IN THE HIGH COURT OF SOUTH AFRICA

GAUTENG DIVISION, PRETORIA

CASE NO. 3623/2021

In the matter between –

SOLIDARITY	First Applicant
AFRIFORUM NPC	Second Applicant
and	
MINISTER OF HEALTH	First Respondent
PRESIDENT OF THE REPUBLIC OF SOUTH AFRICA	Second Respondent
MINISTER OF COOPERATIVE GOVERNANCE AND TRADITIONAL AFFAIRS	Third Respondent
CHAIRPERSON OF THE COVID-19 SCIENTIFIC MINISTERIAL ADVISORY COMMITTEE	Fourth Respondent
MEC FOR HEALTH, WESTERN CAPE	Fifth Respondent
MEC FOR HEALTH, GAUTENG	Sixth Respondent
MEC FOR HEALTH, FREE STATE	Seventh Respondent
MEC FOR HEALTH, EASTERN CAPE	Eighth Respondent
MEC FOR HEALTH, NORTHERN CAPE	Ninth Respondent
MEC FOR HEALTH, LIMPOPO	Tenth Respondent
MEC FOR HEALTH, MPUMALANGA	Eleventh Respondent
MEC FOR HEALTH, NORTH WEST	Twelfth Respondent
MEC FOR HEALTH, KWA-ZULU NATAL	Thirteenth Respondent
PHARMACEUTICAL SOCIETY OF SOUTH AFRICA	Fourteenth Respondent
COUNCIL FOR MEDICAL SCHEMES	Fifteenth Respondent
SOUTH AFRICAN MEDICAL ASSOCIATION	Sixteenth Respondent
PHARMACEUTICAL INDUSTRY ASSOCIATION OF SOUTH AFRICA	Seventeenth Respondent

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FIRST AND SECOND RESPONDENTS' ANSWERING AFFIDAVIT

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I, the undersigned,

DR SABELO SIYABONGA SANDILE BUTHELEZI

do hereby make oath and say that:

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 and second respondents. In this affidavit, I shall either refer to them as the National Government, or simply the government. A confirmatory affidavit from the Presidency confirming my authority to depose to this affidavit on behalf of the second respondent 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. Accordingly, save where the context indicates to the contrary, I 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 Government's legal representatives. I accept such advice as correct.

5 I have read the founding affidavit of Solidarity/Afriforum in this matter and respond to it in what follows. Before doing so, I emphasise the following.

5.1 I deny that all of allegations contained in the Solidarity/Afriforum 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 Solidarity/Afriforum founding affidavit is replete with allegations which are plainly not in Mr Hermann's personal knowledge. Much of it consists of sweeping factual allegations about other persons and institutions without any allegation has personal knowledge of them or any explanation as to how Mr Hermann can have the requisite personal knowledge. Much of it amounts to sheer speculation.

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

5.4 The mere fact that I have responded to some such allegations and assertions 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.

THE FLAWED NATURE OF THIS APPLICATION

6 Solidarity/Afriforum approach this Court on an urgent basis seeking three declaratory orders and a mandamus.

6.1 All four orders are pinned to and stem from a "Covid-19 Response" powerpoint presentation dated 7 January 2021. It reflects aspects of Government's strategy to deal with Covid-19, including Covid-19 vaccines. I deal below with the applicants' misunderstanding of the presentation.

6.2 The case of Solidarity/Afriforum is somewhat equivocal. However, it appears to be their contention that the Covid-19 Response presentation purports to prohibit the private sector and provincial health authorities from themselves procuring, distributing and administering Covid-19 vaccines outside the national government programme. This, they contend, is unconstitutional and unlawful.

6.3 Solidarity/Afriforum accordingly ask for wide-ranging declaratory relief in this regard, as well as an order directing the Minister of Health to amend the Covid-19 Response presentation of 7 January 2021 to make clear that the private sector and provincial health authorities are entitled to procure, distribute and administer Covid-19 vaccines independently from the Government's programme.

A contrived and hypothetical case

7 As will be demonstrated in this affidavit and in legal argument, the Solidarity/Afriforum case is wholly contrived and misconceived, both in fact and in law.

8 I emphasise the following in this regard:

8.1 The Solidarity/Afriforum case is based on a contrived reading of the Covid-19 Response presentation and a failure to understand its purpose.

8.2 The Solidarity/Afriforum case is entirely hypothetical and speculative. They place no evidence <u>at all</u> before this Court that private persons or provincial health departments are seeking to procure the Covid-19 vaccine themselves but have been precluded from doing so by the Covid-19 Response presentation or Government strategy.

8.3 The truth of the matter is that, given the facts I set out, there is presently no realistic way in which private persons or provincial health departments could procure the Covid-19 vaccine themselves. This is for practical reasons unrelated to the Covid-19 Response presentation and Government strategy.

8.4 There is therefore no tangible or justifiable advantage for the applicants which would result from the relief sought being granted and the relief sought would have no practical sigfnificance or them.

8.5 There are a range of other remedies at the disposal of Solidarity/Afriforum if, at some point in the future, it could be shown that they or other private persons are actually able to procure a Covid-19 vaccine but are being precluded from doing so by the Covid-19 Response presentation or government strategy.

9 On all of these bases alone, I submit that the relief sought should be refused.

10 I demonstrate some of these flaws by first dealing with the Solidarity/Afriforum case regarding private persons and then their case regarding provincial health departments.

The case regarding private persons

11 Solidarity/Afriforum seek to advance a case on the entitlement of private persons and institutions to procure, distribute and administer Covid-19 vaccines outside of the Government strategy. But the case is contrived and fatally flawed.

12 The first and most obvious flaw in the application is that Solidarity/Afriforum provide no evidence in their founding papers of a single private person or entity that has sought to procure, distribute and administer Covid-19 vaccines and has been precluded from doing so by the Covid-19 Response presentation.

12.1 The highwater mark of the case in this regard is a series of emails sent from Solidarity to a pharmacy group called Alphapharm enquiring whether it would be possible to obtain 10 000 vaccines outside the government programme.

12.2 The answer from Alpha Pharm, as appears from the annexures to the founding papers, was:

> *"[A]t this stage we have no intention of trying to procure vaccines outside of the Government programme. Our involvement will in all likelihood occur in the 2nd and 3rd phases of the vaccine programme, when private enterprise will be needed to assist In the roll-out to essential workers and the general public."*

12.3 This plainly does not demonstrate that Alphapharm has attempted or wants to procure Covid-19 vaccines outside of the Government programme but considers that the Government Strategy vaccines legally precludes it from doing so. It appears that Alphapharm has simply elected not to do so.

12.4 This sole example therefore cannot remotely sustain Solidarity/Afriforum's purported need for a declaratory order.

12.5 Nor is there any other evidence in the founding papers of what steps Solidarity took to procure the vaccines which they were purportedly seeking for their members. I am advised and submit that Solidarity/Afriforum will be held to their founding papers in this regard and will not be permitted to make out a new case in reply.

13 The second and related flaw in the application is that even if private parties were seeking to procure vaccines themselves (which has <u>not</u> been shown), the bar to them doing so would not emanate from the Government's vaccine strategy. Rather it would be a practical impossibility.

13.1 This is primarily a consequence of the fact that Covid-19 vaccine manufacturers are presently:

13.1.1 only selling their vaccines in very large quantities – literally millions of doses;

13.1.2 only selling their vaccines to national governments or organisations/initiatives consisting of a number of national governments; and

13.1.3 only selling their vaccines provided that the governments concerned sign agreements giving extensive liability indemnities and guarantees which would be beyond the reach of virtually any private person or institution.

13.2 It is therefore unsurprising that Solidarity/Afriforum are unable to point to a single example of a private entity or institution that has concluded an agreement with any vaccine manufacturer.

13.3 Moreover, and even leaving all of the above aside, there is the difficulty for Solidarity/Afriforum of the absence of Covid-19 vaccines being registered for general use by the South African Health Products Regulatory Authority ("**SAHPRA"**).

13.3.1 Solidarity/Afriforum appear constrained to accept (rightly) that no person can procure vaccines and distribute them in South Africa if the vaccines have not been approved by SAHPRA. But this has not yet occurred in a manner that would allow private parties to do so.

13.3.2 In respect of the AstraZeneca vaccine, it has received only SAHPRA approval for distribution of an unregistered medicine

in terms of section 21 of the Medicines and Related Substances Act 101 of 1965 ("**Medicines Act**"). That approval lasts only for six months and is limited to the NDoH. The approval does not extend to private parties or provincial health departments themselves procuring and distributing the vaccine. This is quite apart from the concerns that have now arisen regarding the use of the AstraZeneca vaccine regarding the 501Y.V2 variant in South Africa which I explain below.

13.3.3 In respect of the Johnson & Johnson vaccine, it has not yet received SAHPRA registration or approval due to the very recent stage 3 trial results. It is presently being distributed by the NDoH pursuant to a SAHPRA approved phase 3B-open trial.

14 The third flaw is the nature and effect of the relief sought by Solidarity/Afriforum.

14.1 The Covid-19 Response presentation plainly does not contain any legal prohibition on private parties procuring Covid-19 vaccines. The (ambivalent) suggestions by Solidarity/Afriforum to the contrary are artificial and contrived – apparently in an attempt to generate a purported dispute so that they could approach this Court.

14.2 But the reality of the matter is that Government and its officials have not yet had to determine whether such a legal prohibition is necessary. This is because, as I have explained above, there is no practical

possibility of any private person or institution at this stage procuring such vaccines themselves.

14.3 If such a practical possibility were to eventuate, Government would have to give careful and close scrutiny to the question of whether to impose such a legal prohibition and, if so, in what form and subject to what conditions. This is because the idea of a free-for-all whereby private persons and institutions can themselves procure Covid-19 vaccines outside the Government programme raises very real concerns and risks for the lives and health of South Africans.

14.4 This will be demonstrated by the separate affidavit of Professor Abdool Karim, the Chair of the Ministerial Advisory Committee, supported by Professor Barry Schoub. While the full details of Professor Karim's conerns will appear from his affidavit, I understand that they include that allowing this would:

14.4.1 drive up the prices of Covid-19 vaccines;

14.4.2 result in the South African government and other governments having their vaccine supplies reduced, in favour of private persons with greater resources but less need;

14.4.3 result in vaccines not being distributed to those in greatest need and who are most vulnerable but, instead, being distributed on the basis of who has the greatest financial resources;

14.4.4 create chaos regarding vaccination rollouts by imperilling the ability of the NDoH to keep track of who has been vaccinated and who has not;

14.4.5 ultimately put the health and lives of South Africans at risk by allowing uneven vaccine distribution which would render even those vaccinated susceptible to new variants.

14.5 It is also demonstrated by the expert affidavits of Professor Leslie London, Professor Saad Bin Omer and Dr Tlaleng Mofokeng, filed in this matter by the Health Justice Initiative. I do not deal with those here, save to say that the evidence of the Health Justice Initiative is directly relevant to the matters before this Court and should plainly be admitted.

14.6 Yet, it appears that what Solidarity/Afriforum seek via this application is to prevent any such measures being adopted – in advance of any decision by Government as to whether such measures are necessary and if so, on what terms and subject to what conditions.

14.7 I am advised that this is patently impermissible and untenable. Afriforum/Solidarity cannot preclude Government from making such a decision, if Government ultimately considers it necessary to do.

14.8 I am advised and submit that the approach of Solidarity/Afriforum and the relief sought by them are at odds with well-established legal principles which preclude the Courts, in advance, to make orders that would have the effect of interfering with government policy,

15 The fourth flaw is that, I am advised that in determining whether to grant declaratory relief, a court will take into account considerations of public policy, justice and convenience. Public policy in this regard is sourced *inter alia* in the Constitution.

15.1 But the approach of and relief sought by Solidarity/Afriforum would be at odds with the Constitution, public policy, justice and convenience.

15.2 For example, I understand that Professor Abdool Karim is of the opinion that allowing private persons or institutions to procure their own vaccines would be "*unethical, immoral and deeply damaging*" for our vaccination programme.

15.3 Similarly, the papers filed by the Health Justice Initiative show there are very serious adverse consequences that would flow from the approach of Solidarity/Afriforum.

15.4 What this makes clear is that debates on the "rights" Solidarity/Afriforum purport to assert and whether those are sustainable in a constitutional setting such as ours, faced with an unprecedent global pandemic, cannot be decided in the abstract and at a theoretical level without proper facts before the court. They should only be decided on concrete facts, when it is clear what vaccines are sought to be procured, by who, for who, under what conditions and so on.

The case regarding the Provincial Departments of Health

16 In addition to the relief sought in respect of private persons and institutions, Solidarity/Afriforum also seeks relief in respect of the position of "provincial health authorities". I presume that this refers to the provincial health departments.

17 But Solidarity/Afriforum provide no evidence at all in their founding indicating that any provincial health department wishes to procure, distribute or administer Covid-19 vaccines outside of the national government strategy and has been precluded or even inhibited from doing so by the Covid-19 Response presentation or any national government strategy.

18 The case of Solidarity/Afriforum there cannot get out of the starting blocks with regard to provincial health departments. It is entirely theoretical, speculative and lacking any foundation whatsoever in evidence. There is no basis for any declaratory or other relief in this regard.

19 Moreover, Solidarity/Afriforum fail to appreciate or remotely engage with the fact that the NDoH and provincial health authorities are required by the Constitution and the National Health Act 61 of 2003 ("**the National Health Act**") to collaborate and work consistently with one another. For example:

19.1 Section 41 of the Constitution places a series of obligations on organs of state in different spheres of government, which includes the NDoH and provincial health authorities.

19.2 These include obligations to

19.2.1 foster friendly relations;

19.2.2 assist and support one another;

19.2.3 inform one another of, and consult one another on, matters of common interest;

19.2.4 co-ordinate their actions with one another;

19.2.5 adhere to agreed procedures; and

19.2.6 avoid legal proceedings against one another.

19.3 Similarly the National Health Act emphasises the role of national health policies. For example:

19.3.1 Section 25(1) requires each provincial MEC for health to "*ensure the implementation of national health policy, norms and standards in his or her province*".

19.3.2 Section 25(2) requires the head of each provincial department of health to act in accordance with national health policy and the relevant provincial health policy in respect of a range of issues.

20 Moreover, as government's Covid-19 vaccine strategies make abundantly clear, provincial health authorities are an integral part of the strategy in terms of distributing and administering Covid-19 vaccines. The NDoH and provincial health departments have engaged extensively on all Covid-19 issues and will continue to do so.

21 Accordingly, were any provincial health department to wish to procure, administer Covid-19 vaccines outside the national government strategy, I have no doubt that the department concerned would first seek to engage constructively with the NDoH before actually procuring such vaccines. If any disputes emerged, the NDOH and provincial health department would each be under a constitutional and statutory duty to seek to resolve those concerns amicably. Only if this failed, would legal action be a possibility. There is simply no need for the courts to become involved in these issues at this stage, particularly in an application brought by third parties.

22 The Afriforum/Solidarity case in respect of provincial health authorities is therefore fatally flawed.

23 Even if it were not fatally flawed on this basis, much of what I say regarding the second, third and fourth flaws would apply equally to the attack in relation to the position of provincial health departments.

Conclusion

24 It is therefore quite apparent that the Solidarity/Afriforum application must fail.

25 I therefore invite Solidarity/Afriforum to withdraw this application upon consideration of this answering affidavit. In the event that they do so, no costs will be sought.

26 In the event that they do not do so, costs will be sought at the hearing of this matter on the grounds that this application is an abuse of process and manifestly untenable and inappropriate.

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

27.1 First, I deal with Government's vaccine strategy.

27.2 Second, I deal with the Covid-19 Response presentation relied on by Solidarity/Afriforum.

27.3 Third, and given the criticisms advanced by Solidarity/Afriforum regarding the pace of the vaccine roll-out I deal with the three channels being used by South Africa to procure the vaccines.

27.4 Fourth, I deal with the attempt by Solidarity/Afriforum to rely on vaccine rollouts in other countries.

THE GOVERNMENT'S VACCINE STRATEGY

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

28.1 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.

28.2 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.

28.3 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.

29 In this context, it is clear that no Government can afford to have a fixed or rigid strategy for procuring and distributing vaccines. 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.

30 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.

The initial discussions with vaccine manufacturers

31 From July 2020 onwards, the NDoH and its officials engaged in discussions with various vaccine manufacturers regarding the procurement of Covid-19 vaccines.

32 These were initial discussions aimed at understanding whether and on what basis the manufacturers would be prepared to contract with the NDoH to supply vaccines to be distributed to the South African public.

33 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**").

34 During the period July to December 2020 discussions were held with Pfizer, Johnson and Johnson, the Gamaleya Institute, the Serum Institute and Moderna, as well as Covax.

The appointment of the VMAC

35 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.

36 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.

37 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**.

38 The other members of the VMAC are:

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

38.2 Dr Morena Makhoana, the CEO of Biovac;

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

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

38.5 Prof Greg Hussey, of Vaccines for Africa;

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

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

38.8 Prof Ames Dhai, an ethicist;

38.9 Dr Mark Blecher, of National Treasury.

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

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

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

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

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

The first VMAC advisory – on COVAX

40 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:

40.1 South Africa should participate in the COVAX facility;

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

40.3 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

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

41 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.

42 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

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

44 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.

45 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.

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

46.1 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.

46.2 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.

46.3 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).

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

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

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

46.4.3 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.

47 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.

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

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

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

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

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

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

49 The Vaccine Strategy compromised six elements:

49.1 research and development;

49.2 purchase agreements;

49.3 support for local manufacturing;

49.4 regulatory approvals;

49.5 immunisation administration and monitoring;

49.6 selection criteria for vaccines.

Research and Development

50 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.)

51 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*."

52 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

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

53.1 through the Covax facility; and

53.2 by concluding purchasing agreements with individual vaccine producers.

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

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

Regulatory approvals

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

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

57.1 an early engagement with the SAHPRA;

57.2 putting in place accelerated procedure for authorisation;

57.3 adopting flexibility in relation to labelling and packaging requirements.

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

Immunisation, administration and monitoring

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

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

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

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

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

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

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

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

Selection criteria for vaccines

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

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

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

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

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

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

63.6 Liability attached to specific vaccines.

63.7 Capacity to supply through the development of production capacity.

63.8 Vaccine presentation and suitability for the South African market.

63.9 Local registration is a requirement.

63.10 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

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

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

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

65 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

66 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".

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

Leadership and co-ordination

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

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

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

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

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

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

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

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

70.6 Monitoring and evaluation;

70.7 The chair of the provincial co-ordinating committees;

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

70.9 The World Health Organisation.

71 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:

71.1 EPI;

71.2 CDC;

71.3 SCM;

71.4 HRH;

71.5 PHC;

71.6 Monitoring and evaluation; and

71.7 the provincial private sector co-ordinating committee.

72 The Rollout Strategy also requires provinces to establish structures at the district level in order to manage the mass vaccine roll-outs. It makes clear the critical role played by provincial health departments in this regard.

73 The Rollout Strategy expressly 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

74 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.

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

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

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

75.2.1 2 500 000 essential workers;

75.2.2 1 100 000 persons living in congregate settings;

75.2.3 5 000 000 persons who are over the age of 65 years; and

75.2.4 8,000,000 persons who are over the age of 18 years and who have Covid-19 co-morbidities.

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

76 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 COVID-19 RESPONSE PRESENTATION AND ITS EFFECT

77 In their papers, Solidarity/Afriforum focus on the Covid-19 Response presentation of 7 January 2021 which is annexed to the founding papers. It is this document, they contend, which purports to prohibit private persons and institutions and provincial departments of health from procuring, distributing and administering Covid-19 vaccines outside of the national government strategy.

78 The Covid-19 Response presentation is a powerpoint presentation. It is not a law or even a gazetted policy. It does it purport to be such a law or policy. Nor was that its purpose or intended effect.

79 Instead, the powerpoint presentation was used by Minister Mkhize to assist him in updating the Parliamentary Portfolio Committee of Health on 7 January 2021 on the government's strategy for dealing with Covid-19, including in relation to vaccines.

80 Beyond this, the presentation does not appear to have been issued by the NDoH to the public or to provincial health departments. Nor, to the best of my knowledge, was it even placed on the Government's Covid-19 webpage, including the section devoted to vaccines.

81 At most therefore, the Covid-19 Response presentation is a recordal of government's strategy at a point in time, in order to update Parliament in this regard.

82 There is nothing in the Covid-19 Response presentation which purports to be a legal prohibition on private persons and institutions or provincial health departments from procuring Covid-19 vaccines.

82.1 Solidarity/Afriforum rely on the statement in the Covid-19 Response presentation that:

> *"The SA government will be the sole purchaser of the vaccines for the country. The NDOH will contract with suppliers to purchase stock and allocate to provincial health departments and the private health sector."*

82.2 But nothing in this language or the context of the presentation points to this being a legal prohibition on private persons and institutions or provincial health departments from procuring Covid-19 vaccines.

82.3 Instead, it is patently merely a reflection of national Government's strategy that it intends to be the sole purchaser of vaccines for the country; and that the NDoH will then allocate the vaccines to provincial health departments and the private sector.

82.4 Government has adopted this strategy for very good reason. It has done so mindful of:

82.4.1 The duty Government owes to all South Africans to take reasonable measures to protect their lives and health;

82.4.2 The need to reach herd immunity via vaccinations;

82.4.3 The reality that vaccine manufacturers are only selling vaccines to national governments and so, if national government does not procure the vaccines for all South Africans, they will not be provided to all South Africans; and

82.4.4 Acute concerns about the negative effects that could result were vaccines instead to be procured directly by private persons or institutions, or by provincial health departments. Some of these will be set out in the separate affidavit of Professor Karim to which I have referred earlier.

82.5 The Government's strategy in this regard is no secret. It was reiterated by Minister Mkhize in his speech in Parliament during the debate on the State of the Nation Address on 16 February 2021, where he stated:

> *"To ensure that our battle against the pandemic remains grounded on the principles of "solidarity and compassion", our strategy is that the State will be the sole purchaser of the vaccines for the country, irrespective of the manufacturer and source. The vaccines will be predominantly funded by the fiscus whilst the private sector, in particular private health funders, will augment the funding and other resources required to implement the programme. As such, vaccination will be free at the point of care and no citizen should pay out of pocket when they get inoculated…"*

82.6 A copy of the speech is attached as **Annexure SB6A**.

83 The attempt by Solidarity/Afriforum to now contend that the Covid-19 Response presentation contains a legal prohibition on private persons and institutions or provincial health departments from procuring Covid-19 vaccines is plainly contrived and unsustainable. It does no such thing.

84 But the reality of the matter is that Government and its officials have not yet had to determine whether such a legal prohibition is necessary. This is because, as I have explained above, there is no practical possibility of any private person or institution at this stage procuring such vaccines themselves.

85 If such a practical possibility were to eventuate, Government would have to give careful and close scrutiny to the questions of:

85.1 Whether to impose such a legal prohibition; and

85.2 If so, in what form, for what period, and subject to what conditions.

86 This is because the idea of an effective free-for-all whereby private persons and institutions can themselves procure Covid-19 vaccines outside the Government programme raises very real concerns and risks for the lives and health of South Africans and for the success of Government's Covid-19 strategy.

87 I do not wish to express a final view on this issue at this stage.

87.1 For present purposes it suffices to say that the real concerns that arise:

87.1.1 will be demonstrated by the separate affidavit of Professor Abdool Karim, the Chair of the Ministerial Advisory Committee, supported by the affidavit of Professor Barry Schoub; and

87.1.2 are demonstrated by the expert affidavits of Professor Leslie London, Professor Saad Bin Omer and Dr Tlaleng Mofokeng, filed in this matter by the Health Justice Initiative.

87.2 For example, while the full details of Professor Karim's views will appear from his affidavit, I understand that his concerns include that that allowing this would:

87.2.1 drive up the prices of Covid-19 vaccines;

87.2.2 result in the South African government and other governments having their vaccine supplies reduced, in favour of private persons with greater resources but less need;

87.2.3 result in vaccines not being distributed to those in greatest need and who are most vulnerable, but instead being distributed on the basis of who has the greatest financial resources;

87.2.4 create chaos regarding vaccination rollouts by imperilling the ability of the NDoH to keep track of who has been vaccinated and who has not;

87.2.5 ultimately put the health and lives of South Africans at risk by allowing uneven vaccine distribution which would render even those vaccinated susceptible to new variants.

88 Whether Government would ultimately impose such a prohibition and subject to what terms and conditions would depend on the circumstances then prevailing.

89 What this makes clear is that the relief sought by Solidarity/Afriforum in this matter is impermissible and unsustainable.

THE THREE CHANNELS BEING USED TO PROCURE THE VACCINES

90 In an effort to sustain its case, Solidarity/Afriforum seeks to criticise the Government's vaccine programme as "clearly slow and delayed". Even if it were accurate, this criticism does not sustain or justify the relief sought. But it is also incorrect on the facts, as I demonstrate in what follows.

91 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."*

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

93 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

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

95 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.

96 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.

97 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.

98 I emphasise that 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.

99 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.

99.1 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.

99.2 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.

100 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).

100.1 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.

100.2 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.

101 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.

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

102.1 This down payment of $19.2 million (R 283 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.

102.2 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.

102.3 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.

102.4 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.

103 The assertion in paragraph 77 of the founding papers that the delivery of vaccines to South Africa has been delayed because South Africa had "missed" the deadline for paying the deposit are quite incorrect.

103.1 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).

103.2 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.

103.3 (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 in light of considerations mentioned below.)

The second procurement channel – obtaining vaccines via the African Union

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

105 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.

106 There is not yet finality around the AU process or how doses between the various countries will be divided. Discussions and arrangement 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

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

108 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.

109 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.

110 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.

111 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:

111.1 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.

111.2 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.

111.3 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.

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

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

112.2 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.

112.3 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.

113 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.

114 However, South Africa is not such a country.

114.1 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 R 20 billion for just 67% of the population. But this does not accounted for wasted funds on unsuccessful "bets".

114.2 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.

114.3 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.

115 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.

115.1 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.

115.2 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.

115.3 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.

115.4 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.

115.5 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.

115.6 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.

115.6.1 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*."

115.6.2 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.

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

115.8 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.

115.9 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.

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

116 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.

117 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:

117.1 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;

117.2 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;

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

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

117.5 Cost associated with the vaccine.

118 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.

119 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:

119.1 Pfizer;

119.2 Moderna;

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

119.4 Johnson & Johnson.

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

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

The AstraZeneca vaccine

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

123 The AstraZeneca vaccine's phase 3 trial results were released on 8 December 2020. They indicated a success rate of 70.4%.

124 The AstraZeneca vaccine was first given emergency authorisation in the United Kingdom and Argentina on 30 December 2020. It was approved in India (as Covishield) on 3 January 2020. On 22 January 2021, the SAHPRA granted a section 21 authorisation in terms of the Medicines Act for the AstraZeneca vaccine to be used against Covid-19. A copy is attached marked **Annexure SB12A.**

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

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

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

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

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

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

128.2 500 000 doses would be shipped during February 2021.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

133 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.

134 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.

135 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.

136 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.

137 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.

137.1 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.

137.2 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.

137.3 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.

137.4 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.

137.5 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.

137.6 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.

137.7 The practical effect is that this will allow the Johnson & Johnson vaccines to be administered to health care workers. This process began on 17 February 2021, just two days after the roll-out of AstraZeneca was due to occur. On 19 February 2021 alone, 6500 healthcare workers were vaccinated.

137.8 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

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

139 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.

140 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.

141 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.

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

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

142.2 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.

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

142.4 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.

143 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.

144 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.

145 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.

146 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:

146.1 2 million doses in May;

146.2 1.5 million doses in June;

146.3 1.5 million doses in July;

146.4 1.5 million in August;

146.5 1.5 million doses in September;

146.6 2.5 million doses in October;

146.7 2.5 million doses in November;

146.8 3.5 million doses in December;

146.9 3.5 million doses in January 2022.

147 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

148 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.

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

150 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.

151 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.

152 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.

153 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

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

155 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.

155.1 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.

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

155.3 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.

156 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.

156.1 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.

156.2 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.

THE ATTEMPT TO RELY ON VACCINE ROLLOUTS IN OTHER COUNTRIES

157 It is clear from what I have set out above that Government was proactive and put in place clear vaccine strategies, including procurement strategies.

158 However, in an attempt to bolster their case, Solidarity/Afriforum resort to seeking to rely on how far other countries are in rolling out vaccines.

159 This is an inappropriate and untenable approach because Solidarity/Afriforum offer no evidence at all to suggest that the vaccine rollout in the countries concerned has involved private persons or provincial governments procuring their own vaccines. On the contrary, to the best of my knowledge, all of the countries mentioned by Solidarity/Afriforum have procured vaccines exclusively though their national government and then distributed to provincial authorities and/or the private sector for distribution. The argument advanced is therefore without merit.

160 But, in addition, the point made by Solidarity/Afriforum is entirely contrived. As I demonstrate in what follows, their 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.

161 Solidarity/Afriforum refer (at paragraphs 73 to 76) to four countries that had administered 500 000 or more doses of Covid-19 vaccines: the United Kingdom, China, India and Russia. (They inexplicably leave out the United States.)

161.1 They offer no explanation at all as to what they say these countries have done right as opposed to South Africa. This makes it almost impossible to respond meaningfully to Solidarity/Afriforum's case, save to say the following.

161.2 It appears clear that the United States and the United Kingdom placed 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.

161.3 China and Russia are equally bad comparators. They are large vaccine manufacturers and are using Chinese vaccines and Russian vaccines respectively for their vaccine programmes.

161.4 Similarly, 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.

161.5 These countries are therefore patently bad comparisons.

162 Solidarity/Afriforum then try (at paragraphs 73 to 76) 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 criticise Government.

162.1 Solidarity/Afriforum again offer no explanation at all as to what they says these countries have done right as opposed to South Africa. Again, this makes it almost impossible to respond meaningfully to Solidarity/Afriforum's case, save to say the following.

162.2 Some of the countries mentioned (for example, the United Arab Emirates, Bahrain and Israel) are considerably wealthier than South Africa with their GDP/capita many times as great as South Africa's. Their governments used this advantage to engaged in pre-orders with vaccine manufacturers, with all the risks these entail.

162.3 Bulgaria's government did the same, drawing on its position as a member of the EU, one of the largest and wealthiest blocks of countries in the world, which engaged in centralised procurement of vaccines for all of its members.

162.4 Turkey's government appears to have entered into advance purchase orders with Sinovac long before its stage 3 trial results were announced as recently as 5 February 2021.

162.5 Lastly, the four Latin American governments 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.

163 In the circumstances, Solidarity/Afriforum's arguments on this score are entirely unsustainable.

AD SERIATIM RESPONSE

164 I now turn to deal with the allegations contained in Solidarity/Afriforum'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. I will also not engage in matters of legal argument – these will be dealt in heads of argument and at the hearing of the matter.

165 Where an allegation is made by Solidarity/Afriforum 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 - 3

166 Save to deny that the facts continued in the affidavit fall within Mr Hermann's personal knowledge and are true and correct, I note the contents of these paragraphs.

Ad paragraph 4

167 I reiterate that there is a great deal of information in the founding affidavit that

does not fall within Mr Hermann's knowledge and which constitutes impermissible hearsay evidence. I submit there is no basis for this hearsay evidence contained in the affidavit to be admitted. To do so would indeed prejudice the respondents.

Ad paragraph 5

168 I note the contents of this paragraph but deny that the legal contentions contained in the affidavit are well founded.

Ad paragraphs 6 to 10

169 I note the contents of these paragraphs.

Ad paragraph 11

170 The applicants appear confused about the identity of the chairperson of the MAC. The chairperson of the MAC is Professor Salim Abdool Karim. There is then a separate Vaccines Ministerial Advisory Committee (the VMAC), the chairperson of which is Professor Barry Schoub.

171 To avoid any debate, affidavits from both Professor Karim and Professor Schoub will be filed in this matter.

Ad paragraphs 12 to 24

172 I note the contents of these paragraphs.

Ad paragraphs 25 and 26

173 I deny the contentions contained in these paragraphs . I deny in particular that:

173.1 the relief sought by the applicants is well founded; and

173.2 the relief sought falls within the ambit of sections 38 and 172(1) of the Constitution or section 21(1)(c) of the Superior Courts Act.

174 Legal argument on this score will be advanced at the hearing of the matter.

Ad paragraphs 27 to 40

175 I deny that the first and second applicants have the requisite *locus standi* to seek the relief sought in the present application.

176 Without derogating from the generality of this denial, I emphasise that:

176.1 The applicants have not shown the actual or threatened infringement of any person's rights and have not shown that they act in the public interest; and

176.2 Even if the applicants had established the requisite locus standi in respect of the position of private parties and institutions (which they have not), they have certainly not established the requisite locus standi in respect of the position of provincial health departments.

177 Legal argument on this score will be advanced at the hearing of the matter.

Ad paragraphs 42 to 44

178 I admit the contents of these paragraphs to the extent that they accurately reflect the "Covid-19 vaccine rollout strategy" issued on 3 January 2021. Save as aforesaid, I deny them.

Ad paragraphs 45 to 47

179 I admit the contents of these paragraphs to the extent that they accurately reflect the "Covid-19 response" presentation of 7 January 2021. Save as aforesaid, I deny them.

Ad paragraph 48

180 I deny the contents of this paragraph. There is nothing in the Covid-19 response presentation of 7 January which purports to legally prohibit the private healthcare sector, the private sector or business sector from procuring and distributing Covid-19 vaccines outside the framework of Government's centralised strategy and rollout programme.

Ad paragraphs 49 to 51

181 I admit that the correspondence referred to was sent and that it was not replied to. Given the extraordinary and unprecedented pressures on government in dealing with the Covid-19 pandemic in general and vaccines in particular, this is unsurprising though regrettable.

Ad paragraph 52

182 I deny the contents of this paragraph. The failure to reply to the letter concerned was not intended in any way to confirm of the applicants' purported interpretation and understanding of the position.

183 In any event, whatever purported interpretation and understanding of the position the applicants may have had at the time of launching this application, it ought now to be resolved by the contents of affidavit. There is plainly no longer a live

dispute between the parties on this score, if there ever was one.

Ad paragraphs 53 and 54

184 I deny the contents of these paragraphs. The purported evidence is inadmissible hearsay in a range of respects. In fact it is double or treble hearsay. It falls to be ignored.

185 Indeed, the unreliability of the purported evidence is indicated by the fact that while the author of the electronic media newsletter states that Discovery Health Medical Scheme "cannot choose to purchase suitable vaccines because the government will not allow this", this is entirely at odds with the actual approach of Discovery Health.

185.1 I attach in this regard as **Annexure SB14** a copy of a letter from Discovery Health Medical Scheme to its members on 15 February 2021.

185.2 That letter makes clear that Discovery Health takes the view that the reason it cannot procure the vaccines is because of the practical consideration that the vaccine manufacturers will not sell directly to the private sector instead of to governments.

185.3 There is no suggestion that it is government strategy that has prohibited or prevented it from doing so. Indeed, the letter is supportive of Government's strategy.

Ad paragraphs 55 and 56

186 I deny the contents of these paragraph. The assertions contained in these

paragraphs (and they are mere assertions) involve a contrived and unsustainable reading of the Covid-19 Response presentation.

Ad paragraphs 57 and 58

187 I admit that South Africa continues to battle with the effects of the Covid-19 pandemic. I point out that the second wave referred to has now ended.

Ad paragraph 59

188 I admit that there is a need for government to vaccinate South Africans in an expeditious, systematic and effective manner in order to achieve herd immunity. I deny that this means that a free-for-all approach, whereby the private sector procures its own vaccines, is desirable or in line with this strategy or aim.

Ad paragraph 60

189 I deny the contents of this paragraph. It is an unmotivated assertion for which no proper evidentiary basis is given. I note that the very examples which the applicants refer to as demonstrating effective and quick vaccination in other parts of the world appear to have taken place through programmes where the central government has procured the vaccines, not the private sector outside of the government programme.

Ad paragraphs 61 and 62

190 I deny the contents of these paragraphs.

190.1 For a start, they involve the contrived and untenable reading of the Covid-19 Response presentation.

190.2 Moreover, and in any event, the applicants plainly fail to appreciate the regulatory constraints on who can import, distribute and sell vaccines. This will be addressed in argument to the extent necessary.

Ad paragraph 63

191 If it is alleged that provincial health departments are prohibited by virtue of the Covid-19 response presentation from procuring their own vaccines, then I deny that this is the case. It is a contrived and unsustainable reading of the Covid-19 Response presentation.

192 However, as I have pointed out above, the NDoH and provincial health departments bear a series of obligations flowing from the Constitution and the National Health Act to act in collaboration with and after engagement with one another, including in relation to matters of national health policy. I repeat what I have set out there.

Ad paragraph 64

193 I admit that:

193.1 Some countries commenced vaccination in early December 2020;

193.2 It is desirable to reach herd immunity via vaccinations as soon as possible, provided that this is undertaken in a systematic and structured way that takes account of those who are most vulnerable.

194 Save as aforesaid, I deny the contents of this paragraph. I deny in particular that national government's response was slow and delayed and point out that the

vaccination programme has now begun, despite the unexpected challenges caused by the AstraZeneca test results.

Ad paragraph 65

195 I deny the contents of this paragraph. As I have explained above, quite apart from any government policy or strategy, there is presently no way for the private sector to obtain vaccines.

196 In any event, as is made clear by the expert affidavits filed:

196.1 The question of speed is not the only question. It is critical that the correct people are vaccinated as a priority.

196.2 There is a real risk that if private parties started to procure vaccines this would drive up the price and reduce the availability of vaccines for South Africa and other governments.

Ad paragraph 66

197 I deny the contents of this paragraph.

Ad paragraph 67

198 I deny the contents of this paragraph. For a start, I reiterate that the Covid-19 response document does not contain any legal prohibition in respect of the procuring of the vaccine. In any event, I deny that a centralised system for procuring vaccines would be a violation of any constitutional right, including the right to freedom and security of the person and privacy.

Ad paragraph 68

199 I admit that the emails concerned were exchanged. I deny that they provide any support for the applicants' case. As I have explained earlier, there is nothing in the emails to suggest that Alphapharm considered itself precluded as a matter of law by the Covid-19 Response presentation or government strategy from procuring the vaccines concerned.

Ad paragraphs 69 and 70

200 I admit the contents of these paragraphs to the extent that they accurately reflect the press release issued by the Council of Medical Schemes. Save as aforesaid, I deny the contents of these paragraphs.

201 I reiterate that:

201.1 The Covid-19 Response presentation does not contain any legal prohibition against persons from procuring the vaccine; and

201.2 Any such prohibition, if it were to exist, would not be unlawful and irrational.

Ad paragraphs 71 to 76

202 I deny the contents of these paragraphs. I have dealt above with the attempts by the applicants to compare South Africa to other countries concerned. I pray that what I said there is read as incorporated herein.

Ad paragraph 77

203 I deny the contents of this paragraph. As I have explained above, South Africa

will be one of the countries to receive the first batch of COVAX vaccines.

Ad paragraphs 78 and 79

204 I have dealt above in detail with the Covax arrangement and South Africa's participation therein. I deny the contents of these paragraphs to the extent that they are inconsistent with what is stated there.

Ad paragraphs 80 and 81

205 I admit that:

205.1 the Minister has stated that at least 67% of the South African population will need to be vaccinated to ensure herd immunity;

205.2 the Covax scheme would cover 10% of the population with the vaccine delivered by the second quarter of 2021; and

205.3 doses for the remainder of the population would be sourced by bilateral agreements. I have dealt with these arrangements in detail above.

206 Save as aforesaid, I deny that the applicants are entitled to place any reliance on the article concerned. It is inadmissible hearsay.

Ad paragraph 82

207 I deny the contents of this paragraph. I have dealt in detail above with the status of the bilateral negotiations and agreements concluded by the government.

Ad paragraphs 83 and 84

208 I deny the contents of these paragraphs. I reiterate that:

208.1 The Covid-19 Response presentation does not contain any legal prohibition against persons from procuring the vaccine; and

208.2 Any such prohibition, if it were to exist, would not be unlawful and irrational.

Ad paragraph 85

209 I deny the contents of this paragraph. I refer to the affidavit of Professor Karim which highlights his views on the negative effects that would result were there to be a free-for-all approach of allowing the private sector to procure vaccines itself.

Ad paragraph 86

210 I deny the contents of this paragraph. I reiterate that:

210.1 The Covid-19 Response presentation does not contain any legal prohibition against persons from procuring the vaccine; and

210.2 Any such prohibition, if it were to exist, would not be unlawful and irrational.

Ad paragraph 87

211 There is no evidence before the court that non-governmental organisations wish to procure the vaccines themselves and then distribute them.

Ad paragraphs 88 and 89

212 I note the contents of these paragraphs but deny that the contentions contained therein are well founded.

Ad paragraph 90

213 I note that the aim of the applicants is to "remov[e] any limitation of or restriction on" the private sector procuring vaccines independently of the government's rollout programme. Even here, the applicants are equivocal as to whether such a prohibition exists.

214 I deny that the applicants have made out a proper case for the relief sought.

Ad paragraph 91

215 I note the declaratory order sought but deny that it is sustainable or that the applicants have made out a proper case in this regard.

Ad paragraphs 92.1 to 92.5

216 I note the quotation of section 7(1) and 7(2) of the Constitution but deny that these provisions or other provisions of the Constitution have been violated.

Ad paragraph 92.6

217 I note the contents of this paragraph but deny that the contentions sustain the applicants' case.

Ad paragraphs 92.7 to 92.20

218 I note the contents of these paragraphs and the quotations from various provisions of the Constitution and National Health Act. I deny that the contentions contained in these paragraphs are well founded.

Ad paragraphs 92.21 and 92.22

219 I accept that a strategy of government is not a law. That is precisely why it must be obvious to the applicants that the Covid-19 Response presentation cannot and does not legally prohibit anyone from doing anything.

220 I deny that Covid-19 Response presentation has a "practical regulatory effect", whatever that phrase is intended to mean.

Ad paragraph 92.23

221 I deny the contents of this paragraph.

Ad paragraphs 93.1 to 93.3

222 I admit the contents of these paragraphs.

Ad paragraph 93.4

223 I deny the contents of these paragraphs. The sweeping assertions made are unfounded and the legal conclusions reached are equally unfounded.

Ad paragraph 93.5

224 Save to note the quotation of the principle of legality, I deny the contents of this paragraph.

Ad paragraph 93.6

225 I note the contents of this paragraph.

Ad paragraphs 93.7 – 93.8

226 I deny the contention that the Covid-19 Response presentation requires a

specific statutory power before it can be made. The need to adopt strategies and policies to deal with healthcare challenges flows from a range of constitutional and statutory provisions, including most obviously section 27(2) of the Constitution. The power to formulate government policy in this context plainly falls within the power of the executive.

227 I accept that government policies and strategies must be rational, lawful and constitutional. This strategy plainly is.

Ad paragraph 93.9

228 I accept that government cannot elevate a strategy document to the level of law intended to have binding effect. Government has not done so. There is nothing in the Covid-19 response strategy which suggests that it purports to have legally binding effect.

Ad paragraph 93.10

229 I deny the contents of this paragraph.

Ad paragraphs 94.1 to 94.4

230 I deny that there is any basis for the relief sought by the applicants.

Ad paragraphs 95 to 102

231 I have no difficulty with this matter being dealt with expeditiously, provided that:

231.1 It is on a date agreed between the parties and that suits all parties' counsel; and

231.2 It is heard by a Full Bench, as the parties have already agreed is appropriate.

232 I deny, however, that the applicants have shown any actual harm that will eventuate to them or the public while the matter is pending. As I have explained, the purported dispute is entirely contrived.

Ad paragraph 103

233 I note the contents of this paragraph. I pray that if the application is persisted with following receipt of the answering affidavit, it be dismissed with costs, including the costs of two counsel.

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DR 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 on this the ____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.

_____
COMMISSIONER OF OATHS
Full names:
Address:
Capacity: