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Our Ref: DEM16/0763/ELZANNE JONKER/ks | Your Ref: | Date: 18 January 2021

THE PRESIDENT OF THE REPUBLIC OF SOUTH AFRICA

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Dear Sir

SOUTH AFRICA'S VACCINE ROLL-OUT IN RESPECT OF THE COVID-19 PANDEMIC

1. We act on behalf of the Democratic Alliance. We are instructed as set out below.
2. Following the arrival of the 'Severe Acute Respiratory Syndrome Coronavirus 2' ('the Coronavirus') on our shores at the beginning of 2020, more than 1,3 million South Africans have contracted the virus; some have been asymptomatic and some have been debilitated. According to the figures provided by the national government, 37,105 individuals have died. Covid-19 – the disease caused by the Coronavirus – has been designated as a global pandemic. The World Health Organisation reports that there have been more than two million confirmed worldwide deaths as a result of disease.
3. Some components of the national government's response to the Coronavirus have been laudable. These include various public-health initiatives, such as mandatory mask wearing, hand sanitising and social distancing. Our client continues to support these initiatives.
4. However, in addition to the devastating health and mortality consequences of the Coronavirus, South Africa has suffered a series of accompanying economic and social crises. In response to the Coronavirus, the national government imposed various 'lockdowns' and 'alert levels' that restricted social and economic activity to a degree previously unseen in democratic South Africa. Millions of employment opportunities were lost and Statistics South Africa reported that, in December 2020, the economy was 5,8%

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smaller than at the end of 2019. Some children had as few as 118 scheduled days of school, as opposed to the 202 days they should have had. Health workers at the forefront of the fight against the pandemic are exhausted and constantly exposed to the risk of infection. No one in South Africa has been left unaffected by the pandemic and the national government's response.

5. On 15 March 2020 the Minister of Cooperative Governance and Traditional Affairs ('the COGTA Minister') placed South Africa under a national state of disaster. This has been extended on several occasions; on 13 January 2021 the COGTA Minister extended the state of disaster once again until 15 February 2021. Throughout the state of disaster the COGTA Minister has imposed various regulations that, among other things, make vast inroads on fundamental constitutional rights ('the Disaster Regulations'). People's ability to work, to provide for their families, to gather in social, religious or cultural settings, and even to leave their homes has been restricted or completely negated, at a cost of billions to the economy and unquantifiable harm to civil liberties and socio-economic well-being. By the end of the current extension period, this will have been ongoing for 337 days.
6. Continuing to keep these restrictions in place, in one form or another, is unaffordable and unsustainable. However, the pandemic shows no signs of abating. South Africa is currently battling a second deadly wave and many provinces have not yet reached their peak. The winter months are fast approaching, during which the impact of respiratory viruses such as the Coronavirus are even worse. All indications point to a third wave in the latter half of 2021.
7. The only prospect of returning South Africa to a semblance of constitutional normality, where people are able to live healthy lives, provide for their families and enjoy the freedoms that are rightfully theirs in a democratic society, without the constant intrusion of the Disaster Regulations, is a rapid and widespread vaccination programme. This has long been known, and publicly acknowledged by the national government.
8. At present, there are 289 vaccine candidates, 69 vaccines in clinical testing and ten that are in use around the world.
9. On 9 November 2020 Pfizer and BioNTech announced that their vaccine had been found efficacious against Covid-19. They planned to produce 50 million doses in 2020 and 1,3 billion doses in 2021. Vaccine deliveries in the United States of America began in mid-December. The Pfizer / BioNTech vaccine has now been authorised for use in Argentina,

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Canada, Chile, Singapore, Switzerland, the United Kingdom and various other countries, as well as the European Union. Between July and December 2020, various governments concluded agreements to acquire the vaccine from Pfizer / BioNTech. The first vaccine dose was administered to a member of the public on 8 December 2020.

10. On 30 November 2020 Moderna announced that its vaccine had been found efficacious against Covid-19. It planned to produce 20 million doses in 2020 and one billion doses in 2021. The Moderna vaccine has been authorised for administration in Canada, the European Union, Israel, Switzerland, the United Kingdom and the United States of America. Between August 2020 and January 2021, various governments concluded agreements to acquire the vaccine from Moderna.
11. On 8 December 2020 the University of Oxford and AstraZeneca published a paper showing that, after medical trials (including trials conducted in South Africa), their vaccine had been found efficacious against Covid-19. They plan to produce 3 billion doses in 2021. The AstraZeneca vaccine has been approved for use in Argentina, India, Mexico and the United Kingdom, among others. Governments began concluding agreements with AstraZeneca to acquire its vaccine as early as May 2020.
12. An individual requires the intramuscular injection of at least two doses of each of the above vaccines in order for the immunisation to be effective. There are a further seven vaccines that have been approved for use in various jurisdictions, each with their own storage and dosage requirements.
13. More than 35 million vaccine doses have been administered globally: more than 12 million in the United States of America, more than 10 million in China and almost 1,7 million in the United Arab Emirates. Israel has administered doses of a vaccine to more than 23% of its population. India has commenced administering doses in its programme to vaccinate 300 million people within seven months. Turkey, Serbia, Oman, Mexico and Argentina have all begun vaccinating their citizens.
14. Of critical concern to our client – and to South Africans across the board – is: what is the state of South Africa's vaccine acquisition and roll-out programme?
15. On 11 January 2021, you addressed the nation regarding the national government's efforts to contain the pandemic. You announced the extension of 'adjusted alert level 3' under the Disaster Regulations, with certain variations (such as the closure of all land borders for

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more than a month). You noted that the development of effective Covid-19 vaccines was 'the most promising' initiative to combat the pandemic and that approximately 40 million South Africans would need to be vaccinated in order to achieve population immunity. You noted that the vaccination roll-out would be 'the largest and most complex logistical undertaking' in South Africa's history.

16. You then announced the national government's 'comprehensive vaccination strategy to reach all parts of the country' ('the Strategy'). You stated the following:

16.1 The first component of the Strategy comprises acquiring enough vaccine doses to reach population immunity. To this end, the national government is 'in the process of procuring vaccines through three channels: through the World Health Organization's COVAX facility, through the African Union's vaccine initiative and through direct engagements with vaccine manufacturers'. South Africa will receive doses for 10% of the population through COVAX. The African Union's Vaccine Acquisition Task Team has 'done tremendous work to secure vaccine doses for countries on the continent.' The national government 'has also been engaging directly with several vaccine manufacturers for over six months'. Although other countries have significantly greater purchasing power, 'there are several promising negotiations with a number of different manufacturers that still need to be concluded [and] we have to date secured 20 million doses to be delivered mainly in the first half of the year'.

16.2 The second component of the Strategy entails identifying the population groups in order of priority to receive the vaccine:

In Phase 1, with the first batch of vaccines, we will prioritise around 1.2 million front line health workers.

In Phase 2, when more vaccines arrive, we will prioritise essential workers such as teachers, police, municipal workers and other frontline personnel. We will also prioritise people in institutions like old age homes, shelters and prisons, people over 60 years of age and adults with co-morbidities. The total number we plan to reach in this phase is around 16 million people.

In Phase 3, with increased manufacturer supplies, we will then vaccinate the remaining adult population of approximately 22.5 million people.

- 16.3 The final component of the Strategy is the distribution and administration of the vaccine, which will be overseen by a national coordinating committee that comprises government departments, the private sector and other stakeholders. The vaccines will be administered through public health institutions, private health institutions and workplaces. The acquisition, funding and distribution of vaccines will be supported by an 'inclusive partnership' comprising government, the private sector and medical schemes. Only vaccines approved by the South African Health Products Regulatory Authority ('SAHPRA') will be administered.
17. Your explanation of the Strategy made no reference to the 1,500,000 doses of the AstraZeneca vaccine that Dr Mkhize reported South Africa would receive from the Serum Institute of India during January and February 2021.
18. Your explanation of the Strategy reflects the 'Covid-19 vaccine strategy' and the 'vaccine rollout strategy' published by your government in January 2021. These publications indicate the following:
- 18.1 Various initiatives and mechanisms will be implemented by COVAX to ensure that vaccine doses are made available to participating countries on an equitable basis. COVAX will support access for lower-income countries through the Advance Market Commitment ('AMC') mechanism.
- 18.2 On 31 August 2020, the South African government 'submitted a non-binding expression of interest in the COVAX facility'. The national government estimates that it will be able to vaccinate at least 10% of South Africa's population by means of doses acquired through COVAX.
- 18.3 COVAX will procure its vaccine doses from manufacturers 'by the end of 2021'. However, the South African government anticipates that it 'will receive the first batch of vaccines in quarter two of 2021.'
- 18.4 The national government needs to explore 'advance purchase agreements, direct purchase agreements, and open tender procedures' with individual vaccine producers in order to secure the vaccines that cannot be supplied through COVAX.

- 18.5 Two South African producers – Biovac and Aspen – are 'currently involved in setting up to do the drug product manufacturing for COVID-19 vaccines'.
- 18.6 It will be necessary for the national government 'to put several measures in place to ensure regulatory approvals of safe vaccines'. To this end, SAHPRA has appointed a dedicated team to facilitate the expedited review of any vaccine that is sought to be registered in South Africa. However, '[v]accines containing newer technologies are anticipated to take longer for approval despite the process of expedited review.'
- 18.7 Assuming that SAHPRA approves one or more vaccines for use in South Africa, 'it is unlikely that there will be sufficient vaccines available for use beyond specific high-risk groups in the country before the third quarter of 2021 and even then it is likely that only limited quantities of the vaccine will be available'. The high-risk groups include healthcare workers, persons with co-morbidities, persons in crowded settings and essential workers.
- 18.8 Standard operating procedures are 'currently being developed' to ensure that the roll-out programme is properly implemented. This includes the development of guidelines, the training of healthcare workers and the development of certification tools.
- 18.9 The national government needs to develop selection criteria to inform its negotiations with vaccine producers and to select vaccines for use in South Africa.
19. We note that there are some inconsistencies between the 'vaccine strategy' publication and the 'rollout strategy' publication. The former says that South Africa will receive 'the first batch' of vaccines from COVAX in the second quarter of 2021; presumably, the other doses will follow later in the year. However, Dr Mkhize is recorded as saying that 'the processes will have delivered the vaccine by beginning of second quarter'. Furthermore, the 'rollout strategy' publication itself states that COVAX itself will only receive all of its required doses at the end of 2021.
20. On 13 January 2021 your office issued a publication indicating that, to supplement the vaccines acquired by Africa from COVAX, the African Union's Task Team 'has secured a provisional 270 million vaccine doses for African countries, with at least 50 million being available for the crucial period of April to June 2021'. These include the Pfizer and

AstraZeneca vaccines, which will be supplied by Pfizer, the Serum Institute of India and Johnson & Johnson. The publication noted that 'the COVAX volumes to be released between February and June may not extend beyond the needs of frontline health care workers and may thus not be enough to contain the ever-increasing toll of the pandemic in Africa'.

21. The national government's communication regarding its ability and readiness to implement a large-scale vaccination programme for South Africa's almost 60 million citizens gives rise to deep concerns.
22. First: the national government has only secured vaccine doses through COVAX, and then only in respect of approximately 10% of the population (i.e. approximately 6 million people). However:
 - 22.1 The national government's publications indicate that COVAX will have procured its vaccines by the end of 2021, which is the earliest point at which they could be made available to South Africa. Nevertheless, the national government anticipates that the 'first batch' will be received between April and June 2021. No indications have been given as to: (a) which vaccine will be supplied; (b) what price South Africa will pay; (c) whether the necessary agreements have been concluded with the manufacturers, suppliers and delivery agents; (d) when the vaccine doses will be available for administration in South Africa; and (e) what the other terms are for the provision of these vaccine doses for six million people.
 - 22.2 There are no indications that SAHPRA or any other authority has authorised the vaccine(s) that COVAX will supply for use in South Africa.
 - 22.3 The national government's publication makes reference to COVAX's AMC mechanism. However, South Africa does not fall within the countries designated to benefit from that mechanism.
23. Second: the national government has not concluded any agreements directly with vaccine manufacturers for the supply of any vaccines that have shown positive results after their medical trials. Furthermore, although the African Union has 'secured a provisional 270 million vaccine doses' for the African continent, there are no indications of how many of these doses will be made available to South Africa, if any. It must be borne in mind that the continent has a population in excess of 1,2 billion people who would



require more than 2,4 billion doses of the Pfizer / BioNTech, Moderna or AstraZeneca vaccines.

24. If the national government's aim is to vaccinate 40 million South Africans, it has thus far failed to secure any doses for 34 million of those individuals. Furthermore, it is presently unable to do so given that it has not finalised the selection criteria for vaccines that may be utilised in South Africa.
25. Third: you told the South African people that '20 million doses' of a vaccine have been 'secured to be delivered mainly in the first half of the year'. However, the national government has not concluded the necessary agreements to this effect. No particulars were provided regarding which vaccine has been secured, the price and other terms on which it has been secured, when it will be delivered, whether the necessary storage facilities can be made available (bearing in mind that, for example, the Pfizer / BioNTech vaccine requires ultra-cold storage) and when it will be made available for administration to members of the public. Furthermore, the representation that the doses have 'been secured' contradicts the national government's communications that it has not concluded agreements with any vaccine manufacturers and that, aside from COVAX, no contracts are in place to guarantee delivery of vaccines to South Africa.
26. Fourth: the infrastructure is not in place for the roll-out of vaccines to the wider public in South Africa. Standard operating procedures still need to be developed, staff still need to be trained and guidelines still need to be formulated. There are no nationally determined protocols in place for COVID-19 vaccine administration in public hospitals, let alone in private medical facilities, workplaces and other institutions. All of these very important processes will take time to complete and the national government is therefore far from being able to roll out a vaccine.
27. Fifth: no vaccine has yet been approved by SAHPRA for use in South Africa. SAHPRA is under-resourced and has a significant backlog of medicines requiring registration. There is serious concern that SAHPRA will not be able to approve a vaccine for use in South Africa for a number of months.
28. Sixth: it is unclear whether the national government has secured 1,5 million vaccine doses from the Serum Institute. If so, there are no indications of whether it is the AstraZeneca vaccine that will be provided, when it will be made available and the terms to which South Africa will have to agree to gain access. Similarly, it is unclear whether South Africa will

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have access to any of the 270 million vaccine doses secured by the African Union and, if so, when the doses will be delivered to South Africa or what the applicable terms are.

29. Perhaps most concerning of all is the fact that the national government – according to its own publications – has been aware of the fundamental importance that the roll-out of vaccines will play in combating the Coronavirus since the onset of the pandemic. However, South Africa has barely secured sufficient vaccines to immunise 10% of the population. It has not secured one agreement with a vaccine manufacturer, in circumstances where other governments concluded such agreements as long ago as May 2020. For most of the population, there is no certainty at all as to whether vaccines will be available to them in the foreseeable future, let alone whether the necessary infrastructure will be in place to facilitate the administration of the immunisations. Factors that are entirely within the national government's control – such as the selection criteria for vaccines, the policy framework for the roll-out, the training of medical personnel and the procurement of facilities and infrastructure – have not been finalised and implemented.
30. The Strategy contains a host of best endeavours, hopes, descriptions of ongoing processes and steps that still need to be implemented. However, it contains little that is concrete and almost nothing in the way of a realistic timeline on which South Africans can rely. In this regard, we emphasise the Constitutional Court's finding in the Treatment Action Campaign case, that a reasonable and binding timeline for the delivery of medicines is an essential component of any government programme to combat a health crisis:

The anxiety of the applicants to have the government move as expeditiously as possible in taking measures to reduce the transmission of HIV from mother to child is understandable. One is dealing here with a deadly disease. Once a drug that has the potential to reduce mother-to-child transmission is available, it is desirable that it be made available without delay to those who urgently need it... the nature of the problem is such that it demands urgent attention. Nevirapine is a potentially lifesaving drug. Its safety and efficacy have been established. There is a need to assess operational challenges for the best possible use of Nevirapine on a comprehensive scale to reduce the risk of mother-to-child transmission of HIV. There is an additional need to monitor issues relevant to the safety and efficacy of and resistance to the use of Nevirapine for this purpose. There is, however, also a pressing need to ensure that where possible loss of life is prevented in the meantime... It is necessary that the government programme, as supplemented to comply with the requirements

of this judgment, be communicated to health caregivers in all public facilities and to the beneficiaries of the programme [our emphasis].

31. The result of the Strategy is that, instead of being vaccinated against the Coronavirus, tens of millions of South Africans will have to continue living under a state of national disaster, subject to the restrictions set out in the Disaster Regulations, with the constant spectre of a lethal disease hanging over their heads. All of this for an indeterminate period, while waiting for the national government to do what it should have done months ago.
32. In the light of the above, our clients are concerned that the national government has materially violated a number of constitutional provisions:
 - 32.1 The failure to ensure the timeous and proper provision of one or more Covid-19 vaccines in South Africa, when such vaccines are available, is a violation of everyone's right in terms of section 27(1) of the Constitution to have access to healthcare services; a violation of the national government's obligation, in terms of section 27(2) of the Constitution, to take reasonable measures, within its resources, to achieve the progressive realisation of the right to access healthcare; and a violation of the right to life enshrined in section 11 of the Bill of Rights.
 - 32.2 The failure to ensure the timeous and proper provision of a vaccine will, no doubt, be used by the national government as a justification for the continuation of the state of disaster and the Disaster Regulations. Those regulations (as has been pointed out in numerous instances of litigation) infringe almost every right in the Bill of Rights, including the rights to human dignity, freedom of the person, privacy, free practice of religion and culture, freedom of movement, free practice of one's occupation, property and education. These infringements are unjustifiable given that they could have been avoided had the national government procured and rolled out the vaccine timeously.
 - 32.3 Section 1(c) of the Constitution enshrines the rule of law as a fundamental prescript. The rule of law, in turn, requires that decision-making be rational. It is irrational, and therefore unconstitutional, for the national government, despite having known about the importance of vaccines since the beginning of the pandemic, to have failed to secure sufficient doses of a vaccine for a significant majority of the country and to have failed to implement even a basic policy and infrastructural framework

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for the roll-out of a vaccination programme to immunise approximately 40 million South Africans.

33. In short, the Strategy does not meet the constitutional requirements for a comprehensive vaccination programme to prevent the spread of the Coronavirus.
34. Should you be of the view that the national government has not infringed the provisions of the Constitution as set out above, we have been instructed to demand, as we hereby do, that you provide us with your reasons. We also note that, in another constitutional deviation, our client is suffering from the national government's lack of transparency and accountability in respect of the vaccination programme. There is simply no clarity on what South Africa's vaccination strategy and plan are, what the relevant milestones and timelines are, with whom material contracts have been concluded, what the terms of those contracts are, and, most importantly, when individuals can expect to receive the vaccination that is their fundamental right. Our client therefore demands that your reasons address the following:
 - 34.1 A description (including dates) of what has been done to (a) secure vaccines for the South African population and (b) put in place the necessary regulatory, policy and infrastructural requirements to administer vaccine doses to approximately 40 million South Africans. This includes minutes of the meetings held with Russia, China, Pfizer, AstraZeneca, Johnson & Johnson, Moderna and Cipla as referenced in the national government's publications regarding the vaccine.
 - 34.2 A quantification of the financial resources that the national government has made available to (a) acquire and (b) roll out the administration of vaccines, including an itemisation of public funds, private funds, donor funds and other funds (e.g. loans from multilateral institutions).
 - 34.3 A description of the agreements concluded to date in respect of vaccine supply, including manufacturer's details, the name of the vaccine, number of doses, price paid and delivery date. This must include particulars in respect of vaccines to be acquired from COVAX, from private manufacturers and through the African Union.
 - 34.4 A description of the negotiations currently underway to secure vaccine doses for South Africa, including the identity of the counter-party, the name of the vaccine,

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the number of anticipated doses, the supplier's proposed price and the anticipated delivery date.

34.5 A description of the role of Biovac and Aspen in supplying vaccines to South Africa, including the number of doses that will be supplied and the date by which they will become available for administration to the population.

34.6 A description of the regulatory and policy framework that the national government has put in place to date, including vaccine selection criteria, protocols for vaccine storage and transport, guidelines and standard operating procedures for vaccine administration and training programmes for persons who will administer vaccines. To the extent that these instruments are not yet in place, a description is required of when the process to develop them commenced, what its current status is and what the anticipated date of completion is.

34.7 A description of the vaccine roll-out and administration programme, including: the number of vaccine doses, the type of vaccine and the date by which the relevant doses will be available for distribution in South Africa; the mechanisms, infrastructure and facilities in place to store and transport the doses; the facilities from which the doses will be administered (including the agreements and other arrangements in place with such facilities); and the personnel who will administer the doses (including details of their current employer, designation, qualifications and whether they have agreed to be part of the roll-out).

34.8 An itemisation of the components of the acquisition and roll-out strategy (with reference to the categories of information referred to in the preceding subparagraphs) that still need to be finalised.

34.9 An indication of the dates by which the national government expects that each of its three proposed phases of vaccination will be complete.

35. Our client has no wish to engage in unnecessary litigation. However, it is duty-bound – by the Constitution and its electoral mandate – to address infringements to its constituents' rights and fundamental flaws in government programmes. Should your reasons regarding the above concerns meet the applicable constitutional standard, our client will be satisfied and will do its part in supporting the vaccine acquisition and roll-out strategy. However,

should those reasons be constitutionally lacking, our client reserves its rights to take the necessary action without further recourse to you.

36. Given that all of the requested information is readily at your disposal, our client's demand is that the reasons should be supplied by no later than **Monday, 25 January 2021**.
37. We note Dr Mkhize's previous statement that he could not make information about South Africa's vaccine programme available due to 'non-disclosure agreements and confidentiality clauses'. We point out that, when the national government procures vaccines, it is bound by the Constitution to do so transparently. No contractual provision can override this obligation. In the Treatment Action Campaign case, the Constitutional Court castigated the government's failure to publish the details of its HIV/AIDS treatment programme. Under the heading of 'transparency', the Court said the following:

The magnitude of the HIV/AIDS challenge facing the country calls for a concerted, co-ordinated and co-operative national effort in which government in each of its three spheres and the panoply of resources and skills of civil society are marshalled, inspired and led. This can be achieved only if there is proper communication, especially by government. In order for it to be implemented optimally, a public health programme must be made known effectively to all concerned, down to the district nurse and patients. Indeed, for a public programme such as this to meet the constitutional requirement of reasonableness, its contents must be made known appropriately [our emphasis].
38. In the spirit of transparency our client therefore requests that you make full disclosure of the requested information. We emphasise that such disclosure is not a matter for your discretion but is a constitutional requirement.
39. A further aspect of the Strategy is of immense concern to our client: the attempt to monopolise control of vaccine acquisition and distribution at a national level, with provincial and other authorities, as well as the private sector, simply acting as the national government's implementing agents.
40. On 3 January 2021, the national government published Dr Pillay, the national Health Department's Deputy Director-General, as saying that 'vaccine rollout will be led nationally, there will be one procurement approach and we will then work with our

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provincial colleagues and the private sector for distribution'. On 7 January 2021, Dr Mkhize, the national Minister of Health, gave a presentation to the National Assembly stating that '[t]he SA government will be the sole purchaser of vaccines for the country. The NDOH will contract with suppliers to purchase stock and allocate to provincial health departments and private health sector.'

41. In the light of the concurrent provincial competence for health services and the absence of any statutory basis for the national government to exercise exclusive responsibility for acquiring vaccine doses for South Africa, Dr Mkhize's attempt to assert the national government's monopoly on acquiring Covid-19 vaccines is unconstitutional and unlawful.
42. We have been instructed to notify you that, should the national government attempt to assert any such monopoly, and to prevent any provincial government from acquiring and administering additional vaccines to complement whatever national programme is ultimately rolled out, our client will not hesitate to take the necessary action in response. It is imperative that as many vaccine doses are secured, delivered and administered to the South African population as quickly as possible. To that end, the national government should not attempt to prevent other role-players – whether in the public or in the private sector – from ensuring that the maximum number of South Africans is immunised against the Coronavirus within the shortest possible time. This is particularly the case in the light of the rife corruption and string of irregularities that occurred in the public procurement of PPE during earlier efforts to combat the Coronavirus.

Yours faithfully

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per:

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