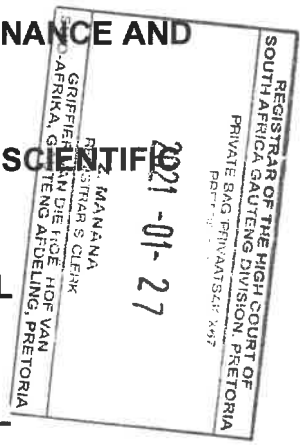
IN THE HIGH COURT OF SOUTH AFRICA
GAUTENG PROVINCIAL DIVISION, PRETORIA

CASE NO: 3623/21

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
MINMISTER OF COOPERATIVE GOVERNANCE AND TRADITIONAL AFFAIRS	THIRD RESPONDENT
THE CHAIRPERSON OF THE COVID-19 SCIENTIFIC MINISTERIAL ADVISORY COMMITTEE	FOURTH RESPONDENT
MEMBER OF THE EXECUTIVE COUNCIL FOR HEALTH, WESTERN CAPE	FIFTH RESPONDENT
MEMBER OF THE EXECUTIVE COUNCIL FOR HEALTH, GAUTENG	SIXTH RESPONDENT
MEMBER OF THE EXECUTIVE COUNCIL FOR HEALTH, FREESTATE	SEVENTH RESPONDENT
MEMBER OF THE EXECUTIVE COUNCIL FOR HEALTH, EASTERN CAPE	EIGHTH RESPONDENT
MEMBER OF THE EXECUTIVE COUNCIL FOR HEALTH, NORTHEN CAPE	NINTH RESPONDENT
MEMBER OF THE EXECUTIVE COUNCIL FOR HEALTH, LIMPOPO	TENTH RESPONDENT



MEMBER OF THE EXECUTIVE COUNCIL FOR HEALTH, MPUMALANGA	ELEVENTH RESPONDENT
MEMBER OF THE EXECUTIVE COUNCIL FOR HEALTH, NORTH WEST	TWELFTH RESPONDENT
MEMBER OF THE EXECUTIVE COUNCIL FOR HEALTH, KWAZULU - NATAL	THIRTEENTH RESPONDENT
PHARMACEUTICAL SOCIETY OF SA	FOURTEENTH RESPONDENT
COUNCIL FOR MEDICAL SCHEMES	FIFTEENTH RESPONDENT
SOUTH AFRICAN MEDICAL ASSOCIATION	SIXTEENTH RESPONDENT
PHARMACEUTICAL INDUSTRY ASSOCIATION OF SA	SEVENTEENTH RESPONDENT

NOTICE OF MOTION

TAKE NOTICE that the Applicants intend making application on **TUESDAY 2 MARCH 2021** at **10:00** (or as soon thereafter as counsel may be heard), for an order in the following terms:

1. That the normal rules in respect of time periods and service be dispensed with and that the application be enrolled and heard by way of urgency in terms of rule 6(12) by the Honourable Court.

2. That it is declared to be the right of any institution, legal persona or natural person in the private sector, as well as any provincial health authority, which are, in the normal course lawfully entitled to procure, distribute and administer approved medicines, to procure, distribute and administer Covid -19 vaccines approved by the South African Health Products Regulatory Authority

(SAHPRA), notwithstanding the national government's roll-out strategy, policy or programme as set out in the National Department of Health's "COVID-19 Response" document dated 7 January 2021, or any other programme or measures adopted by government to procure, distribute and administer approved Covid -19 vaccines to the public.

3. That it is declared that the First Respondent's roll-out strategy, policy or programme, as set out in the National Department of Health's "COVID-19 Response" document dated 7 January 2021, is unconstitutional and unlawful to the extent that it makes the national government the sole agency for the procurement and distribution of approved Covid-19 vaccines to the exclusion of any institution or person in the private sector, or any provincial health authority, which would otherwise, in the normal course lawfully be authorised and entitled to procure, distribute and administer approved Covid -19 vaccines to the public.

4. That it is declared that the First Respondent's measures, as set out in the roll-out strategy, policy or programme of the National Department of Health's "COVID-19 Response" document dated 7 January 2021, are unconstitutional and unlawful to the extent that it limits and infringes upon the rights of any institution or person in the private sector, as well as any provincial health authority, which are, in the normal course lawfully entitled to procure, distribute and administer approved Covid -19 vaccines to the public.

5. That the First Respondent is ordered to amend the government's roll-out strategy, policy or programme, as set out in the National Department of Health's "COVID-19 Response" document dated 7 January 2021, to give effect to the orders in paragraphs 2, 3 and 4 above, and in order to make it unequivocally clear that the government's initiatives to procure, distribute and administer approved Covid -19 vaccines to the public does not preclude any other institution or person in the private sector, as well as any provincial health authority, which are, in the normal course lawfully entitled to procure, distribute and administer approved medicines from doing so in respect of approved Covid-19 vaccines, immediately and independently from the government's programme.

6. That the First Respondent be ordered to pay the costs of the Applicants, such costs to include the costs of two counsel.

7. That any other Respondent who opposes the application be ordered to pay the costs of the Applicants jointly and severally, such costs to include the costs of two counsel.

8. Further and/or alternative relief.

TAKE FURTHER NOTICE that the founding affidavit of **DIRK JOHANNES HERMANN** (together with annexures thereto) will be used in support of the application.

TAKE FURTHER NOTICE that the Applicants have appointed the address of **HURTER SPIES INCORPORATED**, at the address as mentioned below, at which

the Applicants will accept notice and service of all process in this application.

TAKE FURTHER NOTICE that if any of the Respondents intend to oppose this application, they must:

a) Notify the Applicants' attorneys thereof in writing before **16:00** on **2 FEBRUARY 2021** and further that they are required to appoint in such notification an address as referred to in rule 6(5)(b) at which they will accept notice and service of all documents in these proceedings; and

b) File their opposing affidavit/s (if any) on or before **16:00** on **15 February 2021.**

TAKE FURTHER NOTICE that if so advised, the Applicants will file their replying affidavit thereafter (to the extent necessary, if at all).

KINDLY ENROL THE MATTER FOR HEARING ACCORDINGLY.

SIGNED AND DATED AT PRETORIA ON THIS THE 27th DAY OF JANUARY 2021.

HURTER SPIES INC
Attorneys for the Applicants
Second Floor, Block A
Loftus Park
Kirkness Street
Arcadia, Pretoria.

Ref: D Eloff/ D du Plessis
Tel: 012 941 9239
Email: deloff@hurterspies.co.za

TO: THE REGISTRAR HIGH COURT,
PRETORIA

AND TO: THE FIRST RESPONDENT

THE MINISTER OF HEALTH
C/O The State Attorney
316 Thabo Sehume (Andries) Street,
Pretoria
Service by the Sheriff and by email

AND TO: THE SECOND RESPONDENT

PRESIDENT OF THE REPUBLIC OF SOUTH AFRICA
C/O The State Attorney
316 Thabo Sehume Street,
Pretoria
Service by the Sheriff and by email

AND TO: THE THIRD RESPONDENT

THE MINISTER OF COOPERATIVE GOVERNANCE AND TRADITIONAL AFFAIRS
C/O The State Attorney
316 Thabo Sehume Street,

Pretoria

Service by the Sheriff and by email

AND TO: THE FOURTH RESPONDENT

CHAIRPERSON OF THE COVID-19 SCIENTIFIC MINISTERIAL ADVISORY COMMITTEE

C/O Ministry of Health

Civitas Building, Floor 20,

Corner of Struben and Thabo Sehume Streets,

Pretoria

C/O The State Attorney

316 Thabo Sehume Street,

Pretoria

Service by the Sheriff and by email

AND TO: THE FIFTH RESPONDENT

THE MEC FOR HEALTH, WESTERN CAPE PROVINCE

C/O The State Attorney

316 Thabo Sehume Street,

Pretoria

Service by the Sheriff and by email

AND TO: THE SIXTH RESPONDENT

THE MEC FOR HEALTH, GAUTENG

C/O The State Attorney

316 Thabo Sehume Street,

Pretoria

Service by the Sheriff and by email

AND TO: THE SEVENTH RESPONDENT

THE MEC FOR HEALTH, FREE STATE PROVINCE
C/O The State Attorney
316 Thabo Sehume Street,
Pretoria
Service by the Sheriff and by email

AND TO: THE EIGHTH RESPONDENT

THE MEC FOR HEALTH, EASTERN CAPE PROVINCE
C/O The State Attorney
316 Thabo Sehume Street,
Pretoria
Service by the Sheriff and by email

AND TO: THE NINTH RESPONDENT

THE MEC FOR HEALTH, NORTHERN CAPE PROVINCE
C/O The State Attorney
316 Thabo Sehume Street,
Pretoria
Service by the Sheriff and by email

AND TO: THE TENTH RESPONDENT

THE MEC FOR HEALTH, LIMPOPO PROVINCE

C/O The State Attorney
316 Thabo Sehume Street,
Pretoria
Service by the Sheriff and by email

AND TO: THE ELEVENTH RESPONDENT

THE MEC FOR HEALTH, MPUMALANGA PROVINCE
C/O The State Attorney
316 Thabo Sehume Street,
Pretoria
Service by the Sheriff and by email

AND TO: THE TWELFTH RESPONDENT

THE MEC FOR HEALTH, NORTH WEST PROVINCE
C/O The State Attorney
316 Thabo Sehume Street,
Pretoria
Service by the Sheriff and by email

AND TO: THE THIRTEENTH RESPONDENT

THE MEC FOR HEALTH, KWAZULU – NATAL PROVINCE
C/O The State Attorney
316 Thabo Sehume Street,
Pretoria
Service by the Sheriff and by email

AND TO: THE FOURTEENTH RESPONDENT

PHARMACEUTICAL SOCIETY OF SOUTH AFRICA
435 Flinders Lane
Lynnwood
Pretoria
Service by the Sheriff and by email

AND TO: THE FIFTEENTH RESPONDENT

COUNCIL FOR MEDICAL SCHEMES
Block A, Eco Glades 2 Office Park
420 Witch – Hazel Avenue
Eco Park
Centurion
Service by the Sheriff and by email

AND TO: THE SIXTEENTH RESPONDENT

SOUTH AFRICAN MEDICAL ASSOCIATION
Block F, Castle Walk, Corporate Park
Nossob Street,
Erasmuskloof,
Pretoria
Service by the Sheriff and by email

AND TO: THE SEVENTEENTH RESPONDENT

PHARMACEUTICAL INDUSTRY ASSOCIATION OF SOUTH AFRICA

Thornhill Office Park,
Building No 5,
94 Bekker Street,
Vorna Valley,
Midrand

Service by the Sheriff and by email

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

CASE NO:

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MEMBER OF THE EXECUTIVE COUNCIL FOR HEALTH, FREESTATE	SEVENTH RESPONDENT
MEMBER OF THE EXECUTIVE COUNCIL FOR HEALTH, EASTERN CAPE	EIGHTH RESPONDENT
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MEMBER OF THE EXECUTIVE COUNCIL FOR HEALTH, KWAZULU - NATAL	THIRTEENTH RESPONDENT
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SOUTH AFRICAN MEDICAL ASSOCIATION	SIXTEENTH RESPONDENT
PHARMACEUTICAL INDUSTRY ASSOCIATION OF SA	SEVENTEENTH RESPONDENT

FOUNDING AFFIDAVIT

I, the undersigned,

DIRK JOHANNES HERMANN

do hereby make oath and state the following:

1. I am an adult male and the Chief Executive Officer of the First Applicant.

2. I am duly authorised to depose to this affidavit and to institute these proceedings on behalf of the Applicants by virtue of authorising resolutions attached hereto, marked as annexure **"A"** and annexure **"B"**, respectively.

3. The facts deposed to herein fall within my personal knowledge, save where the contrary appears from the context hereof and are, to the best of my knowledge, true and correct.

4. To the extent that information does not fall within my personal knowledge I pray that the above Honourable Court admits such evidence in terms of section 3(1)(c) of the Law of Evidence Amendment Act, No.45 of 1988 in the interests of justice considering *inter alia* the following factors:

   4.1 The nature of the evidence is such that the Applicants do not have direct access to all the sources of information that the Respondents have access thereto;

   4.2 The information originates from reliable sources; and

   4.3 The Respondents will not be prejudiced.

5. Where I make legal submissions herein I do so on the strength of legal advice received, which advice I accept as both correct and good in law.

THE PARTIES

6. The First Applicant is **Solidarity Trade Union**, a registered trade union, registered as such by the Registrar of Trade Unions with registration number LR 2/6/2/1253 in terms of section 96 of the Labour Relations Act, no. 66 of 1995, with head office at DF Malan Avenue, Kloofsig, Centurion.

7. The Second Applicant is **AfriForum NPC**, a non-profit company, duly registered in terms of the company laws of South Africa, with principal place of business at AfriForum Building, corner of DF Malan Avenue and Union Street, Kloofsig, Centurion.

8. The First Respondent is the **Minister of Health,** the member of the national executive responsible for the national Department of Health and national health policy as well as the administration of public health with principal place of administration at Civitas Building, Floor 20, corner Struben and Thabo Sehume Streets, Pretoria and in the care of the State Attorney, Pretoria, at 316 Thabo Sehume Street, Pretoria. The incumbent Minister of Health is Dr Zweli Mkhize.

9. The Second Respondent is the **President of the Republic of South Africa**, cited in his capacity as the Head of State and the head of the national executive in terms of section 83 of the Constitution of 1996, who must *inter alia* in terms of the said section 83 of the Constitution uphold, defend and respect the Constitution as the supreme law of the Republic, with principal place of administration at Union Buildings, Government, Pretoria and in the care of the State Attorney, Pretoria, at 316 Thabo Sehume Street, Pretoria. The national executive is primarily responsible for the co-ordination and management of national disasters in terms section 26 of the Disaster Management Act, No. 57 of 2002 (the "**DMA**"). The Second Respondent has an interest in the application.

10. The Third Respondent is the **Minister of Co-Operative Governance and Traditional Affairs**, with the offices of the ministry situated at 87 Hamilton

Street, Arcadia, Pretoria, Gauteng Province and in the care of the State Attorney, Pretoria situated at 316 Thabo Sehume Street, Pretoria. The Third Respondent is the designated minister in terms of section 3 of the DMA to administer the DMA and has an interest in this application.

11. The Fourth Respondent is the **Chairperson of the Covid-19 Scientific Ministerial Advisory Committee** (**"the MAC"**), a non-statutory advisory committee appointed by the First Respondent, cited in his capacity as the chairperson of the stated committee advising the First Respondent on *inter alia* South Africa's Covid-19 vaccine roll-out strategy and in the care of the Ministry of Health at Civitas Building, Floor 20, corner Struben and Thabo Sehume Streets, Pretoria. The current Chairperson is Professor Barry Schoub.

12. The Fifth Respondent is the **Member of the Executive Council for Health of the Western Cape Province,** with offices at 4 Dorp Street, Cape Town care of the State Attorney, Pretoria, at 316 Thabo Sehume Street, Pretoria. The Fifth Respondent has an interest in the subject matter of this application and in the relief sought.

13. The Sixth Respondent is the **Member of the Executive Council for Health of the Gauteng Province,** with offices at Department of Health, Bank of Lisbon Building, Floor 22, 37 Sauer Street, Johannesburg, care of the State Attorney, Pretoria, at 316 Thabo Sehume Street, Pretoria. The Sixth Respondent has an interest in the subject matter of this application and in the relief sought.

14. The Seventh Respondent is the **Member of the Executive Council for Health of the Free State Province**, with offices at Department of Health, cnr Harvey &

Charlotte Maxeke Streets, Bloemfontein, care of the State Attorney, Pretoria, at 316 Thabo Sehume Street, Pretoria. The Seventh Respondent has an interest in the subject matter of this application and in the relief sought.

15. The Eighth Respondent is the **Member of the Executive Council for Health of the Eastern Cape Province**, with offices at Department of Health, Dukumbana Building, Independence Avenue, Bhisho, Eastern Cape, care of the State Attorney, Pretoria, at 316 Thabo Sehume Street, Pretoria. The Eighth Respondent has an interest in the subject matter of this application and in the relief sought.

16. The Ninth Respondent is the **Member of the Executive Council for Health of the Northern Cape Province**, with offices at, Department of Health, James Exum Building, 144 Du Toitspan Road, Kimberley, Northern Cape, care of the State Attorney, Pretoria, at 316 Thabo Sehume Street, Pretoria. The Ninth Respondent has an interest in the subject matter of this application and in the relief sought.

17. The Tenth Respondent is the **Member of the Executive Council for Health of the Limpopo Province**, with offices at Department of Health, 18 College Street, Polokwane, Limpopo Province, care of the State Attorney, Pretoria, at 316 Thabo Sehume Street, Pretoria. The Tenth Respondent has an interest in the subject matter of this application and in the relief sought.

18. The Eleventh Respondent is the **Member of the Executive Council for Health of the Mpumalanga Province**, with offices at Department of Health, Government Boulevard, Riverside Park, Nelspruit care of the State Attorney,

Pretoria, at 316 Thabo Sehume Street, Pretoria. The Eleventh Respondent has an interest in the subject matter of this application and in the relief sought.

19. The Twelfth Respondent is the **Member of the Executive Council for Health of the North West Province,** with offices at Department of Health, cnr 1St Street and Sekame Road, Mahikeng, Nortwest Province, care of the State Attorney, Pretoria, at 316 Thabo Sehume Street, Pretoria. The Twelfth Respondent has an interest in the subject matter of this application and in the relief sought.

20. The Thirteenth Respondent is the **Member of the Executive Council for Health of the KwaZulu – Natal Province**, with offices at Department of Health, Natalia, 330 Langalibalele (Longmarket) Street, Pietermaritzburg, care of the State Attorney, Pretoria, at 316 Thabo Sehume Street, Pretoria. The Thirteenth Respondent has an interest in the subject matter of this application and in the relief sought.

21.1 The Fourteenth Respondent is the **Pharmaceutical Society of South Africa,** a voluntary association of pharmacists and established for the pharmaceutical profession with principal place of business at 435 Flinders Lane, Lynnwood, Pretoria.

21.2 Amongst the objectives of the Fourteenth Respondent according to its website are the promotion of the professional, educational and economic interests of the members of the society and the pharmaceutical profession, and to uphold and assist in the promotion and maintenance of health of the people of South Africa through the provision of safe dependable pharmaceutical service.

21.3 The Fourteenth Respondent has an interest in the application.

22. The Fifteenth Respondent is the **Council for Medical Schemes**, a statutory juristic person established in terms of section 3 of the Medical Schemes Act, no: 131 of 1998 (**"MSA"**) with principal place of business at Block A, Eco Glades 2 office Park, 420 Witch-Hazel Avenue, Eco Park, Centurion. One of the statutory functions of the Council in terms of section 7 of the MSA is to protect the interests of beneficiaries of medical schemes. The Fifteenth Respondent has an interest in this application.

23. The Sixteenth Respondent is the **South African Medical Association**, a non-profit company with registration number 1927/000136/08, being a professional association for medical practitioners and representing the interests of medical practitioners in the public and private health sector with principal place of business at Block F, Castle walk corporate Park, Nossob Street, Erasmuskloof, Pretoria. The Sixteenth Respondent has an interest in this application.

24. The Seventeenth Respondent is the **Pharmaceutical Industry Association of South Africa,** being a voluntary trade association of companies involved in the manufacture and marketing of prescription medicines in South Africa. Its membership includes a broad representation of foreign multinational and local companies both large and small. The Seventeenth Respondent has its principal place of business at Thornhill Office Park, Building no 5, 94 Bekker Street, Vorna Valley, Midrand. The Seventeenth Respondent has an interest in the application.

PURPOSE OF THE APPLICATION:

25. The purpose of the application is to seek declaratory and ancillary relief concerning the recent roll-out strategy or policy of the First Respondent which purports to centralise and control, under national government, the acquisition, distribution and roll-out of approved Covid -19 vaccines to the public at large, and which, as demonstrated hereunder, accordingly violates or inhibits or limits the freedom and the right of provincial governments, individuals and the private sector to do so, and to seek appropriate relief in this regard.

26. The relief sought by the Applicants fall with the ambit of sections 38 and 172(1) of the Constitution as well as section 21(1)(c) of the Superior Courts Act , No. 10 of 2013.

LOCUS STANDI OF THE FIRST APPLICANT:

27. This application concerns the infringement or threat of infringement of certain rights in the Bill of Rights and other constitutional rights by virtue of a Covid-19 strategy or policy adopted by the national Department of Health.

28. The First Applicant is a trade union with the primary function to protect its members in the work environment. That includes their health in general and, in particular, in the current context, their effective protection against the Covid-19 virus. As such, its interest and that of its members, lie in the rapid and effective management of the Covid-19 pandemic and disaster, which entails the rapid and effective distribution of approved Covid-19 vaccines (for the sake of brevity referred to further as "vaccines").

29. At present, the First Applicant has more than 120 000 members, approximately 10 000 of whom are healthcare workers. Its members are *inter alia* employed with various large industries, including the mining industry, of which some have their own private health systems capable of providing health care services to their workers.

30. Many of its members are members of private medical aid schemes through which they have access to private health care practitioners and facilities.

31. The subject matter of this application also involves the broader public interest, over and above the interests of the Applicants and their members.

32. The First Applicant brings this application:

    32.1 in its own interest in terms of section section 38(a) of the Constitution;

    32.2 in the interest of its members in terms of section 38(e) of the Constitution; and

    32.3 in the public interest in terms of section 38 (d) of the Constitution.

LOCUS STANDI OF THE SECOND APPLICANT:

33. The Second Applicant is a non-profit company and civil rights organisation.

34. In particular, the Second Applicant is committed, by virtue of its memorandum of incorporation, to *inter alia* the continuous monitoring and protection of constitutional and human rights in South Africa, and to taking appropriate action when such rights are infringed or threatened (as this application demonstrates).

35. The Second Applicant has approximately 270 000 registered members, which members are spread throughout South Africa in all walks of life.

36. The Second Applicant and the Second Applicant's members have a direct interest in the subject matter of the current application, namely to ensure that vaccines are procured and distributed in accordance with the Constitution and other health legislation, without protraction or limitation of any freedom through any conduct of the State, and to ensure that that the State does not adopt measures that would impede a rapid and effective distribution of vaccines in order to curb the Covid-19 pandemic in the Republic.

37. In addition to the interests of the Second Applicant and the Second Applicant's members, it is also a matter of public interest that the rule of law is upheld and that national policies are adopted in accordance with the Constitution and existing legislation.

38. This is particularly relevant in light of the subject matter of this application which deals with the procurement and distribution of life-saving vaccines during an international pandemic and national state of disaster.

39. The subject–matter of this application involves the promotion and protection of various constitutional and fundamental human rights.

40. In the premise, the Second Applicant brings the current application:

    40.1 in its own interest as contemplated in section 38(a) of the Constitution;

    40.2 in the public interest as contemplated in section 38(d) of the Constitution); and

40.3 in the interest of its members as contemplated in section 38(e) of the Constitution.

JURISDICTION:

41. The above Honourable Court has the necessary jurisdiction to adjudicate this application by virtue of the fact that, *inter alia*, the Respondents' principal places of business or administration, or addresses for service are within the above Honourable Court's area of jurisdiction.

BACKGROUND AND CONTEXT:

42. On 3 January 2021, the First Respondent issued a public statement describing the national government's strategy relating to the financing and distribution of Covid-19 vaccines as well as the national government's targets regarding the phased approach to vaccine immunisation.

43. The public statement was accompanied by a document called "Covid-19 Vaccine Rollout Strategy" issued by the National Department of Health on 3 January 2021 (the "**3 January Rollout Strategy**"), a copy of which is attached hereto, marked as annexure **"C"**, which provides in material part as follows:

> "*The vaccine rollout will be lead (sic) nationally in close co-ordination with provincial health departments and the private healthcare sector. Committee (sic) will be established at various levels with the relevant stakeholders and expertise to co-ordinate the rollout of the various phases of the vaccine delivery*". (own emphasis added)

44. From pages 11 – 15 of the abovementioned document, the Department of Health determined the phases of vaccination and the sequence of vaccination to various priority groups and targeted sectors of the population, without, however, any indication when the various phases will commence. At this stage, it seemed that government had not yet finally concluded all agreements for the supply of vaccines and the quantities involved and it was still in the process of doing so whilst the administration of vaccines had already commenced in large quantities around the world in various countries.

45. The 3 January Rollout Strategy was followed on 7 January 2021 by a document called "COVID-19 Response" issued by the national Department of Health (the "**7 January Response Strategy**"). A copy of the 7 January Response Strategy is attached hereto, marked as annexure **"D".** The entire document ,in particular with reference to the acquisition of the vaccines and its allocation and distribution, is relevant.

46. The 7 January Response Strategy *inter alia* provides expressly as follows:

> "***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 private health sector*"...
>
> ***Allocation of vaccines*** *to the various priority groups* ***will be guided by the MAC on vaccines***...
>
> ***A national rollout committee*** *will oversee the rollout including both the public and private sectors."*

(underlining and own emphasis added)

47. Pursuant to national government's policy/strategy embodied in the aforesaid documents, that it will be the sole purchaser of Covid-19 vaccines, it appears that the private health sector, private sector and business sector will have the following roles:

"PRIVATE HEALTH SECTOR AND MEDICAL SCHEMES

• Private health coordinating forum will be established consisting of the role players including HASA, IPAs, Retail pharmacies and others (the chair of this forum will participate in the national vaccine coordinating committee chaired by the DG)

• Main roles:

-Coordination of the vaccination of the private health sector employees (eg private hospitals will vaccinate their own employees)

-providing the platform for the vaccination of the communities similar to the CCMDD programmes (GPs, Retail pharmacies)

-Medical schemes to pay for vaccines for their members through an agreed mechanism with government

OTHER PRIVATE SECTOR/BUSINESS SECTOR

• Pooling of funds support the vaccination programme through the SF

• *Promoting the use of vaccine amongst their employees*

• *Provision of vaccination platform through the occupational health systems*"

48. From the 7 January Response Strategy as a whole, it appears clear that the private healthcare sector, private sector and business sector are not free to procure and distribute approved Covid-19 vaccines outside the framework of government's centralised strategy and rollout programme.

49. In order to seek unequivocal clarification on what appears to be the ostensible effect of the strategy/policy, the Applicants' attorneys addressed a detailed letter to the First, Second and Third Respondents on 13 January 2021 in terms of which clarity was sought in the following terms:

"*19. In light of the above, our clients urgently require a written response to the following questions for the sake of transparency (over and above the issues and questions raised above) and in the quest for unequivocal clarity:*

19.1 Will national government prohibit the private procurement and distribution of any Covid -19 vaccines? Is the strategy designed to cause such exclusion? If not, could you kindly clarify the position not only in the interest of our clients but in the interest of the public;

19.2 Will national government prohibit procurement and distribution of any Covid -19 vaccines by provincial departments of health?; and

19.3 If the answers to the above questions in paragraphs 19.1.and 19.2. are affirmative, what empowering statutory provisions does government purport to rely on to have made and enforce the above policy/strategy/decision? In such event, you are also required to provide full reasons for the adoption of the policy/strategy/decision".

50. A copy of the said letter is attached as annexure **"E".**

51. Despite the Applicants' attorneys requiring a response to the letter on or before 20 January 2021, the relevant Respondents failed to reply before the date in question (or at all) despite the letter informing them as follows:

"20. Given the serious and time sensitive nature of the matter our clients request your urgent response by close of business on 20 January 2021. Should our clients not receive a response by the above-mentioned date:

20.1. Our clients will assume that the answers to the questions posed in paragraph 19.1 and 19.2 are affirmative and, furthermore, that there is no empowering provisions on which government can rely upon in order to make and enforce the vaccine centralisation policy; and

20.2. Our clients will be compelled to approach the High Court for appropriate relief.

21. Our clients wish to remind you of the obligation in terms of decisions of our courts, placed on organs of state and particularly members of cabinet, to respond to correspondence directed to it which obligation is

further accentuated by the constitutional nature and paramount public importance of the subject matter of this letter".

52. Despite pointing out that the purpose of the letter was to seek more clarity (in the event that the Applicants' interpretation and understanding of the position was incorrect), and despite the obvious importance of the matter as well as the public interest and constitutional principles which government is obliged to honour, such as responsiveness, transparency, accountability and clarity, it is regrettable that there was no response to the letter. Not even an acknowledgment of receipt of the letter. The silence must be then interpreted as a confirmation of the Applicants' interpretation and understanding of the position.

53. But the interpretation is not only that of the Applicants. On 13 January 2021, *Medical Brief*, an electronic media newsletter distributed to mainly the medical fraternity, stated as follows:

"Private sector hamstrung

As regards procurement, Discovery, the country's largest private medical scheme, has reportedly secured and ring - fenced funding for the vaccination of 2 million of its members. However, it cannot choose to purchase suitable vaccines because the government will not allow this.

This is also why mining companies cannot meet a demand from the Association of Mineworkers and Construction Union (Amcu) that they 'directly procure the vaccine for the employees', rather than wait for the government to provide. This step cannot be taken, says Mineral's Council SA spokesperson Charmane

Russell, because 'the government has made it clear that private sector organisations or medical schemes will not be permitted to procure independently for their own members'".

54. A copy of the article is attached as annexure **"F".**

55. From all of the above, it is clear that the strategy/policy adopted by the First Respondent has the aim and effect that the private sector (which includes the private healthcare sector, the private sector and the business sector) is excluded or limited from procuring and distributing Covid-19 vaccines independently and freely from the government's framework at any point in time and from the outset.

56. It amounts to a state monopoly and centralised control over the procurement, distribution, allocation, and administration of vaccines as well as control over the rollout without any clarity on the timelines by when each of the phases will commence.

57. This is despite the life threatening second wave of the pandemic which the country is experiencing at this point (which necessitated moving the country back to Level 3 lockdown regulations) with the concomitant adverse economic effect in all walks of life, but in particular on the private sector which is battling to survive in many instances.

58. As at 22 January 2021, South Africa ranked no 15 of all countries relating to Covid-19 infections, with the total number of infections standing at **1380 807** since the beginning of the pandemic, according to statistics of *Worldometer* (https://www.worldometers.info/coronavirus/). With the total number of deaths

standing at **39 501** as at 22 January 2021, South Africa ranks no. 14 in the world.

59. All of the aforementioned accentuates the urgent need to vaccinate as much (ideally two thirds) of the population as speedily as possible, in a rapid and effective manner, in order to achieve herd immunity as soon as possible.

60. The centralised control of the vaccination process and the stifling of the private sector through bureaucratic measures to do so freely, can only result in unwarranted protraction in the distribution and administration of vaccines to the population.

61. To illustrate by way of a practical example: no private health care practitioner can procure approved vaccines and administer them to his or her patients freely and independently from the outset.

62. The example applies equally to pharmacies and local pharmaceutical agents or companies which might be able to procure such approved vaccines independently from government through private contracting. It applies to large industries, such as mining companies, that have their own sophisticated health care service systems, which cannot freely and independently from government vaccinate their own workers outside of the government's procurement and rollout strategy/policy.

63. Similarly, provincial health departments, which have concurrent constitutional competence with the national government to provide health care services to the public, may also not do so. The strategy/policy prohibits or limits or inhibits provincial governments from procuring and distributing Covid-19 vaccines on

their own outside of the framework of the national government's policy or strategy.

64. Whilst speed is of the essence in the acquisition and administration of large quantities of vaccines in order to achieve the desired herd immunity as soon as possible, and in order to address the pandemic (and whilst a large number of countries have already commenced in early December 2020 with the administration of vaccines to their populations), the national government's response was clearly slow and delayed with the result that not a single person in South Africa, as at date hereof, has been vaccinated.

65. The present policy/strategy of the government, as embodied in the documents already mentioned herein above, is likely to exacerbate the delay as it inhibits the private sector from procuring and administering vaccines independently and freely from government, and parallel to the government's strategy.

66. Despite having afforded the government an opportunity to provide a rationale or reasons for the policy/strategy, none has been forthcoming.

67. Furthermore, as can be seen from the"**7 January Response Strategy"** under the heading *"Vaccine Overview",* there are various vaccines which have been manufactured by different pharmaceutical manufacturers, with the result that the entire private sector and members of the public will be entirely dependent upon the vaccine which government elects to procure, regardless of their own views or preferences. This will curtail the rights of medical practitioners and

pharmacists to prescribe or dispense a vaccine which, in their professional opinion ,would be best in the interests of their patients. In turn it would infringe upon the rights of a patient or member of the public to select a particular vaccine which he/she prefers to take. This is a severe curtailment of various constitutional rights, including the right to freedom and security of the person, and to privacy.

68. The practical limiting effect of the policy/strategy is further illustrated by the fact that when the First Applicant through its Professional Guild made enquires between 22 January 2021 and 26 January 2021 with a prominent pharmacy group called *"Alphapharm"* with a view to obtaining vaccines for its approximately 10,000 healthcare members, it was informed that *Alphapharm* had no intention of procuring vaccines outside of the government program and that its involvement in all likelihood will only occur in the second and third phases of the vaccine program of the government when private enterprise will be needed to assist in the roll out to essential workers and the general public. In this regard I attach a copy of the email exchange as annexures **"FA 1 – FA3".**

69. I further attach as annexure **"FB"** a copy of a press release issued by the Council for Medical Schemes (Fifteenth Respondent) on 5 January 2021.

70. According to the aforesaid press release, the Covid-19 vaccine has been included in the amended Prescribed Minimum Benefit regulations approved by the First Respondent. This means that members and beneficiaries of medical

schemes are entitled by law to the Covid-19 vaccine as part of their Prescribed Minimum Benefits. Despite this, members and beneficiaries of medical schemes are not able to obtain this benefit, freely and independently from the government's policy/rollout strategy. Indeed, until government's rollout commences, and even then, only once such members and beneficiaries qualify in terms of the policy/strategy, they will not be able to obtain such benefit at all. This is plainly unlawful and amounts to irrational conduct on the part of the First Respondent.

71. The data on the extent of the roll-out of vaccines in other countries as at date hereof, including developing countries, demonstrates to what extent South Africa is lagging behind.

72. In order to contextualise national government's failure in the procurement and administration of Covid-19 vaccines thus far, I attach two schedules of data compiled by a research facility known as "Our World in Data" (based at the University of Oxford, specifically at the Oxford Martin Programme on Global Development), marked as annexures **"G"** and annexure **"H"**, respectively. The data was downloaded on 21 January 2021 from the following internet address: https://ourworldindata.org/covid-vaccinations.

73. The data shows that **57** countries have already commenced by early January 2021 (some already by December 2020) with the vaccination of their populations. It also demonstrates that such countries were able to secure, pro–actively, agreements with manufacturing pharmaceutical companies for the

acquisition of vaccines in 2020. According to this data, some countries have already vaccinated between 20 to 33 out of 100 of their population (such as Israel and the United Arab Emirates). South Africa's name is glaringly absent from the list of countries.

74. On 22 January 2013 the British Prime Minister, Mr Boris Johnson, announced on Twitter that 5,4 million people across the United Kingdom had received their first vaccine doses. He also stated that during the preceding day the UK managed to administer 400 000 vaccinations.

75. According to the data compiled by "Our World in Data", various developing countries have not only obtained Covid-19 vaccines, but have started to administer same. By way of example, if one has regard to the other "BRICS" countries, as at 20 January 2021: Brazil has administered 28 543 vaccines, China has administered 15 million vaccines, India has administered 674 835 vaccines and Russia has administered 1 million vaccines.

76. As such, South Africa is the only "BRICS" country which has not yet procured and/or administered Covid-19 vaccines. This is astounding, especially if one considers that other developing countries such as Argentina, Bahrain, Bulgaria, Chile, Costa Rica and Turkey have procured and administered Covid-19 vaccines.

77. This also strengthens reports in the media that South Africa has twice missed the payment deadlines, in October and December 2020, in respect of the

payment deposits required through participation in the COVAX scheme for the acquisition of vaccines.

78. The attached annexure **"I"** is a copy from the website of GAVI, the global vaccine alliance, which explains, through Dr Seth Berkley, the Chief Executive Officer of GAVI, what COVAX is all about. What appears from the article is that the number of doses which self–financing countries will obtain will depend on how much they buy into it.

79. According to this article, countries can receive enough doses to vaccinate up to 20% of their population. At this stage it is not clear how many doses the government has secured and will pay for via the COVAX scheme. The article also confirms that upfront payments by countries had to be made by 9 October 2020, a deadline which the government has apparently missed.

80. According to another article published in *Medical Brief* titled: *"Growing anger over SA government's vaccine fiasco",* dated 6 January 2021, the First Respondent in a media briefing on 3 January 2020 stated that at least 67% of the South African population will need to be vaccinated to ensure herd immunity and referred to the phases of the roll-out and the prioritisation of sectors of the population in terms thereof. The First Respondent also stated, according to the report, that the COVAX scheme would cover 10% of the population, with vaccine delivered by the second quarter of 2021, and that enough doses to cover the remaining 57% of the population would have to be sourced through bilateral agreements.

81. A copy of this article is annexed hereto as annexure **"J"**.

82. At the time of preparation of this affidavit, it was by no means clear whether any such bilateral agreements have been concluded to vaccinate the remainder of the population, and by when the vaccines will be procured and will arrive in South Africa (save for media reports stating that government indicated that the first vaccines will arrive by the end of January 2021).

83. Under these circumstances, it is incomprehensible and completely irrational that government has proclaimed itself as the sole buyer of the vaccines, and seeks to control the roll-out. In practical terms, it will mean that the entire population, including the private sector, must fall in with the ability of government to secure all agreements and funding for the acquisition of vaccines to vaccinate at least 67% of the population and must fall in line with government's yet uncertain time frames and its programme to roll out the vaccines.

84. It is incomprehensible that the private sector is inhibited and stifled from proceeding immediately, freely and independently from governmental control, to conclude their own agreements for the acquisition of approved vaccines (and to commence with the administration of vaccinations where and when they are able to do so).

85. From the outset the Applicants need to make their position clear. The Applicants are not against efforts by the national government to procure large quantities of the vaccines, especially in order to ensure that health care workers and the public health sector, as well as the poor and underprivileged members of society, have access to vaccines as expeditiously as possible. The difficulty lies with government proclaiming itself as the sole buyer of vaccines, and its intention to centralise control, and to coordinate itself, through its own structures and programmes, the distribution and administration of vaccines.

86. In the same vein, it is irrational and incomprehensible that the private sector is precluded from procuring, distributing, and administering vaccines independently and freely, in accordance with their own processes, parallel to and in co-ordination with, the endeavours of government.

87. Conceivably, private non–governmental organisations might also want to do so for the benefit of the poor in the country in instances where they are capable and authorised to do so. Here, Gift of the Givers, a well-known organisation that has earned world-wide reknown in addressing disasters here and abroad, springs to mind.

88. When the Applicants addressed the letter to the Respondents, the Respondents were informed and advised that the strategy/policy:

88.1 constitutes an unjustifiable limitation of various constitutional and fundamental human rights; and

88.2 is arbitrary, irrational and *ultra vires*.

89. The Applicants expand below on this unconstitutional, irrational and unlawful approach by the First Respondent and national government as a whole.

MERITS AND RELIEF SOUGHT:

90. The relief sought by the Applicants is aimed at removing any limitation of or restriction on the private sector to procure, distribute and administer vaccines independently and freely from the procurement and rollout programme of the national government.

91. *Inter-alia*, the Applicants seek a declaratory order that the strategy/policy of the First Respondent, to the extent that it prohibits or prevents or limits the private sector from so doing, be declared a violation of fundamental rights and unconstitutional. I proceed to deal with the grounds upon which the Applicants rely in this regard. Further argument will be made with reference to these grounds at the hearing of the application.

92. Infringement of various constitutional rights

92.1 In terms of section 7(1) of the Constitution, the Bill of Rights enshrines the right of all people in our country and affirms the democratic values of human dignity, equality and freedom. This accords with the founding values as stated in section 1(a) of the Constitution which place an obligation on the state to advance human rights and freedoms.

92.2 In terms of section 7(2) of the Constitution, the state must respect, promote and fulfil the rights in the Bill of Rights.

92.3 The prohibition, limitation or curtailment on the private sector to procure and distribute and administer vaccines freely and independently from government, and the requirement that the private sector simply fall in line with the government's vaccination procurement and rollout programme, amounts to an unjustifiable and unwarranted limitation on the freedom of the private sector and individuals to have free access to healthcare, more particularly, the acquisition, distribution and administration of vaccines.

92.4 It infringes and inhibits, unjustifiably, the rights of individuals who are able to purchase vaccines for purposes of being vaccinated from the private health sector independently and freely from the strategy/policy and rollout programme of the government.

92.5 It infringes section 7(1) of the Bill of Rights referred to above. In doing so, the state fails to advance human rights and freedoms in this respect.

92.6 The entire concept of **disaster management**, which government is dealing with in the presence of the disastrous pandemic which is continuously and seriously affecting the lives of people and their livelihoods on an on-going basis, requires government to respond rapidly and effectively in measures which it adopts. In terms of the definition of *disaster management* in the DMA *disaster management* measures should be aimed at *inter alia*:

- preventing or reducing the risk of disasters;
- mitigating the severity or consequences of disasters; and
- a rapid and effective response to disasters.

92.7 The approach as embodied in the strategy/policy documents is likely to protract and delay the vaccination of the population, rapidly and effectively, and violates fundamental rights and/or threatens such violation.

92.8 More specifically, the policy/strategy infringes upon the fundamental right in section 22 of the Constitution which provides that every citizen has the right to choose their trade, occupation or profession freely. The practice of a trade, occupation or profession may be regulated by law. The right in section 22 can only be curtailed by a law.

92.9 In this regard, the policy/strategy infringes upon the vested rights of pharmaceutical companies, pharmacists and medical practitioners authorised to procure, sell, dispense and/or administer medicines in terms of the Medicines and Related Substances Act, No. 101 of 1965 (the "**MRSA**"), the Health Professions Act no 56 of 1974 (in particular section 52 thereof), and the Pharmacy Act No. 53 of 1974.

92.10 As such, the policy/strategy constitutes an arbitrary limitation of the rights and independence of medical practitioners and pharmacists in private practice to procure for their practices vaccines from pharmaceutical companies and to dispense same to their patients in

line with their professional obligations as well as their statutory and constitutional rights in terms of section 22 of the Constitution.

92.11 Health services professionals and providers as well as health establishments are also regulated by the National Health Act No. 61 of 2003 (the "**National Health Act**").

92.12 The objects of the National Health Act in terms of section 2 are *inter alia* :-

- protecting, respecting, promoting and fulfilling the rights of the people of South Africa to the progressive realisation of the constitutional right of access to healthcare services;

- protecting, respecting, promoting and fulfilling the rights of the people of South Africa and to an environment that is not harmful to their health or well-being.

92.13 In terms of section 3(1) of the National Health Act, the First Respondent has an obligation to endeavour to protect, promote, improve and maintain the health of the population. Any measures adopted by him must fulfil this obligation. To the extent that the policy/strategy places a limitation on the private sector, as already referred to, it fails to meet this obligation and frustrates the fulfilment of the objects of the National Health Act.

92.14 In terms of section 20(3)(b) of the National Health Act, every health establishment must implement measures to minimise disease

transmission. For the reasons already mentioned, the policy/ strategy, to the extent that it limits private health establishments from procuring and administering vaccines, frustrates the fulfilment of this obligation.

92.15 A health establishment is defined as the whole or part of a public or private institution, facility, building or place, whether for profit or not, that is operated or designed to provide inpatient or outpatient treatment, diagnostic or therapeutic interventions, nursing, rehabilitative, palliative, convalescent, preventative and other health services.

92.16 Section 27(1)(a) of the Constitution provides that everyone has the right to have access to healthcare services. In terms of section 27(2), the state has the obligation to take reasonable legislative and other measures, within its available resources, to achieve the progressive realisation of the rights under section 27(1), which includes the right to have access to healthcare services.

92.17 The right of access to healthcare services in terms of section 27 is part of the cluster of socio economic rights under this section and such rights are closely related to the founding values of human dignity, equality and freedom and has immense human and practical significance in a society based on such values.

92.18 To the extent that the policy/strategy limits the rights of persons in the private sector to independently obtain and receive vaccination for Covid-19 it infringes or limits the right to healthcare services.

92.19 To the extent that the policy/strategy, for the reasons already mentioned herein before, is likely to cause a delay and to protract the vaccination of the entire population, and limits the rights of the private sector and individuals, it infringes or threatens the right of everyone to an environment that is not harmful to their health or well-being in terms of section 24(a) of the Constitution.

92.20 The rights in the Bill of Rights may only be limited, in terms of section 36 of the Constitution, in terms of law of general application to the extent that the limitation is reasonable and justifiable in an open and democratic society based on human dignity, equality and freedom taking into account the relevant factors listed in section 36.

92.21 The policy/strategy of the government is by no means a law, although it has a practical regulatory effect, and furthermore does not comply with the justification requirements in terms of section 36 of the Constitution.

92.22 The policy/strategy cannot override, amend or be in conflict with laws, including the Constitution.

92.23 For the reasons stated above, the limitations imposed by government are unlawful and unconstitutional to the extent already mentioned.

93 Arbitrary, irrational and *ultra vires*

93.1 The exercise of public power must comply with the Constitution, which is the supreme law of South Africa, and the doctrine of legality, which is part of the rule of law.

93.2 It is a requirement of the rule of law that the exercise of public power by the executive and other functionaries should not be arbitrary. Also, decisions must be rationally related to the purpose for which the power was given, otherwise they are irrational and inconsistent with the rule of law. In addition, the rule of law also requires that rules and laws must be clear.

93.3 As such, it follows that in order to pass constitutional scrutiny the exercise of public power by the executive and other functionaries must not be arbitrary and/or irrational and/or vague.

93.4 When the policy/strategy is considered against this backdrop, the following renders it arbitrary and/or irrational and/or vague, namely:

93.4.1 The policy/strategy will result in undue strain being placed on government resources which will, ultimately, result in a delay in the procurement and distribution of Covid-19 vaccines.

93.4.2 In this sense, the policy/strategy is self-defeating and irrational. As alluded to above, if the private sector is able to procure and distribute Covid-19 vaccines independently, it will enable government to focus on the vaccination of the most vulnerable members of society. The restriction on the private sector is likely to delay and protract the vaccination of the population, and is, as a means, irrational in order to achieve the ultimate goal of herd immunity as rapidly and effectively as possible.

93.4.3 The centralisation and over-concentration of power which underlies the policy/strategy is particularly concerning against the backdrop of our constitutional values in an open and free democratic society.

93.4.4 The policy/strategy is inflexible and, as a result, unreasonable. This is particularly concerning as I am advised that the Constitutional Court had already (in the context of the HIV pandemic and the provision of the Nevirapine drug to mothers and new-born children) warned government that its policies must be flexible and must avoid exclusion. From the Constitutional Court's perspective, I am advised that inclusion, rather than exclusion, should be the preferred approach to be adopted by government when formulating policies (especially in the context of combatting a pandemic such as Covid-19) when it deals with access to healthcare services.

93.5 The legislature and the executive are constrained by the principle that they may exercise no power and perform no function beyond that conferred upon them by law. In formulating and implementing the policy/strategy, the First Respondent has acted *ultra vires* the governing legislation in that the First Respondent does not have the power to adopt and implement the policy/strategy.

93.6 It should be recalled that the Applicants' letter, annexure **"E"**, specifically called upon the Respondents to clarify "... *what empowering*

statutory provisions does government purport to rely on to have made and enforce the above policy/strategy/decision" – to which the Applicants received no response.

93.7 The policy/strategy does not purport to originate from the laws already mentioned above, namely the DMA, the MRSA and/or the National Health Act.

93.8 To the extent that it may be contended by the government Respondents that the policy/strategy falls within the general power and prerogative of the executive, it must still pass constitutional muster and the test of rationality and may not, in itself, be in conflict with laws such as already mentioned.

93.9 Furthermore, government cannot elevate such policy to the level of a law intended to have a binding effect which places an obligation on the private sector to comply with it.

93.10 To the extent that the Respondents may contend that the interpretation of the Applicant of the policy/strategy, regarding the limitation on the private sector, is unjustified, then it is submitted that the policy/strategy documents are vague and ambiguous, insofar as the position of the private sector is concerned in order to procure, distribute and administer the vaccines independently from the program of the government. That, in itself, especially considering the national importance of the matter, provides all the more reason for a declaratory order so as to remove such vagueness and/or uncertainty.

94 Relief

94.1 In terms of section 38 of the Constitution, where a right in the Bill of Rights has been infringed or threatened, the court may grant appropriate relief, including a declaration of rights.

94.2 Also, in terms of section 21(1)(c) of the Superior Courts Act, No. 10 of 2013 (the "**Superior Courts Act**"), a division of the High Court has the power in its discretion, and at the instance of any interested person, to enquire into and determine any existing, future or contingent right or obligation, notwithstanding that such person cannot claim any relief consequential upon the determination.

94.3 In terms of section 172(1) of the Constitution, the court is duty bound to declare any law or conduct that is inconsistent with the Constitution invalid to the extent of such inconsistency. Furthermore, the court is enjoined with a wide discretion to make an order that is just and equitable in the circumstances.

94.4 The relief sought in the notice of motion is founded upon the aforementioned provisions.

URGENCY:

95 The application is self-evidently urgent in that if the application is not heard on an urgent basis, the Applicants, the Applicants' members, and the public, will be subjected to the policy/strategy, which will prevent the private procurement and distribution of life-saving Covid-19 vaccines at a time when the country and its people cannot risk any further delays in obtaining vaccines and being vaccinatedin order to protect themselves, and for the population to achieve herd immunity as soon as possible.

96 Time is of the essence, for purposes of the procurement, distribution and administrations of vaccines, rapidly and effectively and as widely as possible, in order to minimise the effect of the Covid-19 pandemic as expeditiously as possible.

97 There is an obvious great measure and degree of urgency in the relief sought and the Applicants cannot, in the circumstances, and in the interest of their members and in the public interest, receive redress in the ordinary course.

98 Following the issuing of the latest roll-out strategy on 7 January 2021, the Applicants deemed it reasonable to address correspondence in the form of a letter dated 13 January 2021 to the Respondents, in an endeavour to resolve uncertainty and to address the Applicants' concerns.

99 As a result of the failure by the Respondents to answer the letter, the Applicants were left with no choice other than to instruct their legal representatives to prepare this application. The Applicants did so without any delay.

100 The Applicants, together with their legal representatives, have considered the degree of urgency of the matter and, in formulating the timelines in the notice of motion, catered for such degree of urgency in order to afford the Respondents an adequate and reasonable opportunity to file their answering affidavits (also considering the importance of the matter for government).

101 As regards the reasons why the Applicant would not be afforded substantial redress in due course, I am advised that if the matter is only heard in the ordinary course, the harm done to the Applicants, the Applicants' members and the general public will be irreversible in that the Applicants, the Applicants' members and the general public would be unconstitutionally deprived of the ability to procure life-saving Covid-19 vaccines, which may result in unnecessary death and illness – which can be prevented if the matter is heard on an urgent basis.

102 The above is particularly concerning if one has regard to the fact that South Africa is already behind other states in the procurement and roll-out of Covid-19 vaccines.

CONCLUSION:

103 In all of the circumstances, the Applicants pray for the relief as set out in the notice of motion, together with costs including the costs of the employment of two counsel.

DJ HERMANN

THUS SWORN AND SIGNED AT PRETORIA ON THIS 27th DAY OF JANUARY 2021, BEFORE ME, Kevin de Bruin, COMMISSIONER OF OATHS, THE DEPONENT HAVING ACKNOWLEDGED THAT THE DEPONENT UNDERSTANDS THE CONTENTS OF THIS AFFIDAVIT, HAS NO OBJECTION IN TAKING THE OATH AND REGARDS THE OATH AS BINDING ON THE DEPONENT'S CONSCIENCE AFTER COMPLYING WITH THE REQUIREMENTS OF GOVERNMENT NOTICE R1258, DATED 21 JULY 1972, AS AMENDED.

COMMISSIONER OF OATHS

NAME:

CAPACITY: KEVIN EBEN DE BRUIN
PRACTISING ATTORNEY
COMMISSIONER OF OATHS (EX OFFICIO)

ADDRESS: 4th Floor, Building A, Loftus Park
402 Kirkness Street, Arcadia, PTA, 0007
Fax: 012 321 0039 Email: kevin@mketsu.co.za

"A"

SOLIDARITY TRADE UNION

REG. NO. LR2/6/2/1253

(HEREINAFTER "SOLIDARITY")

RESOLUTION PASSED BY THE EXECUTIVE COMMITTEE OF SOLIDARITY (TRADE UNION) ON 25 JANUARY 2021

It is resolved that –

a) An urgent application be instituted by Solidarity in order to challenge the ostensible decision by national government to centralise the procurement and distribution of COVID-19 vaccines and which prohibits the private procurement of any COVID-19 vaccine and that its attorneys be instructed to give effect to this resolution.

b) **Dirk Johannes Hermann** in his capacity as Chief Executive Officer of the Solidarity trade union is hereby authorised to represent Solidarity in the urgent application. regarding the procurement and distribution of COVID-19 vaccines.

c) **Dirk Johannes Hermann** is hereby authorised to depose to any affidavits and to sign any documents on behalf of Solidarity that may be necessary to give effect to the resolution passed herewith.

Head: Legal Department

AJ van der Bijl 25/01/2021

Exco member

"B"

AFRIFORUM NPC

2005/042861/08

(HEREINAFTER "AFRIFORUM")

RESOLUTION PASSED BY BOARD OF DIRECTORS OF AFRIFORUM NPC ON 25 JANUARY 2021

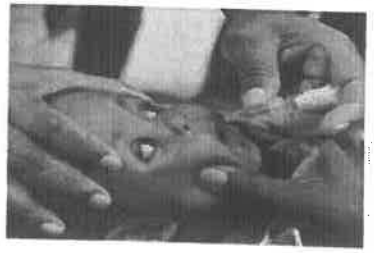
It is resolved that –

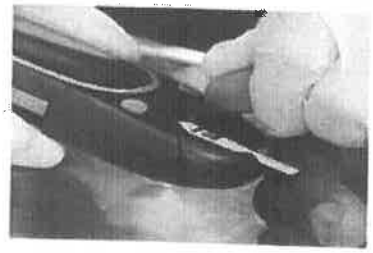
a) **AfriForum** institutes together with **Solidarity Trade Union** an urgent application to the High Court to challenge the ostensible decision by national government to centralise the procurement and distribution of COVID-19 vaccines and which prohibits the private procurement and distribution of any COVID-19 vaccine and instructs for this purpose its attorneys to prepare such application.

b) **Dirk Johannes Hermann** in his capacity as Chief Executive Officer of Solidarity represents AfriForum in the said application to court.

c) **Dirk Johannes Hermann** is hereby authorised to depose to any affidavits and to sign any documents that may be necessary to give effect to the resolution passed herewith.

Chief Executive Officer: Carl Martin Kriel





Covid-19 Vaccine Rollout Strategy

03 January 2020

health
Department:
Health
REPUBLIC OF SOUTH AFRICA

NATIONAL DEVELOPMENT PLAN 2030

Phila

Introduction

- Covid-19 pandemic had a multi-sectoral impact on South Africa, including a significant socioeconomic impact, and an impact on healthcare cost.
- One intervention to rapidly interrupt Covid-19 transmission is an effective **vaccination.**
- There are currently over 240 Covid-19 vaccines in development worldwide, with over 42 in clinical trials and several that have emerged as being effective after phase 3 studies.
- The data suggests these vaccines are safe and effective
- A Ministerial Advisory Committee on Covid-19 Vaccines has been appointed consisting of experts in the field. They have developed a **strategy** to ensure equitable access to vaccines.
- The strategy includes the various purchasing mechanisms, funding implications, local manufacturing opportunities and **identifying priority groups for vaccination.**

Purpose and Scope of Ministerial Advisory Committee on Covid-19 Vaccines

Primary objective of the MAC on Vaccines - developing the National COVID-19 Vaccine Framework; provide Minister of Health with advice on:

- Current scientific evidence and best practices;
- The appropriate vaccine options based on evidence-based medicine reviews;
- vaccine purchasing options that are available globally (e.g. COVAX Facility);
- The budget implications of the vaccine options;
- the priority groups for vaccination;
- the vaccine rollout strategy; and
- the development and manufacture of a COVID-19 vaccine.

Ministerial Advisory Committee on Covid-19 Vaccines

- The Ministerial Advisory Committee (MAC) on Vaccines is a non-statutory, advisory Committee appointed by the Minister of Health.
- **Members of the Ministerial Advisory Committee on Vaccine include:**

Prof Barry Schoub	Chair Person	Vaccinology and virology
Dr Anban Pillay	Member	DDG: NDOH
Dr Morena Makhoana	Member	CEO Biovac
Ms Glaudina Loots	Member	DSI
Dr Boitumelo Semete-Makokotlela	Member	CEO SAHPRA
Prof Greg Hussey	Member	UCT training programme: VACFA
Prof Jeff Mphahlele	Member	MRC; immunologist; SAHPRA board
Prof Helen Rees	Member	Expert adviser WHO, Gavi, CEPI. WHO's RITAG and NAGI
Prof Ames Dhai	Member	Ethicist
Dr Mark Blecher	Member	National Treasury
Prof Salim Abdool Karim	Observer	Chairperson: MAC on Covid-19
Bishop Malusi Mpumlwana	Observer	Chairperson: Multi-Sectoral MAC on Social Behaivour

health
Department:
Health
REPUBLIC OF SOUTH AFRICA

NATIONAL DEVELOPMENT PLAN 2030

Phila

Vaccines Acquisition Task Team

Primary objective of the task team is to co-ordinate the private sector vaccine financing, procurement, logistics and administration.

The Task Team is made up of the ffg members:

Mr Adrian Gore

Mr Sandile Zungu

Mr Lex Cochrane

Prof Schoub

Dr Aquina Thulare

Dr Anban Pillay

WHY ARE VACCINES IMPORTANT

The aim of vaccination is to:

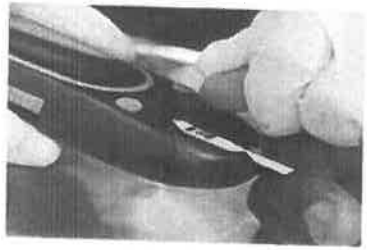
- To prevent **morbidity and mortality**.
- To **achieve herd immunity** and **prevent ongoing transmission**.

When a person gets vaccinated against a disease, their risk of infection is also reduced – personal protection

'Herd immunity', also known as **'population immunity'**, is the indirect protection from an infectious disease that happens when immunity develops in a population either through vaccination or through previous infection.

Herd immunity does not mean unvaccinated or individuals who have not previously been infected are themselves immune. Instead, herd immunity exists when individuals who are not immune, but live in a community with a high proportion of immunity, have a reduced risk of disease as compared to non-immune individuals living in a community with a small fraction of immunity.

Lowering the possibility for a pathogen to circulate in the community protects those who cannot be vaccinated (due to health conditions, like allergies, or their age) from the disease targeted by the vaccine.



Vaccine Rollout Framework

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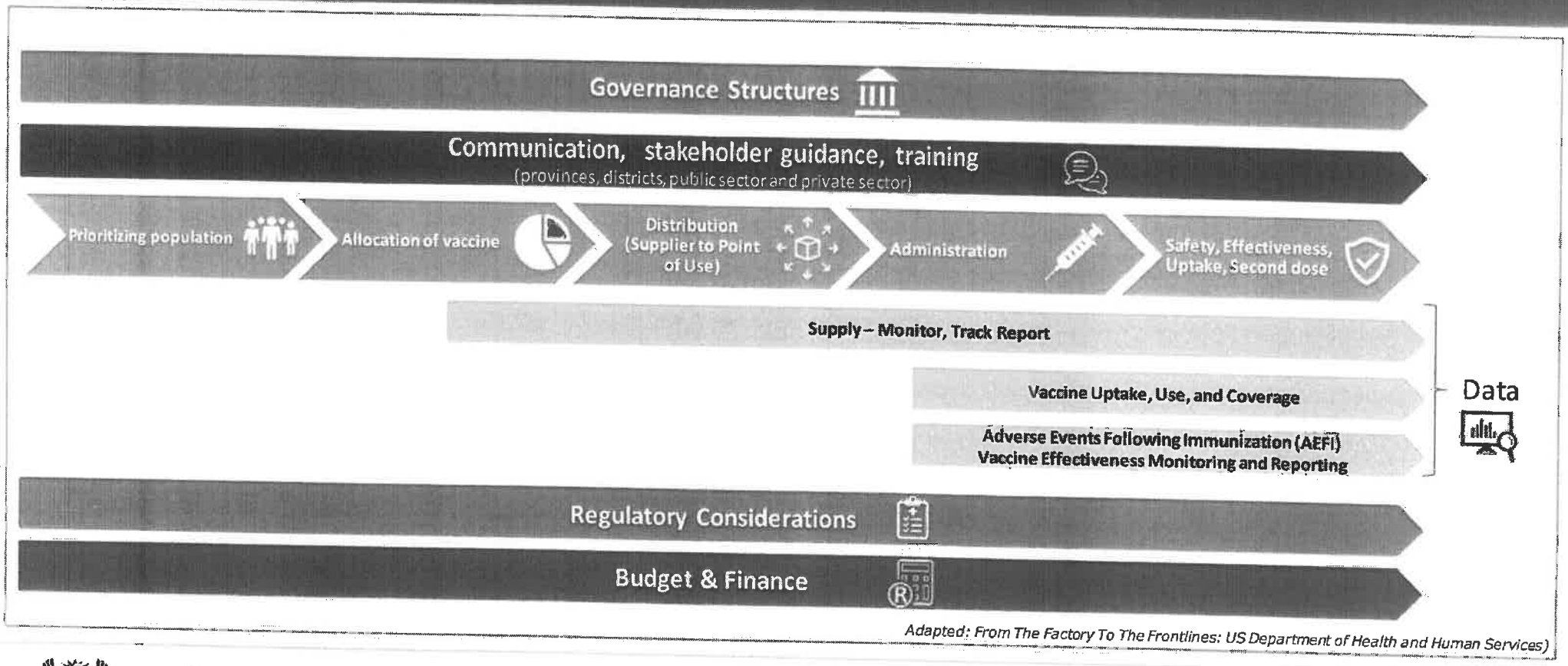
FRAMEWORK FOR VACCINE IMPLEMENTATION



Adapted: From The Factory To The Frontlines: US Department of Health and Human Services)

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LEADERSHIP AND CO-ORDINATION

- The vaccine rollout will be lead nationally in close co-ordination with provincial health departments and the private healthcare sector. Committee will be established at various levels with the relevant stakeholders and expertise to co-ordinate the rollout of the various phases of the vaccine delivery.

- A **national vaccine co-ordinating committee** established at the NDOH by the DG with representatives from various clusters involved:
  - Expanded Programme for Immunisation (EPI), Communicable Disease Cluster (CDC), Medicines,Supply Chain Management (SCM), Information Systems, Human Resources for Health (HRH), Primary Health Care (PHC), Monitoring and evaluation,
  - The chair of the provincial co-ordinating committees
  - The chair of the national private sector, co-ordinating committee
  - World Health Organisation
  - Committee chaired will be chaired by Dr Bamford

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

- **Private health sector co-ordinating committee** which includes medical schemes, private hospital association, pharmacies groups, general practitioner and specialist associations, nursing association, allied health professions associations, logistics providers, pharmaceutical manufacturers, employers, labour unions, business associations.

PHASED APPROACH FOR VACCINE INTRODUCTION

Phase I

Front line health care workers (HCW)

Target population: 1,250,000

Phase II

Essential workers

Target population: 2,500,000

Persons in congregate settings

Target population: 1,100,000

Persons >60 years

Target population: 5,000,000

Persons >18 years with co-morbidities

Target population: 8,000,000

Phase III

Other persons >18 years

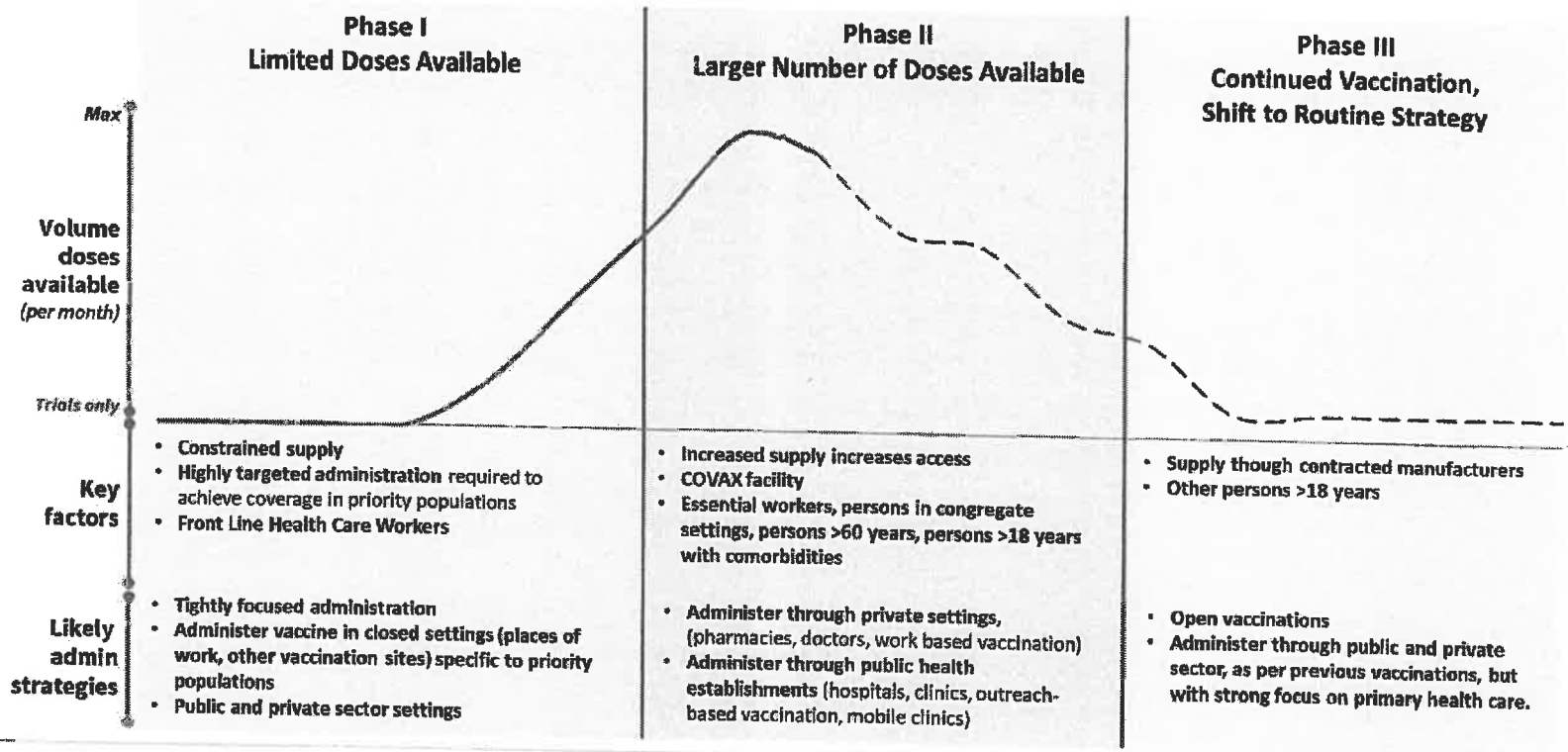
Target population: 22,500,000

IDENTIFICATION AND PRIORITISATION OF TARGET POPULATION

Phase	Priority Group	Definition
II	Essential workers (2 500 000)	Police officers, miners and workers in the security, retail food, funeral, teachers banking and essential municipal and home affairs, border control and port health services.
	Persons in congregate settings (1 100 000)	Persons care homes, detention centres, shelters and prisons . In addition, people working in the hospitality and tourism industry, and educational institutions are also at risk.
	Persons 60 years and older (5 000 000)	
	Persons older than 18 years with co-morbidities	Persons living with uncontrolled diabetics, chronic lung disease , poorly controlled cardiovascular disease, renal disease, HIV, tuberculosis and obesity.

PHASED APPROACH BASED ON AVAILABILITY OF VACCINES

Distribution will adjust as volume of vaccines increases, moving from targeted to broader population reach (phased approach)



Adapted: From the factory to the frontlines: US Department of Health and Human Services
Illustative and not to scale.

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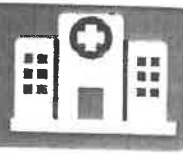
PHASE 1: HEALTH CARE WORKER SERVICE DELIVERY PLATFORM

Work-based vaccination programme: District level private and public hospitals



- Most suitable for hospital linked HCWs

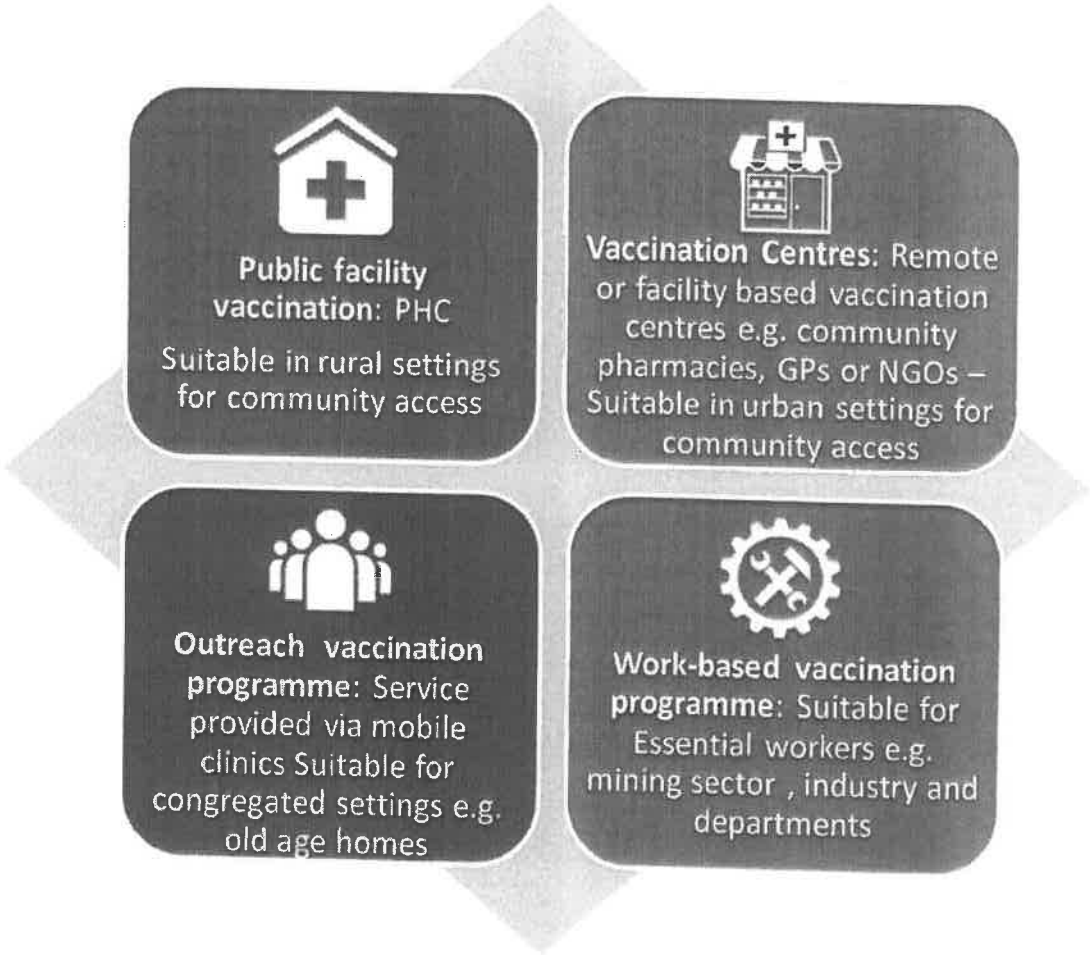
Outreach work-based vaccination programme: Mobile teams move from facility to facility

- Most suitable for HCWs in PHC, CHC and private medical centres

Vaccination Centres: Remote or facility-based vaccination centres e.g. community pharmacies

- Suitable for independent HCWs

PHASE 2 AND 3: HIGH RISK PRIORITY GROUPS AND GENERAL PUBLIC SERVICE DELIVERY PLATFORMS



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VACCINE SELECTION

- **Six key considerations in the selection of Covid-19 vaccines** for the South African setting:
  - The key consideration is AVAILABILITY of vaccine that is also:
  - **Safe, efficacious and good quality - SAHPRA**
  - **Ease of use** and schedule (including number of doses required)
  - Stability during **storage and distribution**
  - **Supply and sustainability** (i.e. supplier capacity)
  - **Cost**

REGULATORY MATTERS

- Vaccines must be **safe and effective** - Medicines and Related Substances Act 101 of 1965
- South African Health Products Regulatory Authority (SAHPRA) put several measures in place to ensure expedited regulatory approvals of safe vaccines. These measures include:
  - **Agreements with EMA, USFDA, MHRA, and TGA** – SAHPRA will thus be able to use their assessment reports as a reliance approach to reduce timelines in the evaluation process.
  - **SAHPRA has adopted a priority review approach for all COVID-19 vaccine applications** since the onset of the pandemic. Thus, the process of expedited review will apply to any COVID-19 vaccine registration application.
  - **Flexibility in relation to labelling and packaging requirements** effected in terms of effect Section 36 of the Medicines Act (exemption of medicines by the Minister of Health from certain requirements of the Medicines Act) for specific labelling and packaging requirement exemptions.
  - **Authorisation in terms of Section 21** of the Medicines Act where manufacturers have not submitted dossiers to SAHPRA

Note: NDoH has been meeting with vaccine manufacturers who are being encouraged to submit dossiers to SAHPRA

PROCUREMENT

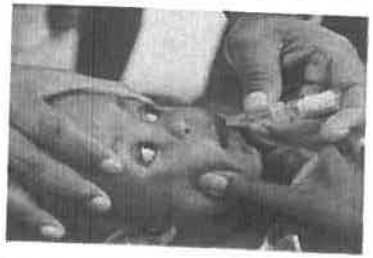
- Governed by
  - **Public Finance Management Act 1 of 1999**
  - **Medicines and Related Substances Act 101 of 1965**
- **Emergency procurement procedures** for vaccine, service providers in logistics, training, communication, HR where no contracts are available.
- **Request deviation from NT** for deviation from normal supply chain processes for vaccines
- **SAHPRA registration/approval required**
- Competitive bid process based on registration status, available stock and cost effectiveness - shortened time frames to be considered

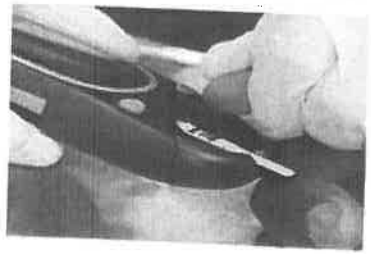
DISTRIBUTION: SECURITY

- **Distribution security**
  - Vehicle tracking and monitoring (central distributor / contract distributors)
- **Safety and security at administration sites**
- **Track and traceability** of vaccines using **barcode scanning**
- **Safe and secure disposal** of all vaccine packaging and vials
- **Data verification** of volumes distributed vs volumes administered
- Monitoring of **vaccine wastage**

DATA FOR VACCINE MANAGEMENT AND SURVEILLANCE

- Data needed for monitoring vaccine **uptake and coverage, prioritization, planning, safety monitoring and vaccine effectiveness studies.**
- To meet anticipated needs of stakeholders, **electronic vaccination data system (EVDS)** is in the process of being developed.
- EVDS will **leverage off existing systems** which are currently deployed and implemented at scale.
- **EVDS must support collection and provision of the following information**
  - **Patient information** (including demographics, number of doses, etc.)
  - **Health establishment** where service is accessible (name and type, e.g. clinic)
  - **Vaccine administered** (manufacturer, batch number, etc.)
  - **Safety information** as part of a pharmacovigilance plan (Adverse Events Following Immunization – AEFI)
  - **A record of vaccination issued to individuals where appropriate and required**





Negotiations with Vaccine Manufacturers

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VACCINE OVERVIEW

- We have met with vaccine producers in China and Russia

- Since last year the National Department of Health and the Ministerial Advisory committee has had discussions with potential vaccine suppliers. The suppliers that we have met with include:
  - Pfizer
  - Astra Zenca
  - Johnson and Johnson
  - Moderna
  - Cipla

- Many of the manufacturers requested a non disclosure agreement before they could share details of their vaccine offer.

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VACCINE OVERVIEW

Pfizer /BioNTech Vaccine

- Regulatory: EUA by FDA and a number of other countries (with bilateral deals) including WHO PQ. SAHPRA filing not completed.
- Efficacy: 95% protection – 2 dose vaccine
- Rollout has happened in a few countries already where bilateral deals had occurred very early on.
- Storage: minus 70 deg C which is a limitation for SA as we have limited commercial ultra low cold chain storage in SA only suitable for small volume.

AstraZeneca/ University of Oxford Vaccine

- Regulatory: Product has been approved as EUA by MHRA and DCGI
- Efficacy: 70% efficacy – 2 dose vaccine
- AZ has outsourced the production of the vaccine to various sites globally. The largest vaccine producer globally is Serum institute of India (SII). SII does not have a presence in SA and its local partner is Cipla.
- This vaccine is likely to be widely used globally due to temp stability and volumes that AZ committed to produce through partners and their tiered price model
- Storage: 2 – 8 deg C

VACCINE OVERVIEW

Johnson and Johnson

- Regulatory: Product has been approved as yet – dossier submission expected in January
- Single dose product that is much easier for administration and more cost effective
- Product will also be manufactured at the Aspen facility on a contract basis

Moderna

Regulatory: EUA by FDA

Two dose vaccine

Storage: **minus** 20 deg C

No office in SA and no expectation of filing the dossier with SAHPRA

Vaccine Procurement

- The COVAX facility has focused most of its agreements on vaccines suitable for developing nations where capacity for ultra cold storage is limited or non-existent

- Pfizer was the first vaccine to become available and developed nations particularly have already signed up bilateral agreements before development was even complete. Hence we see the rollout of the Pfizer vaccine across various countries with bilateral deals.

- Covax has focused on vaccines that can be stored at usual cold storage facilities produced by Astra Zenca, Johnson and Johnson and others. The Astra Zeneca vaccine has just been approved in the UK and India which will now allow for mass production to proceed. Astra Zeneca has established contract manufacture agreements with several manufacturers across the world to achieve their target of 2 billion doses by year end. The largest vaccine producer globally is Serum Institute of India and will be producing the Astra Zeneca Vaccine for mainly developing and developed countries.

Vaccine Procurement

- **We are working to secure a sufficient supply of vaccines in the shortest possible time to protect the most vulnerable in our community**

- South Africa is part of the global pooled procurement initiative co-ordinated by Covid-19 Vaccines Global Access Facility, commonly known as COVAX. We are part of the first group of countries that will receive an allocation of vaccines from COVAX. We have been advised that we should expect the vaccines in the second quarter of 2021. We have been in constant contact with COVAX who have advised us that they are working very hard to bring the bring batches releases forward to quarter one.

- We are also having parallel bilateral discussions with a number of vaccine manufacturers as indicated earlier and will make further announcements once firm agreements are in place.

- These bilateral negotiations with some of the suppliers hves progressed well and we are fairly confident that we will have supply in quarter one. We cannot announce the details of this supply until this is confirmed by a signed contract.

COVID-19 Response

07 JANUARY 2021

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COVID 19: South Africa Epidemiology and Surveillance

As of the 06th January 2021

- The majority of new cases today are from **KwaZulu-Natal**, which accounted for **30,9%** (6 742) of all new positives reported today, followed by **Gauteng** which accounted for **26,4%** (5 754) and **Western Cape** which accounted for **17,2%** (3 766).
- Limpopo accounted for 7,2%; Mpumalanga accounted for 5,0%; Eastern Cape accounted for 5,0%; North West accounted for 4,5%; Free State accounted for 2,0% and the Northern Cape accounted for 1,2% of new cases.

Province	Updated Cases Post Harmonisation	New Cases	% New Cases	Total Cumulative Cases	% Total Cases	Total Deaths	Case Fatality Rate	Total Recoveries	Active Cases	New Case Incidence per 100k Population
	05 January 2021	06 January 2021	06 January 2021	06 January 2021	06 January 2021	06 January 2021		06 January 2021	06 January 2021	
Eastern Cape	174859	1082	5.0%	175,941	15.3%	8292	4.7%	162,039	5,610	16.1
Free State	63971	438	2.0%	64,409	5.6%	2215	3.4%	55,629	6,565	15.0
Gauteng	304447	5754	26.4%	310,201	27.0%	5923	1.9%	268,551	35,727	**37.2**
KwaZulu-Natal	223541	6742	30.9%	230,283	20.0%	4870	2.1%	148,420	76,993	**58.5**
Limpopo	29264	1576	7.2%	30,840	2.7%	636	2.1%	22,612	7,592	**26.9**
Mpumalanga	39527	1224	5.6%	40,751	3.5%	664	1.6%	34,646	5,441	**26.2**
North West	42166	993	4.5%	43,159	3.8%	648	1.5%	35,553	6,958	**76.8**
Northern Cape	26096	257	1.2%	26,353	2.3%	417	1.6%	23,194	2,742	6.3
Western Cape	223888	3766	17.2%	227,654	19.8%	7703	3.4%	178,595	41,356	**53.8**
Unknown	0	0	0.0%	0	0.0%	0	0.0%	0	0	0.0
Total	**1,127,759**	**21,832**		**1,149,591**		**31,368**	**2.7%**	**929,239**	**188,984**	**39.0**

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COVID-19 Trends: 7 day moving average

As of the 05th January 2021

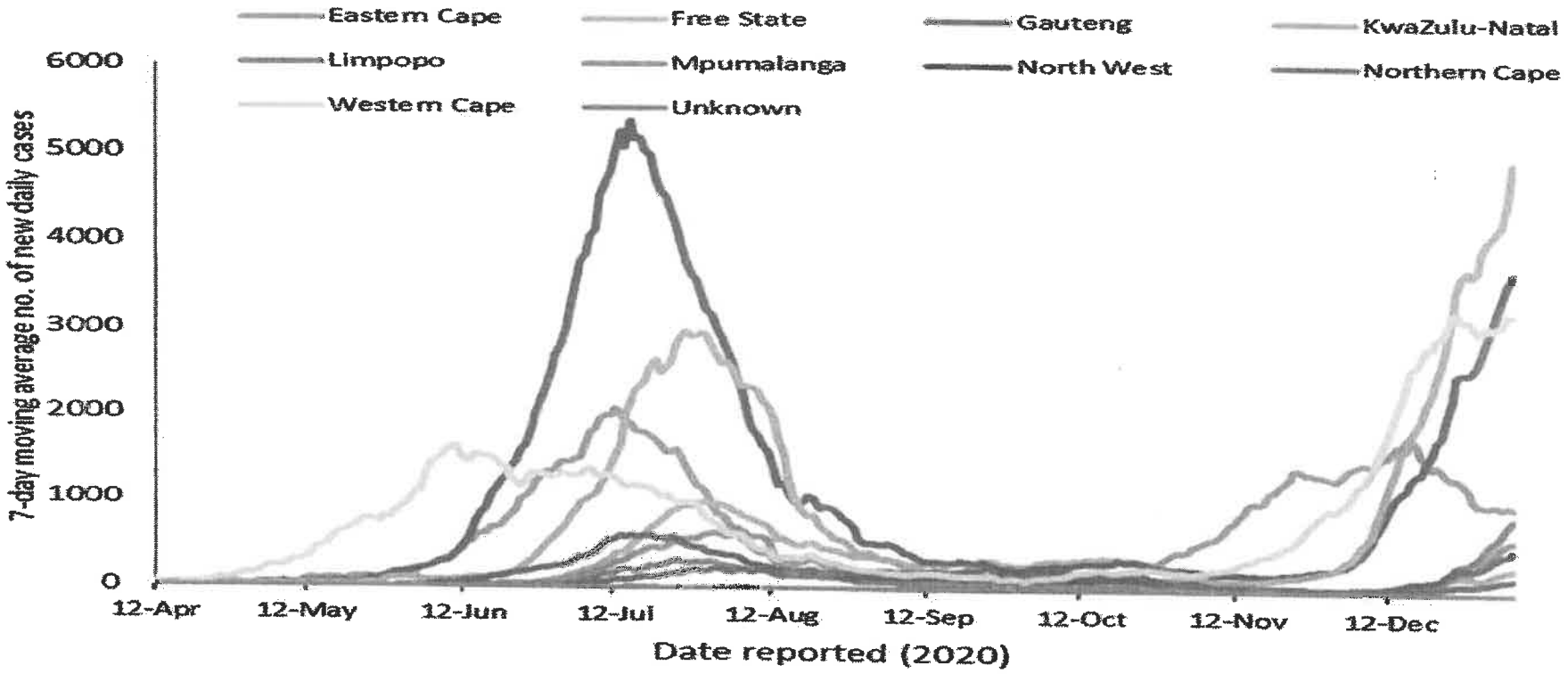
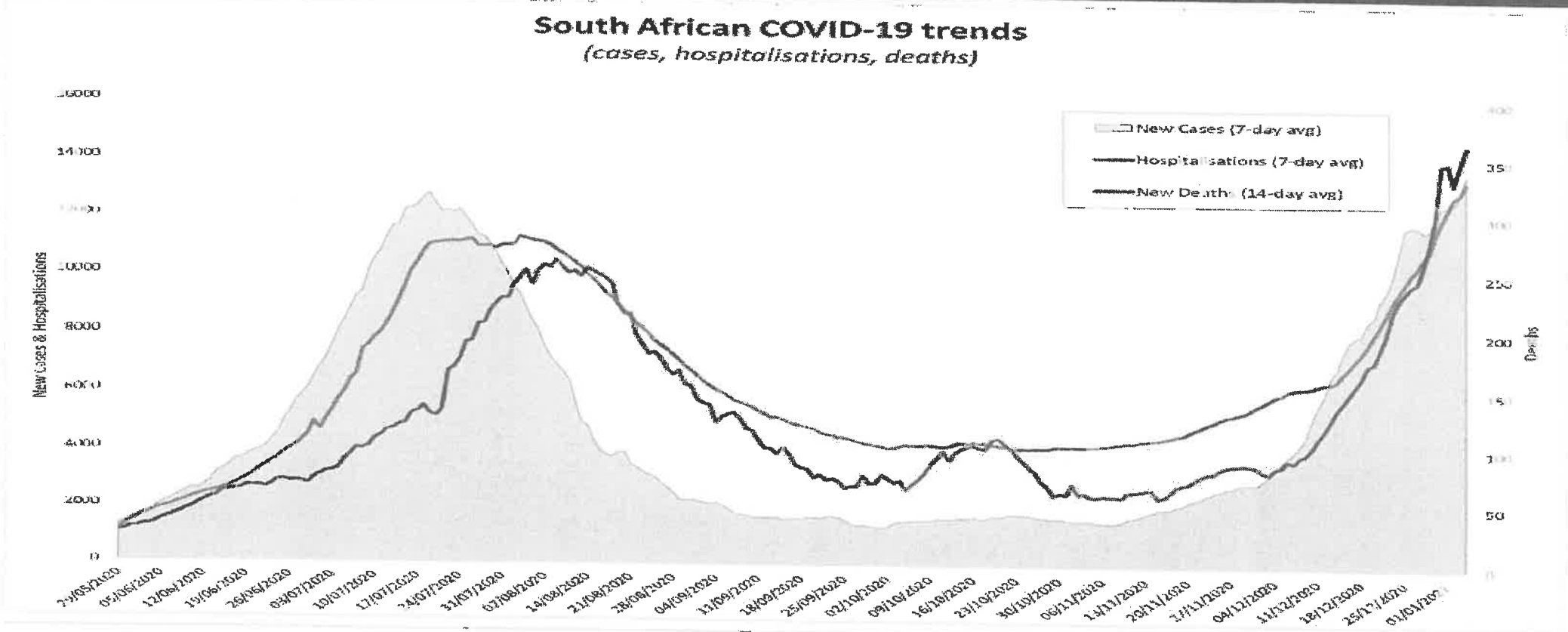


Figure 2. 7-day moving average number of new cases by province and date of reporting, 12 April to date, South Africa

COVID-19 Trends: National New Cases, Hospitalizations & Deaths

As of the 05th January 2021



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VACCINE ROLL OUT PLAN

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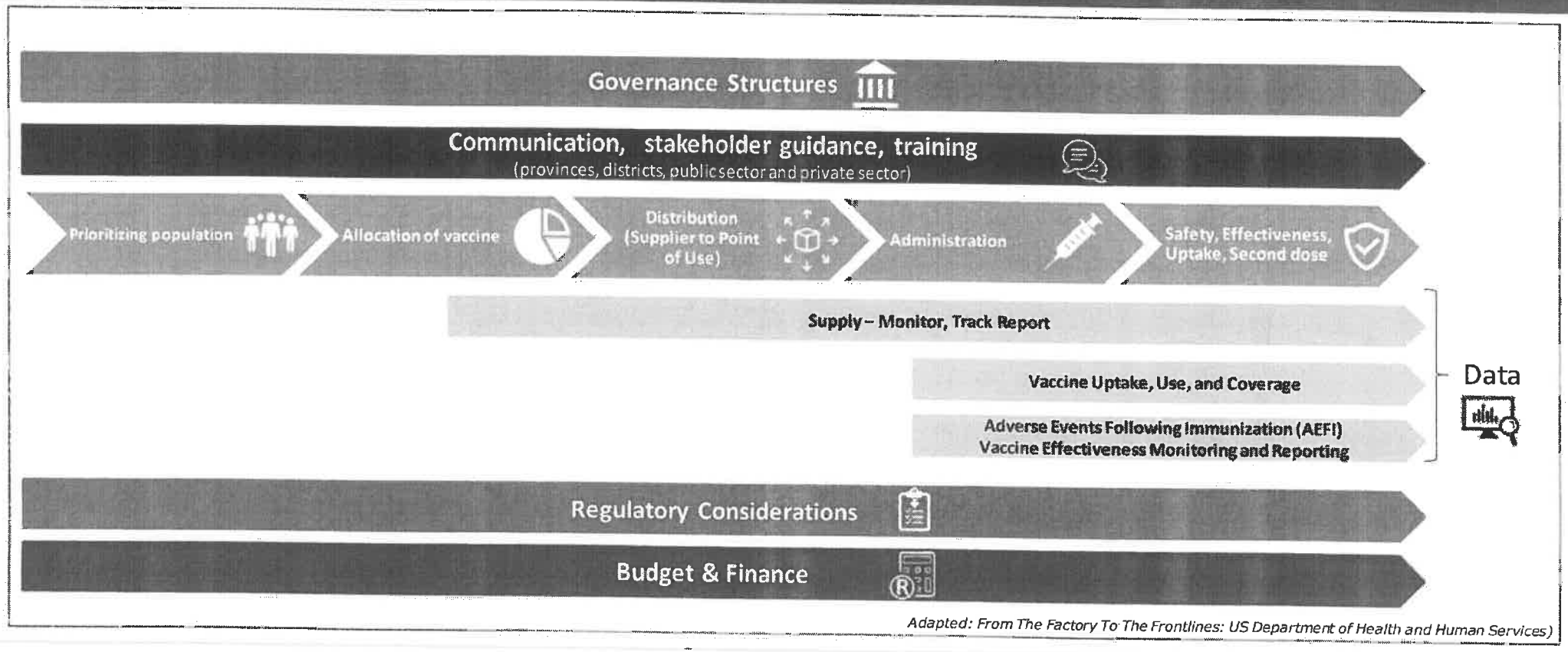
FRAMEWORK FOR VACCINE IMPLEMENTATION



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WHY ARE VACCINES IMPORTANT

The aim of vaccination is to:

- To prevent **morbidity and mortality.**
- To **achieve herd immunity** and **prevent ongoing transmission.**

When a person gets vaccinated against a disease, their risk of infection is also reduced – personal protection

'Herd immunity', also known as **'population immunity'**, is the indirect protection from an infectious disease that happens when immunity develops in a population either through vaccination or through previous infection.

Herd immunity does not mean unvaccinated or individuals who have not previously been infected are themselves immune. Instead, herd immunity exists when individuals who are not immune, but live in a community with a high proportion of immunity, have a reduced risk of disease as compared to non-immune individuals living in a community with a small fraction of immunity.

Lowering the possibility for a pathogen to circulate in the community protects those who cannot be vaccinated (due to health conditions, like allergies, or their age) from the disease targeted by the vaccine.

KEY PRINCIPLES

- **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 private health sector.
- Given the limited availability of vaccines it will be necessary to procure available stock from different manufacturers hence there may be **multiple vaccines in the programme** that are **NOT interchangeable in a 2 dose vaccine schedule**
- **Allocation of vaccines** to the various priority groups will be **guided by the MAC on vaccines**.
- The vaccination system should be based **on pre-vaccination registration and appointment system for vaccination**
- All vaccinated persons should be on a **national register and will be provided a vaccination card**.
- **A national rollout committee** will oversee the rollout including both the public and private sectors.

LEADERSHIP AND CO-ORDINATION

- A **national vaccine co-ordinating committee** established at the NDOH with representatives from various clusters:
- Chaired by DG, co-chaired by Dr Lesley Bamford
  - Expanded Programme for Immunisation (EPI): Ms Marione Schonfeldt
  - Communicable Disease Cluster (CDC): Ms Tsakani Furumele
  - Medicines: Ms Khadija Jamaloodien
  - Supply Chain Management (SCM): Ms Dikeledi Tshabalala/Office of CPO, National Treasury
  - Health Information Systems: Ms Milani Wolmarans
  - Human Resources for Health (HRH), Human Resource Development (HRD): Mr Victor Khanyile/Dr Nonhlanhla Makanya
  - Primary Health Care (PHC): Mr Rams Morewane
  - Hospital Services: Dr Anban Pillay
  - Monitoring and evaluation: Ms Thulile Zondi
  - Communication: Mr Popo Maja
  - Provinces: HODs
  - SAMHS
  - SALGA
  - Private sector: Chairperson of Private Sector Co-ordinating Committee
  - Civil Society (TBA)
  - WHO
- **Provincial co-ordinating committees** appointed by HODs with representation from similar functionaries

LEADERSHIP AND CO-ORDINATION- STAKEHOLDERS

MINISTERIAL ADVISORY COMMITTEES

- The MAC on Vaccines with continue to provide ongoing scientific guidance using latest or emerging data on vaccines as they evolve and advise on necessary adjustments to the plan.
- The MAC on Social and Behaviour Change will drive a concerted social mobilization campaign to all the sectors:
  - -Focusing on correcting myths about vaccines
  - -Emphasizing on the importance of NPIs even if someone is vaccinated
  - -promoting the use of the vaccines
  - -availing some of the facilities for mass vaccinations

ORGANISED LABOUR

- Organized labour will assist with mobilization of their membership for the vaccination
- Campaign to demystify the vaccines
- Through the OHSC, assist with overseeing vaccination programme in the workplaces

OTHER CIVIL SOCIETY FORMATIONS

- Correct community messaging of the vaccine

LEADERSHIP AND CO-ORDINATION- PRIVATE SECTOR

PRIVATE HEALTH SECTOR AND MEDICAL SCHEMES

- Private health coordinating forum will be established consisting of the role players including HASA, IPAs, Retail pharmacies and others (the chair of this forum will participate in the national vaccine coordinating committee chaired by the DG)
- Main roles:

-Coordination of the vaccination of the private health sector employees (eg private hospitals will vaccinate their own employees)

-providing the platform for the vaccination of the communities similar to the CCMDD programmes (GPs, Retail pharmacies)

-Medical schemes to pay for vaccines for their members through an agreed mechanism with government

OTHER PRIVATE SECTOR/BUSINESS SECTOR

- Pooling of funds support the vaccination programme through the SF
- Promoting the use of vaccine amongst their employees
- Provision of vaccination platform through the occupational health systems

IDENTIFICATION AND PRIORITISATION OF TARGET POPULATION

Vaccines will not be available for everyone immediately, and a **prioritization system** will have to be applied.

Guided by the MAC on Vaccines.

Priority will be given to those:

- in roles considered to be **essential for societal functioning**;
- **most at risk** of infection and serious outcomes, for example, those over 60 years, those with comorbid conditions and those living in overcrowded settings,
- **most at risk of transmitting** SARS-CoV-2 to others.

- Decisions will also be based on efficacy of a vaccine for a specific population and on the doses available.

PHASED APPROACH FOR VACCINE INTRODUCTION

Phase I

Health care workers (HCW)

All health sector workers

Target population: 1,250,000

Phase II

Essential workers

Target population: 2,500,000

Persons in congregate settings

Target population: 1,100,000

Persons >60 years

Target population: 5,000,000

Persons >18 years with co-morbidities

Target population: 8,000,000

Phase III

Other persons >18 years

Target population: 22,500,000

PHASE I: HEALTH CARE WORKERS

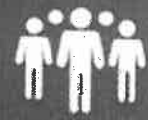
- Health workers will be divided into risk categories with those in the priority categories receiving vaccination first.
- These risk categories are linked to the PPE Risk Categories, and reflect risk of risk of contracting Covid-19.

Category 1	Those conducting aerosol-generating procedures i.e. intubation, ventilation, taking Covid-19 specimens
Category 2	Those in direct contact with known or suspected Covid-19 patients
Category 3	Those in contact with patients (who are not known or suspected to have Covid-19)
Category 4	Those not in contact with patients

IDENTIFICATION AND PRIORITISATION OF TARGET POPULATION

Phase	Priority Group	Definition
II	Essential workers	Teachers, police officers, military, miners and workers in the security, retail food, funeral, banking and essential municipal and home affairs, border control and port health services.
	Persons in congregate settings	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.
	Persons 60 years and older	-
	Persons older than 18 years with co-morbidities	Persons living with HIV, tuberculosis, diabetics, chronic lung disease, cardiovascular disease, renal disease, obesity, etc

IDENTIFICATION AND PRIORITISATION OF TARGET POPULATION



UNRESOLVED ISSUES- MAC STILL WORKING ON THESE

Should pregnant women and children be vaccinated?

- Safety and efficacy of vaccines in children and pregnant women are currently not known.
- Vaccination is currently not recommended.
- Guidance will be updated as new evidence becomes available.

Should people who are known to have had Covid-19 infection be vaccinated?

- This includes persons who tested positive during their illness, as well as patients with positive antibody tests
- Best practice currently remains unclear
- Guidance is awaited from WHO and the Vaccine MAC

VACCINE SELECTION

- **Six key considerations in the selection of Covid-19 vaccines** for the South African setting:

  - **Vaccine Supply and sustainability** (i.e. supplier capacity)
  - **Safety, efficacy and immunogenicity** (reactogenicity, short and long term safety and efficacy, population groups studied as well as humoral vs. cellular immunogenicity)
  - **Ease of use** and schedule (including number of doses required)
  - Stability during **storage and distribution**
  - **Cost**
  - **SAHPRA approval** (full licensure or emergency use authorisation)

VACCINE OVERVIEW

VACCINES AT ADVANCED STAGES OF STUDY

Pfizer /BioNTech Vaccine

- Regulatory approval: EUA by FDA and a number of other countries (with bilateral deals) including WHO PQ. SAHPRA filing not completed.
- Efficacy: > 90% protection – 2 dose vaccine
- Rollout has happened in a few countries already where bilateral deals had occurred very early on.
- Storage: minus 70 deg C which is a limitation for SA as we have limited commercial ultra low cold chain storage in SA only suitable for small volume.

AstraZeneca/ University of Oxford Vaccine

- Regulatory Approval: Product has been approved as EUA by MHRA and DCGI
- Efficacy: 70% efficacy – 2 dose vaccine
- AZ has outsourced the production of the vaccine to various sites globally. The main vaccine producer globally is Serum institute of India (SII).
- This vaccine is likely to be widely used globally due to temp stability and volumes that AZ committed to produce through partners and their tiered price model
- Storage: 2 – 8 deg C

VACCINE OVERVIEW

Johnson and Johnson

- Regulatory Approval: Product has not been approved as yet – dossier submission expected in January
- Single dose product that is much easier for administration and more cost effective
- Product will also be manufactured at the Aspen facility on a contract basis
- **Status of engagements:**

Moderna

Regulatory approval: EUA by FDA

Two dose vaccine

Storage: **minus** 20 deg C

Sinopharm vaccine (China)

Approved in China, Egypt and a number of middle East countries incl UAE (79% efficacy)

REGULATORY MATTERS

- Vaccines must be **safe and effective** - Medicines and Related Substances Act 101 of 1965
- South African Health Products Regulatory Authority (SAHPRA) put several measures in place to ensure expedited regulatory approvals of safe vaccines. These measures include:
  - **Agreements with EMA, USFDA, MHRA, and TGA** – SAHPRA will thus be able to use their assessment reports as a reliance approach to reduce timelines in the evaluation process.
  - **SAHPRA has adopted a priority review approach for all COVID-19 vaccine applications** since the onset of the pandemic. Thus, the process of expedited review will apply to any COVID-19 vaccine registration application.
  - **Flexibility in relation to labelling and packaging requirements** effected in terms of effect Section 36 of the Medicines Act (exemption of medicines by the Minister of Health from certain requirements of the Medicines Act) for specific labelling and packaging requirement exemptions.
  - **Authorisation in terms of Section 21** of the Medicines Act where manufacturers have not submitted dossiers to SAHPRA

Note: NDoH has been meeting with vaccine manufacturers who are being encouraged to submit dossiers to SAHPRA

REGULATORY MATTERS

- **Covid-19 vaccine products based on new technology,** never licensed before – therefore transparent and effective vaccine safety surveillance and causality assessment systems to continuously monitor vaccine safety
- **Active and passive surveillance (SAHPRA)**
  - Active – adaptation of Yellow Vaccine Card System
  - Passive – MedSafety app for electronic reporting of all AEFI (including causality assessment) from both the public and private sector
- **Use electronic reporting system** to collect core variables required for AEFI causality assessment, for assessment by the **National Immunisation Safety Expert Committee (NISEC)**
- Availability of **reporting tools and coordinated reporting lines** (Case reporting and case investigation forms)
- **Surveillance to enable data sharing** (NDOH, WHO, SAHPRA)

DISTRIBUTION

Vaccines for Health Care Workers

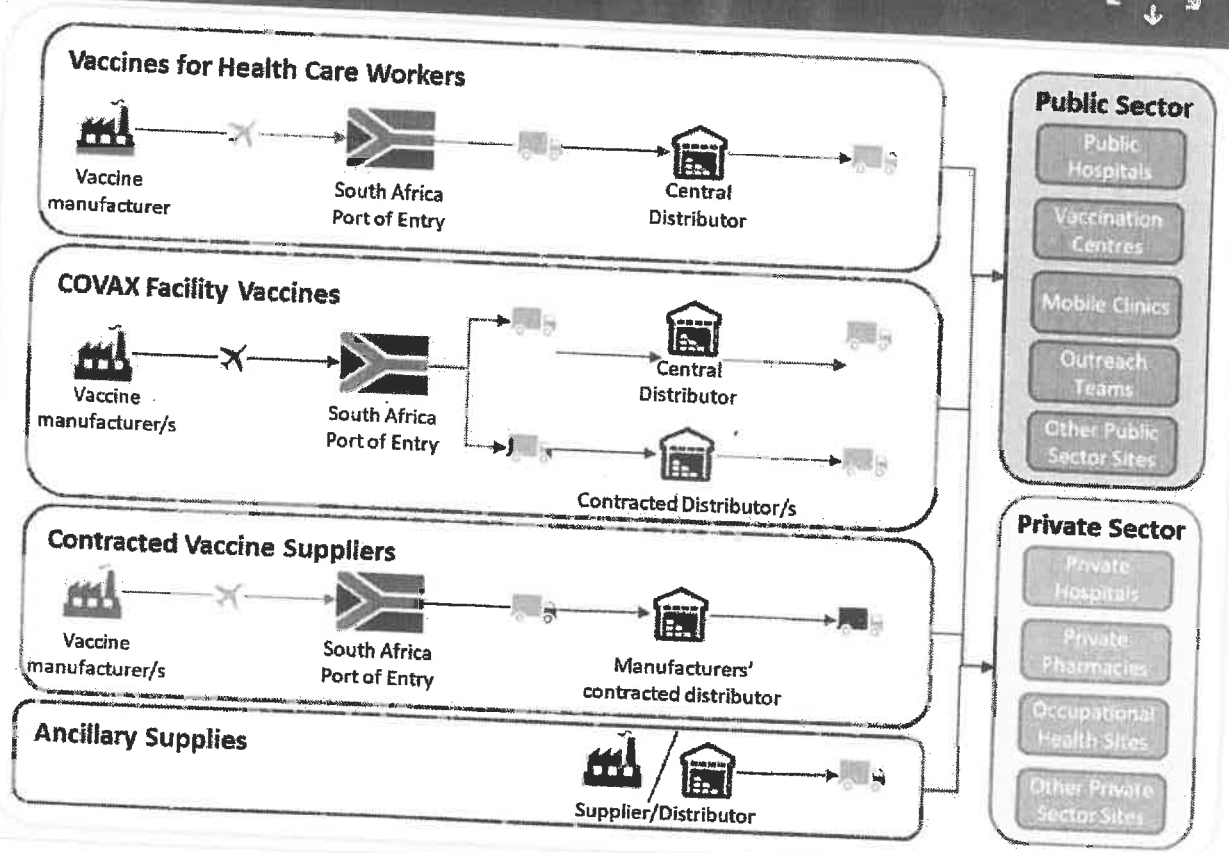
- Outsourced storage and distribution
  - Central Distributor

COVAX Facility Vaccine

- Outsourced storage and distribution
  - Central Distributor
  - Contracted distributors (competitive bid)

Contracted Vaccine Suppliers

- Supplier will be responsible for storage and distribution with direct delivery to identified vaccine administration sites



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NATIONAL DEVELOPMENT PLAN 2030

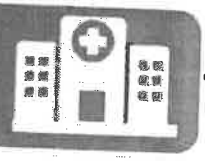
Phila

DISTRIBUTION: SECURITY

- **Distribution security**
  - Vehicle tracking and monitoring (central distributor / contract distributors)
- **Safety and security at administration sites**
  - Security deployment and presence
- **Track and traceability** of vaccines using **barcode scanning**
- **Safe and secure disposal** of all vaccine packaging and vials
- **Data verification** of volumes distributed vs volumes administered
- Monitoring of **vaccine wastage**

PHASE 1: HEALTH CARE WORKER SERVICE DELIVERY PLATFORM

Work-based vaccination programme: Public and private hospitals



- Most suitable for hospital linked HCWs

Outreach work-based vaccination programme: Mobile teams move from facility to facility

- Most suitable for HCWs in PHC, CHC and private medical centres

Vaccination Centres: Remote or facility-based vaccination centres e.g. pharmacies or other settings

- Suitable for independent HCWs

ADMINISTRATION: PHASE 1

Work-based vaccination programme: Hospitals

Model: Hospital vaccinates all staff working in the hospital (both public and private hospitals)

- Provided through occupational health centres or services (where these exist)
- Vaccine delivered to the hospital – stored in hospital pharmacy in accordance with vaccine presentation
- Vaccination team from the facility provides on-site vaccination service to all health workers in the hospital. Vaccinators may be occupational health workers or other staff members.
- Virtual training sent in advance to hospital vaccination team
- Resources: Vaccinators (available), ancillary supplies, emergency equipment, waste disposal

ADMINISTRATION

Work-based vaccination programme: Outreach teams

Model: Outreach teams vaccinate health workers in smaller health facilities (Hub and Spoke Model)

- Vaccine distributed to hospital for collection daily – stored in accordance with vaccine presentation
- Mobile clinics/teams move from facility to facility vaccinating eligible health care workers - health facilities include PHC facilities, CHCs and private medical centres
- Teams coordinated by District Health Services
- Identified by district occupational health and safety committee
- Virtual training provided to outreach teams
- Resources: Human resources (retired nurses, partners), ancillary supplies, waste management

ADMINISTRATION

Vaccination centres

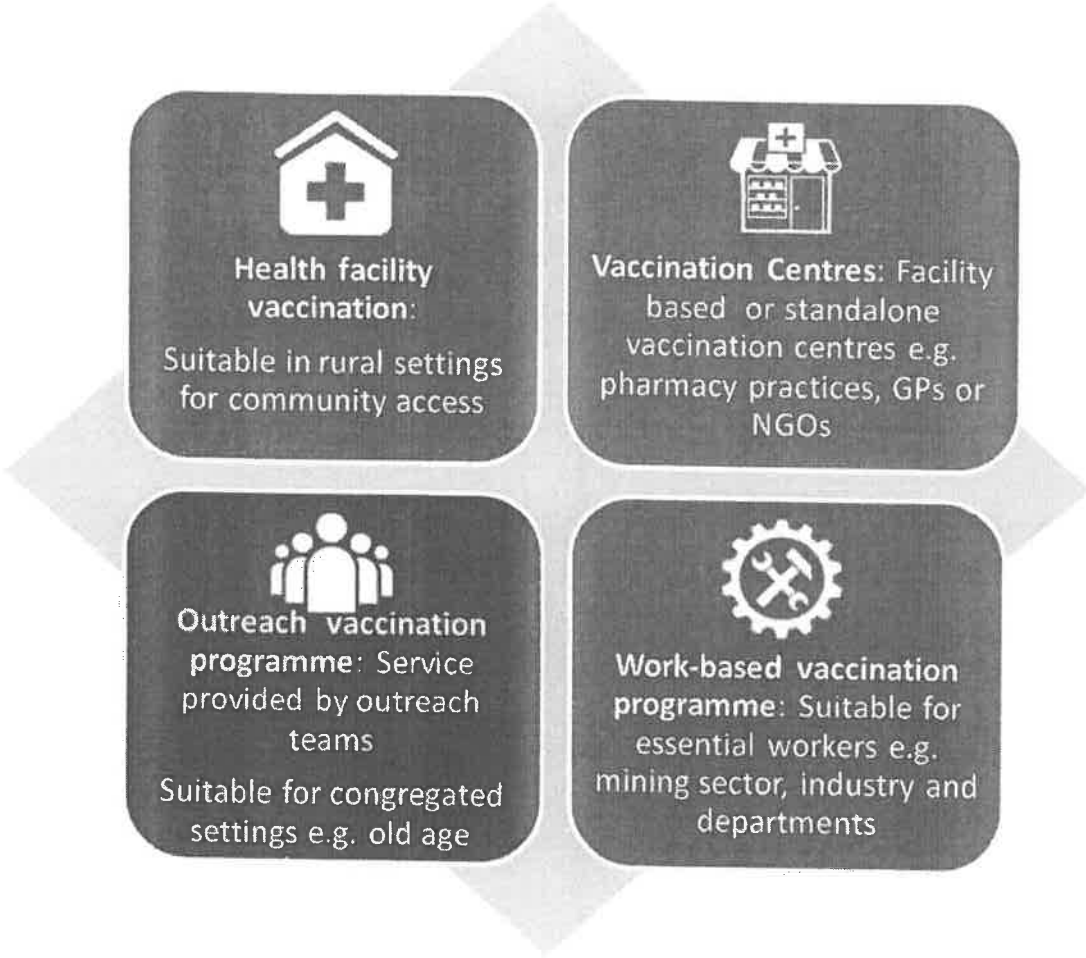
Model: Additional sites for vaccination created (may be linked to a health facility/pharmacy or be standalone)

- Suitable for reaching eligible health workers not working in a health facility with occupational health services
- Vaccination centres set up per district.
- Distribution to vaccination point – stored in accordance with vaccine presentation
- Good option for urban settings, and reaching independent HCWs
- Will require participation of private and public sector to share the burden of service delivery
- Short term contract nurses to provide vaccination for the required period
- Other resources: ancillary supplies, emergency supplies, waste disposal

How will health workers access the vaccine?

Place of work		Vaccinated at:	Responsibility:
Health workers employed in hospitals	All health workers	At their hospital	Occupational health services Hospital services
Health workers working in smaller health facilities	All health workers CHWs linked to health facilities	At workplace	Occupational health services District Health Services
Health workers not linked to a facility	EMS staff Independent practitioners CHWs not linked to a facility Traditional healers Administrative staff	At Vaccination Centre	Co-ordinated by District Health Services May involve private and public sector providers

PHASE 2 AND 3: HIGH RISK PRIORITY GROUPS AND GENERAL PUBLIC SERVICE DELIVERY PLATFORMS



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PHASE 2 and 3 DELIVERY PLATFORMS

- Need to balance vaccine roll-out with ongoing provision of essential services
- Health facilities and outreach teams will shift to providing services to other target groups
- Vaccination centres will play a larger role, so additional sites will be established.
  - Pharmacies (independent or pharmacy groups)
  - Mass vaccination centres in urban centres
    - Individuals
    - Groups e.g. essential workers
  - Other settings – community halls, churches, schools
- Registration and accreditation of non-facility sites process will be in place

RESOURCE REQUIREMENTS

Vaccinators

- 40 million people over 12-month period (two doses)
- 316 000 vaccinations per day
- Each vaccinator can vaccinate 50 people per day
- Approximately 6300 full-time vaccinators
- Additional vaccinators may be recruited from, amongst others:
  - Clinical associates
  - Post-Community service nurses and doctors
  - Contract nurses (already part of the HPV vaccination campaign)
  - Final year medical and nursing students
  - Other cadres (may require changes to scope of practice)
  - Other

Managers

- All provinces advised to appoint a full-time, dedicated cold chain manager
- Supervisors/Accreditors

ADMINISTRATION: Safety, effectiveness, uptake, second dose

- Perceived vaccine safety essential component of acceptability of the vaccine
- Vaccine confidence increase through transparent and effective vaccine safety surveillance and causality assessment
- Use electronic reporting system to collect core variables required for AEFI causality assessment
- SAHPRA to implement Yellow Vaccine Card System – to be adapted for RSA for active surveillance
- SAHPRA to implement MedSafety app for electronic reporting of all AEFI for passive surveillance
- Ensure availability of reporting tools and reporting lines which facilitate causality assessment of cases from the private and public sector (Case reporting and case investigation forms)
- Surveillance to enable data sharing (NDOH, WHO, SAHPRA)

AEFI surveillance for Covid vaccine to be finalized and vaccinators trained

COMMUNICATION, STAKEHOLDER GUIDANCE, TRAINING

Communication

- Targeted Stakeholder engagements with a clear roll out plan:

-Community Leadership (Political leaders, traditional leaders, religious leaders

-media

-unions

-Civil society

Ongoing updates on the progress of the programme

COMMUNICATION, STAKEHOLDER GUIDANCE, TRAINING

Training and supervision

- Develop training material – virtual and in person where allowed
- Develop training plan
- Develop supervision, criteria and tools
- Develop vaccination field guide
- Ensure availability of IEC material

Post introduction evaluation will be conducted

DATA FOR VACCINE MANAGEMENT AND SURVEILLANCE

- Data needed for monitoring vaccine **uptake and coverage, prioritization, planning, safety monitoring and vaccine effectiveness studies.**
- To meet anticipated needs of stakeholders, **electronic vaccination data system (EVDS)** is in the process of being developed.
- EVDS will **leverage off existing systems** which are currently deployed and implemented at scale.
- **EVDS must support collection and provision of the following information**
  - **Patient information** (including demographics, number of doses, etc.)
  - **Health establishment** where service is accessible (name and type, e.g. clinic)
  - **Vaccine administered** (manufacturer, batch number, etc.)
  - **Safety information** as part of a pharmacovigilance plan (Adverse Events Following Immunization – AEFI)
  - **A record of vaccination issued to individuals where appropriate and required**

DATA

EVD Requirements – Functionality

- Pre-registration of HCWs during Phase 1, other recipients during Phase 2 in order to receive vaccination appointment.
- Prepopulated with existing databases (Persal, Health Professional Councils, HPRS (includes SASSA database)).
- Consent form (for vaccination, to use personal data, to use location data).
- Vaccinators must be able to see whether it is an individual's first or second dose and which vaccine has been administered. (Dose alerts - vaccine dependent)
- Link to NHLS / NICD to determine effectiveness of vaccine i.e. if patient later tests positive
- Include Adverse events following immunisation (AEFI) monitoring
- Data sharing with SAHPRA apps e.g. Yellow Vaccine Safety Card (Active surveillance) and MedSafety app (Passive surveillance)
- Send reminders or notifications for subsequent doses including date and facility
- Recipients can use app as proof of vaccination.

DATA

National Data Dashboard

- A national public data dashboard that will show numbers vaccinated daily will be developed and this will be updated daily (the elements of this dashboard will be finalized soon)

Reports:

- Number of doses administered per vaccine per location per reporting period
- Vaccine coverage in target population
- Vaccine refusal rate and reason
- For vaccines requiring a second dose a schedule of the number of doses required per day/week and per vaccine.
- A list of non-adherent patients for follow up – track and trace functionality

ROLES AND RESPONSIBILITIES: National Department of Health

- Finalise and implement financing model
- Establish a National Co-ordinating Structure with clear reporting lines
- Vaccine procurement (and distribution to identified vaccination sites)
- Work with SAHPRA and other stakeholders to address regulatory issues
- Development of electronic information system
- Development and distribution of key documents including guidelines and training materials
  - Guidance regarding procurement of ancillary supplies will be sent during 2nd week of January
- In collaboration with provincial Departments of Health:
  - Finalise national implementation plan
  - Develop a Communication strategy and plan
  - Support implementation
- Private sector buy-in and collaboration (including system for accreditation of private sector sites)

ROLES AND RESPONSIBILITIES: Provincial Departments of Health

- Establish a Covid-19 Vaccine Task Team with similar functions as national team.
- The task team will be responsible for:
  - Development and implementation of a provincial plan based on the national implementation plan. The plan must identify target population, service points, availability of vaccinators, transport and supplies.
  - Ensuring that HCWs register on the electronic system.
  - Procurement of needles/syringes/waste disposal
  - Liaise with national DOH regarding distribution of vaccines
  - Monitoring of coverage
  - Stakeholder liaison including liaison with the private sector

INDICATIVE TOTAL BUDGET FOR VACCINATION

- Total budget [billions 2020/21 ZAR]

10%	30%	50%	67%	100% of population
2.4	9.0	15.6	20.6	30.0

- Assumptions based on the following distribution into vaccine options:
  5% Moderna (R536 per dose)
  5% Pfizer (R299)
  70% AstraZeneca (R54)
  20% J+J (R153)
  Additional cost of distribution, administration (PHC, outreach, mass vaccination, community pharmacy), training, M+E, demand creation and No-fault immunisation compensation scheme between R270 and R64
  Excludes Solidarity Fund donation and recoupment of fees from medical aids

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prokureurs • attorneys

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URGENT

Our ref. DJ Eloff / MAT3627

13 January 2021

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The Chairperson
Ministerial Advisory Committee

Dear Sirs /Madam

RE: SOLIDARITY & AFRIFORUM // MINISTER OF HEALTH – PROCUREMENT AND ROLLOUT OF SARS-COV-2 VACCINE

1. We act on behalf of the Solidarity Trade Union and AfriForum NPC (hereafter referred to as "our clients").

2. Solidarity is a registered trade union registered as such by the Registrar of Trade Unions in terms of section 96 of the Labour Relations Act, no. 66 of 1995. Solidarity has more than 120 000 members of which nearly 10 000 members are healthcare workers.

3. AfriForum is a registered not for profit company and civil rights organisation with over 265 000 registered members. It has an interest in the protection of constitutional and human rights. In particular, AfriForum is committed to the continuous monitoring of the status of civil rights in South Africa, and to taking appropriate action when such rights are violated or at risk of being violated.

4. The issues addressed herein are also in the public interest.

5. This letter is directed to all of the above-mentioned parties, who have certain obligations in relation to disaster management in terms of the Disaster Management Act, 2002 as a result of the Covid -19 pandemic; the promotion and protection of the health of the citizens of the Republic and the promotion and protection of all constitutional values, freedoms and rights.

6. The purpose of this letter is to seek clarity and to raise certain concerns on behalf of our clients, their members as well as their supporters regarding the government's strategy on the Covid -19 vaccine, specifically regarding its procurement and distribution.

7. In our clients' endeavour to seek clarity we trust that this letter will be received and responded to in the interest and spirit of the constitutional principles of accountability, transparency, clarity and responsiveness.

BACKGROUND

8. On 3 January 2021, the Ministry of Health held a public briefing on South Africa's Covid -19 vaccine strategy, which was accompanied by a short written public statement. This statement contains the broadly described strategy of government relating to the financing and distribution of Covid -19 vaccines for the South African public. It also sets out some targets regarding the phased approach to vaccine immunisation.

9. During the briefing, and through subsequent media engagements by representatives of the Department of Health, it was made clear that government appears to have arrogated the power onto itself as the sole buyer of approved Covid -19 vaccines and to control and centralise the procurement and distribution of all Covid -19 vaccines. In doing so, it is by no means clear whether it is intended that private sector organisations such pharmacies, medical practitioners or medical aid schemes or others, who are entitled by law in the ordinary course to obtain the vaccines, are excluded and not permitted to procure and sell the vaccines to their patients or members independently from the state's endeavours to do so. Moreover, it appears from the strategy that provincial health departments will also not be allowed to procure any Covid -19 vaccines despite the fact that that health services are the concurrent constitutional competence of national and provincial government.

10. It is also by no means clear whether the strategy is in the nature of a policy or the implementation of legislation. If it is the last mentioned, it is also not clear in terms of which provision or statute the power is exercised. As set out herein below, your clarification is required.

11. In a document titled "Covid -19 Response" issued by the National Department of Health dated 7 January 2020 the following is inter alia stated on page 9 under the heading "Key Principles" concerning the vaccine roll out plan:

*"**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 private health sector.....*

***Allocation of vaccines** to the various priority groups will be guided by the MAC on vaccines"*

12. By virtue of the public statement referred to above, coupled with various media reports and the government's vaccine strategic framework, our clients' interpretation of government's strategy regarding the procurement and distribution of Covid -19 vaccines can be summarised as follows:

    12.1. National government has usurped the exclusive function and power to procure and to allocate any Covid -19 vaccines. National government has excluded private

procurement by the private health sector, outside of national government, of any approved Covid -19 vaccines;

12.2. National government has prohibited procurement of any Covid -19 vaccines by provincial health departments; and

12.3. All citizens are left at the mercy of government's procurement and allocation of Covid -19 vaccines (and the timing thereof), which is already delayed in comparison to various other countries and probably not compliant with the requirement of an effective and rapid response to the disaster in terms of the requirements of the Disaster Management Act.

13. As explained herein below, if it is indeed the intention of government to centralise and control the procurement of vaccines to the exclusion of others, including the private health sector then, our clients are firmly of the view that (i) no enabling statutory provisions exist which grant the Minster of Health the powers to prohibit the private procurement of any Covid -19 vaccines and (ii) the Minister of Health's policy regarding the procurement and distribution of Covid -19 vaccines violates several constitutional rights and contravenes various statutory provisions.

14. If our clients' interpretation is not correct, you are requested to clarify the position, officially, in order to remove any uncertainty.

CONCERNS WITH THE PURPORTED CENTRALISATION OF PROCUREMENT AND DISTRIBUTION OF COVID-19 VACCINES

15. At the outset, the ostensible proposed centralisation policy/strategy/decision undoubtedly constitutes an unjustifiable limitation of various constitutional rights including, but not limited to:

15.1. Section 1(a) - The advancement of human rights and freedoms;

15.2. Section 10 of the Constitution, which provides that: "*Everyone has inherent dignity and the right to have their dignity respected and protected*";

15.3. Section 11 – The right to life. It speaks for itself that any measure resulting in the inhibition to freely acquire approved vaccines by any individual through a private health practitioner and to await the government's roll out plan is likely to delay vaccination of the population and will, inevitably, place lives at risk,

15.4. Section 12(1)(a) of the Constitution, which provides that: "*Everyone has the right to freedom and security of the person, which includes the right not to be deprived of freedom arbitrarily or without just cause*";

15.5. Section 12(2)(b) of the Constitution, which provides that: "*Everyone has the right to bodily and psychological integrity, which includes the right to security in and control over their body*";

15.6. Section 27(1)(a) of the Constitution, which provides that: "*Everyone has the right to have access to health care services*";

15.7. Section 27(2) which places a positive obligation on the state to achieve the progressive realisation of each of these rights; and

15.8. Section 27(3) of the Constitution, which provides that: "*No one may be refused emergency medical treatment*". You will appreciate that the country is facing a continuous emergency, especially with the current second wave, and it is all the more important that there be immediate and free access to the acquisition of the approved Covid -19 vaccines without any impediment to the private health sector. That will not impede government at all to procure vaccines.

16. It should also be noted that when formulating and implementing policies (such as the Covid - 19 vaccine policy), the state must give effect to its constitutional obligations. In *Minister of Health and Others v Treatment Action Campaign and Others (No 2)* 2002 (5) SA 721 (CC) the Constitutional Court was critical of the government regarding an inflexible policy of government in the relation to the availability of Nevarapine for the treatment of HIV and the protraction it caused was not reasonable. Policies had to be consistent with the constitution and the law. The message from this judgement is clear, namely that government should not adopt inflexible policies, especially considering when dealing with a pandemic such as was the case with HIV during the *Treatment Action Campaign* case and dealing with access to health care.

17. In addition to the aforementioned constitutional concerns, the proposed vaccine policy also contravenes and/or is incompatible and/or ignores various other statutory provisions, for example:

17.1. To the extent that the Minister of Health seeks to rely on the Disaster Management Act, disaster management is premised upon an integrated multi-sectoral multi-disciplinary process of planning and implementation of measures aimed at a "... *rapid and effective response to disasters*" (section 1 of the Disaster Management Act). Owing to the fact that the Covid -19 vaccine centralisation policy would neither result in a "rapid" nor an "effective" response to the Covid -19 pandemic, any reliance upon the Disaster Management Act would be misplaced and misconceived;

17.2. The centralisation strategy/policy/decision seemingly ignores the provisions of the National Health Act, No. 61 of 2003 (the "**NHA**"), which obliges every health establishment (as defined) to implement measures to minimise disease transmission (section 20 of the NHA). The same can be said for section 3 of the NHA which obliges the Minister of Health to determine policies and measures necessary "... *to protect, promote, improve and maintain the health and wellbeing of the population*";

17.3. The centralisation policy infringes upon the vested rights of manufacturers, distributors, wholesalers, pharmacists and persons licensed to dispense medicines in terms of the Medicines and Related Substances Act, No. 101 of 1965 (the "**MRSA**") to possess and sell medicine; and

17.4. It inhibits the rights and independence of medical practitioners to procure themselves vaccines from pharmaceutical companies and to dispense same to their patients in line with their professional obligations as well as statutory and constitutional rights.

18. In addition to what is set out above, our clients have additional concerns regarding the rationality and feasibility of the centralisation policy ostensibly adopted government:

18.1. Firstly, the centralised approach will undoubtedly lead to a delayed response in procurement of the vaccines (which delay would have unmitigated health and economic

consequences). In this regard, our clients note that South Africa is already behind other countries in procuring and distributing Covid -19 vaccines and prohibiting private procurement would place South Africa even further behind;

18.2. Secondly, the Council for Medical Schemes announced on 5 January 2021 that Covid -19 vaccines will be included as a prescribed minimum benefit ('PMB') after amendments to PMB regulations. Prohibiting private procurement of any Covid -19 vaccines by medical aid schemes (which includes the Government Employees Medical Scheme or "GEMS") will consequently lead to medical aids being unable and prohibited from providing the PMB and therefore rendering medical aids unable to comply with their statutory obligations; and

18.3. Thirdly, the prohibition to procure Covid -19 vaccines which is placed on the private sector, including but not limited to medical aid schemes and private hospital groups, infringes upon these entities' responsibilities to protect their members and patients, and impedes their ability to fulfil their duty of care.

DEMAND

19. In light of the above, our clients urgently require a written response to the following questions for the sake of transparency (over and above the issues and questions raised above) and in the quest for unequivocal clarity:

19.1 Will national government prohibit the private procurement and distribution of any Covid -19 vaccines? Is the strategy designed to cause such exclusion? If not, could you kindly clarify the position not only in the interest of our clients but in the interest of the public;

19.2 Will national government prohibit procurement and distribution of any Covid -19 vaccines by provincial departments of health?; and

19.3 If the answers to the above questions in paragraphs 19.1.and 19.2. are affirmative, what empowering statutory provisions does government purport to rely on to have made and enforce the above policy/strategy/decision? In such event, you are also required to provide full reasons for the adoption of the policy/strategy/decision.

20. Given the serious and time sensitive nature of the matter our clients request your urgent response by close of business on **20 January 2021**. Should our clients not receive a response by the above-mentioned date:

    20.1. Our clients will assume that the answers to the questions posed in paragraph 19.1 and 19.2 are affirmative and, furthermore, that there is no empowering provisions on which government can rely upon in order to make and enforce the vaccine centralisation policy; and

    20.2. Our clients will be compelled to approach the High Court for appropriate relief.

21. Our clients wish to remind you of the obligation in terms of decisions of our courts, placed on organs of state and particularly members of cabinet, to respond to correspondence directed to it which obligation is further accentuated by the constitutional nature and paramount public importance of the subject matter of this letter.

Yours faithfully,

HURTER SPIES INC
Per. Daniël Eloff

MEDICAL Brief
Africa's Medical Media Digest

SA's COVID-19 failures: 'It's ideology as much as customary incompetence'

JANUARY 13TH, 2021 | POLICY AND LAW

There is more than just the government's customary incompetence behind it's failures during the COVID-19 pandemic, writes Anthea Jeffreys of the **Institute of Race Relations** in the ***Daily Friend***. It's about piloting aspects of the mooted **National Health Insurance**.

South Africa has more than 1.1 million Covid-19 infections and in excess of 31 000 Covid-related deaths. A stricter curfew and many other controls have recently been introduced and harsher lockdowns may yet be introduced at massive economic cost. And still the government has done nothing to secure Covid vaccines on the scale required to generate herd immunity.

Why this 'colossal mismanagement' of the vaccine procurement process, as **Cosatu** calls it? And why is the vaccine roll-out plan quickly cobbled together by health minister Dr Zweli Mkhize so 'very scant on details and ambiguous on timelines, especially on delivery dates', as **Nehawu** queries?

Desire for control

Government's customary incompetence is no doubt partly to blame, but there is more to it than that. Ideology is the decisive factor, along with the ANC's desire for comprehensive control. Equally important is the opportunity the ruling party now sees to 'pilot' the vital 'single-buyer' element in the proposed National Health Insurance (NHI) scheme.

Ideology requires that vaccines be sourced – not from the 'imperialist' West and its private corporations – but rather from China and Russia and their state-controlled entities. Which is why Nehawu 'demands' that the government buy solely from these two countries, 'while waiting' for Covax vaccines to be made available under this global scheme.

Ideology further requires that the entire vaccination procurement and distribution process be controlled by the government. Union members need to be involved as well, says Nehawu, to ensure priority for the poor. But private medical schemes and hospital groups cannot be allowed any influence because of their 'prioritisation of profits over lives'.

Ideology at the root

Ideology lies also at the root of the government's refusal to allow the private sector to buy vaccines directly from the pharmaceutical companies whose approved products are already being rolled out in some 30 countries. According to deputy director general of health Anban Pillay, 'a single procurement approach' is instead envisaged. 'As a country we will buy a stock for the entire country and that will be used to distribute to our partners.'

Which 'partners' will be allowed into the distribution process will be decided by the government too. According to Mkhize's plan, the list will not be confined to public and private healthcare providers, but will extend to 'civil society, labour, and traditional leaders', all of whom will have to report to 'provincial and district coordinating councils'.

There will be many jobs for cadres in this complex coordinating process. There will also be many opportunities for ANC insiders to draw 'rents' from the trade unions, traditional leaders, and other entities wanting to participate.

Private sector hamstrung

As regards procurement, **Discovery**, the country's largest private medical scheme, has reportedly secured and ring-fenced funding for the vaccination of 2 million of its members. However, it cannot choose to purchase suitable vaccines because the government will not allow this.

This is also why mining companies cannot meet a demand from the **Association of Mineworkers and Construction Union** (Amcu) that they 'directly procure the vaccine for their employees', rather than wait for the government to provide. This step cannot be taken, says **Minerals Council SA** spokesperson Charmane Russell, because 'the government has made it clear that private sector organisations or medical schemes will not be permitted to procure independently for their own members.'

NHI pilot by the backdoor

Behind Pillay's insistence on 'a single procurement point', controlled by the state, lies an ideological desire to use the vaccine roll-out as an unofficial 'pilot' for the NHI. The proposed NHI is to be a 'single-payer' system (one of the few in the world), in which the government, through the state-controlled NHI Fund, will carry out all procurement, decide all treatment protocols, and stipulate all prices for healthcare goods and services.

Hence, if Covid vaccine procurement is made the sole function of the government, the **SACP/ANC** alliance will soon be able to claim a massive step forward towards the 'single-payer' NHI.

But a centralised government monopoly over vaccine procurement and distribution will put all the country's eggs in one basket, excluding competition and increasing the risks of failure. It is also likely to prove cumbersome, incompetent, and wide open to corruption – especially in the purchase of ancillary goods and services such as needles, syringes, transport, and secure storage.

Fortunately for most South Africans, the single-buyer provisions in the 2019 NHI Bill have not yet been enacted into law. Hence, private companies and other entities still have the legal capacity to buy directly from the suppliers of their choice.

There is, however, a significant impediment in the Medicines and Related Substances Act of 1965 (the 1965 Act) and its prohibition on the sale of unregistered medicines. Covid vaccines must thus be registered by the **South African Health Products Regulatory Authority** (SAHPRA), which replaced the **Medicines Control Council** (MCC) in 2018.

There was a time, back in the late 1990s, when the MCC was so independent of the ANC that it refused to bow to major pressure from Thabo Mbeki, then deputy president, and Nkosazana Dlamini-Zuma, then minister of health, to allow the use of Virodene, a dangerous industrial solvent, as a treatment for HIV/AIDS.

The ANC, which reportedly had a 6% stake in the company producing Virodene, was outraged. Dlamini-Zuma told the media she wanted 'the power to overrule' the MCC – and took steps to achieve just that. MCC chair Professor Peter Folb was summarily removed in 1998, as was MCC registrar Johann Schlebusch and his deputy.

Dlamini-Zuma's next planned step was to disband the MCC and replace it with a new body under her control. However, she found she lacked the statutory authority to do so. That changed in 2003, when the 1965 Act was amended to create a new MCC appointed entirely by the minister. A 2008 amendment act provided for the establishment of SAHPRA, which is also subject to ministerial control.

By the time SAHPRA became operative in 2018, the backlog in unresolved applications had grown from an average of 600 under Folb to around 16,000. Some of these dated back to 1992.

Though some 3,000 applications for now outdated products have been discarded, the backlog still remains. It will be difficult to reduce, moreover, as SAHPRA receives some 4,700 new applications every year, but processes only about 2,550 applications a year.

Long delays in Covid vaccine registration could thus arise. However, SAHPRA is committed to collaborating with global regulatory agencies to speed up the registration process – and various vaccines have already been approved by the **United States**, the **United Kingdom**, the **European Union**, **Israel**, and **India**.

SAHPRA can thus rely on the stringent assessments already carried out by reputable regulatory agencies, rather than insisting on its own evaluations. It has also indicated in recent guidelines that exemption from normal testing may be considered for Covid vaccines.

Political pressure

The risk, however, is that political pressure could be brought to bear, as it was on the MCC on Virodene. In this scenario, SAHPRA might be swift to register Chinese or Russian vaccines, while insisting on more comprehensive evaluations for other products.

If South Africa's only approved vaccines are **Chinese** or **Russian** ones given apparent ideological preference, even more South Africans will become reluctant to accept inoculation. By contrast, there will be fewer fears of adverse side-effects if people can choose from a range of suitable vaccines.

While many other countries forge ahead with vaccinations and look forward to reopening their economies, here the government's main priority remains the pursuit of its destructive NDR ideology. That must now change.

The government's desired monopoly over vaccine procurement and distribution cannot be accepted, while SAHPRA should fast-track the registration of all suitable vaccines in a professional and even-handed way. No individual should be forced to accept inoculation – but a choice of approved vaccines from a range of private and public providers should be made available to all those wanting to proceed.

Daily Friend article

TAGS AMCU ANBAN PILLAY ANTHEA JEFFREYS CHARMANE RUSSELL INSTITUTE OF RACE RELATIONS MEDICINES AND RELATED SUBSTANCES ACT OF 1965 MEDICINES CONTROL COUNCIL (MCC) MINERALS COUNCIL SA NATIONAL HEALTH INSURANCE NEHAWU SINGLE PROCUREMENT APPROACH SOUTH AFRICAN HEALTH PRODUCTS REGULATORY AUTHORITY (SAHPRA)

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Deel van die Solidariteit Beweging

From: Gavin Harrington <gavin.harrington@alphapharm.co.za>
Sent: Tuesday, 26 January 2021 06:23
To: Henru Kruger <henru@solidariteit.co.za>
Subject: Re: COVID19 Vaccine

Morning Henru,

Unfortunately at 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.

Kindest regards
Gavin

On Mon, Jan 25, 2021 at 4:24 PM Henru Kruger <henru@solidariteit.co.za> wrote:

> Good afternoon.
>
> I trust that you are keeping well.
>
> What we urgently need to know is whether we will be able to obtain the vaccines outside of the government program, please?
>
> Thank you very much.

Henru Krüger

Beroepsgilde Sektorhoof: Professioneel

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Deel van die Solidariteit Beweging

From: palesa.mbatha@alphapharm.co.za <palesa.mbatha@alphapharm.co.za> **On Behalf Of** Speak-To-Us AlphaPharm
Sent: Monday, 25 January 2021 12:37
To: Henru Kruger <henru@solidariteit.co.za>
Cc: Neil Swart <neil.swart@alphapharm.co.za>; Gavin Harrington <gavin.harrington@alphapharm.co.za>
Subject: Re: COVID19 Vaccine

Good day Henru Kruger,

We hope you are well. Thank you for taking our call earlier today. We have forwarded your request to our key contacts, which we have also copied in this response. They will assist you further with your request.

Kind regards,

The Alpha Pharm Team

On Fri, Jan 22, 2021 at 9:57 AM Henru Kruger <henru@solidariteit.co.za> wrote:

> Good morning.

We are asking for assistance, please.

Solidarity needs to urgently acquire Covid19 vaccines for our healthcare worker members.

Can Alphapharm please assist us in directly purchasing 10 000 vaccines?

We hope to hear from you soonest.

Kind regards.

Henru Krüger

Beroepsgilde Sektorhoof: Professioneel

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Let's go green and keep the office clean.

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PRESS RELEASE

Reference:	COVID-19 Vaccine and the medical scheme industry
Contact person:	Ms Mmatsie Mpshane
Contact number:	071 371 5667
E-mail:	media@medicalschemes.co.za
Date:	5 January 2021

Press Release 1 of 2021: COVID-19 vaccine and the medical schemes industry

The Council for Medical Schemes (CMS), in executing its mandate as the medical schemes regulator, has been co-ordinating public-private sector collaborations aimed at ensuring that there is universal access to the COVID-19 vaccine, in line with the country's priorities and individual health needs.

As such, the COVID-19 vaccine has been included in the amended Prescribed Minimum Benefit regulations, approved by the Minister of Health Dr Zweli Mkhize, recently.

This amendment includes the insertion of the Diagnosis and Treatment Pair in the list of Prescribed Minimum Benefits under the heading "Respiratory System" Treatment: screening, clinically appropriate diagnostic tests, ***vaccination***, medication, medical management including hospitalisation and treatment of complications, and rehabilitation of COVID-19.

The CMS has been in continuous engagements with the National Department of Health and industry associations such as the Health Funders Association (HFA) and the Board of Health Funders (BHF), which have supported an approach that seeks to ensure universal access, provisioning and availability of the COVID-19 vaccine, for those that are prioritised.

The public-private collaborative approach is aimed at supporting the national effort of achieving a herd immunity of 67% and more through the equitable access to the vaccine, particularly because the COVID-19 pandemic is a national and international public health crisis that affects all.

The CMS acknowledges that there may be an additional cost burden to medical schemes for the provision of the vaccine, but this is not expected to be prohibitively high. In addition, industry associations have assured the CMS that vaccine costs can be absorbed by most medical schemes.

The Minister of Health has directed the CMS continue engagements with the medical schemes and associations in the quest to develop a detailed framework that will guide the industry and the members of the public on this concession.

There are several issues which need further exploration and discussion before there is agreement on them. These include the development of:

- A clear criteria on prioritised populations
- Clinical guidelines and protocols
- Guidelines on medical scheme liquidity management and scheme reserve requirements
- The vaccine funding model and mechanism
- The appropriate funding vehicle
- Governance processes for the prevention of Fraud, Waste and Abuse
- Possible exemption of the COVID-19 from single exit price (SEP) requirements

Whilst these engagements are ongoing, the CMS, in line with its mandate, will continue to ensure that the rights of medical scheme members are protected at all times.

/Ends/

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Cumulative COVID-19 vaccinations doses

Country	Start	End	Absolute Change	Relative Change
Argentina	700 in Dec 29	247,933 in Jan 20	+247,233	+35,319%
Austria	8,360 in Jan 5	150,703 in Jan 20	+142,343	+1,703%
Bahrain	38,965 in Dec 23	143,596 in Jan 19	+104,631	+269%
Belgium	296 in Dec 28	126,328 in Jan 19	+126,032	+42,578%
Brazil	0 in Jan 16	28,543 in Jan 20	+28,543	
Bulgaria	1,719 in Dec 29	22,226 in Jan 19	+20,507	+1,193%
Canada	297 in Dec 14	651,139 in Jan 19	+650,842	+219,139%
Chile	420 in Dec 24	50,924 in Jan 19	+50,504	+12,025%
China	1.50 million in Dec 15	15.00 million in Jan 20	+13.50 million	+900%
Costa Rica	55 in Dec 24	24,859 in Jan 15	+24,804	+45,098%
Croatia	7,864 in Dec 30	54,304 in Jan 19	+46,440	+591%
Cyprus	3,901 in Jan 6	10,226 in Jan 15	+6,325	+162%
Czechia	13,000 in Jan 4	108,239 in Jan 17	+95,239	+733%
Denmark	6,573 in Dec 27	182,032 in Jan 19	+175,459	+2,669%
England	564,832 in Dec 20	4.42 million in Jan 19	+3.85 million	+682%
Estonia	207 in Dec 28	20,478 in Jan 20	+20,271	+9,793%
European Union	1 in Dec 25	6.47 million in Jan 19	+6.47 million	+647,273,000%
Finland	1,767 in Dec 31	62,061 in Jan 20	+60,294	+3,412%
France	1,000 in Jan 4	585,664 in Jan 19	+584,664	+58,466%
Germany	24,225 in Dec 27	1.30 million in Jan 19	+1.27 million	+5,256%
Gibraltar	420 in Jan 10	7,017 in Jan 19	+6,597	+1,571%
Greece	386 in Dec 28	107,335 in Jan 20	+106,949	+27,707%
Hungary	1,094 in Dec 28	133,257 in Jan 19	+132,163	+12,081%
Iceland	4,875 in Dec 30	6,205 in Jan 20	+1,330	+27%
India	0 in Jan 15	674,835 in Jan 19	+674,835	
Ireland	1,800 in Dec 31	94,000 in Jan 17	+92,200	+5,122%

Israel	56 in Dec 19	2.94 million in Jan 20	+2.94 million	+5,243,991%
Italy	6,940 in Dec 27	1.24 million in Jan 20	+1.23 million	+17,729%
Kuwait	2,500 in Dec 28	2,500 in Dec 28	+0	+0%
Latvia	597 in Dec 28	17,633 in Jan 19	+17,036	+2,854%
Lithuania	1 in Dec 25	60,447 in Jan 19	+60,446	+6,044,600%
Luxembourg	1,200 in Dec 30	5,294 in Jan 19	+4,094	+341%
Malta	130 in Dec 28	14,276 in Jan 19	+14,146	+10,882%
Mexico	2,924 in Dec 24	498,122 in Jan 19	+495,198	+16,936%
Netherlands	6,000 in Jan 6	100,000 in Jan 20	+94,000	+1,567%
Northern Ireland	3,623 in Dec 13	160,396 in Jan 19	+156,773	+4,327%
Norway	5 in Dec 27	55,662 in Jan 19	+55,657	+1,113,140%
Oman	1,717 in Dec 28	28,049 in Jan 18	+26,332	+1,534%
Poland	2,000 in Dec 28	541,229 in Jan 19	+539,229	+26,961%
Portugal	4,828 in Dec 28	106,000 in Jan 15	+101,172	+2,096%
Romania	2,066 in Dec 28	308,384 in Jan 20	+306,318	+14,827%
Russia	28,500 in Dec 15	1.00 million in Jan 13	+971,500	+3,409%
Saudi Arabia	100,000 in Jan 6	295,530 in Jan 17	+195,530	+196%
Scotland	18,901 in Dec 13	314,079 in Jan 19	+295,178	+1,562%
Serbia	7,000 in Jan 8	18,136 in Jan 14	+11,136	+159%
Seychelles	0 in Jan 9	7,000 in Jan 16	+7,000	
Singapore	3,400 in Jan 11	6,200 in Jan 12	+2,800	+82%
Slovakia	245 in Jan 5	72,060 in Jan 19	+71,815	+29,312%
MexicoSlovenia	5,934 in Jan 3	43,869 in Jan 19	+37,935	+639%
Spain	82,834 in Jan 4	1.03 million in Jan 20	+943,103	+1,139%
Sweden	4,115 in Dec 27	146,775 in Jan 17	+142,660	+3,467%
Switzerland	0 in Dec 23	110,000 in Jan 19	+110,000	
Turkey	0 in Jan 13	1.05 million in Jan 20	+1.05 million	
United Arab Emirates	826,301 in Jan 5	2.16 million in Jan 20	+1.33 million	+162%

United Kingdom	663,809 in Dec 20	5.07 million in Jan 19	+4.41 million	+664%
United States	556,208 in Dec 20	15.71 million in Jan 19	+15.15 million	+2,724%
Wales	8,177 in Dec 13	176,186 in Jan 19	+168,009	+2,055%
World	297 in Dec 14	46.89 million in Jan 19	+46.89 million	+15,788,120%

https://ourworldindata.org/covid-vaccinations

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Cumulative COVID-19 vaccinations per 100 people

Country	Start	End	Absolute Change	Relative Change
Argentina	0.00 in Dec 29	0.55 in Jan 20	+0.55	
Austria	0.09 in Jan 5	1.67 in Jan 20	+1.58	+1,756%
Bahrain	2.29 in Dec 23	8.44 in Jan 19	+6.15	+269%
Belgium	0.00 in Dec 28	1.09 in Jan 19	+1.09	
Brazil	0.00 in Jan 16	0.01 in Jan 20	+0.01	
Bulgaria	0.02 in Dec 29	0.32 in Jan 19	+0.30	+1,500%
Canada	0.00 in Dec 14	1.73 in Jan 19	+1.73	
Chile	0.00 in Dec 24	0.27 in Jan 19	+0.27	
China	0.10 in Dec 15	1.04 in Jan 20	+0.94	+940%
Costa Rica	0.00 in Dec 24	0.49 in Jan 15	+0.49	
Croatia	0.19 in Dec 30	1.32 in Jan 19	+1.13	+595%
Cyprus	0.45 in Jan 6	1.17 in Jan 15	+0.72	+160%
Czechia	0.12 in Jan 4	1.01 in Jan 17	+0.89	+742%
Denmark	0.11 in Dec 27	3.14 in Jan 19	+3.03	+2,755%
England	1.00 in Dec 20	7.85 in Jan 19	+6.85	+685%
Estonia	0.02 in Dec 28	1.54 in Jan 20	+1.52	+7,600%
European Union	0.00 in Dec 25	1.45 in Jan 19	+1.45	
Finland	0.03 in Dec 31	1.12 in Jan 20	+1.09	+3,633%
France	0.00 in Jan 4	0.90 in Jan 19	+0.90	
Germany	0.03 in Dec 27	1.55 in Jan 19	+1.52	+5,067%
Gibraltar	1.25 in Jan 10	20.83 in Jan 19	+19.58	+1,566%
Greece	0.00 in Dec 28	1.03 in Jan 20	+1.03	
Hungary	0.01 in Dec 28	1.38 in Jan 19	+1.37	+13,700%
Iceland	1.43 in Dec 30	1.82 in Jan 20	+0.39	+27%
India	0.00 in Jan 15	0.05 in Jan 19	+0.05	
Ireland	0.04 in Dec 31	1.90 in Jan 17	+1.86	+4,650%
Israel	0.00 in Dec 19	33.93 in Jan 20	+33.93	

Italy	0.01 in Dec 27	2.05 in Jan 20	+2.04	+20,400%
Kuwait	0.06 in Dec 28	0.06 in Dec 28	+0.00	+0%
Latvia	0.03 in Dec 28	0.93 in Jan 19	+0.90	+3,000%
Lithuania	0.00 in Dec 25	2.22 in Jan 19	+2.22	
Luxembourg	0.19 in Dec 30	0.85 in Jan 19	+0.66	+347%
Malta	0.03 in Dec 28	3.23 in Jan 19	+3.20	+10,667%
Mexico	0.00 in Dec 24	0.39 in Jan 19	+0.39	
Netherlands	0.04 in Jan 6	0.58 in Jan 20	+0.54	+1,350%
Northern Ireland	0.19 in Dec 13	8.47 in Jan 19	+8.28	+4,358%
Norway	0.00 in Dec 27	1.03 in Jan 19	+1.03	
Oman	0.03 in Dec 28	0.55 in Jan 18	+0.52	+1,733%
Poland	0.01 in Dec 28	1.43 in Jan 19	+1.42	+14,200%
Portugal	0.05 in Dec 28	1.04 in Jan 15	+0.99	+1,980%
Romania	0.01 in Dec 28	1.60 in Jan 20	+1.59	+15,900%
Russia	0.02 in Dec 15	0.69 in Jan 13	+0.67	+3,350%
Saudi Arabia	0.29 in Jan 6	0.85 in Jan 17	+0.56	+193%
Scotland	0.35 in Dec 13	5.75 in Jan 19	+5.40	+1,543%
Serbia	0.10 in Jan 8	0.27 in Jan 14	+0.17	+170%
Seychelles	0.00 in Jan 9	7.12 in Jan 16	+7.12	
Singapore	0.06 in Jan 11	0.11 in Jan 12	+0.05	+83%
Slovakia	0.00 in Jan 5	1.32 in Jan 19	+1.32	
Slovenia	0.29 in Jan 3	2.11 in Jan 19	+1.82	+628%
Spain	0.18 in Jan 4	2.19 in Jan 20	+2.01	+1,117%
Sweden	0.04 in Dec 27	1.45 in Jan 17	+1.41	+3,525%
Switzerland	0.00 in Dec 23	1.27 in Jan 19	+1.27	
Turkey	0.00 in Jan 13	1.25 in Jan 20	+1.25	
United Arab Emirates	8.35 in Jan 5	21.85 in Jan 20	+13.50	+162%
United Kingdom	0.98 in Dec 20	7.47 in Jan 19	+6.49	+662%
United States	0.17 in Dec 20	4.75 in Jan 19	+4.58	+2,694%
Wales	0.26 in Dec 13	5.59 in Jan 19	+5.33	+2,050%

World	0.00 in Dec 14	0.60 in Jan 19	+0.60

https://ourworldindata.org/covid-vaccinations

3 September – by Dr Seth Berkley, CEO of Gavi, the Vaccine Alliance

TOPICS: COVAX COVID-19

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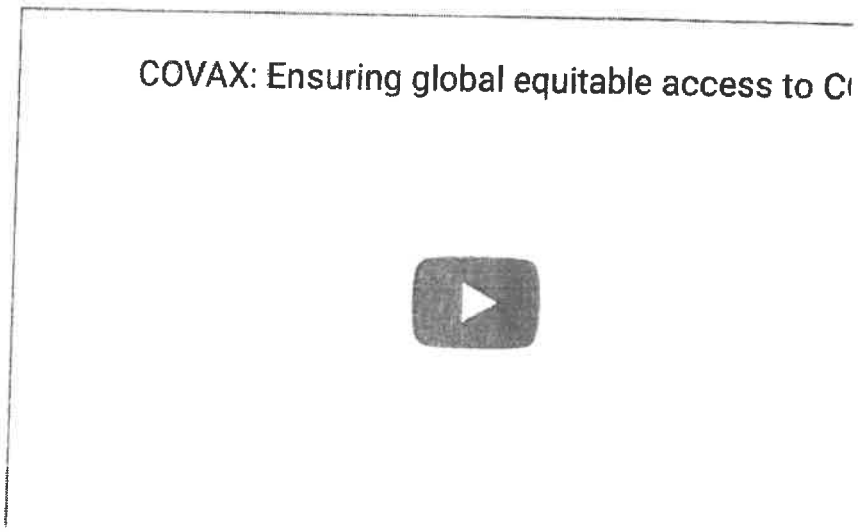
At an early stage during this pandemic, it quickly became apparent that to end this global crisis we don't just need COVID-19 vaccines, we also need to ensure that everyone in the world has access to them. This triggered global leaders to call for a solution that would accelerate the development and manufacture of COVID-19 vaccines, as well as diagnostics and treatments, and guarantee rapid, fair and equitable access to them for people in all countries. Today we have that solution – COVAX. The result of an extraordinary and unique global collaboration, with more than two-thirds of the world engaged – COVAX has the world's largest and most diverse portfolio of COVID-19 vaccines, and as such represents the world's best hope of bringing the acute phase of this pandemic to a swift end.

WHAT IS COVAX?

COVAX is one of three pillars of the Access to COVID-19 Tools (ACT) Accelerator, which was launched in April by the World Health Organization (WHO), the European Commission and France in response to this pandemic. Bringing together governments, global health organisations, manufacturers, scientists, private sector, civil society and philanthropy, with the aim of providing innovative and equitable access to

COVID-19 diagnostics, treatments and vaccines. The COVAX pillar is focussed on the latter. It is the only truly global solution to this pandemic because it is the only effort to ensure that people in all corners of the world will get access to COVID-19 vaccines once they are available, regardless of their wealth.



Coordinated by Gavi, the Vaccine Alliance, the Coalition for Epidemic Preparedness Innovations (CEPI) and the WHO, COVAX will achieve this by acting as a platform that will support the research, development and manufacturing of a wide range of COVID-19 vaccine candidates, and negotiate their pricing. All participating countries, regardless of income levels, will have equal access to these vaccines once they are developed. The initial aim is to have 2 billion doses available by the end of 2021, which should be enough to protect high risk and vulnerable people, as well as frontline healthcare workers.

For lower-income funded nations, who would otherwise be unable to afford these vaccines, as well as a number of higher-income self-financing countries that have no bilateral deals with manufacturers, COVAX is quite literally a lifeline and the only viable way in which their citizens will get access to COVID-19 vaccines. For the wealthiest self-financing countries, some of which may also be negotiating bilateral deals with vaccine manufacturers, it serves as an invaluable insurance policy to protect their citizens, both directly and indirectly. On the one hand it will provide direct

protection by increasing their chances of securing vaccine doses. Yet, at the same time by procuring COVID-19 vaccines through COVAX, these nations will also indirectly protect their citizens by reducing the chances of resurgence by ensuring that the rest of the world gets access to doses too.

WHY WE NEED COVAX

COVAX is necessary because without it there is a very real risk that the majority of people in the world will go unprotected against SARS-CoV-2, and this would allow the virus and its impact to continue unabated. COVAX has been created to maximise our chances of successfully developing COVID-19 vaccines and manufacture them in the quantities needed to end this crisis, and in doing so ensure that ability to pay does not become a barrier to accessing them.

To do this, first we need COVID-19 vaccines that are both safe and effective, which is by no means a certainty. There are currently more than 170 candidate vaccines in development, but the vast majority of these efforts are likely to fail. Based on previous vaccine development, those at the preclinical trial stage have roughly a 7% chance of succeeding, while the ones that make it to clinical trials have about a 20% chance. To increase the chances of success, COVAX has created the world's largest and most diverse portfolio of these vaccines, with nine candidate vaccines already in development and a further nine under evaluation.

COVAX has been created to maximise our chances of successfully developing COVID-19 vaccines and manufacture them in the quantities needed to end this crisis.

By joining COVAX, both self-financing countries and funded countries will gain access to this portfolio of vaccines, as and when they prove to be both safe and effective. Self-financing countries will be guaranteed sufficient doses to protect a certain proportion of their population, depending upon how much they buy into it. Subject to

funding availability, funded countries will receive enough doses to vaccinate up to 20 per cent of their population in the longer term. Since demand is initially likely to exceed supply once vaccines do become available, allocation will be spread across countries based on the number of doses that are available and increase as that availability increases.

To make all this a reality, Gavi has created the COVAX Facility through which self-financing economies and funded economies can participate. Within this also sits an entirely separate funding mechanism, the Gavi COVAX Advance Market Commitment (AMC), which will support access to COVID-19 vaccines for lower-income economies. Combined, these make possible the participation of all countries, regardless of ability to pay.

Read more: COVAX / COVID-19 / Vaccine support / About Gavi

WHAT IS THE COVAX FACILITY?

The principal role of the COVAX Facility is to maximise the chances of people in participating countries getting access to COVID-19 vaccines as quickly, fairly and safely as possible. By joining the Facility, participating countries and economies will not only get access to the world's largest and most diverse portfolio of COVID-19 vaccines, but also an actively managed portfolio. The Facility continually monitors the COVID-19 vaccine landscape to identify the most suitable vaccine candidates, based on scientific merit and scalability, and works with manufacturers to incentivise them to expand their production capacity in advance of vaccines receiving regulatory approval.

Normally, manufacturers are reluctant to risk making the significant investments needed to build or scale-up vaccine manufacturing facilities until they have received approval for a vaccine. But in the context of the current pandemic, which is costing the global economy US$ 375 billion every month, this would inevitably lead to significant delay and initially vaccine shortages once vaccines

are licensed. To avoid this, the Facility is working with manufacturers to provide investments and incentives to ensure that manufacturers are ready to produce the doses we need as soon as a vaccine is approved. The Facility will also use the collective purchasing power that comes from having so many countries participate in order to negotiate highly competitive prices from manufacturers that are then passed on to participants.

The Facility continually monitors the COVID-19 vaccine landscape to identify the most suitable vaccine candidates, based on scientific merit and scalability.

Self-financing countries and economies participating in the Facility can request vaccine doses sufficient to vaccinate between 10-50% of their populations. The amount they pay into the Facility will reflect the number of doses they have requested. For these countries the Facility serves as a critical insurance policy that will significantly increase their chances of securing vaccines, even if their own bilateral deals fail. And by pooling resources through the Facility, participating countries and economies are essentially helping to increase the world's chances of bringing about COVID-19 vaccines as quickly as possible, and in the quantities that we need.

While there are no guarantees that any COVID-19 vaccine candidates will ultimately succeed, taking this global approach and sharing the risks through the Facility offers our best shot at beating this virus by enabling the world to share the rewards.

At the time of writing this, 78 higher-income countries and economies have now confirmed their interest in participating the COVAX Facility, with more possibly to follow. This shows that the COVAX Facility is open for business and attracting the type of interest across the world that we had hoped for. Countries now have until 18 September to commit to legally binding agreements to participate and make their upfront payments into the Facility by 9 October.

COMMITTED VS OPTIONAL PURCHASE

Self-financing countries joining the COVAX Facility have two ways in which they can participate, through a Committed Purchase Arrangement or an Optional Purchase Arrangement.

As the name implies, self-financing countries opting for a Committed Purchase will need to make committed guarantees to procure an agreed volume of doses through the Facility. In exchange for this firm commitment these participants will be required to provide a lower upfront payment of US$ 1.60 per dose, or 15% of the total cost per dose. Under this type of agreement, participants are effectively committing to purchase a set number of vaccines that, once available, will be fairly and equitably allocated amongst participants. Countries will have the ability to opt out of purchasing a vaccine should the price of the vaccine be twice (or more) that which was expected.

For the Optional Purchase Arrangement, participants can choose to opt out of receiving any vaccine, without jeopardising their ability to receive their full share of doses of other candidates, subject to supply becoming available. This type of agreement may be more attractive to participants that already have bilateral agreements with manufacturers, through which they may already have secured sufficient doses of that particular vaccine.

The trade-off for these participants, who will have greater choice, is that they will be required to pay a higher proportion of the total cost per dose up front, making a down payment of US$ 3.10 per dose and a risk-sharing guarantee of US$ 0.40 per dose to help protect the Facility against any liabilities resulting from participants deciding not to purchase a particular vaccine candidate after the Facility has already entered into a contract with the manufacturer. Also, by opting out of

vaccines that have been allocated to them and waiting for another to become available, these countries may inevitably experience a delay in receiving their full committed volume of vaccines. In the end, the total cost for the vaccines will be the same for the two options. As a pass-through facility, participants will pay the amount for the doses that was negotiated by the facility, plus a speed premium invested in accelerating and scale-up of manufacturing, as well as a very small fee for the operation of the facility. Some manufacturers will be providing vaccines at flat prices where others will be tiering the prices based upon income levels.

WHAT IS THE GAVI COVAX AMC?

The primary focus of the Gavi COVAX AMC is to ensure that the 92 middle- and lower-income countries that cannot fully afford to pay for COVID-19 vaccines themselves get equal access to COVID-19 vaccines as higher-income self-financing countries and at the same time. Funding for the Gavi COVAX AMC is entirely separate from that of the COVAX Facility, which means that the AMC is in no way cross-subsidised by the funds of self-financing participants. Instead the AMC will be funded mainly through Official Development Assistance (ODA), as well as contributions from the private sector and philanthropy.

So far, the AMC has raised about US$ 700 million of the initial seed capital target of US$ 2 billion that is needed by the end of 2020. So, in addition to deciding how they participate in the Facility, sovereign donors will need to decide to what extent they wish to contribute or allocate ODA towards this target and do so in a timely manner. Since no one is safe until everyone is safe, the Gavi COVAX AMC is the only way in which all countries will get equal and fair access to COVID-19 vaccines.

HOW WILL VACCINE DOSES BE ALLOCATED?

Once any of the COVAX portfolio vaccines have successfully undergone clinical trials and proved themselves to be both safe and effective, and have received regulatory approval, available doses will be allocated to all participating countries at the same rate, proportional to their total population size. A small buffer of about 5% of the total number of available doses will be kept aside to build a stockpile to help with acute outbreaks and to support humanitarian organisations, for example to vaccinate refugees who may not otherwise have access.

Even though self-financing participants can request for enough doses to vaccinate between 10-50% of their population, no country will receive enough doses to vaccinate more than 20% of its population until all countries in the financing group have been offered this amount. The only exception is those countries who have opted to receive fewer than 20%.

WHAT NOW?

The fact that the global community has come so far so quickly and built such a comprehensive and effective global solution to this pandemic is a remarkable accomplishment. Now we need to implement it, and this hinges on countries buying into the COVAX Facility so that it can make urgent investments now.

Having so many self-financing economies sign up to join the COVAX Facility is a tremendous step forward, and means we can now begin work signing formal agreements with vaccine manufacturers and developers to secure doses. This will not only allow COVAX to increase our chances of successfully developing COVID-19 vaccines, but also ensure that we have necessary productive capacity in place to manufacture the volumes of doses we need, the moment a vaccine is ready.

In addition to this we need countries to urgently fill the funding gaps that still exist for research and development in COVID-19 vaccines. CEPI is leading the COVAX vaccines research and development

work, with nine vaccine candidates already supported, eight of which are already in clinical trials. Governments have already committed US$ 1.4 billion towards this effort, but an additional US$ 1 billion is still needed to continue to move the portfolio forwards.

It is also essential that the Gavi COVAX AMC meets its fundraising target of at least US$ 2 billion by the end of 2020, and also continues to discuss details with AMC-eligible economies what their participation will mean for them. This will be critical to ensuring that ability to pay does not become a barrier to accessing COVID-19 vaccines, a situation that would leave the majority of the world unprotected and which would allow this pandemic to continue far longer than necessary.

The views expressed in this article are those of the author alone and not Gavi, the Vaccine Alliance

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Growing anger over SA government's vaccine 'fiasco'

JANUARY 6TH, 2021 IN FOCUS, PUBLIC HEALTH

South African medical scientists, joined by activist groups, health workers and opposition parties, have slammed the government and its **Medical Advisory Committee** (MAC) over the "perilous fiasco" of the vaccine roll-out, reports ***MedicalBrief***. It's a mobilisation reminiscent of the activist wave that the government faced over HIV/Aids in the late 1990s and early 2000s.

A statement released at the weekend and signed by some of the country's leading medical figures under the auspices of the **Progressive Health Forum**, says that it "beggars belief" that middle-income country South Africa has left itself dependent on the COVAX initiative set up to assist poor countries, and criticises the government's playing down of the importance of vaccines in relation to non-pharmaceutical interventions.

Business Day reports that following the scientists' statement and as SA cases of COVID-19 rise to the highest daily levels, the "lack of a coherent vaccine strategy is leading to a growing outcry from doctors and nurses and from opposition political parties".

SA's official opposition, the **Democratic Alliance** (DA) has written to the Speaker of the **National Assembly** to again request an urgent debate of national importance regarding the government's vaccination-plan. Accusing the Health minister of raising more questions than answers in his briefings on vaccinations, the DA Shadow Minister for Health, Siviwe Gwarube, has also submitted a **Promotion of Access to Information Act** (PAIA) application to obtain information on the procurement process and the distribution mechanisms and methods of the vaccines.

More than 7,500 health professionals have signed an online petition demanding a detailed vaccine plan from the government. **Agri SA** has expressed concern at the government's perceived lack of urgency by the government in securing enough vaccines, rather than the initial 10% announced by President Cyril Ramaphosa, who said only 10% of South Africans would get the vaccine, with health workers taking priority.

The **Congress of SA Trade Unions** (Cosatu), a key government ally, said in a statement: "It is clear that we are dealing with colossal mismanagement of the vaccine procurement process". It described Mkhize's briefing as publicity stunt: "What the minister presented is bunk and the country should not accept it. South Africans are familiar with the egregious policy failures with deadly consequences as we saw with the mismanagement of the Aids pandemic."

"It is clear that we are dealing with colossal mismanagement of the vaccine procurement process and frontline workers, the elderly and those with comorbidities will pay with their lives. This is hiding the fact that there are 40 countries that have already begun immunising their people, some since December and some are South Africa's

peers in the middle-income bracket."

Solidarity union was especially critical of the government's strategy of controlling procurement but expecting private sector resources. Said the union: 'The state cannot be in control while the private sector provides the finances. The state has a poor management record. During the pandemic, the government has repeatedly proven that it is not competent to take the lead. It is this incompetence that has led to the delay in obtaining the vaccine, and the government should be kept as far away from this process as possible.'

The **Institute of Race Relations** (IRR) said in a statement it was considering a legal challenge on "compelling action to ensure that South Africans have access to a vaccine". The IRR CEO, Dr Frans Cronje, said: "It is not good enough to say there is a plan to procure vaccines. South Africans need to know what has been procured and when it will be available". Cronje added that the IRR believed that the government, with support from the private sector, could 'easily and rapidly finance vaccine procurement'

Content of PHF statement

The PHF statement, published in a variety of newspapers, notes that the "stunning reality" is that the SA government has failed to secure vaccine supply, nor does it have a plan for mass inoculation in the foreseeable future "that can withstand scrutiny". "This lack of foresight," they write, "will visit on us the consequences of the greatest man-made failure to protect the population since the Aids pandemic... A high probability of a reprise of this is a monumental and unforgivable failing."

They signatories, a number of who were dropped from Health Minister Dr Zweli Mkhize's MAC – speculatively because they were too outspoken – called for the advice given by the MAC on vaccines to the government to be made public. They have harsh words for their medical peers serving on the MAC, whom they accuse of either condoning the government's strategy or else participating in a "cover-up".

"The posture of the Ministerial Advisory Committee on Vaccines appointed last September, suggests that it has been dragooned into the specious approach of the department. The comments of the chairman of the vaccine committee align closely with the comments of the Deputy Director-General and other officials of the department who are supposed to lead the vaccine acquisition programme of the government. Their admonishment that vaccines are not a silver bullet", or that they "do not end epidemics" are frankly astounding.

"Several advisories of the vaccine committee have been issued, but none have been published. The committee's silence on the matter has been deafening. This suggests that the committee either concurs with this lack of transparency and condones a wholly inadequate vaccine acquisition policy, or it does not, but has been officially muzzled.

"This can only mean that the responsible officials have indeed missed the vaccine boat and a huge damage limitation exercise is underway to escape scrutiny and likely censure for this unforgivable failure, which will be measured in lives lost in their thousands, sickness for tens of thousands, a broken healthcare system and profound and ongoing economic damage.

"It is unconscionable that this has been allowed to occur and it is to the discredit of the advisory committee that it appears to have been enlisted in this exercise. Its members have the ability and expertise to produce a transparent and accelerated vaccine acquisition strategy, measured in weeks, not months. That such a strategy

is lacking puts them in the invidious position of having to reaffirm their scholarly credibility and ethical composure. This dissonance deepens the suspicion that the committee is not free to do its work.

"In a moment of existential threat, this incoherence in lead institutions is simply intolerable."

"South Africans, pummelled mercilessly by the pandemic, have an untrammelled right to demand the immediate public disclosure of the advisories of the vaccine MAC and a full account of the disposal of any of its recommendations. There must be no further cover-up..."

The signatories — "writing in their personal capacities and with the support of colleagues here and abroad" — are Dr Aslam Dasoo (Convenor of the Progressive Health Forum), Prof Glenda Gray (President of the SA Medical Research Council), Prof Guy Richards (Emeritus Professor in Critical Care at Wits University), Prof Marc Mendelson (Head of Infectious Diseases and HIV at the University of Cape Town), Dr Fareed Abdullah (AIDS and TB Research at the SAMRC), Prof Francois Venter (CEO of Ezintsha at Wits), Prof James McIntyre (School of Public Health at UCT), Dr Adrienne Wulfsohn, (Specialist in Emergency Medicine at Inkosi Albert Luthuli Hospital) and Prof Alex van den Heever (School of Governance at Wits).

Government and the MAC's position

The government's position on the vaccine rollout has been maddeningly vague, its critics claim. In his New Year's address, President Cyril Ramaphosa said the "vaccine will come", while the Deputy Director-General of Health, Anban Pillay, suggested this would only happen in the second quarter of 2021.

In Mkhize's briefing on Sunday, 3 January 2021, he announced that at least 67% of the South African population will need to be vaccinated against Covid-19 to ensure herd immunity. The vaccine would be rolled out in three phases, with the 1.25-million healthcare workers in the country having first access.

The second phase would see essential workers and those living in congregate spaces, such as care centres and prisons, offered the vaccine. Those classed as essential workers include miners, teachers and police officers. The second phase, which will require roughly 16-million doses, will also include those aged 60 and older as well as those with comorbidities.

The third phase would see the vaccine being made available to an additional 40-million people.

Mkhize said the COVAX agreement would see enough vaccines to cover 10% of the population delivered by the second quarter of 2021. He added that enough doses to cover the remaining 57% of the population would have to be sourced through bilateral agreements.

The government hoped to conclude negotiations with coronavirus vaccine suppliers and begin vaccinating frontline healthcare workers in February. Mkhize said government departments were working urgently to secure vaccines through bilateral deals with manufacturers. He said the target date was "really more our wish" and no deals had been reached to deliver vaccines by February, but the government was "fighting" to secure supplies before the second quarter of the year.

Prof Barry Schoub, Chair of the MAC on COVID-19 vaccines, responded in ***Daily Maverick*** to the criticisms, "to address an urgent and earnest appeal to civil society groups ... please stop insinuating false hopes and expectations to the public for immediate solutions to the COVID-19 crisis". The availability of a vaccine would

not be a "magic wand and any suggestion that it may be is dangerously threatening the public motivation to continue with the non-pharmaceutical interventions".

"There is a growing groundswell of impatience, and sometimes even a demanding anger, resulting from the delay in having COVID-19 vaccines in the country ... Undoubtedly the issue is becoming more and more emotional and a hot political weapon. Activist groups, such as the C19 People's Initiative, have also sprung into action, alluding to the laudable and effective HIV treatment campaign. However, while the intent is commendable, it must be balanced against raising false expectations which could imperil the crucial non-vaccine Covid infection prevention precautions which will still be critically needed for some time to come.

"The delay has simply come about as a result of the grotesque selfishness of high-income countries. middle-income countries, like South Africa, would be roundly condemned should they have considered gambling with their much more limited taxpayers' money for vaccines still undergoing investigative trials, when it was unknown whether they would be safe and effective.

"We cannot afford to create false hopes and false expectations which, unfortunately, vaccine activism may be in danger of doing. Vaccines will not immediately allow us all to go back to our pre-Covid lives. Sustaining human behavioural dedication to fight an unseen enemy is challenging, uncomfortable and even irritating. But it depends critically on the support of all sections of the community. It is fragile and can be easily fractured by the seduction of a magic vaccine. It is equally easy to look for a scapegoat.

"Arguably, there may well seem to be a lacuna in communicating adequate assurance to the public. But let me state that there are indeed very extensive behind the scenes efforts to acquire safe and effective vaccines as soon as possible, and also to develop a comprehensive vaccine strategy."

Schoub said that South Africa could not afford to buy vaccines in advance like many rich countries have done because it would have meant purchasing vaccines on risk. In other words the government would have had to pay for vaccines that were still being tested even if they failed to work.

Other reaction

In an interview with ***Groundup***, Shabir Madhi, professor of vaccinology at Wits University, said this was "nonsense". He said that making an "advance market commitment" to vaccine producers would mean only paying if the vaccine was successfully brought to market. This is why countries like Canada have enough vaccines committed to it to vaccinate their entire population.

An editorial in ***Maverick Citizen*** says that the polarisation over SA "feels like the bad old days of Aids".

"The informed anger of leading scientists is understandable. The obfuscation of government and vaccine MAC Chairperson Prof Barry Schoub is unacceptable. Accusing activists of "raising false expectations" rather than dealing with their complaints is bound to harden divisions. Health activists don't give trust away freely anymore: COVID-19 corruption and, before that, the millions of wasted lives caused by Aids denialism are still too fresh in our memories.

"The truth is that the government did drop the ball on vaccines. There's no point in denying it, doing so just draws out the conflict. The truth is that government did hand-pick a Ministerial Advisory Committee (MAC) on Vaccines that left out expert scientists and civil society experts who are unwilling to wear a muzzle in return for the

privilege of advising government.

"Government needs civil society and it needs all the medical profession, not just those that will toe its line. Twenty years ago, when the **Treatment Action Campaign** (TAC) catalysed an international mobilisation to help South African and other developing countries fight Aids, it was civil society pressure, which made antiretroviral medicines affordable.

"Today, civil society still has a critical role to play in ensuring that safe and efficacious vaccine access is determined by science and medicine, not blocked by either profiteering, corruption or the geopolitics of big powers like China or Russia who might link vaccine access to economic favours and expanding spheres of influence."

Full BusinessLIVE report (Subscription Required)

Full Progressive Health Forum statement in Daily Maverick

Health workers petition

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EDITOR'S PICK