no specific practical problems experienced with the plan (because it still awaits full implementation, upon the arrival of the vaccines); and

141.3.2 Where the plan is by its very nature evolving and flexible to take account of the unprecedented challenges faced and the need to adjust speedily.

141.4 This is plainly untenable. If it is the case, once the vaccines arrive and are administered, that problems or delays are experienced in the plan, the NDoH will adjust it accordingly. If it fails to do so and problems persist, that is the very earliest moment that complaints could be made by the DA. (Though one would hope that, instead of playing politics via the courts around such a critical issue, the DA would seek to help resolve the problems constructively instead.)

141.5 I therefore submit that this Court does not even need to enter into the second leg of the DA's attack.

142 The DA's attack on this leg is unsustainable for another reason. Its attack is directed only at National Government.

142.1 Yet it is quite clear, even from the Vaccine Strategy and the Rollout Strategy, that it is ultimately each province that will have its own plan for distributing the vaccines allocated to that province. This is precisely the case.

142.2 The DA offers no evidence at all for its wide-ranging allegations about what the provinces do or do not know and whether they are prepared.

142.3 Indeed, a number of provinces (including Gauteng and the Western Cape) have come on public record saying that they are ready to roll-out the vaccines when they arrive.

143 Nevertheless, for the sake of completeness, I point out the following regarding the roll-out plans.

The plan in the strategy documents

144 It was clear already from the Vaccine Strategy and Rollout Strategy documents that the NDoH was actively involved in planning and preparing for the administering of the vaccines.

145 The strategy documents speak for themselves and I highlight only the following aspects for the sake of convenience.

146 The strategy document is clear that the vaccine rollout will be lead nationally and in close co-ordination with both the provincial health departments and the private healthcare sector. To facilitate delivery, the following Committees were contemplated by the strategy document:

146.1 a national vaccine co-ordinating committee established at the Department of Health by the Director General with representatives from various clusters involved.[1]

146.2 provincial co-ordinating committees, that are appointed by Heads of Departments ("**HOD**s");[2] and

146.3 a private health sector co-ordinating committee.[3]

147 All of these have been established, though a more up to date and complete list of the relevant committees is referred to below. In addition, each province has its own implementation team.

148 I referred earlier to the three different phases of vaccine roll-out. The strategy documents explain what platforms or venues will be used at each stage.

149 During phase 1, three places have been identified as most appropriate platforms or venues where people can access the vaccines. These are:

149.1 at places of employment, such as private and public hospitals;

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1 These representatives are from: the Expanded Programme for Immunisation ("EPI"), Communicable Disease Cluster ("CDC"), Medicines, Supply Chain Management ("SCM"), Information Systems, Human Resources for Health ("HRH"), Primary Health Care ("PHC"), Monitoring and evaluation; the chair of the provincial co-ordinating committees; the chair of the national private sector, co-ordinating committee; World Health Organisation; and Committee chaired will be chaired by Dr Bamford.

2 Representation on the provincial committees is from Expanded Programme for Immunisation(EPI), Communicable Disease Cluster (CDC), Medicines ,Supply Chain Management (SCM), Information Systems, Human Resources for Health (HRH), Primary Health Care (PHC), Monitoring and evaluation and the provincial private sector co-ordinating committee. Provinces will have to establish structures at district level to manage the mass rollout.

3 This committee includes which includes medical schemes, private hospital association, pharmacies groups, general practitioner and specialist associations, nursing association, allied health professions associations, logistics providers, pharmaceutical manufacturers, employers, labour unions, business associations

149.2 Through outreach vaccination programmes, where mobile teams move from facility to facility; and

149.3 vaccination centres, whether remote based on facility based (such as community pharmacies).

150 For phase 2 and phase 3, access to the vaccine is to be made available what the strategy refers to as general public service delivery platforms. These include:

150.1 ordinary public healthcare facilities, such as hospitals;

150.2 remote or facility-based vaccination centres, such as community pharmacies, general practitioners (doctors)'s offices, or non-governmental organizations ("**NGOs**").

150.3 outreach vaccination programmes which would be provided through mobile clinics. These would be most suitable for congregated settings, such as old age homes; and

150.4 work-based vaccination programmes which would be better suited to essential workers, for example in the mining sector.

151 The strategy documents make clear that security of the vaccines is important during the rollout stage. The following measures will be implemented to ensure security during distribution.

151.1 the vehicles carrying the vaccine will be tracked and monitored;

151.2 the administration sites will be secured;

151.3 the actual doses will be tracked and traceable via the use of barcode scanning. Appended to this is the safe and secure disposal of vaccine packaging and vials; and

151.4 there will be data verification between volumes that have been distributed, as checked against volumes that have been administered.

152 I now turn to highlight certain examples of the implementation steps taken by Government before turning to the Vaccine Implementation plan.

The appointment of Biovac

153 Because some of the vaccines concerned are being bought from pharmaceutical manufacturers that do not have their own presence in South Africa and because the NDoH is not a pharmaceutical company and therefore cannot itself receive and process vaccines, it was necessary to appoint a company to do so.

154 Biovac is a company that specialises in human vaccines. It could both manufacture vaccines and distribute vaccines. The NDoH appointed Biovac to be the custodian of the vaccines concerned and to provide support to it under section 21 of the Medicines Act. I must make clear that although Biovac needed to be the recipient and custodian of the vaccines, the government of South Africa is the owner of these vaccines.

155 This appointment was made pursuant to a deviation applied for and granted by National Treasury.

155.1 On 7 January 2021, the NDoH applied for a deviation in respect of two aspects: (a) to use the single source procurement method to appoint the Biovac Institute for the short term (3 months) to provide storage and distribution services for vaccines procured urgently to immunise frontline health care workers; and (b) to request approval for a closed bid procurement process to the four service providers (Biovac Institute, Imperial Health Sciences, DSV and United Pharmaceutical Distributors), in order to secure the services of transport and logistics providers that comply with regulatory requirements to store and distribute Covid-19 vaccines for a period of 6 months.

155.2 In the application, the NDoH recognised that: "*the urgent procurement of vaccine to immunise our front-line health care workers within the next two months will also require transport, storage and distribution.*"

155.3 A copy of the application is attached marked **Annexure SB14.**

155.4 This was granted by National Treasury on the same day. A copy of the decision of National Treasury is attached marked **Annexure SB15**.

155.5 I point out, however, that the second aspect of the deviation – paragraph (b) above – was never applied because it was ultimately decided instead to issue an open tender as appears from what I set out below.

156 In order to receive the AstraZeneca vaccine, Biovac had to be granted a permit by Genetically Modified Organisms Council ("**GMO Council**"). The GMO Council is an entity within the Department of Agriculture, Forestry and Fisheries. The

AstraZeneca vaccine has genetically modified organisms, that is why a permit was necessary so that it could be registered in South Africa registration by the SAHPRA.

157 Prior to the first batch of AstraZeneca vaccines landing at the airport, Biovac hired a security company to guard its premises in order to ensure the security of the vaccines. It was also urged to work with the South African Police Service ("**SAPS**") and the South African National Defence Force ("**SANDF**") to ensure the security and safety of the vaccines.

158 As custodian, Biovac transported and stored the vaccines in accordance with the SAHPRA requirements.

159 The plan was for Biovac to then transport and deliver the vaccines in every province, in accordance with the plans that each province had for the rollout of the vaccines.

159.1 Getting the vaccines to the different provinces was either going to be done by road (escorted by the SAPS and the G4S security), or by air, accompanied by pharmacists from Biovac.

159.2 Once in the provinces, the pharmaceutical depot in each province would take delivery of the vaccines, though in some instances Biovac would deliver to distribution sites closer to where the vaccines would be administered. These pharmaceutical depots fall under the Health Department, and the actual person taking delivery of the vaccines would be a pharmacists, who would sign off on them.

159.3 Upon delivery, the pharmacist from the provincial department of health will verify the integrity of the vaccine and then takes over custody and must ensure proper administration thereafter.

159.4 This process of delivering the vaccines to the different provinces has now been delayed by the developments regarding the AstraZeneca vaccine, which meant the distribution of those vaccines has been paused.

160 Biovac's mandate on a sole source basis was only in relation to phase 1. The government has commenced an open-tender process for the other phases of the vaccine rollout.

The Electronic Vaccination Data System

161 On 5 February 2021, the Minister launched the Electronic Vaccination Data System ("**EVDS**"). This ground-breaking initiative enables persons to register for the vaccine through their cell phones. The NDoH will then be able to relay information to the general public about vaccines. It will also be able to store information on when the vaccine was administered at which hospital and so on. This is important for monitoring purposes. This development enhances the vaccine rollout.

162 As at 14 February 2021, more than 325 000 people had already registered on the EVDS for purposes of phase 1 of the roll-out.

163 I draw attention to the following features of the EVDS:

163.1 It allows pre-registration of healthcare workers during Phase 1, and other recipients during Phase 2, in order to receive a vaccination appointment;

163.2 It is currently prepopulated with information from existing databases of healthcare worker data from public and private sectors and will be populated with other databases as we move to Phases 2 and 3;

163.3 It includes a consent form for vaccination, for use of personal data and for use of location data;

163.4 Vaccinators will be able to see whether it is an individual's first or second dose and which vaccine has been administered;

163.5 It will be linked to the NHLS / NICD to determine effectiveness of vaccine i.e. if patient later tests positive;

163.6 It will allow for adverse events following immunisation (AEFI) monitoring;

163.7 It will allow for data sharing with SAHPRA apps e.g. Yellow Vaccine Safety Card (active surveillance) and MedSafety app (passive surveillance);

163.8 It will send reminders or notifications for subsequent doses including date and facility; and

163.9 Recipients will be able to use the app as proof of vaccination.

The Vaccine Implementation Plan

164 I have already referred to the fact that the Vaccine Strategy and Rollout Strategy documents contain various details of the plan for administering the vaccine. However, I accept that these are at a relatively high-level.

165 For that reason, from at least 2 January 2021, the NDoH has also been developing a Vaccine Implementation Plan. The plan is constantly developing and being adjusted in relation to what is required. I attach three versions of the plan:

165.1 Version 1 of the plan is the plan as it stood on approximately 19 January 2021. It is attached as **Annexure SB16**.

165.2 Version 2 of the plan is the plan as it stood in early February 2021, shortly before the announcement of the disappointing AstraZeneca results with all of the consequences that these entailed. It is attached as **Annexure SB17**.

165.3 Version 3 of the plan is the plan as it currently stands. It is attached as **Annexure SB18**.

166 I emphasise that it is critical that the plan be flexible and adaptable to changing environments. Given the speed with which South Africa has moved to obtain vaccine doses following the relevant stage 3 test results and regulatory approvals, there has been a need for considerable speed and adaptability in the

plans for the administering of the vaccines. The plans must take account of and constantly be adapted to both:

166.1 which vaccines are actually available when (because different vaccines require different number of doses, different storage regimes and so on); and

166.2 the constantly evolving science around the vaccines.

167 A fixed or rigid plan is neither practically possible or desirable.

168 The plans referred to have not until now not themselves been released to the public. This is because the plan was not yet final and, just as it was about to be finalised, the news regarding the AstraZeneca results broke. This has led to a significant and rapid shift in the roll-out plans to avoid delay. I explain this in greater detail below.

169 But I emphasise that key elements of the plan have already been made public. For example, on 5 February 2021, the Minister of Health made a presentation on the Covid-19 Vaccine Roll-out to the Parliamentary Portfolio Committee on Health. A copy of the presentation is attached marked **Annexure SB19**. It contains a great detail of information on the roll-out plan. The presentation was also made available to the media and received significant coverage.

Key elements of Version 2 of the plan

170 I have explained above that Version 2 of the plan has been superseded by Version 3 of the plan due to the disappointing AstraZeneza results and the shift to Johnson & Johnson.

171 However, I emphasise that even Version 2 of the plan (from early February 2021) remains relevant because, once South Africa moves beyond the initial Johnson & Johnson doses and has greater numbers of vaccine doses available, with fewer restrictions, it will likely return to that version of the Plan, suitably amended and adjusted.

172 The Plan deals with both vaccine acquisition and roll-out. In terms of the Plan, the governance structure is as follows:

172.1 an Inter-Ministerial Committee on Vaccination which oversees the vaccination of all South Africans;

172.2 the VMAC, whose responsibility it is to develop a strategy to ensure equitable access to vaccines in South Africa;

172.3 The MAC on Social and Behaviour Change, which will drive a concerted social mobilisation campaign to all the sectors;

172.4 The COVID-19 Vaccine Acquisition Task Team, whose objective is to coordinate the private sector vaccine financing, procurement, logistics, and administration;

172.5 The National Vaccine Coordinating Committee ("**NVCC**") established by the Director-General: Health, tasked to lead the national vaccine scale-up in close coordination with provincial health departments and the private healthcare sector.

172.6 The Provincial Vaccine Coordinating Committees, which are structures in different provinces, created to coordinate the provincial and district level roll-out of COVID-19 vaccines. Members are appointed by the Provincial Heads of Department, representing similar functionaries as the National Vaccine Coordinating Committee.

172.7 The Private Health Sector Coordinating Committee, a forum that is constituted by private sector stakeholders including Medical Schemes, the Hospital Association of South Africa ("**HASA**"), Independent Practitioners Associations ("**IPAs**"), retail pharmacies and groups, specialist associations, nursing association, health professions associations, logistics providers, pharmaceutical manufacturers, employers, and business associations. The chair of this forum participates in the National Vaccine Coordinating committee.

173 The Plan ascribes different roles to the NDoH and provincial health departments.

174 The provincial health departments are required to:

174.1 Establish a Provincial Vaccine Coordinating Committee, with similar functions to the national committee;

174.2 Develop and implement a provincial micro-plan based on the national implementation plan. The plan must:

174.2.1 Define the relevant governance structures at a provincial, district and facility level.

174.2.2 Identify the target population, by priority group, estimate the size and location.

174.2.3 Identify vaccination sites and service points, including public and private sites.

174.2.4 Identify, train and provider supervision for the vaccinators, plus transport, and supplies.

174.2.5 Define the plan for the procurement of ancillary supplies and waste disposal services

174.2.6 Determine the ideal provincial distribution plan for the vaccines.

174.2.7 Include a demand creation and communication plan, aligned with the national communication strategy.

174.3 Liaise with the NDoH regarding the distribution of vaccines;

174.4 Monitoring of coverage

174.5 Ensure that the required data is collected and share with the NDoH

174.6 Create demand; and

174.7 Liaise with the different stakeholders, including with the private sector.

175 Various administration platforms will be applicable for the different vaccination phases.

176 There are four such platforms, which will be used at various stages across the implementation of the vaccination programme. These are as follows:

176.1 Platform 1: Work-based vaccination programme (Occupational Health approach).

176.2 Platform 2: Outreach vaccination programme. Here, mobile clinics/teams will move from facility to facility and vaccinate the eligible population. These teams will include vaccinators from the private and public sectors. Contract nurses or school health nurses may be employed to provide these services where applicable

176.3 Platform 3: Vaccination centres. These will include centres linked to a health facility (such as a hospital, medical centre or clinic); a community pharmacy; and standalone vaccination centres. These may be small centres, although mass vaccination centres are likely to be needed in metropolitan areas

176.4 Platform 4: Primary Health Centres (such as doctors' consultation rooms).

177 The approach that will be used in Phase I is summarised in the table below:

Place of work	Target population	Vaccination site	Responsibility

Health workers employed in hospitals	All health workers	Hospital	Occupational health services Hospital services
Health workers working in smaller health facilities	All health workers CHWs linked to health facilities	Workplace (provided by outreach team)	Occupational health services District Health Services
Health workers not linked to a facility	EMS staff Independent practitioners CHWs not linked to a facility Traditional healers Administrative staff	Vaccination Centre	Coordinated by District Health Services May involve private and public sector providers

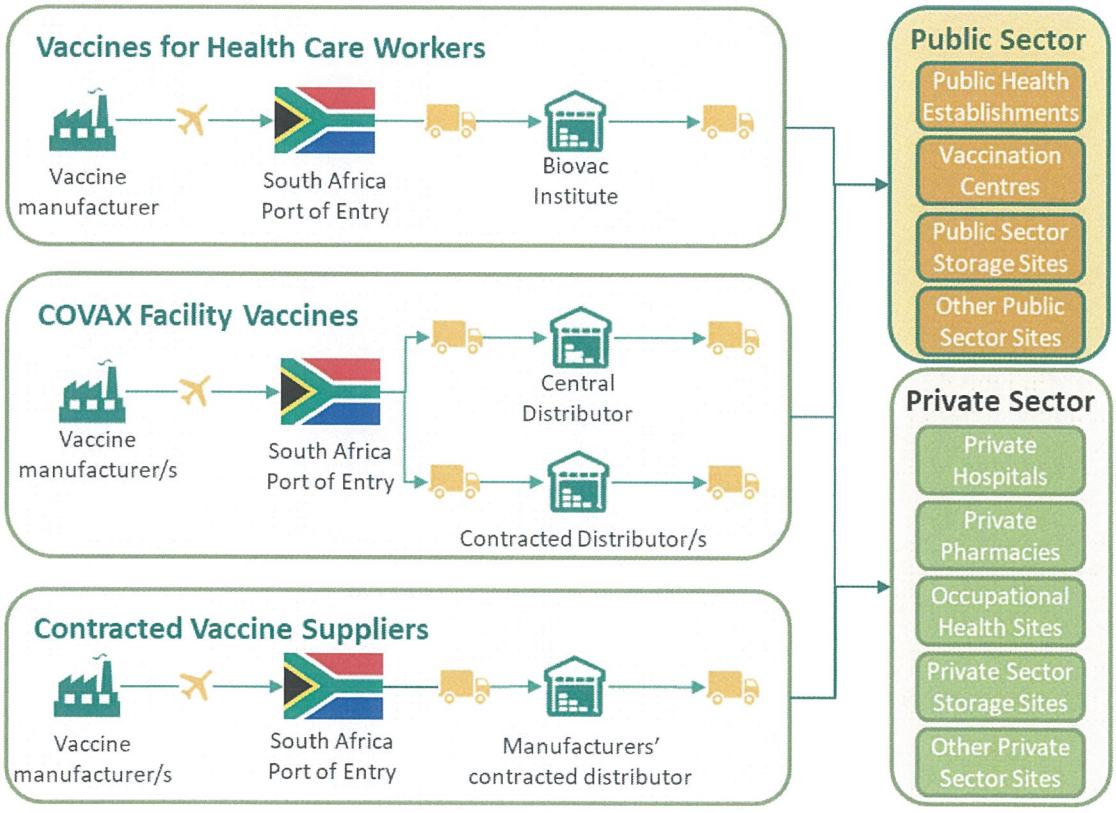
178 The plan envisages the activation of 2000 sites across the nine Provinces during phase 1.

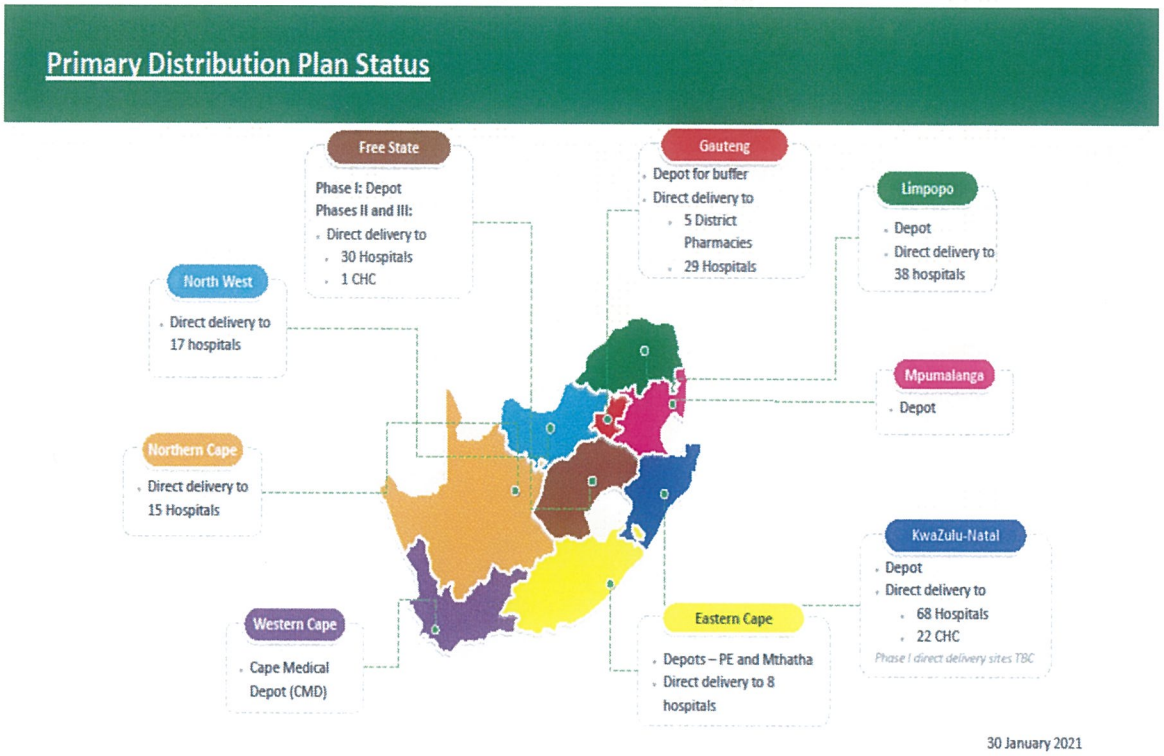
179 The approach that will be used in Phases 2 and 3 is summarised in the table below

Platform	Location	Phase I	Phase II & Phase III
Work-based vaccination programme	• Public and private hospitals • Industry • Government departments	Hospital linked HCWs	Essential workers e.g., mining sector, industry, and departments
Outreach work-based vaccination programme	Mobile teams move from facility to facility	HCWs in PHC, CHC and private medical centres	Congregated settings e.g., old age homes
Vaccination Centres: Remote or facility-based vaccination centres	• Community pharmacies • General practitioners • NGO's	Independent HCWs	Urban settings for community access
Public facility vaccination	• Primary health care clinics • Community health centres		Rural settings for community access

180 Once vaccines are allocated to a public or private sector entity, the distributor will deliver the vaccine to the designated location. Vaccines will be distributed from the distributors' storage facility to the vaccination sites, including public and private hospitals and clinics, private pharmacies and doctors, occupational health sites (including mines and large employers), and other vaccine storage and distribution sites.

181 Outreach vaccination teams will need to be associated with one of the above delivery points, from where they will regularly collect the vaccines and ancillary supplies. Each province has identified the distribution sites to which vaccine will be delivered.





182 Sufficient well-trained component persons are required to distribute, store, administer and record the vaccine introduction throughout the public and private health sectors. Additional human resources which include staff for community mobilisation, cold chain and supply chain management, vaccine administration is required for the successful vaccine introduction. These persons will be trained by following a set of seven modules which cover all components of Covid-19 vaccination. These modules are:

182.1 Module 1: Introduction to Covid-19 vaccination programme

182.2 Module 2: Storage, handling, delivery, and waste management of COVID-19 vaccines,

182.3 Module 3: Organising COVID-19 vaccination sessions,

182.4 Module 4: Adverse Events following Immunisation AEFI monitoring for COVID-19 vaccination,

182.5 Module 5; Data management based on the EVDS

182.6 Module 6: Communication about COVID-19 vaccination

182.7 Module 7: Ethical considerations for the COVID-19 vaccination programme.

183 Training plans have been developed across all levels: national level, province, district, public and private sectors. Multiple training approaches and platforms are being used to reach as wide an audience as possible in the shortest possible time. This may include virtual training, computer-based training and in-person training.

Key elements of Version 3 of the plan

184 I have explained above the disappointing AstraZeneca results and how these have meant that the roll-out plan had to be halted.

185 In the few days since this news was released, the NDoH has moved extremely rapidly to engage with Johnson & Johnson and secure the 80 000 doses every 14 days from it.

186 However, this has also meant adjustments to the roll-out plan for two reasons:

186.1 First, rather than having one million doses available immediately (as was the case under the original plan), there will now initially be 80 000 doses every two weeks.

186.2 Second, as I have explained above the registration-status of the Johnson & Johnson vaccine means that it is being administered as part of a phase 3B trial, together with the Medical Research Council. This has meant that, initially only a limited number of sites – all research sites – will be used rather than the much larger number of sites envisages in the plan.

187 I attach as **Annexure SB20** a presentation containing details of the current plan for the distribution of the Johnson & Johnson dosages. I emphasise that given the pace at which Government has had to adapt and consult with stakeholder, this plan will itself need to be adjusted and adapted in light of practical experiences with it. That said, it contains a great detail of government's plans.

188 I highlight just some aspects:

188.1 Once the Johnson & Johnson vaccine has arrived and been cleared through the customs processes, it will be transported to Biovac where it will be stored and processed prior to distribution to all nine provinces.

188.2 The Johnson & Johnson rollout plan still prioritises health care workers on the front line.

188.3 There are five steps for healthcare workers to participate:

188.3.1 Register on EVDS (although contingency arrangements have been made for a paper-based registration).

188.3.2 Respond to SMS invite for early access

188.3.3 Provide consent to take part

188.3.4 Receive your vaccination voucher

188.3.5 Attend vaccination centre for administration

188.4 16 public sector hospitals have been identified for the first two-week period.

188.5 16 of the ENSEMBLE Research sites have been identified as Primary Distribution Sites receiving product that would have been stored by Biovac.

188.6 The ENSEMBLE Research sites were chosen based on proximity to the identified public sectors hospitals.

188.7 Six (6) of these ENSEMBLE Research sites are either within the grounds of the public sector hospital complex or within 1km

189 The sixteen hospitals for the first two week period are as follows:

Hospital	Province	HCW	Supply Research Site	Distance from Research Site (km)	Doses (public & private)
ec Livingstone Hospital	Eastern Cape	2 135	PHOENIX Pharma (Pty) Ltd	6	*3 200*
ec Nelson Mandela Academic Hospital	Eastern Cape	3 314	Nelson Mandela Academic Research Unit	1	*4 920*
fs Universitas (C) Hospital	Free State	2 544	Josha Research CRS	5	3 800
gp Chris Hani Baragwanath Hospital	Gauteng	7 426	Soweto HVTN CRS	0	11 080
gp Steve Biko Academic Hospital	Gauteng	3 803	Synexus SA - Watermeyer	12	5 720
kz Inkosi Albert Luthuli Central Hospital	KwaZulu-Natal	3 868	CAPRISA eThekwini CRS	6	5 760
kz Prince Mshiyeni Memorial Hospital	KwaZulu-Natal	3 380	Chatsworth CRS	8	5 040
lp Polokwane (Pietersburg) Hospital	Limpopo	2 747	Elandsdoorn CRS	191	4 080
lp Mankweng Hospital	Limpopo	2 055	Elandsdoorn CRS	201	3 080
mp Rob Ferreira Hospital	Mpumalanga	1 326	Mzansi Ethical Research Centre	189	2 000
mp Witbank Hospital	Mpumalanga	1 099	Mzansi Ethical Research Centre	32	1 640
nw Klerksdorp-Tshepong Tertiary Hospital	North West	3 856	Aurum Institute Klerksdorp CRS	0	5 760
nw Job Shimankana Tabane Hospital	North West	1 762	Aurum Institute Rustenburg CRS	1	2 640
nc Robert Mangaliso Sobukwe Hospital	Northern Cape	2 599	Clinical HIV Research Unit (CHRU)	520	3 920
wc Groote Schuur Hospital	Western Cape	3 847	Groote Schuur HIV CRS	0	5 760
wc Tygerberg Hospital	Western Cape	4 935	FAM-CRU (Family Clinical research Unit)	1	7 400
				TOTAL	**78 880**

190 The plan envisaged Provincial Departments of Health playing a major role:

190.1 Provincial Covid-19 vaccine coordinators are to liaise with NDoH/MRC consortium to align with the national plan. They must encourage enrolment and ensure that health care workers enrol on the EVDS.

190.2 They must also develop and implement provincial based-plans, guided by the national plan. Each plan must identify:

190.2.1 Target population,

190.2.2 Vaccination sites (service points), and ensure they are ready to vaccinate (checklist available)

190.2.3 identify, train and register vaccinators

190.2.4 Logistics: Transport and supplies.

190.3 The NDoH has set up meetings to formally communicate proposed site list with Provincial Heads of Department; and engage provincial DoH bilaterally prior to the commencement of the vaccination programme.

190.4 CEOs of Hospitals will be expected to:

190.4.1 Engage health care workers in order to request those interested to enrol onto EVDS.

190.4.2 Ensure vaccinators and the required administration support is available to operationalise the vaccination programme.

190.4.3 Ensure that sites comply with readiness checklist, and are ready to Vaccinate.

191 In line with this key role for provinces:

191.1 On 13-14 February 2021, the presentation referred to above and attached was shared and discussed with the nine Provincial Covid-19 Vaccine Co-ordinators;

191.2 On 15-16 February 2021, extensive and lengthy webinars took place with the nine Provincial Covid-19 Vaccine Co-ordinators and their teams, including hospital representatives.

THE COMPLAINT ABOUT TRANSPARENCY

192 The DA's contention that Government has not been transparent with its plans is entirely without merit. By way of example.

192.1 The three VMAC advisories have all been made public.

192.2 The Vaccine Strategy has been made public.

192.3 The Rollout Strategy has been made public.

192.4 The briefing to the Portfolio Committee on 5 February 2021 on the roll-out strategy has been made public.

192.5 When the AstraZeneca news broke on 7 February 2021, a lengthy public NDoH webinar about the news and the adjusted plans was held on 8 February 2021.

192.6 National Treasury has been entirely open about the deviation requests it received related to the vaccines and their outcomes, as shown by the letter to Corruption Watch attached to the DA's papers.

192.7 Numerous documents, speeches and statements regarding the vaccine issue have been available via the National Government and DOH websites.

192.8 The government website (www.gov.za) has set up a page dedicated solely to the Covid-19 vaccine. The page offers updates on the vaccine, the vaccine strategy, the self-registration portal of the EVDS system, vaccine myths and facts and so on.

192.9 The vaccine procurement progress has repeatedly been discussed by the President, the Minister of Health, the Chair of the VMAC and NDOH officials in public addresses, parliamentary processes and interviews.

192.10 The Minister and Dr Pillay have spent many hours being interviewed and answering questions on different platforms: radio, television and social media.. That is the antithesis of opacity.

193 Where plans have not previously been made public (such as the actual draft Vaccine Plan referred to above), this is because the plan was still being developed.

194 If there are any aspects that have not been made public this is a consequence of two constraints:

194.1 The speed at which Government is working in an effort to ensure the most expeditious roll-out possible; or

194.2 The non-disclosure agreements signed by Government with the vaccine manufacturers.

194.2.1 I note the DA's complaint regarding this and its contention that these non-disclosure agreements are undesirable or unlawful. In principle, I agree that Government would much prefer to share this information immediately with the public.

194.2.2 But the Government has had no option. The vaccine manufacturers are insistent on this confidentiality and if Government did not agree or comply, they would simply refuse to contract with Government. Given the extraordinary "sellers' marker" we are in – where everyone around the world is clamouring to buy the vaccines – this is no idle threat.

194.2.3 If the choice is between getting some vaccines and having some degree of confidentiality versus not getting the vaccines at all, the choice is obvious.

AD SERIATIM RESPONSE

195 I now turn to deal with the allegations contained in the DA's founding affidavit insofar as is necessary. In doing so I will seek to avoid repeating what I have already said and I ask that what is set out above in this affidavit be read as incorporated herein wherever appropriate.

196 Where an allegation is made by the DA in its founding affidavit and is in any way inconsistent with what is stated in any part of this affidavit, it must be taken to be denied by me.

Ad paragraphs 1 and 2

197 I admit the allegations contained in these paragraphs.

Ad paragraphs 3 and 4

198 I deny the allegations contained in these paragraphs. As I have indicated above, the affidavit is replete with allegations of a factual nature which plainly do not fall within Mr Steenhuisen's personal knowledge and which rely on what may, at best, be called speculation. I repeat that I do not accept that the DA is entitled to rely on such statements in the course of this litigation.

Ad paragraph 5

199 The answer that I have filed speaks for itself and it is clear that much of what the DA says is not common cause.

200 I note that although Mr Steenhuisen complains, on the one hand, that the government has been opaque by its strategy regarding Covid-19 vaccines, on the other hand he admits that there is enough information on the subject in the public domain to enable the DA to put an entire narrative before this court. The contradiction speaks for itself.

Ad paragraph 6

201 I deny that it is in the interests of justice for the DA to be permitted to rely on the extensive hearsay and speculation that it does. I refer to what I have stated above in this regard.

Ad paragraph 7

202 I note the contents of this paragraph but deny that the legal submissions made are correct as a matter of law. All questions of law will be addressed in the course of written and oral argument.

Ad paragraphs 8 and 9

203 I admit the contents of these paragraphs.

Ad paragraph 10

204 I have dealt above with when various vaccines were put through medical trials and approved for use by the relevant regulators. As I have indicated, it is only extremely recently that vaccines were approved for use by any country and, thus far, only one vaccine has been fully approved for use in South Africa. I admit that a small number of governments placed large scale orders during the course of 2020 and received vaccines earlier than other governments as a consequence. Again I deal with this in detail above and refer to what is stated there.

Ad paragraph 11

205 I deny the allegations contained in this paragraph. I have set out in detail above numerous steps that the South African government has taken in order to procure

vaccines and to prepare for the administration of those vaccines when they arrive.

Ad paragraphs 12 and 13

206 I admit that the government's aim is to vaccinate approximately two-thirds of the South African population.

207 The number of doses of vaccine required will depend on which vaccines are used as some involve single doses and others involve double doses. I deny that only 1.5 million doses have been secured for delivery during the course of this year and refer to what is stated above in this regard.

208 I deny further that there has been "no indication at all" of how, when and from who additional doses will be acquired.

Ad paragraphs 14 to 16

209 I deny the allegations contained in these paragraphs. They are entirely speculative and Mr Steenhuisen does not put forward any proper basis for them. They are in any event incorrect save for the recognition that much of the work will be done by provincial health authorities and public hospitals. I refer to what is stated above in this regard.

Ad paragraph 17

210 I deny that the criticisms of government's policies and strategies are well-founded. The policies and strategies are set out above and I submit that they are appropriate, rational and reasonable in the circumstances, particularly given

the continuing need for flexibility in the light of the considerations that I have set out above.

Ad paragraph 18

211 I deny the contents of this paragraph.

Ad paragraphs 19 and 20

212 I deny the contents of this paragraph. Far from there being a "almost total lack of transparency", the government has conducted itself with extraordinary transparency and engagement with the public. No specificity is provided regarding private sector actors who have availed themselves to assist and allegedly have no knowledge of what is required and when they will be called upon. Mr Steenhuisen in any event does not put forward any proper factual basis for such a broad sweeping allegation and it is incorrect.

213 I deny further that individuals awaiting immunisation have no idea when their vaccines will arrive or whether they will be capable of being administered. The government has made clear in its public statements the phases that will be followed in the administration of the vaccine and I have referred above to the electronic system which has been set up in order to cater for healthcare workers during the first phase and other persons during the second and third phases.

Ad paragraphs 21 and 22

214 I deny the contents of this paragraph. I regret that the application appears to be brought for the purpose of seeking to gain political mileage from what is indeed

a fundamental issue. This is most regrettable. I agree that the procuring and administering of the vaccines are urgent but that does not render this application urgent, if that is what the applicant is suggesting.

215 I deny that the applicant had "no choice" but to request this court to exercise its section 172(1) powers. On the contrary, there were numerous avenues open to the DA in Parliament (where it is the official opposition) and beyond in order to address such concerns as it may have.

Ad paragraphs 23 and 24

216 I deny the contents of these paragraphs. I do not agree with the DA's characterisation of its case nor do I accept that the case is sustainable as a matter of law.

Ad paragraphs 25 to 35

217 I note the parties cited in this application.

218 I deny that the DA has properly brought this application in the public interest or that this is the only way in which the DA could hold the National Executive accountable and assist in realising the access to healthcare services and ensuring transparency. As I have indicated, there were numerous other routes available to the DA in order to do so.

Ad paragraphs 36 and 37

219 I admit the allegations contained in these paragraphs.

Ad paragraphs 38 to 43

220 I deny that there is any proper basis to contend that there has been significant under-reporting of Covid-19 deaths. Mr Steenhuisen does not explain on what evidentiary basis he reaches this conclusion.

221 I admit the allegations insofar as they accurately reflect what is stated by the VMAC or the Medical Research Council. I also admit that whichever numbers one relies on, there is no question that Covid-19 has been widespread and lethal in South Africa.

Ad paragraphs 44 to 46

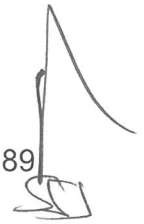
222 I admit the contents of these paragraphs.

Ad paragraphs 47 to 51

223 It is not clear what the relevance of these allegations are to the present application beyond illustrating that damage is caused by Covid-19 and there is a need to take measures to combat it. Nevertheless for present purposes, I do not dispute the allegations.

Ad paragraphs 52 and 53

224 The second wave has now abated. I admit that there is a possibility of a further wave of infections in the future and that vaccinations are an important component of seeking to prevent such waves of infections in the future.



Ad paragraphs 54 to 87

225 I note the allegations contained in these paragraphs. While I do not agree with the manner in which the DA has characterised the regulations put in place and the effect of such regulations, for present purposes there is no need to deal with this dispute.

226 It suffices to record that the Supreme Court of Appel has, very recently, upheld the lawfulness of government's regulations in virtually all respects and dismissed a challenge to them. If the DA had specific concerns about the regulations concerned, it ought to have brought challenges in respect of such regulations or proceeded with the challenges it did bring. There is accordingly no need to deal with these paragraphs any further for purposes of this application.

Ad paragraphs 88 to 98

227 For present purposes I do not dispute the contents of these paragraphs, save where they are inconsistent with what I have stated in the substantive portion of this affidavit above.

Ad paragraph 99

228 I note the contents of this paragraph. I note, in particular, the concession that phase 3 trials are *"large scale trials involving thousands of participants that are sufficiently broad to provide reliable evidence of safety and efficacy."* As I have indicated above, South Africa took the position that it would not contract for a vaccine until phase 3 trials in respect of that vaccine had been concluded.

Ad paragraphs 100 to 103

229 I have dealt with the DA's comparisons between South Africa and other countries in detail above. I pray that what I have set out there be incorporated herein. I reiterate that the comparisons that the DA seeks to draw are:

229.1 irrelevant to the question of whether the government has behaved lawfully, rationally and reasonably; and

229.2 in any event contrived and unfounded for the reasons I have articulated.

Ad paragraphs 104 and 105

230 I deny the contents of this paragraph. As indicated, South Africa took delivery of one million doses of Astra Zeneca on 1 February 2021 and will shortly be taking delivery of 80,000 doses of Johnson & Johnson vaccine every two weeks. I deny that government has "failed" at all.

231 I deny further that the government's conduct is inconsistent with its acknowledgement of the importance of widespread vaccination.

Ad paragraphs 106 to 113

232 I admit the contents of these paragraphs to the extent that they are consistent with the government statements relied on. Save as aforesaid, they are denied.

Ad paragraph 114

233 I deny the contents of this paragraph. It is simply factually incorrect, as I have

explained above.

Ad paragraph 115

234 I admit the NDOH submitted the application for procurement deviation on 6 January 2021 and that the reference to "6 January 2020" was an error.

Ad paragraph 116

235 The letter speaks for itself. Beyond that, I deny the contents of this paragraph. It amounts to sheer speculation, which is unfounded. I have explained in detail above the reasons for government's approach as to when it would contract with manufacturers for vaccines.

Ad paragraphs 117 and 118

236 I deny the contents of this paragraph. As I have set out above, government had numerous and extensive engagements with the relevant vaccine manufacturers long before 6 January 2021.

237 Moreover, the practical reality is that even if government had applied for deviation sooner – for example at the beginning of December shortly after the first phase 3 trial results had occurred – this would have made little practical difference to when the vaccines would have been delivered to South Africa. The practical reality was that it was countries who engaged in advance purchase orders prior to phase 3 trial results who would always receive the bulk of the vaccine supplies initially. For the reasons I have articulated, this possibility was not practically available to South Africa.

Ad paragraphs 119 to 121

238 I admit the contents of these paragraphs to the extent that they are consistent with the documents relied on. Save as aforesaid they are denied.

Ad paragraph 122

239 I deny the contents of this paragraph. There is no showing of a failure by the government to act whatsoever.

Ad paragraphs 123 to 131

240 I admit the contents of these paragraphs to the extent they are consistent with the documents set out. Save as aforesaid, they are denied.

Ad paragraphs 132 and 133

241 I have dealt in detail with the COVAX procurement above. I reiterate that South Africa will be receiving vaccines via COVAX as part of the first batch of countries to do so.

Ad paragraphs 134 to 138

242 I admit the contents insofar as they are consistent with the government's statements relied on. Save as aforesaid they are denied. I have dealt with the vaccines being obtained by the African Union above.

Ad paragraphs 139 and 140

243 I deny the contents of these paragraphs. The criticism of the President is unfounded. As I have indicated in detail above, it is quite correct that the

government has been engaging directly with several vaccine manufacturers since July 2020. There is nothing in the application for deviation to Treasury on 6 January 2021 that gainsays this.

Ad paragraphs 141 to 147

244 I admit the contents of these paragraphs to the extent that they are consistent with the government statements referred to. Save as aforesaid, they are denied.

Ad paragraphs 148 to 150

245 I have dealt above with the manner in which the vaccines will be administered and the phases that will be used in this regard. At all times the government has acted on the advice of the VMAC in this regard.

Ad paragraphs 151 to 156

246 I admit the contents of these paragraphs to the extent that they are consistent with the government statements quoted. Save as aforesaid, they are denied.

Ad paragraphs 157 to 160

247 I deny the contents of these paragraphs. I deny, in particular, that the comparisons sought to be drawn with other countries is appropriate, relevant or helpful and I have set out in detail above the reasons for the approach that the government has taken. I submit that it is imminently lawful, rational and reasonable.

Ad paragraphs 161 and 162

248 I admit that the correspondence referred to was exchanged. The fact that the government could not, within one week, commit to providing a comprehensive response to the DA in no way indicates that the government did not have a comprehensive and coordinated plan prepared. With respect, responding to the DA's letter is not the main or sole priority of the Department of Health or government officials.

Ad paragraph 163

249 I deny the contents of this paragraph.

250 It is not correct that the applicant had "no choice" but to institute these proceedings. If it were seriously intent on engaging constructive with the government, it would have afforded the government more time to respond to its letter of 18 January 2021.

Ad paragraphs 164 to 170

251 The effect of section 27 of the Constitution in the context of Covid-19 and the availability of vaccines is a matter for argument. It will be addressed at such.

Ad paragraph 171

252 I deny that the national government has in any way breached section 27 of section 237 of the Constitution.

Ad paragraph 172

253 I deny that government has in any way failed in the manner in which it dealt with the question of vaccines. Moreover, I point out that even if government had begun rolling out vaccines in late 2020, this would likely not have not prevented the second wave.

Ad paragraphs 173 and 174

254 I note the DA's criticism of the President's analysis. I deny that it is well-founded. Government's strategy throughout has been to procure vaccines in a manner that is as expeditious and sustainable as possible. Given the rapid pace of vaccine development, it is quite likely that additional vaccines will come on stream in due course. Moreover, it would be a mistake for government to over-commit to ordering any particular kind of vaccine given the risks involved in over-reliance on a vaccine which may ultimately prove unsuitable. The recent experiences of government, documented above, have made that clear.

Ad paragraph 175

255 I deny the contents of this paragraph.

Ad paragraphs 176 and 177

256 I deny the contents of this paragraph. I have dealt with the COVAX facility above.

Ad paragraph 178

257 I deny the contents of this paragraph. There is no basis at all to suggest that the COVAX arrangement – which is being used worldwide – is somehow unreliable

or that a contingency plan should be put in place for it.

Ad paragraph 179

258 I deny the contents of this paragraph. It amounts to sheer speculation with no basis at all. In any event, as I have explained above, the arrangement reached with Johnson & Johnson is now that its single does vaccines will be used to vaccinate healthcare workers in phase 1.

Ad paragraph 180

259 I again deny the allegations contained in these paragraphs. No proper basis is put up for the concern that is raised.

Ad paragraphs 181 to 183

260 I deny the contents of these paragraphs. I have dealt with the African Union channel above.

Ad paragraph 184

261 I deny the contents of this paragraph. I have dealt with the Johnson & Johnson arrangements and its provision of vaccines above.

Ad paragraphs 185 to 188

262 I deny the contents of these paragraphs.

Ad paragraph 189

263 I admit the contents of this paragraph to the extent it is consistent with the

government documents concerned. Save as aforesaid, they are denied.

Ad paragraphs 190 and 191

264 I deny the contents of these paragraphs. I have set out in detail above the various strategies and plans that government has put in place to deal with both vaccine acquisition and vaccine administration.

Ad paragraphs 192 and 193

265 I deny the contents of this paragraph.

Ad paragraphs 194 to 196

266 I deny the contents of these paragraphs. I have set out above the strategies and plans that government has put in place.

Ad paragraph 197

267 I deny the contents of this paragraph. The DA has placed no evidence at all before this court in support of the sweeping allegation made.

Ad paragraphs 198-200

268 I deny the contents of these paragraph. The DA has placed no evidence at all before the Court to indicate that there has been a delay in obtaining the necessary facilities or that this in turn will delay the rolling out of vaccines.

Ad paragraph 201

269 I admit the contents of this paragraph to the extent that they are consistent with

the government's statement quoted. Save as aforesaid, they are denied.

Ad paragraphs 202 and 203

270 I deny the contents of these paragraphs.

Ad paragraphs 204 to 207

271 The effect of sections 27, 195 and 217 of the Constitution, as well as the Rule of Law, is a matter for legal argument and will be addressed as such.

Ad paragraphs 208 and 209

272 I deny the contents of these paragraphs. It is quite apparent from the DA's own affidavit that there is extensive information in the public domain regarding government strategies and polices. Moreover, my affidavit makes quite clear that this is the case. The complaint about the lack of transparency is therefore entirely unfounded.

Ad paragraph 210

273 It is true that in certain circumstances the government has had to delay the announcement of its negotiation with vaccine manufacturers or has had to withhold certain details. As explained above, this is because the vaccine manufacturers insisted on this as a precondition for the negotiations and/or the conclusion of contracts.

274 While, of course, the government would prefer to disclose all information to the public immediately, this was simply not possible in the circumstances. If

government had insisted on this, the vaccine manufacturers would have refused to continue negotiating or would have refused to contract and then the vaccines in question would not have been procured. Faced with this scenario, the government's choice was obvious and plainly lawful.

Ad paragraphs 211 to 213

275 While I accept the importance of transparency, I deny that it was not observed and deny further that the government's conduct was inconsistent with the Constitution. I in any event deny that the transparency complaint (if well-founded) would entitle the DA to the relief it seeks.

Ad paragraph 214

276 I deny that the DA is entitled to rely on section 41 of the Constitution in order to found a cause of action. The DA is not and does not purport to be a sphere of government.

Ad paragraph 215

277 I admit that health services is a concurrent competence shared between the national and provincial spheres.

Ad paragraph 216

278 I deny the contents of this paragraph. The planning that has gone on is extensive and is set out above.

Ad paragraphs 217 to 219

279 I deny the contents of these paragraphs. The DA provides no evidentiary basis whatsoever for the sweeping allegations that it makes.

Ad paragraphs 220 and 221

280 I deny the contents of these paragraphs.

Ad paragraph 222

281 I note the contents of this paragraph.

Ad paragraphs 223 to 227

282 I deny the contents of these paragraphs. There is no basis for them whatsoever.

Ad paragraphs 228 to 230

283 I deny that the DA is entitled to any declaration of invalidity in terms of section 172 of the Constitution.

Ad paragraphs 231 to 236

284 I deny the contents of these paragraphs. Even if the DA had established an entitlement to declaratory relief under section 172(1)(a) of the Constitution (which it has not), the relief sought is manifestly inappropriate and involves an overreach.

285 If the DA had established any unlawfulness or unconstitutionality, the appropriate order would be a declaratory order which would then allow government to deal

with the consequences thereof. Given the facts set out above, there can be no serious suggestion that such wide-ranging remedial relief is remotely appropriate.

Ad paragraphs 238 to 246

286 Whilst I do not accept that the case is well founded or that it is urgent that the relief sought be granted, I do not object to the matter being heard on an expedited timetable agreed between the parties. In the circumstances it is not necessary for me to address the question of urgency further.

Ad paragraph 247

287 I deny the contents of this paragraph. I deny again that it was "necessary" for the DA to bring this application. In light of the answering affidavit now filed which ought to ally the DA's misconceptions and concerns, I invite the DA to withdraw this case. In that event no order for costs will be sought. If, however, the DA persists in this application after receipt of the answering affidavit, costs will be sought.

Ad paragraph 248

288 I pray that the application be dismissed.

SABELO SIYABONGA SANDILE BUTHELEZI

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 SANDTON on this the 17 day of FEBRUARY 2021, 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.

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